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Design Controls - 21 CFR 820.30 From June 1, 1997 through May 31, 1998, all GMP inspections of medical device manufacturers will include an assessment of the firm's design controls utilizing the Design Control Inspectional Strategy (DCIS) included in CP7382.830 Attachment F (also available electronically on CDRH's home page and the Banyan Bulletin Board under DFI Live, Medical Device Reference Materials.) This strategy constitutes the method of conducting an inspection of design controls. For this first year, a transition period for design controls, no observation relative to design controls (or changes or software - see Moratorium memo dated June 6, 1997, Attachment B) will be included on the FDA 483 or used to support any regulatory action. If the design of a device is found to be unsafe or ineffective for its intended use, FDA can take action under other sections (non-GMP) of the Food, Drug and Cosmetic Act (FD&C Act). Observations relative to design control requirements, changes and software will be recorded on the DCIS report. The DCIS report will become part of the firm's EIR and will be available under Freedom of Information (FOI). Portions of the report may be purged to protect confidential and trade secret information. Therefore, it is important for the investigator to identify which portions of the DCIS report the manufacturer considers confidential to assist the agency in its FOI determinations. Do not collect documents or records, during the transition year (June 1, 1997 - May 31, 1998) to document areas in need of improvement that are included on the DCIS report. Do not collect documents or records merely to assist you in writing the DCIS report. You will need to take good notes to assist you with this task or write the responses, etc. directly onto the automated report. Exception is the general design control planning procedure, if available, as noted on the Design Control Inspectional Strategy. The listed Areas in Need of Improvement should be written in the same manner required for an FDA 483 observation. [Previous Page] [Table Of Contents] [Next Page] Return to: Page Top | Inspection Start







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