FINAL

Design Control Inspectional Strategy

Revised February, 1998

All Previous Editions Are Obsolete Effective through May 31, 1998

Instructions:

1. This is intended to be an information gathering document. Information that cannot be gathered may indicate an item or area in need of improvement. This document should not be used as an enforcement tool from June 1, 1997 through May 31, 1998.

2. The normal collection of documentation to establish a nonconformance will not be required. However, the documents reviewed should be referenced and addressed in the responses to the questions.

3. A copy of this completed Design Control Inspectional Strategy will be known as the Design Control Inspectional Strategy Report (the report). The original report will become a part of the official EIR as an attachment. One copy of the report will be issued to the manufacturer at the time of the inspection closeout meeting. A second copy of the report along with copies of Forms 481(E), 481(A), 481(C) if used, and the overall design control procedure if collected, will be forwarded to the Center for Devices and Radiological Health, OC/HFZ-306, Attention: Joy Lazaroff.

4. The Design Control Inspectional Strategy Report is to be completed by the Investigator based on the Investigator's own evaluation of the manufacturer's Design Control System. This is to be accomplished via the Investigator's own review and assessment of the firm's procedures and their implementation. The Investigator should not merely ask the Design Control questions and record the firm's verbal response. If a firm has completed a DCIS report as part of an evaluation of their own internal systems, the Investigator may not accept that report in lieu of the Investigator's own evaluation. Investigators shall not look at the firm's completed DCIS report until after the Investigator has completed their own evaluation of the firm's design controls. Do not collect a copy of the firm's completed DCIS report.

5. If the firm has made no design changes, and has no ongoing or planned design projects, the Investigator must still inspect the Design Change procedures and complete the Design Change section of the DCIS report. If the firm has established additional Design Control procedures, the Investigator must also review those procedures and complete the appropriate sections of the DCIS report.

6. Items recorded in the Areas Of Needed Improvement section of this report must be written in the format and language of an FDA-483 Observation in accordance with current IOM guidance. However, do not annotate Areas Of Needed Improvement.

7. Since this report will be a part of the manufacturer's EIR, it will be available to the public through the Freedom of Information Act (FOIA). Any trade secret or proprietary information that this report may contain should be specifically noted by the FDA Investigator in cooperation with the manufacturer to aid in determining where redaction may be required for purposes of filling FOIA requests.

8. Most sections of the regulation have a clause requiring specific documentation of the person(s) involved, dates, identification of project, etc. that is not identified as a requirement in Section 820.30(j), Design History File (DHF). Since these specific DHF requirements are only addressed in the individual sections, areas of improvement would be cited in those respective sections and not in Section 820.30(j), Design History File.

Notes:

1. Please identify device types traditionally manufactured by the firm if no specific project is available for review. This information should be recorded under 820.30(a), General, Question #1, of the report.

2. In addition to his/her signature, the Investigator must legibly print or type his/her name.

3. There are four PAC Codes available for reporting Design Control inspections as follows:

82830D = Domestic Design Control Inspections.
83830D = Domestic Pre-Approval Design Control Inspections.
82R915 = Foreign Design Control Inspections.
83R915 = Foreign Pre-Approval Design Control Inspections.

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820.30(a) General

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Regulatory Requirements

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 below.

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

Questions

1. Select and describe a device that was subject to design controls and indicate whether it was an original design or a modification to an existing design. (This includes any changes to an existing device that occurred after June 1, 1997.)

2. For the device selected, identify at what stage in the design and development effort design controls were applied. If the design and development effort has not been completed, identify the current status of the design and development effort. (Note, if the design and development effort was initiated prior to June 1, 1997, identify the date the design effort was initiated.)

820.30(b) Design and Development Planning

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Regulatory Requirements

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

Questions

1. Summarize the format and structure of the design and development planning process for the chosen device. (If the manufacturer has established a written procedure used to control or describe their overall design process, attach a copy. Note, this is not a specific requirement under the regulation but may be useful during the one year learning phase.)

2. Determine if the plan describes or references and assigns responsibility for the implementation of each of the following:

    * Risk Analysis
    * Design Input
    * Design Output
    * Design Review
    * Design Verification
    * Design Validation
    * Design Transfer
    * Design Changes
    * Interfaces

3. Determine whether the plan has been reviewed, updated, and approved as design and development evolves.

820.30(c) Design Input

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Regulatory Requirements 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.

Questions

1. Summarize the manufacturer's written procedure(s) for identification and control of design input. From what sources are design inputs sought?

2. Do design input procedures cover the relevant aspects, such as: (Mark all that apply and list additional aspects.)

   * intended use
   * user/patient/clinical
   * performance characteristics
   * safety
   * limits and tolerances
   * risk analysis
   * toxicity and biocompatibility
   * electromagnetic compatibility (EMC)
   * compatibility with accessories/auxiliary devices
   * compatibility with the environment of intended use
   * human factors
   * physical/chemical characteristics
   * labeling/packaging
   * reliability
   * statutory and regulatory requirements
   * voluntary standards
   * manufacturing processes
   * sterility
   * MDRs/complaints/failures and other historical data
   * design history files (DHFs)

3. For the specific design covered, how were the design input requirements identified, reviewed for adequacy, and documented?

4. Summarize the process for resolving incomplete, ambiguous, or conflicting requirements. For the design reviewed, identify any incomplete, ambiguous, or conflicting requirements that were not resolved per the manufacturer's procedures.

5. Summarize how general input information and requirements are translated to specific requirements or specifications.

6. Summarize how the design input addresses the user interface: the hardware (and software, if applicable) features that define the interactions between users and equipment. For example, are exploratory studies (e.g., interviews), usability studies (e.g., user evaluation, task analysis, risk analysis, or workload analysis), or any combination thereof conducted? Describe the method(s) used.

7. Summarize the methods used for any risk analysis done at the design input stage.

8. For an electrically powered device, where electromagnetic compatibility (EMC) should have been considered in the design, determine the following:

   * How has EMC been addressed with regard to the device use environment? For example, the interface with other medical devices or the interference from other consumer products.

   * If complaint or failure data for similar devices distributed by the manufacturer indicated EMC problems, did the manufacturer use this information in establishing the design requirements for the new device?

   * Identify any relevant EMC standards used as a part of the design input process.

9. Who is responsible for review and approval of the design input requirements? Has approval been documented?

820.30(d) Design Output

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Regulatory Requirements

Each manufacturer shall establish and maintain procedures for defining an documenting design output in terms that allow an adequate evaluation o 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.

Questions

1. How do the design and development procedures identify and define design output?
2. Explain how design outputs are expressed in terms that allow comparison to design inputs.
3. How are the characteristics essential to the proper functioning of the device identified in the design output?
4. Provide some examples of acceptance criteria for design output.
5. Who is responsible for review and approval of the design output prior to release? Has approval been documented?

820.30(e) Design review

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Regulatory Requirements

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).

Questions

1. Summarize the manufacturer's procedure(s) that defines and controls formal design reviews. Discuss any alternative terminology for design review used by the manufacturer pertaining to design review activities.

2. What has the manufacturer identified as appropriate stages of design and development for formal design reviews.

3. What documentation exists to demonstrate that the manufacturer has conducted formal design reviews at the identified stages?

4. What mechanisms in the design review procedure exist to assure that formal design reviews are comprehensive and systematic? How are problems or action items identified during a design review handled?

5. Select a problem or action item that was identified during a formal design review and summarize its disposition if completed.

6. How does the design review procedure(s) assure identification of organizational functions which should be represented at formal design reviews?

7. Review the documentation from at least one formal design review and verify that the appropriate organizational functions participated, including at least one individual not having direct responsibility for the design stage being reviewed. If not, explain.

8. How does the design review procedure(s) assure that identified design inputs are addressed by design outputs? How is this documented?

820.30(f) Design Verification

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Regulatory Requirements

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. Questions

1. Briefly describe the manufacturer's procedure(s) for design verification.

2. Provide example(s) of significant point(s) during the design process where verifications were conducted. (Verification may occur at one point or multiple points.)

3. Choose one specific input requirement. Describe the verification methods and activities used to confirm that the input requirement has been fulfilled by the design output.

4. In terms of human factors or user interface, what verification methods have been employed to confirm that the input requirements are met (e.g., usability testing such as prototyping, simulations).

5. Does the verification data show that output meets input? If output does not meet input, provide an example of how the manufacturer resolved the discrepancy.

6. Does the design history file identify the methods of design verification, dates, and individuals performing verification activities?

820.30(g) Design Validation

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Regulatory Requirements

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

Questions

1. Summarize the design validation procedure(s).

2. Briefly describe at least one design validation activity performed on production or equivalent devices.

3. If design validation activities were performed on non-production devices, then how were the devices shown to be equivalent to production devices?

4. What evaluations (clinical or other activities) were performed to assist in validating that the device design meets defined user need and intended uses? Design validation activities may include:

   * Clinical studies approved via Internal Review Boards (IRBs) and Investigational Device Exemptions (IDEs), or IRB alone for non-significant devices.
   * 510(k) historical database search.
   * Clinical evaluations in clinical or nonclinical settings.
   * Literature searches.
   * Review of labels and labeling, packaging, and other historical product information.

5. Describe the actual or simulated use conditions under which the finished device was evaluated to validate the design.

6. How did the manufacturer resolve discrepancies encountered during design validation activities? Provide an example of an unresolved discrepancy, if any, and the manufacturer's justification for leaving the discrepancy unresolved.

7. If the device contains software, explain the method(s) by which the software has been validated.

8. Give a few examples of how risks have been identified, analyzed, and reduced. Were tools such as Failure Mode Effects Analysis (FMEA), Failure Mode Effects and Criticality Analysis (FMECA), Fault Tree Analysis, etc. utilized? Provide examples of any risks that were not resolved.

9. Based upon the review of the design history file, does the documentation identify the design, methods of design validation, dates, and individuals performing design validation activities? Explain any discrepancies.

820.30(h) Design Transfer

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Regulatory Requirements

Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

Questions

1. Describe the procedure(s) for transferring the design output for the device from design to manufacturing.

2. Select at least one design feature and review the transfer process to confirm that procedures from design transfer were followed and design output was correctly translated into production specifications.

820.30(i) Design Changes

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Regulatory Requirements

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.

Questions

1. When in the design process does the firm begin to control design changes?
2. What criteria in the design change procedure(s) are used to control changes to approved elements of the design?
3. Does the design change procedure(s) address when verification of changes is sufficient in lieu of validation of changes?
4. For design changes that were verified but not validated, what was the justification that validation was unnecessary?
5. Who is authorized to review and approve design changes before they are implemented, and how is the approval documented?

820.30(j) Design History File

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Regulatory Requirements

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.

Questions

1. How does the manufacturer maintain and retain the contents of the design history file?
2. List the key elements in the manufacturer's design history file and explain how these elements support that the design was developed in accordance with the design plan and procedures.
3. If more than one device shares a common design history file, how does the firm identify each device within the family or group having common design characteristics?