Center for Devices and Radiological Health

DESIGN CONTROL GUIDANCE

FOR

MEDICAL DEVICE MANUFACTURERS

This Guidance relates to
FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001

March 11, 1997

FOREWORD

To ensure that good quality assurance practices are used for the design of medical devices and that they are consistent with quality system requirements worldwide, the Food and Drug Administration revised the Current Good Manufacturing Practice (CGMP) requirements by incorporating them into the Quality System Regulation, 21 CFR Part 820. An important component of the revision is the addition of design controls.

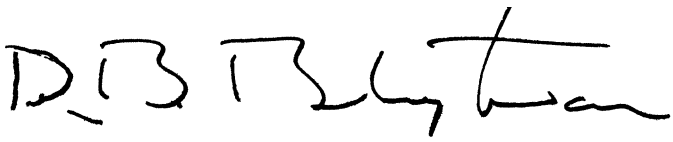
Because design controls must apply to a wide variety of devices, the regulation does not prescribe the practices that must be used. Instead, it establishes a framework that manufacturers must use when developing and implementing design controls. The framework provides manufacturers with the flexibility needed to develop design controls that both comply with the regulation and are most appropriate for their own design and development processes.

This guidance is intended to assist manufacturers in understanding the intent of the regulation. Design controls are based upon quality assurance and engineering principles. This guidance complements the regulation by describing its intent from a technical perspective using practical terms and examples.

Draft guidance was made publicly available in March, 1996. We appreciate the many comments, suggestions for improvement, and encouragement we received from industry, interested parties, and the Global Harmonization Task Force (GHTF) Study Group 3. The comments were systematically reviewed, and revisions made in response to those comments and suggestions are incorporated in this version. As experience is gained with the guidance, FDA will consider the need for additional revisions within the next six to eighteen months.

The Center publishes the results of its work in scientific journals and in its own technical reports. Through these reports, CDRH also provides assistance to industry and to the medical and healthcare professional communities in complying with the laws and regulations mandated by Congress. These reports are sold by the Government Printing Office (GPO) and by the National Technical Information Service (NTIS). Many reports, including this guidance document, are also available via Internet on the World Wide Web at www.fda.gov.

We welcome your comments and suggestions for future revisions.



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PREFACE

Effective implementation of design controls requires that the regulation and its intent be well understood. The Office of Compliance within CDRH is using several methods to assist manufacturers in developing this understanding. Methods include the use of presentations, teleconferences, practice audits, and written guidance.

Those persons in medical device companies charged with responsibility for developing, implementing, or applying design controls come from a wide variety of technical and non-technical backgrounds—engineering, business administration, life sciences, computer science, and the arts. Therefore, it is important that a tool be provided that conveys the intent of the regulation using practical terminology and examples. That is the purpose of his guidance.

The response of medical device manufacturers and other interested parties to the March, 1996 draft version of this guidance has significantly influenced this latest version. Most comments centered on the complaint that the guidance was too prescriptive. Therefore, it has been rewritten to be more pragmatic, focusing on principles rather than specific practices.

It is noteworthy that many comments offered suggestions for improving the guidance, and that the authors of the comments often acknowledged the value of design controls and the potential benefit of good guidance to the medical device industry, the public, and the FDA. Some comments even included examples of past experiences with the implementation of controls.

Finally, there are several people within CDRH that deserve recognition for their contributions to the development of this guidance. Al Taylor and Bill Midgette of the Office of Science and Technology led the development effort and served as co-chairs of the CDRH Design Control Guidance Team that reviewed the comments received last spring. Team members included Ashley Boulware, Bob Cangelosi, Andrew Lowrey, Deborah Lumbardo, Jack McCracken, Greg O'Connell, and Walter Scott. As the lead person within CDRH with responsibility for implementing the Quality System Regulation, Kim Trautman reviewed the guidance and coordinated its development with the many other concurrent and related activities. Their contributions are gratefully acknowledged.

FDA would also like to acknowledge the significant contributions made by the Global Harmonization Task Force (GHTF) Study Group 3. The Study Group reviewed and revised this guidance at multiple stages during its development. It is hoped that this cooperative effort will lead to this guidance being accepted as an internationally recognized guidance document through the GHTF later this year.

Lillian J. Gill
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