An EduQuest Advisory:

Correlation (Cross-Walk) between 21 CFR Part 820 and Best Practices in Design Controls

Prepared by:

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About EduQuest:

- Global team of FDA compliance experts based near Washington, DC
- Founded by former senior officials from FDA's Office of Regulatory Affairs (ORA) Headquarters
- Advisors to medical device, pharmaceutical, biologics and tobacco companies worldwide since 1995
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Subpart B--Quality System Requirements

820.20 Management Responsibility

Topic	Requirement	Relation to Design Controls
Sec. 820.20 (a) Quality policy	Management with executive responsibility shall **establish** its **policy and objectives** for, and commitment to, quality.	All regulated facilities need to have a quality policy and the objectives for quality design should be defined, documented and implemented.
	Management with executive responsibility shall ensure that the quality policy is **understood, implemented**, and **maintained** at all levels of the organization.	All personnel, even those involved in R&D need to be aware of the quality policy and be actively implementing quality into design.
Sec. 820.20 (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.	There must be adequate personnel to assure proper design and proper design change.
Sec. 820.20 (b)(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,	Design personnel, especially management of R&D, must be provided the necessary responsibility and authorities to manage, perform and assess design and design changes. Normally this would mean that if the design engineers are not ready to release design to commercial production, that decision should not be one that can be overridden by someone not knowledgeable about the design of that product, i.e. a non-design engineer.
	and provide the **independence** and **authority** necessary to perform these tasks.	They must also be provided the independence to perform and assess design and design changes. Normally this would mean that if the design engineers are not ready to release design to commercial production, that decision should not be one that can be overridden by someone not knowledgeable

Topic	Requirement	Relation to Design Controls
		about the design of that product, i.e. a non-design engineer.

Topic	Requirement	Relation to Design Controls
Sec. 820.20 (b)(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.	Necessary resources for proper design and development from identification of design inputs through to the transfer of design are required. Resources included personnel, time, money, equipment, facilities, etc. Design personnel must be trained to design controls, your design control procedures, including design change, as well as other relevant quality system requirements and procedures (CAPA, supplier management, etc.).
Sec. 820.20 (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.	Design control processes and projects should be reflected in the quality plan.
	The manufacturer shall **establish** how the requirements for quality will be met.	The design control procedures must align with the quality policy and quality plan.
Sec. 820.20 (e) Quality system procedures	Each manufacturer shall **establish** quality system **procedures** and instructions.	The design control procedures.
	An outline of the structure of the documentation used in the quality system shall be **established** where appropriate.	The design control procedures should be in accordance with established document management procedures and processes.

820.22 Quality Audit

Topic	Requirement	Relation to Design Controls
Sec. 820.22 Quality audit	Each manufacturer shall **establish procedures** for quality audits	Audit procedures must include audits of design and design change.
	and conduct such audits to assure that the quality system is **in compliance** with the **established** quality system requirements	Design control audits must assure that the design control procedures comply with the firm's quality system requirements as well as FDA and other regulatory bodies and that all design projects, including design changes, are performed in accordance with established design control procedures.
	and to determine the **effectiveness** of the quality system.	The audits must show that the design control procedures and processes in place are effective – i.e. produce verified and validated designs that meet the requirement to be non-adulterated and not misbranded.
	Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited.	Design personnel may not audit design controls.
	Corrective action(s), including a re-audit of deficient matters, shall be taken when necessary.	

Topic	Requirement	Relation to Design Controls
	A report of the results of each quality audit, and re-audit(s) where taken, shall be made and such reports shall be **reviewed by management** having responsibility for the matters audited.	Audit findings should be provided to the management over design and design change and that management will be responsible for documenting the audit findings as non-conformances when applicable, investigating them for root cause and taking appropriate corrections, corrective actions and where possible preventive actions.
	The dates and results of quality audits and re-audits shall be **documented**.	

820.25 Personnel

Topic	Requirement	Relation to Design Controls
Sec. 820.25 (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**.	Personnel involved in design and design change must have documentation that shows they have the necessary education, background, training and experience. This means having job descriptions that include the required education, background and experience needed for the job and the training required once the person is hired. The resume or CV provides evidence that design personnel have the required education, background and experience.
Sec. 820.25 (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**.	The training records show they have gotten the training required.
Sec. 820.25 (b) (1) Training	As part of their training, personnel shall be **made aware** of device **defects** which may occur from the improper performance of their specific jobs.	Obviously design personnel must be made aware of how failure to do proper design can result in defective designs in the marketplace.
Sec. 820.25 (b) (2) Training	Personnel who perform verification and validation activities shall be made **aware of defects** and errors	This applies equally to design and manufacturing personnel.

	that may be encountered as part of their job functions.	

Subpart C--Design Controls

820.30 Design controls

Topic	Requirement	Relation to Design Controls
Sec. 820.30 (a) (1) General	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.	Required for many devices but not all. Medical has some in which design controls are not required, yet they utilize them in any case.
Sec. 820.30 (a) (2) General	The following class I devices are subject to design controls:	
Sec. 820.30 (a) (2) (i) General	Devices automated with computer software; and	This includes software that is a device, including medical records software, which is not yet classified.

Topic	Requirement	Relation to Design Controls
Sec. 820.30 (a) (2) (ii) General	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.	
Sec. 820.30 (b) Design and development planning	Each manufacturer shall **establish** and maintain **plans** that describe or reference the design and development activities	Design plans for each design project. For a design change made through the ECO process – the change request acts as the design plan. The schedule is part of the plan. What needs to be in the Design History File throughout the design project is the current schedule showing what has been done and when and what is planned next. The final completed schedule is all that needs to be maintained at the end of the design project showing what was done and when.
	and define responsibility for implementation.	Need to include the design team and their responsibilities in the plan.

Topic	Requirement	Relation to Design Controls
	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.	Need to include how the team will interface with others in the organization during design – including supplier management, manufacturing, test lab, clinical, marketing, regulatory, quality, etc.
	The plans shall be **reviewed, updated, and approved** as design and development evolves.	Plans, and change requests, are reviewed and approved. Plans are not deviated from; they are updated to reflect the change in plan. Plan changes are reviewed and approved by the same level of management that approved the initial plan.
Sec. 820.30 (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**.	There must be design input procedures and they need to include the process by which the design inputs are determined, documented and reviewed and approved. They need to include what source documents and data go into determining the design inputs. A top down risk analysis must be done against the initial design inputs to assure an understanding of the relative risks associated with the design input requirements are understood (ISO 14971). The FDA's Do it by Design guidance provides a list of the input data sources FDA expects to be considered.
	The **procedures** shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements.	The procedures need to describe how you will make sure there are no incomplete, ambiguous and conflicting design input requirements.
	The design input requirements shall be **documented** and shall be reviewed and approved by a designated individual(s).	Should have a standard format for documenting requirements. Requirements need to be written in a manner that allows design outputs to be inspected, measured, analyzed or tested against them or be capable of being translated into something that can be compared to an output. They need to concise and not complex. They need to be

Topic	Requirement	Relation to Design Controls
		traceable, therefore a procedure for tracing inputs through to final outputs and verification and validation activity plans or scripts and to verification and validation activity results. Tracing should also demonstrate the implementation of risk mitigations spelled out in the bottom-up risk assessment performed as design progresses to output specifications, including manufacturing process design.
	The approval, including the date and signature of the individual(s) approving the requirements, shall be **documented**.	This is the document that really starts design. So the approval of this document should happen at the first formal design review and needs to have only "shall" requirements. It can be revised as design progresses if needed but since it is the document that governs what happens next in design it needs to be well thought out and complete before initial approval.
Sec. 820.30 (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 includes each document produced after the initial design input requirement document. This includes next level documents that further translate design inputs into ever narrower design output specifications. The final design output is the device master record which includes all drawings, materials specifications, supplier identification, acceptance activities (incoming, in-process and finished product), packaging and labeling procedures and materials, and manufacturing processes.
	Design output procedures shall contain or make reference to **acceptance criteria**	Design output procedures need to include how design outputs will be documented to show what their acceptance criteria will be. For example: a drawing for a component has many dimensions but not all of them will matter at the time of incoming to assure acceptability so how will you document and where which dimensions need to assessed at incoming. So the documenting of the design output will include documentation of what dimensions and how the output is to be assessed for acceptability for use. This must be done for all outputs – including drawings for components, subassemblies and top assemblies as well as manufacturing processes.

Topic	Requirement	Relation to Design Controls
	and shall ensure that those design outputs that are essential for the **proper functioning of the device** are identified.	In addition to the above: The procedures must include how the design outputs will be documented to show which outputs are essential for the proper functioning of the device. This can be a drawing, a dimension or parameter on a drawing or a process or a process parameter.
	Design output shall be **documented**, reviewed, and approved before release.	Approval of outputs should be at an appropriate level. Review of outputs should include a review of evidence that shows the outputs conform to design inputs. If the trace documentation is complete, it will facilitate that review.
	The approval, including the date and signature of the individual(s) approving the output, shall be **documented**.	

Topic	Requirement	Relation to Design Controls
Sec. 820.30 (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.	These design reviews are not peer reviews they are formal reviews that must include some level of management beyond the team. These formal reviews move design forward. FDA expects at least two of these design reviews at a minimum – the Initial Design Input Review that approves the initial design inputs requirements and the design plan and the Final Design Review that releases design to the marketplace. For a design change, the approval of the design request and the approval to implement the change are the two formal design reviews needed at a minimum. The design plan must state the design reviews to be held for any given design project unless the required reviews are defined in a written design review procedure and the project is not going to deviate from that procedure. The design review procedures should describe what design reviews are normally held, how they are to be conducted and documented, and who is required to attend.
	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 minutes of the design review should always included who attended and in what capacity.

Topic	Requirement	Relation to Design Controls
	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).	At a minimum, need an agenda for the review, minutes of the review including action items and key decisions (which ideally should be kept separate from the minutes). Action items need to be followed and eventually documented as resolved.
Sec. 820.30 (f) Design verification	Each manufacturer shall **establish** and maintain **procedures** for verifying the device design	There need to be design verification procedures. Design verification activities (inspection, measurement, analysis and test) are the activities that get you from design inputs through to final design outputs. Tracing is in itself a verification activity.
	Design verification shall confirm that the design output meets the design input requirements	Verification proves that the design output is appropriate relative to the design input – the outputs are the correct dimensions, tolerances, materials, etc.
	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.	Results include the method – if a test was performed, you will need to document the appropriateness of the test method – especially if it is a test method you devised. This may require test method validation. Also assure all equipment has been calibrated, maintained, qualified or validated prior to use and document this.
Sec. 820.30 (g) Design validation	Each manufacturer shall **establish** and maintain **procedures for validating** the device design.	There need to be design validation procedures. . Design validation activities (inspection, measurement, analysis and test) are the activities that are done to show the device performs and functions as intended by the design inputs and will meet user needs. Design validation needs to be done on frozen design.
	Design validation shall be performed under defined operating conditions on initial production units, lots, or	The production processes for components, subassemblies or top assemblies must be at the stage whereby they can be validated although validation is not required to have been completed prior to

Topic	Requirement	Relation to Design Controls
	batches, or their equivalents.	building the units to be used in design validation. All materials and components, etc. must come from the suppliers that will be used for commercial production units.
	Design validation shall ensure that devices conform to defined user needs and intended uses	This is defined users needs and your intended uses. Design validation is not merely clinical trial or usability studies.
	and shall include testing of production units under actual or simulated use conditions.	Simulated testing needs to be validated for applicability unless a standard method is being utilized.
	Design validation shall include software validation and risk analysis, where appropriate.	All software that is part of or is a finished medical device must be validated. FDA's guidance for Software Design and Development should be followed. Risk analysis is always appropriate in today' regulatory environment and begins at the design input stage and continues for the life of the device. FDA recognizes ISO 14971 for performing proper risk management.
	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.	Results include the method – if a test was performed, you will need to document the appropriateness of the test method – especially if it is a test method you devised. This may require test method validation. Also assure all equipment has been calibrated, maintained, qualified or validated prior to use and document this.

Topic	Requirement	Relation to Design Controls
Sec. 820.30 (h) Design transfer	Each manufacturer shall **establish** and maintain **procedures** to ensure that the device design is correctly translated into production specifications.	There needs to be design transfer procedures. Design transfer begins early in design. It includes the identification of suppliers, facilities, production process design, training of production personnel as well as others, design of service processes, installation procedures, packaging and labeling procedures, etc.
Sec. 820.30 (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	There needs to be design change procedures for changes made during design as well as for changes made after the design is released to commercial production. Validation is required (remember this is performance, functionality and may include clinical trials or usability studies) unless you can document with scientific rationale why verification only will suffice. Design changes are those changes that may affect the physical design of the device (this may include changes to suppliers, or to production processes or methods or equipment or materials).
Sec. 820.30 (j) Design history file	Each manufacturer shall **establish** and **maintain** a DHF for each type of device.	There needs to be a DHF by device or device family. Not by design project.
	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	The DHF must show the complete design history of the device overtime, including design changes made through the ECO process. Therefore the DHF needs to be named and maintained in such a manner that you can equate design changes in the ECO system to a specific DHF for the device. The DHF is a compilation of living and historical documents. Living documents include the design input documents, design output documents, risk documents, and trace documents. They can also include verification and validation activity plans, protocols or scripts and the most recent results.

Topic	Requirement	Relation to Design Controls
		Historical documents include design plans, design reviews, prior verification and validation activity results, etc.

Subpart D--Document Controls

820.40 Document Controls

Topic	Requirement	Relation to Design 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:	The Design History File and all documents should be handled as formal documents and records in accordance with established document control procedures.
Sec. 820.40 (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.	All design control procedures, documents, records, forms, templates, etc. should go through appropriate document review and approval. The purpose of document control is to make sure documents are formatted correctly and meet internal documentation requirements as well as making sure that only approved documents are available for use.
	The approval, including the date and signature of the individual(s) approving the document, shall be **documented.**	Ditto
	Documents **established** to meet the requirements of this part shall be **available** at all locations for which they are designated, used, or otherwise necessary,	Design History file documents, especially those that are living documents, need to be available at the design facility. All risk documents should also be available at the manufacturing facility as well as facilities conducting complaint, CAPA or other failure investigations and those places where decisions are made regarding post-market reporting and field actions. The device

Topic	Requirement	Relation to Design Controls
		master record should be available at the manufacturing facilities but be available to design engineers and those involved in making, reviewing and approving design changes.
	and all obsolete documents shall be promptly **removed** from all points of use or otherwise prevented from unintended use.	
Sec. 820.40 (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.	Ditto for design documents. Document change control controls the change from the aspect of assuring the documents are revised correctly and approval is obtained and proper revision control is utilized.
	Approved changes shall be communicated to the appropriate personnel in a timely manner.	Ditto, includes training to changes.
	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.	This is really making sure revision control is appropriately documented and maintained.

Subpart E--Purchasing Controls

820.50 Purchasing Controls

Topic	Requirement	Relation to Design 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.**	Supplier management procedures need to ensure that supplier qualification begins in design.
Sec. 820.50 (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:	
Sec. 820.50 (a) (1) Purchasing controls	Evaluate and select potential suppliers, contractors, and consultants on the basis of their **ability to meet specified requirements**, including quality requirements.	This process begins in design.

Topic	Requirement	Relation to Design Controls
	The evaluation shall be **documented**.	
Sec. 820.50 (a) (2) Purchasing controls	Define the type and extent of **control** to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.	This should be tied to whether the supplier is supplying an essential output.
Sec. 820.50 (a) (3) Purchasing controls	**Establish** and maintain records of acceptable suppliers, contractors, and consultants.	
Sec. 820.50 (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.	This should be based on the risk assessment performed during design.

Topic	Requirement	Relation to Design Controls
	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

Topic	Requirement	Relation to Design Controls
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 mix-ups.	During design all components, parts, sub-assemblies and top assemblies need to be identified as for “Research purposes only – not for commercial distribution.” Or something similar to make sure the product will not end up in commercially distributed devices.

820.65 Traceability

Topic	Requirement	Relation to Design Controls
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.	How the devices will be identified for traceability should be made during design of the product and the product labeling – if it is to be manufactured into the device, design verification and validation must show that the addition of the identifying number does not adversely affect the device performance.
	The procedures shall facilitate corrective action.	
	Such identification shall be **documented** in the DHR	

Subpart G--Production and Process Controls

820.70 Production and Process Controls

Topic	Requirement	Relation to Design Controls
Sec. 820.70 (a) General	Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications.	The design and development of the production processes are the activities required during design transfer.
	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.	The needed specifications are design outputs and V&V should determine whether the manufacturing process could impact the design of the product and determine the controls necessary to prevent it.
	Where process controls are needed they shall include:	
Sec. 820.70 (a) (1) General	**Documented** instructions, standard operating **procedures** (SOP's), and methods that define and control the manner of production;	These instructions need to be developed as part of design transfer.

Topic	Requirement	Relation to Design Controls
Sec. 820.70 (a) (2) General	Monitoring and control of process parameters and component and device characteristics during production;	Design transfer activity.
Sec. 820.70 (a) (3) General	Compliance with specified reference standards or codes;	Design transfer activity.
Sec. 820.70 (a) (4) General	The approval of processes and process equipment; and	Design transfer activity.
Sec. 820.70 (a) (5) General	Criteria for workmanship which shall be expressed in **documented** standards or by means of identified and approved representative samples	Design transfer activity.
Sec. 820.70 (b) Production and process changes	Each manufacturer shall **establish** and maintain **procedures for changes** to a specification, method, process, or procedure.	Many of these changes may also be design changes; therefore, design engineers need to have visibility to changes made in manufacturing to determine whether additional design V&V may be required to approve the change.
	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	See above.

Topic	Requirement	Relation to Design Controls
Sec. 820.70 (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.	Design transfer activity.
	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.	
Sec. 820.70 (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.	Design transfer activity.
	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.	Design transfer activity. (If applicable).

Topic	Requirement	Relation to Design Controls
Sec. 820.70 (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.	Design transfer activity.
Sec. 820.70 (f) Buildings	Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling.	Design transfer activity.
Sec. 820.70 (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.	Design transfer activity.
Sec. 820.70 (g) (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.	Design transfer activity.
	Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be **documented**.	Design transfer activity.

Topic	Requirement	Relation to Design Controls
Sec. 820.70 (g) (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**.	
Sec. 820.70 (g) (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.	Design transfer activity.
Sec. 820.70 (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.	Design transfer activity. Should also be assessed via design V&V.
	The removal or reduction of such manufacturing material shall be **documented**.	Design transfer activity. And design V&V.

Topic	Requirement	Relation to Design Controls
Sec. 820.70 (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.	Design transfer activity. Also applies to software and automated test equipment used in design V&V.
	All software changes shall be **validated** before approval and issuance	Design transfer activity. Also applies to software and automated test equipment used in design V&V.
	These validation activities and results shall be **documented**.	Design transfer activity. Also applies to software and automated test equipment used in design V&V.

820.72 Inspection, Measuring, and Test Equipment

Topic	Requirement	Relation to Design Controls
820.72 (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.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
	Each manufacturer shall **establish** and maintain **procedures** to ensure that equipment is routinely calibrated, inspected, checked, and maintained.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
	The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
	These activities shall be **documented**.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.

Topic	Requirement	Relation to Design Controls
820.72 (b) Calibration	Calibration procedures shall include specific directions and limits for accuracy and precision.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
	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.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
	These activities shall be **documented**.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
820.72 (b) (1) Calibration standards	Calibration standards used for inspection, measuring, and test equipment shall be **traceable** to national or international standards.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
	If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.

Topic	Requirement	Relation to Design Controls
	If no applicable standard exists, the manufacturer shall **establish** and maintain an in-house standard.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
820.72 (b) (2) Calibration records	The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be **documented**.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.
	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.	Design transfer activity. Also applies to software and automated and other test equipment used in design V&V.

820.75 Process Validation

Topic	Requirement	Relation to Design Controls
820.75 (a) Process validation	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.	Design transfer activity.
	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**.	Design transfer activity.
820.75 (b) Process validation	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.	Design transfer activity.
820.75 (b) (1) Process validation	Each manufacturer shall ensure that validated processes are performed by **qualified individual(s)**.	Design transfer activity.

Topic	Requirement	Relation to Design Controls
820.75 (b) (2) Process validation	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**.	Design transfer activity.
820.75 (c) Process validation	When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform **revalidation** where appropriate.	Design transfer activity. For design/production/process changes.
	These activities shall be **documented**.	Design transfer activity. For design/production/process changes.

Subpart H--Acceptance Activities

820.80 Receiving, In-Process, and Finished Device Acceptance

Topic	Requirement	Relation to Design Controls
820.80 (a) General	Each manufacturer shall **establish** and maintain **procedures** for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.	Design transfer activity. From design V&V and supplier management activities.
820.80 (b) Receiving acceptance activities	Each manufacturer shall **establish** and maintain **procedures** for acceptance of incoming product.	Design transfer activity. From design V&V and supplier management activities.
	Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements.	Design transfer activity. For all product used for prototype and V&V builds.
	Acceptance or rejection shall be **documented**.	Design transfer activity. For all product used for prototype and V&V builds.
820.80 (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.	Design transfer activity. For all product used for prototype and V&V builds.

Topic	Requirement	Relation to Design Controls
	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.**	Design transfer activity. For all product used for prototype and V&V builds.
820.80 (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.	Design transfer activity. For all product used for prototype and V&V builds.
	Finished devices shall be held in **quarantine** or otherwise adequately controlled until released.	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
	Finished devices shall not be released for distribution until:	
820.80 (d) (1) Final acceptance activities	The **activities** required in the DMR are **completed**;	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
820.80 (d) (2) Final acceptance activities	The associated data and documentation is **reviewed**;	Design transfer activity.

Topic	Requirement	Relation to Design Controls
		For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.

Topic	Requirement	Relation to Design Controls
820.80 (d) (3) Final acceptance activities	the release is authorized by the **signature** of a designated individual(s); and	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
820.80 (d) (4) Final acceptance activities	the authorization is **dated**	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
820.80 (e) Acceptance records	Each manufacturer shall document **acceptance activities** required by this part. These records shall include:	Design transfer activity. For all product used for prototype and V&V builds.
820.80 (e) (1) Acceptance records	The acceptance activities performed;	Design transfer activity. For all product used for prototype and V&V builds.
820.80 (e) (2) Acceptance records	the **dates** acceptance activities are performed;	Design transfer activity. For all product used for prototype and V&V builds.
820.80 (e) (3) Acceptance records	the results;	Design transfer activity. For all product used for prototype and V&V builds
820.80 (e) (4) Acceptance records	the **signature** of the individual(s) conducting the acceptance activities; and	Design transfer activity. For all product used for prototype and V&V builds.
820.80 (e) (5) Acceptance records	where appropriate, the equipment used.	Design transfer activity. For all product used for prototype and V&V builds
	These **records** shall be part of the DHR	Design transfer activity. For all product used for prototype and V&V builds.

820.86 Acceptance Status

Topic	Requirement	Relation to Design Controls
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.	Design transfer activity. For all product used for prototype and V&V builds.
	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	Design transfer activity. For all product used for prototype and V&V builds.

Subpart I--Nonconforming Product

820.90 Nonconforming Product

Topic	Requirement	Relation to Design Controls
820.90 (a) Control of nonconforming product	Each manufacturer shall **establish** and maintain **procedures** to control product that does not conform to specified requirements.	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
	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**	
820.90 (b) Nonconformity review and disposition		
820.90 (b) (1) Nonconformity review and	Each manufacturer shall **establish** and maintain **procedures** that define the responsibility for review and the authority for the **disposition** of	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released

Topic	Requirement	Relation to Design Controls
disposition	nonconforming product.	for commercial distribution.
	The **procedures** shall set forth the review and disposition process.	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
	Disposition of nonconforming product shall be **documented**.	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
	Documentation shall include the **justification** for use of nonconforming product and the signature of the individual(s) authorizing the use	Design transfer activity. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
820.90 (b) (2) Nonconformity review and disposition	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.	Design transfer activity. If standard rework is to be allowed and written in to the manufacturing procedures. For all product used for prototype and V&V builds. No finished device for other than a design validation build can be released for commercial distribution.
	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

Topic	Requirement	Relation to Design Controls
820.100 (a) Corrective and preventive action	Each manufacturer shall **establish** and maintain **procedures** for implementing corrective and preventive action. The procedures shall include requirements for:	CAPA applies to design activities when a corrective or preventive action includes a design change. Or when a design V&V failure can be an indication of a problem with product in the market place (a failure during design V&V for a design change that is not limited to the portion of design undergoing change).
820.100 (a) (1) Corrective and preventive action	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.	This analysis should also be done to help determine appropriate design input requirements for new designs or next generation designs.
	Appropriate **statistical methodology** shall be employed where necessary to detect recurring quality problems;	
	Investigating the cause of nonconformities relating to product, processes, and the quality system;	CAPA applies to design activities when a corrective or preventive action includes a design change. Or when a design V&V failure can be an indication of a problem with product in the market place (a failure during design V&V for a design change that is not limited to the portion of design undergoing change).

Topic	Requirement	Relation to Design Controls
820.100 (a) (3) Corrective and preventive action	Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;	Design change control.
820.100 (a) (4) Corrective and preventive action	Verifying or validating the corrective and preventive action to ensure that such **action is effective** and does not adversely affect the finished device;	Design V&V for design changes.
820.100 (a) (5) Corrective and preventive action	Implementing and recording changes in methods and procedures needed to **correct and prevent** identified quality problems;	Systemic actions to assure design controls function more effectively.
820.100 (a) (6) Corrective and preventive action	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	Feedback to design to improve the design process.
820.100 (a) (7) Corrective and preventive action	Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for **management review**.	

Topic	Requirement	Relation to Design Controls
820.100 (b) Corrective and preventive action	All activities required under this section, and their results, shall be **documented**.	

Subpart K--Labeling and Packaging Control

820.120 Device Labeling

Topic	Requirement	Relation to Design Controls
820.120 Device labeling	Each manufacturer shall **establish** and maintain **procedures** to control labeling activities.	Design transfer activity.
820.120 (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.	Design transfer activity.
820.120 (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.	Design transfer activity.
	The release, including the date and signature of the individual(s) performing the examination, shall be **documented** in the DHR.	Design transfer activity.

Topic	Requirement	Relation to Design Controls
820.120 (c) Labeling storage	Each manufacturer shall store labeling in a manner that provides proper identification and is designed to **prevent mix-ups**.	Control of label/labeling for V&V builds needs to be established.
820.120 (d) Labeling operations	Each manufacturer shall control labeling and packaging operations to prevent labeling mix-ups. The label and labeling used for each production unit, lot, or batch shall be **documented** in the DHR.	Control of label/labeling for V&V builds needs to be established.
820.120 (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	Control of prototypes to assure they are not commercially distributed is required. The control number for prototypes should differ than for commercial production units.

820.130 Device Packaging

Topic	Requirement	Relation to Design Controls.
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	Design transfer activity.

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

820.140 Handling

Topic	Requirement	Relation to Design Controls
820.140 Handling	Each manufacturer shall **establish** and maintain **procedures** to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling	Design transfer activity.

820.150 Storage

Topic	Requirement	Relation to Design Controls
820.150 (a) Storage	Each manufacturer shall **establish** and maintain **procedures** for the control of storage areas and stock rooms for product to prevent mix-ups, 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.	Design transfer activity.
	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	Design transfer activity.
820.150 (b) Storage	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

Topic	Requirement	Relation to Design Controls
820.160 (a) Distribution	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.	Prototype and design V&V builds may not be distributed. A design validation product may be re-qualified for commercial distribution if the final design and process used to build the product has been deemed to be at production or production equivalent status after all design V&V and process validations are complete and signed off as approved.
	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**.	Design transfer activity.
820.160 (b) Distribution	Each manufacturer shall maintain distribution records which include or refer to the location of:	Design transfer activity – update ERP system with new design or change design.
820.160 (b)(1) Distribution	The name and address of the initial consignee;	
820.160 (b)(2) Distribution	The identification and quantity of devices shipped;	

Topic	Requirement	Relation to Design Controls
820.160 (b)(3) Distribution	The date shipped; and	
820.160 (b)(4) Distribution	Any control number(s) used	

820.170 Installation

Topic	Requirement	Relation to Design Controls
820.170 (a) Installation	Each manufacturer of a device requiring installation shall **establish** and maintain adequate installation and **inspection instructions**, and where appropriate **test procedures**.	Design transfer activity – if an installed device.
	Instructions and procedures shall include directions for ensuring proper installation so that the device will **perform as intended** after installation.	Design transfer activity.
	The manufacturer shall distribute the instructions and **procedures** with the device or otherwise make them available to the person(s) installing the device.	
820.170 (b) Installation	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.	

Subpart M--Records

820.180 General Requirements

Topic	Requirement	Relation to Design Controls
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.	All design control procedures and all documents and records to be maintained as part of design.
	Such records, including those not stored at the inspected establishment, shall be made **readily available** for review and copying by FDA employee(s).	All design control procedures and all documents and records to be maintained as part of design.
	Such records shall be legible and shall be **stored** to minimize deterioration and to prevent loss.	All design control procedures and all documents and records to be maintained as part of design.
	Those records stored in automated data processing systems shall be **backed up**	All design control procedures and all documents and records to be maintained as part of design.
820.180(a) General requirements: 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.	All design control procedures and all documents and records to be maintained as part of design.

Topic	Requirement	Relation to Design Controls
820.180(b) General requirements: 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.	All design control procedures and all documents and records to be maintained as part of design.
820.180(c) General requirements: 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 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	

820.181 Device Master Record

Topic	Requirement	Relation to Design Controls
820.181 Device master record	Each manufacturer shall maintain device master records (DMR's).	The final design output.
	Each manufacturer shall ensure that each DMR is prepared and approved in accordance with §820.40	The final design output and transferred from design to manufacturing.
	The DMR for each type of device shall include, or refer to the **location** of, the following information:	
820.181 (a) Device master record	Device **specifications** including appropriate drawings, composition, formulation, component specifications, and software specifications;	The final design output.
820.181 (b) Device master record	Production process **specifications** including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;	The final design output.
820.181 (c) Device master record	Quality assurance **procedures** and specifications including acceptance criteria and the quality assurance equipment to be used;	The final design output.

Topic	Requirement	Relation to Design Controls
820.181 (d) Device master record	Packaging and labeling **specifications**, including methods and processes used; and	The final design output.
820.181 (e) Device master record	Installation, maintenance, and servicing procedures and methods	The final design output.

820.184 Device History Record

Topic	Requirement	Relation to Design Controls
820.184 Device history record	Each manufacturer shall maintain device history records (DHR's)	DHRs are needed for all prototype and design V&V builds.
	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.	DHRs are needed for all prototype and design V&V builds.
	The DHR shall include, or refer to the **location** of, the following information:	

Topic	Requirement	Relation to Design Controls
820.184(a) Device history record	The dates of manufacture;	DHRs are needed for all prototype and design V&V builds.
820.184(b) Device history record	The quantity manufactured	DHRs are needed for all prototype and design V&V builds.
820.184(c) Device history record	The quantity released for distribution;	DHRs are needed for all prototype and design V&V builds.
820.184(d) Device history record	The acceptance records which demonstrate the device is manufactured in accordance with the DMR	DHRs are needed for all prototype and design V&V builds.
820.184(e) Device history record	The primary identification label and labeling used for each production unit; and	DHRs are needed for all prototype and design V&V builds.
820.184(f) Device history record	Any device identification(s) and control number(s) used	DHRs are needed for all prototype and design V&V builds.

820.186 Quality System Record

Topic	Requirement	Relation to Design Controls
820.186 Quality system record	Each manufacturer shall maintain a quality system record (QSR).	Design control procedures and records associated with design and development but not specific to a particular product (calibration, validation, maintenance, etc.)
	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	Design control procedures and records associated with design and development but not specific to a particular product (calibration, validation, maintenance, etc.)
	Each manufacturer shall ensure that the QSR is prepared and approved in accordance with §820.40.	Design control procedures and records associated with design and development but not specific to a particular product (calibration, validation, maintenance, etc.)

820.198 Complaint Files

Topic	Requirement	Relation to Design Controls
820.198 (a) Complaint files	Each manufacturer shall maintain complaint files.	Complaint data is relevant to design to help establish design input requirements for new or next generation design.
	Each manufacturer shall **establish** and maintain **procedures** for receiving, reviewing, and evaluating complaints by a formally designated unit.	
	Such procedures shall ensure that:	
820.198 (a) (1) Complaint files	All complaints are processed in a uniform and timely manner;	
820.198 (a) (2) Complaint files	Oral complaints are **documented** upon receipt; and	
820.198 (a) (3) Complaint files	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.	

Topic	Requirement	Relation to Design Controls
820.198 (b) Complaint files	Each manufacturer shall **review and evaluate** all complaints to determine whether an investigation is necessary.	Design data (reliability data, risk data, etc.) should be used to help determine whether an investigation is required.
	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	Support not to investigate should be provided from design documentation.
820.198 (c) Complaint files	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.	
820.198 (d) Complaint files	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**	

Topic	Requirement	Relation to Design Controls
	In addition to the information required by §820.198(e), records of investigation under this paragraph shall include a determination of:	
820.198 (d) (1) Complaint files	Whether the device failed to meet specifications;	
820.198 (d) (2) Complaint files	Whether the device was being used for treatment or diagnosis; and	
820.198 (d) (3) Complaint files	The relationship, if any, of the device to the reported incident or adverse event.	
820.198 (e) Complaint files	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	
820.198 (e) (1) Complaint files	The name of the device;	
820.198 (e) (2)	The date the complaint was received;	

Topic	Requirement	Relation to Design Controls
Complaint files		
820.198 (e) (3) Complaint files	Any device identification(s) and control number(s) used	
820.198 (e) (4) Complaint files	The name, address, and phone number of the complainant	
820.198 (e) (5) Complaint files	The nature and details of the complaint;	
820.198 (e) (6) Complaint files	The dates and results of the investigation;	
820.198 (e) (7) Complaint files	Any corrective action taken; and	
820.198 (e) (8) Complaint files	Any reply to the complainant.	
820.198 (f) Complaint files	When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the	

Topic	Requirement	Relation to Design Controls
	investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.	
820.198 (g) Complaint files	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:	
820.198 (g) (1) Complaint files	A location in the United States where the manufacturer's records are regularly kept; or	
820.198 (g) (2) Complaint files	The location of the initial distributor.	

Subpart N--Servicing

820.200 Servicing

Topic	Requirement	Relation to Design Controls
820.200 (a) Servicing	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.	Design transfer activity.
820.200 (b) Servicing	Each manufacturer shall **analyze** service reports with appropriate statistical methodology in accordance with §820.100.	
820.200 (c) Servicing	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	
820.200 (d) Servicing	Service reports shall be **documented** and shall include	
820.200 (d) (1) Servicing	The name of the device serviced;	

Topic	Requirement	Relation to Design Controls
820.200 (d) (2) Servicing	Any device identification(s) and control number(s) used;	
820.200 (d) (3) Servicing	The date of service;	
820.200 (d) (4) Servicing	The individual(s) servicing the device;	
820.200 (d) (5) Servicing	The service performed; and	
820.200 (d) (6) Servicing	The test and inspection data	

Subpart O--Statistical Techniques

820.250 Statistical Techniques

Topic	Requirement	Relation to Design Controls
820.250 (a) Statistical techniques	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.	All V&V activities that include sampling will be supported by statistically valid sample sizes. Includes activities relative to usability studies, customer satisfaction surveys, clinical trials, etc. Statistically valid test cases which may make more sense for design V&V should also be justified by valid statistical methodology.
820.250 (b) Statistical techniques	Sampling plans, when used, shall be written and based on a valid **statistical rationale**.	All V&V activities that include sampling will be supported by statistically valid sample sizes. Includes activities relative to usability studies, customer satisfaction surveys, clinical trials, etc. Statistically valid test cases which may make more sense for design V&V should also be justified by valid statistical methodology.
	Each manufacturer shall **establish** and maintain **procedures** to ensure that sampling methods are adequate for their intended use and to ensure that when changes do occur, the sampling plans are reviewed.	All V&V activities that include sampling will be supported by statistically valid sample sizes. Includes activities relative to usability studies, customer satisfaction surveys, clinical trials, etc. Statistically valid test cases which may make more sense for design V&V should also be justified by valid statistical methodology.
	These activities shall be **documented**	All V&V activities that include sampling will be supported by statistically valid sample sizes. Includes activities relative to usability studies, customer satisfaction surveys, clinical trials, etc. Statistically valid test cases which may make more sense for design V&V should also be justified by valid statistical methodology.

Other regulations that apply:

21 CFR Part 807 - 510(k)
21 CFR Part 812 – Investigational Device Exemptions
21 CFR Part 801 – Labeling
21 CFR Part 862-892 – Device classifications
21 CFR Part 814 – Premarket Approvals
21 CFR Part 50 - Informed Consent
21 CFR Part 54 – Financial Disclosure for Clinical Investigators
21 CFR Part 56 – Institutional Review Board

Also, statements in the Food, Drug and Cosmetic Act for device premarket approval (515) or premarket notification (510(k))

Appendix A: Definitions

(a) Act means the Federal Food, Drug, and Cosmetic Act, as amended (sections 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.

(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.

(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 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) Non-conformity means the non-fulfillment of a specified requirement.

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