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.

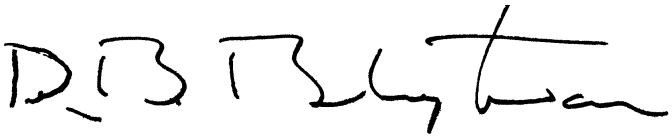
Because design controls must apply to a wide variety of devices, the regulation does not prescribe the practices that must be used. Instead, it establishes a framework that manufacturers must use when developing and implementing design controls. The framework provides manufacturers with the flexibility 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Draft guidance was made publicly available in March, 1996.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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ACKNOWLEDGEMENT

FDA wishes to acknowledge the contributions of the Global Harmonization Task Force (GHTF) Study Group 3 to the development of this guidance. As has been stated in the past, FDA is firmly committed to the international harmonization of standards and regulations governing medical devices. The GHTF was formed in 1992 to further this effort. The GHTF includes representatives of the Canadian Ministry of Health and Welfare; the Japanese Ministry of Health and Welfare; FDA; industry members from the European Union, Australia, Canada, Japan, and the United States; and a few delegates from observing countries.

Among other efforts, the GHTF Study Group 3 started developing guidance on the application of design controls to medical devices in the spring of 1995. Study Group 3 has recognized FDA's need to publish timely guidance on this topic in conjunction with promulgation of its new Quality System Regulation. The Study Group has therefore devoted considerable time and effort to combine its draft document with the FDA's efforts as well as to review and comment on FDA's subsequent revisions. FDA, for its part, delayed final release of its guidance pending final review by the Study Group. As a result, it is hoped that this document, with some minor editorial revisions to make the guidance global to several regulatory schemes, will be recognized through the GHTF as an international guidance document.

TABLE OF CONTENTS

INTRODUCTION

I. PURPOSE

This guidance is intended to assist manufacturers in understanding quality system requirements concerning design controls. Assistance is provided by interpreting the language of the quality systems requirements and explaining the underlying concepts in practical terms.

Design controls are an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. Design controls make systematic assessment of the design an integral part of development. As a result, deficiencies in design input requirements, and discrepancies between the proposed designs and requirements, are made evident and corrected earlier in the development process. Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use.

In practice, design controls provide managers and designers with improved visibility of the design process. With improved visibility, managers are empowered to more effectively direct the design process—that is, to recognize problems earlier, make corrections, and adjust resource allocations. Designers benefit both by enhanced understanding of the degree of conformance of a design to user and patient needs, and by improved communications and coordination among all participants in the process.

The medical device industry encompasses a wide range of technologies and applications, ranging from simple hand tools to complex computer-controlled surgical machines, from implantable screws to artificial organs, from blood-glucose test strips to diagnostic imaging systems and laboratory test equipment. These devices are manufactured by companies varying in size and structure, methods of design and development, and methods of management. These factors significantly influence how design controls are actually applied. Given this diversity, this guidance does not suggest particular methods of implementation, and therefore, must not be used to assess compliance with the quality system requirements. Rather, the intent is to expand upon the distilled language of the quality system requirements with practical explanations and examples of design control principles. Armed with this basic knowledge, manufacturers can and should seek out technology-specific guidance on applying design controls to their particular situation.

When using this guidance, there could be a tendency to focus only on the time and effort required in developing and incorporating the controls into the design process. However, readers should keep in mind the intrinsic value of design controls as well. It is a well-established fact that the cost to correct design errors is lower when errors are detected early in the design and development process. Large and small companies that have achieved quality systems certification under ISO 9001 cite improvements in productivity, product quality, customer satisfaction, and company competitiveness. Additional benefits

are described in comments received from a quality assurance manager of a medical device firm regarding the value of a properly documented design control system:

> "...there are benefits to an organization and the quality improvement of an organization by having a written design control system. By defining this system on paper, a corporation allows all its employees to understand the requirements, the process, and expectations of design and how the quality of design is assured and perceived by the system. It also provides a baseline to review the system periodically for further improvements based on history, problems, and failures of the system (not the product)."

II. SCOPE

The guidance applies to the design of medical devices as well as the design of the associated manufacturing processes. The guidance is applicable to new designs as well as modifications or improvements to existing device designs. The guidance discusses subjects in the order in which they appear in FDA's Quality System regulation and is cross-referenced to International Organization for Standards (ISO) 9001:1994, *Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*, and the ISO draft international standard ISO/DIS 13485, *Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001*, dated April 1996.

Design controls are a component of a comprehensive quality system that covers the life of a device. The assurance process is a total systems approach that extends from the development of device requirements through design, production, distribution, use, maintenance, and eventually, obsolescence. Design control begins with development and approval of design inputs, and includes the design of a device and the associated manufacturing processes.

Design control does not end with the transfer of a design to production. Design control applies to all changes to the device or manufacturing process design, including those occurring long after a device has been introduced to the market. This includes evolutionary changes such as performance enhancements as well as revolutionary changes such as corrective actions resulting from the analysis of failed product. The changes are part of a continuous, ongoing effort to design and develop a device that meets the needs of the user and/or patient. Thus, the design control process is revisited many times during the life of a product.

Some tools and techniques are described in the guidance. Although aspects of their utility are sometimes described, they are included in the guidance for illustrative purposes only. Including them does not mean that they are preferred. There may be alternative ways that are better suited to a particular manufacturer and design activity. The literature contains an abundance of information on tools and techniques. Such topics as project management, design review, process capability, and many others referred to in this guidance are

available in textbooks, periodicals, and journals. As a manufacturer applies design controls to a particular task, the appropriate tools and techniques used by competent personnel should be applied to meet the needs of the unique product or process for that manufacturer.

III. APPLICATION OF DESIGN CONTROLS

Design controls may be applied to any product development process. The simple example shown in Figure 1 illustrates the influence of design controls on a design process.

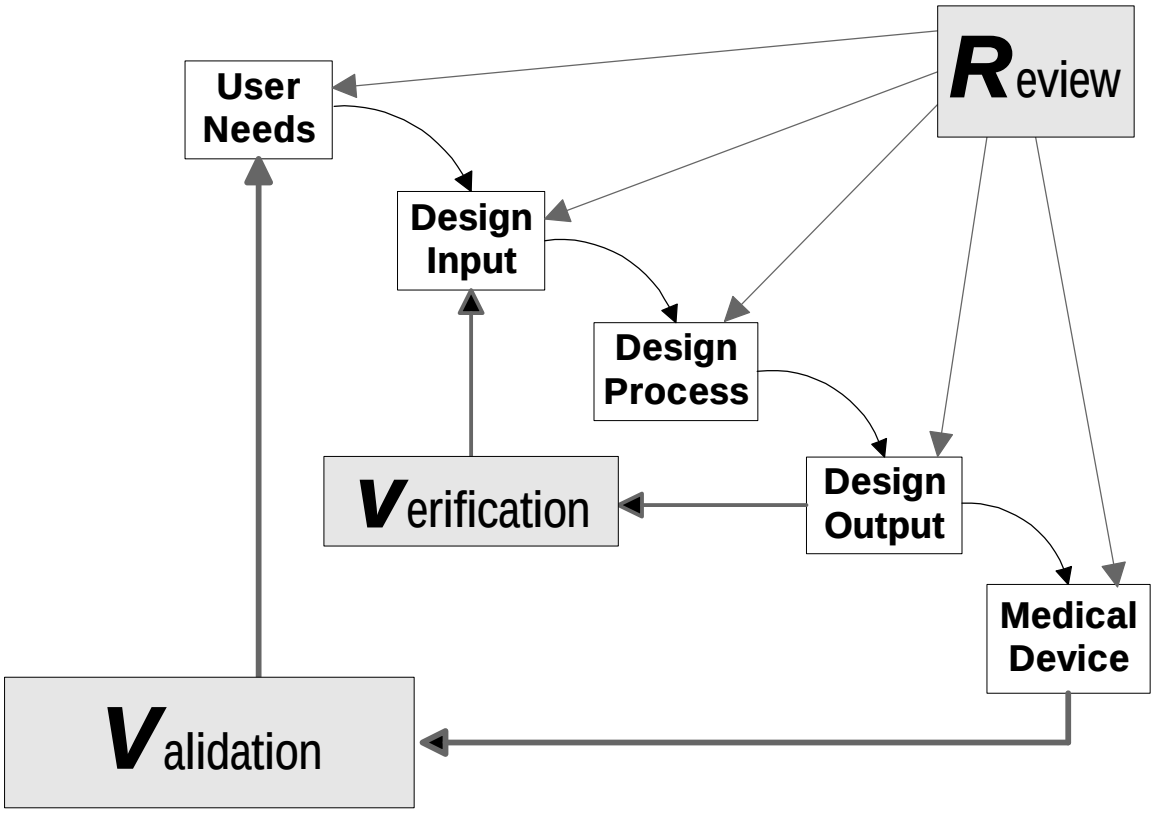

Figure 1 – Application of Design Controls to Waterfall Design Process (figure used with permission of Medical Devices Bureau, Health Canada)

The development process depicted in the example is a traditional waterfall model. The design proceeds in a logical sequence of phases or stages. Basically, requirements are developed, and a device is designed to meet those requirements. The design is then evaluated, transferred to production, and the device is manufactured. In practice, feedback paths would be required between each phase of the process and previous phases, representing the iterative nature of product development. However, this detail has been omitted from the figure to make the influence of the design controls on the design process more distinct.

The importance of the design input and verification of design outputs is illustrated by this example. When the design input has been reviewed and the design input requirements are determined to be acceptable, an iterative process of translating those requirements into a device design begins. The first step is conversion of the requirements into system or high-level specifications. Thus, these specifications are a design output. Upon verification that the high-level specifications conform to the design input requirements, they become the design input for the next step in the design process, and so on.

This basic technique is used repeatedly throughout the design process. Each design input is converted into a new design output; each output is verified as conforming to its input; and it then becomes the design input for another step in the design process. In this manner, the design input requirements are translated into a device design conforming to those requirements.

The importance of design reviews is also illustrated by the example. The design reviews are conducted at strategic points in the design process. For example, a review is conducted to assure that the design input requirements are adequate before they are converted into the design specifications. Another is used to assure that the device design is adequate before prototypes are produced for simulated use testing and clinical evaluation. Another, a validation review, is conducted prior to transfer of the design to production. Generally, they are used to provide assurance that an activity or phase has been completed in an acceptable manner, and that the next activity or phase can begin.

As the figure illustrates, design validation encompasses verification and extends the assessment to address whether devices produced in accordance with the design actually satisfy user needs and intended uses.

An analogy to automobile design and development may help to clarify these concepts. Fuel efficiency is a common design requirement. This requirement might be expressed as the number of miles-per-gallon of a particular grade of gasoline for a specified set of driving conditions. As the design of the car proceeds, the requirements, including the one for fuel efficiency, are converted into the many layers of system and subsystem specifications needed for design. As these various systems and subsystems are designed, design verification methods are used to establish conformance of each design to its own specifications. Because several specifications directly affect fuel efficiency, many of the verification activities help to provide confirmation that the overall design will meet the fuel efficiency requirement. This might include simulated road testing of prototypes or actual road testing. This is establishing by objective evidence that the design output conforms to the fuel efficiency requirement. However, these verification activities alone are not sufficient to validate the design. The design may be validated when a representative sample of users have driven production vehicles under a specified range of driving conditions and judged the fuel efficiency to be adequate. This is providing objective evidence that the particular requirement for a specific intended use can be consistently fulfilled.

CONCURRENT ENGINEERING. Although the waterfall model is a useful tool for introducing design controls, its usefulness in practice is limited. The model does apply to the development of some simpler devices. However, for more complex devices, a concurrent engineering model is more representative of the design processes in use in the industry.

In a traditional waterfall development scenario, the engineering department completes the product design and formally transfers the design to production. Subsequently, other departments or organizations develop processes to manufacture and service the product. Historically, there has frequently been a divergence between the intent of the designer and the reality of the factory floor, resulting in such undesirable outcomes as low manufacturing yields, rework or redesign of the product, or unexpectedly high cost to service the product.

One benefit of concurrent engineering is the involvement of production and service personnel throughout the design process, assuring the mutual optimization of the characteristics of a device and its related processes. While the primary motivations of concurrent engineering are shorter development time and reduced production cost, the practical result is often improved product quality.

Concurrent engineering encompasses a range of practices and techniques. From a design control standpoint, it is sufficient to note that concurrent engineering may blur the line between development and production. On the one hand, the concurrent engineering model properly emphasizes that the development of production processes is a design rather than a manufacturing activity. On the other hand, various components of a design may enter production before the design as a whole has been approved. Thus, concurrent engineering and other more complex models of development usually require a comprehensive matrix of reviews and approvals to ensure that each component and process design is validated prior to entering production, and the product as a whole is validated prior to design release.

RISK MANAGEMENT AND DESIGN CONTROLS. Risk management is the systematic application of management policies, procedures, and practices to the tasks of identifying, analyzing, controlling, and monitoring risk. It is intended to be a framework within which experience, insight, and judgment are applied to successfully manage risk. It is included in this guidance because of its effect on the design process.

Risk management begins with the development of the design input requirements. As the design evolves, new risks may become evident. To systematically identify and, when necessary, reduce these risks, the risk management process is integrated into the design process. In this way, unacceptable risks can be identified and managed earlier in the design process when changes are easier to make and less costly.

An example of this is an exposure control system for a general purpose x-ray system. The control function was allocated to software. Late in the development process, risk analysis of the system uncovered several failure modes that could result in overexposure to the

patient. Because the problem was not identified until the design was near completion, an expensive, independent, back-up timer had to be added to monitor exposure times.

THE QUALITY SYSTEM AND DESIGN CONTROLS. In addition to procedures and work instructions necessary for the implementation of design controls, policies and procedures may also be needed for other determinants of device quality that should be considered during the design process. The need for policies and procedures for these factors is dependent upon the types of devices manufactured by a company and the risks associated with their use. Management with executive responsibility has the responsibility for determining what is needed.

Example of topics for which policies and procedures may be appropriate are:

- risk management
- device reliability
- device durability
- device maintainability
- device serviceability
- human factors engineering
- software engineering
- use of standards
- configuration management
- compliance with regulatory requirements
- device evaluation (which may include third party product certification or approval)
- clinical evaluations
- document controls
- use of consultants
- use of subcontractors
- use of company historical data

SECTION A. GENERAL

I. REQUIREMENTS

§ 820.30(a) General.

(1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a) (2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:

(i) Devices automated with computer software; and

(ii) The devices listed in the chart below.

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

II. DEFINITIONS

§ 820.3 (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.

§ 820.3 (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.

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

Cross reference to ISO 9001:1994 and ISO/DIS 13485 Section 4.4.1 General.

III. DISCUSSION AND POINTS TO CONSIDER

The essential quality aspects and the regulatory requirements, such as safety, performance, and dependability of a product (whether hardware, software, services, or processed materials) are established during the design and development phase. Deficient design can be a major cause of quality problems.

The context within which product design is to be carried out should be set by the manufacturer's senior management. It is their responsibility to establish a design and development plan which sets the targets to be met. This plan defines the constraints within which the design is to be implemented.

The quality system requirements do not dictate the types of design process that a manufacturer must use. Manufacturers should use processes best suited to their needs. However, whatever the processes may be, it is important that the design controls are applied in an appropriate manner. This guidance document contains examples of how this might be achieved in a variety of situations.

It is important to note that the design function may apply to various facets of the operation having differing styles and time scales. Such facets are related to products, including services and software, as well as to their manufacturing processes.

Senior management needs to decide how the design function is to be managed and by whom. Senior management should also ensure that internal policies are established for design issues such as:

- assessing new product ideas
- training and retraining of design managers and design staff
- use of consultants
- evaluation of the design process
- product evaluation, including third party product certification and approvals
- patenting or other means of design protection

It is for senior management to ensure that adequate resources are available to carry out the design in the required time. This may involve reinforcing the skills and equipment available internally and/or obtaining external resources.

SECTION B. DESIGN AND DEVELOPMENT PLANNING

I. REQUIREMENTS

§ 820.30(b) Design and development planning.

- Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation.
- 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.

Cross-reference to ISO 9001:1994 and ISO/DIS 13485 sections 4.4.2 Design and development planning and 4.4.3 Organizational and technical interfaces.

II. DISCUSSION AND POINTS TO CONSIDER

Design and development planning is needed to ensure that the design process is appropriately controlled and that device quality objectives are met. The plans must be consistent with the remainder of the design control requirements. The following elements would typically be addressed in the design and development plan or plans:

- Description of the goals and objectives of the design and development program; i.e., what is to be developed;
- Delineation of organizational responsibilities with respect to assuring quality during the design and development phase, to include interface with any contractors;
- Identification of the major tasks to be undertaken, deliverables for each task, and individual or organizational responsibilities (staff and resources) for completing each task;
- Scheduling of major tasks to meet overall program time constraints;
- Identification of major reviews and decision points;
- Selection of reviewers, the composition of review teams, and procedures to be followed by reviewers;
- Controls for design documentation;
- Notification activities.

Planning enables management to exercise greater control over the design and development process by clearly communicating policies, procedures, and goals to members of the

design and development team, and providing a basis for measuring conformance to quality system objectives.

Design activities should be specified at the level of detail necessary for carrying out the design process. The extent of design and development planning is dependent on the size of the developing organization and the size and complexity of the product to be developed. Some manufacturers may have documented policies and procedures which apply to all design and development activities. For each specific development program, such manufacturers may also prepare a plan which spells out the project-dependent elements in detail, and incorporates the general policies and procedures by reference. Other manufacturers may develop a comprehensive design and development plan which is specifically tailored to each individual project.

In summary, the form and organization of the planning documents are less important than their content. The following paragraphs discuss the key elements of design and development planning.

ORGANIZATIONAL RESPONSIBILITIES. The management responsibility section of the quality system requirements[1] requires management to establish a quality policy and implement an organizational structure to ensure quality. These are typically documented in a quality manual or similarly named document. In some cases, however, the design and development plan, rather than the quality manual, is the best vehicle for describing organizational responsibilities relative to design and development activities. The importance of defining responsibilities with clarity and without ambiguity should be recognized. When input to the design is from a variety of sources, their interrelationships and interfaces (as well as the pertinent responsibilities and authorities) should be defined, documented, coordinated, and controlled. This might be the case, for example, if a multidisciplinary product development team is assembled for a specific project, or if the team includes suppliers, contract manufacturers, users, outside consultants, or independent auditors.

TASK BREAKDOWN. The plan establishes, to the extent possible:

- The major tasks required to develop the product
- The time involved for each major task
- The resources and personnel required
- The allocation of responsibilities for completing each major task
- The prerequisite information necessary to start each major task and the interrelationship between tasks
- The form of each task output or deliverable
- Constraints, such as applicable codes, standards, and regulations

[1] § 820.20 of the FDA Quality System Regulation; section 4.1 of ISO 9001 and ISO/DIS 13485.

Tasks for all significant design activities, including verification and validation tasks, should be included in the design and development plan. For example, if clinical trials are anticipated, there may be tasks associated with appropriate regulatory requirements.

For complex projects, rough estimates may be provided initially, with the details left for the responsible organizations to develop. As development proceeds, the plan should evolve to incorporate more and better information.

The relationships between tasks should be presented in such a way that they are easily understood. It should be clear which tasks depend on others, and which tasks need to be performed concurrently. Planning should reflect the degree of perceived development risk; for example, tasks involving new technology or processes should be spelled out in greater detail, and perhaps be subjected to more reviews and checks, than tasks which are perceived as routine or straightforward.

The design and development plan may include a schedule showing starting and completion dates for each major task, project milestone, or key decision points. The method chosen and the detail will vary depending on the complexity of the project and the level of risk associated with the device. For small projects, the plan may consist of only a simple flow diagram or computer spreadsheet. For larger projects, there are a number of project management tools that are used to develop plans. Three of the most commonly used are the Program Evaluation and Review Technique (PERT), the Critical Path Method (CPM), and the Gantt chart. Software is available in many forms for these methods. When selecting these tools, be careful to choose one that best fits the needs of the project. Some of the software programs are far more complex than may be necessary.

Unless a manufacturer has experience with the same type of device, the plan will initially be limited in scope and detail. As work proceeds, the plan is refined. Lack of experience in planning often leads to optimistic schedules, but slippage may also occur for reasons beyond the control of planners, for example, personnel turnover, materiel shortage, or unexpected problems with a design element or process. Sometimes the schedule can be compressed by using additional resources, such as diverting staff or equipment from another project, hiring a contractor, or leasing equipment.

It is important that the schedule be updated to reflect current knowledge. At all times, the plan should be specified at a level of detail enabling management to make informed decisions, and provide confidence in meeting overall schedule and performance objectives. This is important because scheduling pressures have historically been a contributing factor in many design defects which caused injury. To the extent that good planning can prevent schedule pressures, the potential for design errors is reduced.

However, no amount of planning can eliminate all development risk. There is inherent conflict between the desire to maximize performance and the need to meet business objectives, including development deadlines. In some corporate cultures, impending deadlines create enormous pressure to cut corners. Planning helps to combat this dilemma by ensuring management awareness of pressure points. With awareness, decisions are

more likely to be made with appropriate oversight and consideration of all relevant factors. Thus, when concessions to the clock must be made, they can be justified and supported.

SECTION C. DESIGN INPUT

I. REQUIREMENTS

§ 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.
- 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 designated individual(s).
- The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

Cross reference to ISO 9001:1994 and ISO/DIS 13485 section 4.4.4 Design input.

II. DEFINITIONS

§ 820.3(f) *Design input* means the physical and performance requirements of a device that are used as a basis for device design.

III. DISCUSSION AND POINTS TO CONSIDER

Design input is the starting point for product design. The requirements which form the design input establish a basis for performing subsequent design tasks and validating the design. Therefore, development of a solid foundation of requirements is the single most important design control activity.

Many medical device manufacturers have experience with the adverse effects that incomplete requirements can have on the design process. A frequent complaint of developers is that "there's never time to do it right, but there's always time to do it over." If essential requirements are not identified until validation, expensive redesign and rework may be necessary before a design can be released to production.

By comparison, the experience of companies that have designed devices using clear-cut, comprehensive sets of requirements is that rework and redesign are significantly reduced and product quality is improved. They know that the development of requirements for a medical device of even moderate complexity is a formidable, time-consuming task. They accept the investment in time and resources required to develop the requirements because they know the advantages to be gained in the long run.

Unfortunately, there are a number of common misconceptions regarding the meaning and practical application of the quality system requirements for design input. Many seem to arise from interpreting the requirements as a literal prescription, rather than a set of principles to be followed. In this guidance document, the focus is on explaining the principles and providing examples of how they may be applied in typical situations.

CONCEPT DOCUMENTS VERSUS DESIGN INPUT In some cases, the marketing staff, who maintain close contact with customers and users, determine a need for a new product, or enhancements to an existing product. Alternatively, the idea for a new product may evolve out of a research or clinical activity. In any case, the result is a concept document specifying some of the desired characteristics of the new product.

Some members of the medical device community view these marketing memoranda, or the equivalent, as the design input. However, that is not the intent of the quality system requirements. Such concept documents are rarely comprehensive, and should not be expected to be so. Rather, the intent of the quality system requirements is that the product conceptual description be elaborated, expanded, and transformed into a complete set of design input requirements which are written to an engineering level of detail.

This is an important concept. The use of qualitative terms in a concept document is both appropriate and practical. This is often not the case for a document to be used as a basis for design. Even the simplest of terms can have enormous design implications. For example, the term "must be portable" in a concept document raises questions in the minds of product developers about issues such as size and weight limitations, resistance to shock and vibration, the need for protection from moisture and corrosion, the capability of operating over a wide temperature range, and many others. Thus, a concept document may be the starting point for development, but it is not the design input requirement. This is a key principle—the design input requirements are the result of the first stage of the design control process.

RESEARCH AND DEVELOPMENT. Some manufacturers have difficulty in determining where research ends and development begins. Research activities may be undertaken in an effort to determine new business opportunities or basic characteristics for a new product. It may be reasonable to develop a rapid prototype to explore the feasibility of an idea or design approach, for example, prior to developing design input requirements. But manufacturers should avoid falling into the trap of equating the prototype design with a finished product design. Prototypes at this stage lack safety features and ancillary functions necessary for a finished product, and are developed under conditions which preclude adequate consideration of product variability due to manufacturing.

RESPONSIBILITY FOR DESIGN INPUT DEVELOPMENT. Regardless of who developed the initial product concept, product developers play a key role in developing the design input requirements. When presented with a set of important characteristics, it is the product developers who understand the auxiliary issues that must be addressed, as well as the level of detail necessary to design a product. Therefore, a second key principle is that

the product developer(s) ultimately bear responsibility for translating user and/or patient needs into a set of requirements which can be validated prior to implementation. While this is primarily an engineering function, the support or full participation of production and service personnel, key suppliers, etc., may be required to assure that the design input requirements are complete.

Care must be exercised in applying this principle. Effective development of design input requirements encompasses input from both the product developer as well as those representing the needs of the user, such as marketing. Terminology can be a problem. In some cases, the product conceptual description may be expressed in medical terms. Medical terminology is appropriate in requirements when the developers and reviewers are familiar with the language, but it is often preferable to translate the concepts into engineering terms at the requirements stage to minimize miscommunication with the development staff.

Another problem is incorrect assumptions. Product developers make incorrect assumptions about user needs, and marketing personnel make incorrect assumptions about the needs of the product designers. Incorrect assumptions can have serious consequences that may not be detected until late in the development process. Therefore, both product developers and those representing the user must take responsibility for critically examining proposed requirements, exploring stated and implied assumptions, and uncovering problems.

Some examples should clarify this point. A basic principle is that design input requirements should specify what the design is intended to do while carefully avoiding specific design solutions at this stage. For example, a concept document might dictate that the product be housed in a machined aluminum case. It would be prudent for product developers to explore why this type of housing was specified. Perhaps there is a valid reason—superior electrical shielding, mechanical strength, or reduced time to market as compared to a cast housing. Or perhaps machined aluminum was specified because a competitor's product is made that way, or simply because the user didn't think plastic would be strong enough.

Not all incorrect assumptions are made by users. Incorrect assumptions made by product developers may be equally damaging. Failure to understand the abuse to which a portable instrument would be subjected might result in the selection of housing materials inadequate for the intended use of the product.

There are occasions when it may be appropriate to specify part of the design solution in the design input requirements. For example, a manufacturer may want to share components or manufacturing processes across a family of products in order to realize economies of scale, or simply to help establish a corporate identity. In the case of a product upgrade, there may be clear consensus regarding the features to be retained. However, it is important to realize that every such design constraint reduces implementation flexibility and should therefore be documented and identified as a possible conflicting requirement for subsequent resolution.

SCOPE AND LEVEL OF DETAIL. Design input requirements must be comprehensive. This may be quite difficult for manufacturers who are implementing a system of design controls for the first time. Fortunately, the process gets easier with practice. It may be helpful to realize that design input requirements fall into three categories. Virtually every product will have requirements of all three types.

- Functional requirements specify what the device does, focusing on the operational capabilities of the device and processing of inputs and the resultant outputs.
- Performance requirements specify how much or how well the device must perform, addressing issues such as speed, strength, response times, accuracy, limits of operation, etc. This includes a quantitative characterization of the use environment, including, for example, temperature, humidity, shock, vibration, and electromagnetic compatibility. Requirements concerning device reliability and safety also fit into this category.
- Interface requirements specify characteristics of the device which are critical to compatibility with external systems; specifically, those characteristics which are mandated by external systems and outside the control of the developers. One interface which is important in every case is the user and/or patient interface.

What is the scope of the design input requirements development process and how much detail must be provided? The scope is dependent upon the complexity of a device and the risk associated with its use. For most medical devices, numerous requirements encompassing functions, performance, safety, and regulatory concerns are implied by the application. These implied requirements should be explicitly stated, in engineering terms, in the design input requirements.

Determining the appropriate level of detail requires experience. However, some general guidance is possible. The marketing literature contains product specifications, but these are superficial. The operator and service manuals may contain more detailed specifications and performance limits, but these also fall short of being comprehensive. Some insight as to what is necessary is provided by examining the requirements for a very common external interface. For the power requirements for AC-powered equipment, it is not sufficient to simply say that a unit shall be AC-powered. It is better to say that the unit shall be operable from AC power in North America, Europe, and Japan, but that is still insufficient detail to implement or validate the design. If one considers the situation just in North America, where the line voltage is typically 120 volts, many systems are specified to operate over the range of 108 to 132 volts. However, to account for the possibility of brownout, critical devices may be specified to operate from 95 to 132 volts or even wider ranges. Based on the intended use of the device, the manufacturer must choose appropriate performance limits.

There are many cases when it is impractical to establish every functional and performance characteristic at the design input stage. But in most cases, the form of the requirement can be determined, and the requirement can be stated with a to-be-determined (TBD) numerical value or a range of possible values. This makes it possible for reviewers to

assess whether the requirements completely characterize the intended use of the device, judge the impact of omissions, and track incomplete requirements to ensure resolution.

For complex designs, it is not uncommon for the design input stage to consume as much as thirty percent of the total project time. Unfortunately, some managers and developers have been trained to measure design progress in terms of hardware built, or lines of software code written. They fail to realize that building a solid foundation saves time during the implementation. Part of the solution is to structure the requirements documents and reviews such that tangible measures of progress are provided.

At the other extreme, many medical devices have very simple requirements. For example, many new devices are simply replacement parts for a product, or are kits of commodity items. Typically, only the packaging and labeling distinguishes these products from existing products. In such cases, there is no need to recreate the detailed design input requirements of the item. It is acceptable to simply cite the predecessor product documentation, add any new product information, and establish the unique packaging and labeling requirements.

ASSESSING DESIGN INPUT REQUIREMENTS FOR ADEQUACY. Eventually, the design input must be reviewed for adequacy. After review and approval, the design input becomes a controlled document. All future changes will be subject to the change control procedures, as discussed in Section I (Design Changes).

Any assessment of design input requirements boils down to a matter of judgment. As discussed in Section E (Design Review), it is important for the review team to be multidisciplinary and to have the appropriate authority. A number of criteria may be employed by the review team.

- Design input requirements should be unambiguous. That is, each requirement should be able to be verified by an objective method of analysis, inspection, or testing. For example, it is insufficient to state that a catheter must be able to withstand repeated flexing. A better requirement would state that the catheter should be formed into a 50 mm diameter coil and straightened out for a total of fifty times with no evidence of cracking or deformity. A qualified reviewer could then make a judgment whether this specified test method is representative of the conditions of use.
- Quantitative limits should be expressed with a measurement tolerance. For example, a diameter of 3.5 mm is an incomplete specification. If the diameter is specified as 3.500±0.005 mm, designers have a basis for determining how accurate the manufacturing processes have to be to produce compliant parts, and reviewers have a basis for determining whether the parts will be suitable for the intended use.
- The set of design input requirements for a product should be self-consistent. It is not unusual for requirements to conflict with one another or with a referenced industry standard due to a simple oversight. Such conflicts should be resolved early in the development process.

- The environment in which the product is intended to be used should be properly characterized. For example, manufacturers frequently make the mistake of specifying "laboratory" conditions for devices which are intended for use in the home. Yet, even within a single country, relative humidity in a home may range from 20 percent to 100 percent (condensing) due to climactic and seasonal variations. Household temperatures in many climates routinely exceed 40 °C during the hot season. Altitudes may exceed 3,000 m, and the resultant low atmospheric pressure may adversely affect some kinds of medical equipment. If environmental conditions are fully specified, a qualified reviewer can make a determination of whether the specified conditions are representative of the intended use.
- When industry standards are cited, the citations should be reviewed for completeness and relevance. For example, one medical device manufacturer claimed compliance with an industry standard covering mechanical shock and vibration. However, when the referenced standard was examined by a reviewer, it was found to prescribe only the method of testing, omitting any mention of pass/fail criteria. It was incumbent on the manufacturer in this case to specify appropriate performance limits for the device being tested, as well as the test method.

EVOLUTION OF THE DESIGN INPUT REQUIREMENTS. Large development projects often are implemented in stages. When this occurs, the design input requirements at each stage should be developed and reviewed following the principles set forth in this section. Fortunately, the initial set of requirements, covering the overall product, is by far the most difficult to develop. As the design proceeds, the output from the early stages forms the basis for the subsequent stages, and the information available to designers is inherently more extensive and detailed.

It is almost inevitable that verification activities will uncover discrepancies which result in changes to the design input requirements. There are two points to be made about this. One is that the change control process for design input requirements must be carefully managed. Often, a design change to correct one problem may create a new problem which must be addressed. Throughout the development process, it is important that any changes are documented and communicated to developers so that the total impact of the change can be determined. The change control process is crucial to device quality.

The second point is that extensive rework of the design input requirements suggests that the design input requirements may not be elaborated to a suitable level of detail, or insufficient resources are being devoted to defining and reviewing the requirements. Managers can use this insight to improve the design control process. From a design control perspective, the number of requirements changes made is less important than the thoroughness of the change control process.

SECTION D. DESIGN OUTPUT

I. REQUIREMENTS

§ 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 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.

Cross-reference to ISO 9001:1994 and ISO/DIS 13485 section 4.4.5 Design output.

II. DEFINITIONS

§ 820.3(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.

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

III. DISCUSSION AND POINTS TO CONSIDER

The quality system requirements for design output can be separated into two elements: Design output should be expressed in terms that allow adequate assessment of conformance to design input requirements and should identify the characteristics of the design that are crucial to the safety and proper functioning of the device. This raises two fundamental issues for developers:

- What constitutes design output?
- Are the form and content of the design output suitable?

The first issue is important because the typical development project produces voluminous records, some of which may not be categorized as design output. On the other hand, design output must be reasonably comprehensive to be effective. As a general rule, an item is design output if it is a work product, or deliverable item, of a design task listed in

the design and development plan, and the item defines, describes, or elaborates an element of the design implementation. Examples include block diagrams, flow charts, software high-level code, and system or subsystem design specifications. The design output in one stage is often part of the design input in subsequent stages.

Design output includes production specifications as well as descriptive materials which define and characterize the design.

PRODUCTION SPECIFICATIONS. Production specifications include drawings and documents used to procure components, fabricate, test, inspect, install, maintain, and service the device, such as the following:

- assembly drawings
- component and material specifications
- production and process specifications
- software machine code (e.g., diskette or master EPROM)
- work instructions
- quality assurance specifications and procedures
- installation and servicing procedures
- packaging and labeling specifications, including methods and processes used

In addition, as discussed in Section H (Design Transfer), production specifications may take on other forms. For example, some manufacturers produce assembly instructions on videotapes rather than written instructions. Similarly, a program diskette, used by a computer-aided milling machine to fabricate a part, would be considered a production specification. The videotape and the software on the program diskette are part of the device master record.

OTHER DESCRIPTIVE MATERIALS. Other design output items might be produced which are necessary to establish conformance to design input requirements, but are not used in its production. For example, for each part which is fabricated by computer-aided machine, there should be an assembly drawing which specifies the dimensions and characteristics of the part. It is a part of the design output because it establishes the basis for the machine tool program used to fabricate the part. Other examples of design output include the following:

- the results of risk analysis
- software source code
- results of verification activities
- biocompatibility test results
- bioburden test results

FORM AND CONTENT. Manufacturers must take steps to assure that the design output characterizes all important aspects of the design and is expressed in terms which

allow adequate verification and validation. Two basic mechanisms are available to manufacturers to accomplish these objectives.

- First, the manufacturer proactively can specify the form and content of design output at the planning stage. For some types of design output, form and content may be codified in a consensus standard which can be referenced. In other cases, a manufacturer could specify the desired characteristics, or even simply specify that the form and content of an existing document be followed.
- Second, form and content can be reviewed retroactively as a part of the design verification process. For example, the verification of design output could include assessing whether specified documentation standards have been adhered to.

As these examples illustrate, conformance with the quality system requirements concerning design output generally requires no "extra" effort on the part of the manufacturer, but simply the application of some common sense procedures during the planning, execution, and review of design tasks.

SECTION E. DESIGN REVIEW

I. REQUIREMENTS

§ 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.
- 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).

Cross-reference to ISO 9001:1994 and ISO/DIS 13485 section 4.4.6 Design review.

II. DEFINITIONS

§ 820.3(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.

III. DISCUSSION AND POINTS TO CONSIDER

In general, formal design reviews are intended to:

- provide a systematic assessment of design results, including the device design and the associated designs for production and support processes;
- provide feedback to designers on existing or emerging problems;
- assess project progress; and/or
- provide confirmation that the project is ready to move on to the next stage of development.

Many types of reviews occur during the course of developing a product. Reviews may have both an internal and external focus. The internal focus is on the feasibility of the design and the produceability of the design with respect to manufacturing and support

capabilities. The external focus is on the user requirements; that is, the device design is viewed from the perspective of the user.

The nature of reviews changes as the design progresses. During the initial stages, issues related to design input requirements will predominate. Next, the main function of the reviews may be to evaluate or confirm the choice of solutions being offered by the design team. Then, issues such as the choice of materials and the methods of manufacture become more important. During the final stages, issues related to the verification, validation, and production may predominate.

The term "review" is commonly used by manufacturers to describe a variety of design assessment activities. Most, but not all, of these activities meet the definition of formal design reviews. The following exceptions may help to clarify the distinguishing characteristics of design reviews.

- Each design document which constitutes the formal output, or deliverable, of a design task is normally subject to evaluation activities, sometimes referred to as informal peer review, supervisory review, or technical assessment. These activities, while they may be called reviews, are often better described as verification activities, because they are not intended to be comprehensive, definitive, and multidisciplinary in their scope. Rather, their purpose is to confirm that design output meets design input. Verification activities affect and add to the design output, and are themselves subject to subsequent design review.
- Developers may conduct routine or ad hoc meetings to discuss an issue, coordinate activities, or assess development progress. Decisions from such meetings may not require formal documentation; however, if a significant issue is resolved, this should be documented. If the outcome results in change to an approved design document, then applicable change control procedures should be followed, as discussed in Section I (Design Changes).

Control of the design review process is achieved by developing and implementing a formal design review program consistent with quality system requirements. The following issues should be addressed and documented in the design and development plan(s).

NUMBER AND TYPE OF REVIEWS. It is a well-accepted fact that the cost to correct design errors increases as the design nears completion, and the flexibility to implement an optimal solution decreases. When an error is discovered at the end of the development cycle, difficult decisions have to be made regarding an acceptable corrective action. When that corrective action is implemented in haste, the result is often an unintended consequence leading to a new problem. Thus, formal design reviews should be planned to detect problems early. A corollary is that planners should presume that problems will be detected, and allocate a reasonable amount of time to implement corrective actions. Typically, formal reviews are conducted at the end of each phase and at important milestones in the design process.

As discussed in Section C (Design Input), it is beneficial in almost every case to conduct a formal review of the design input requirements early in the development process. The number of reviews depends upon the complexity of the device.

- For a simple design, or a minor upgrade to an existing product, it might be appropriate to conduct a single review at the conclusion of the design process.
- For a product involving multiple subsystems, an early design task is to allocate the design input requirements among the various subsystems. For example, in a microprocessor-based system, designers must decide which functions will be performed by hardware and which by software. In another case, tolerance buildup from several components may combine to create a clearance problem. System designers must establish tolerance specifications for each component to meet the overall dimensional specification. In cases like these, a formal design review is a prudent step to ensure that all such system-level requirements have been allocated satisfactorily prior to engaging in detailed design of each subsystem.
- For complex systems, additional reviews are often built into the development plan. For example, engineering sketches may be developed for prototyping purposes prior to development of production drawings. Evaluation of the prototype would typically culminate in a formal design review. Similarly, software development commonly includes a high-level design phase, during which requirements are elaborated to a greater level of detail and algorithms are developed to implement key functions. A formal design review would typically be conducted to review this work prior to beginning detailed coding.

There are a number of approaches to conducting formal design reviews at the end of the design process. In some organizations, engineering essentially completes the design, tests an engineering prototype, and conducts a formal design review prior to turning the design over to manufacturing. In such cases, an additional review will be needed after the design has been validated using production devices.

In some instances, components having long lead times may enter production prior to completion of the overall device design. The primary motivation for early production is to reduce time to market. The manufacturer runs the business risk that the design review at the end of the design process will uncover a defect that must be corrected in production devices before any devices are distributed.

All of these approaches to scheduling formal design reviews are valid. What is important is that the manufacturer establish a reasonable rationale for the number and type of reviews, based on sound judgment.

SELECTION OF REVIEWERS. In determining who should participate in a formal design review, planners should consider the qualifications of reviewers, the types of expertise required to make an adequate assessment, and the independence of the reviewers. Each of these concerns is discussed briefly in the following paragraphs.

Qualifications. Formal design reviews should be conducted by person(s) having technical competence and experience at least comparable to the developers. For a small manufacturer, this may require that an outside consultant be retained to participate in the evaluation of the design.

A manufacturer will often employ one or more specialists to conduct certain types of specialized assessments which are beyond the capabilities of the designers. For example, a mechanical engineer may be retained to perform a structural analysis of a design, and perhaps conduct vibration testing to verify its performance under stress. Such specialists may be assigned to participate in the formal design review. Alternatively, they may be assigned to make an independent assessment and submit observations and recommendations to the reviewers. Either approach is valid.

Types of expertise required. Many medical device designs involve a number of technologies, such as electronics, mechanics, software, materials science, or pneumatics. In addition, a variety of clinical and manufacturing issues may influence the design. Manufacturers should carefully consider which interests should be represented at formal design reviews. Subtle distinctions in reviewer perspective may have dramatic impact on device quality. For example, the marketing department of a small manufacturer shared a new design with several surgeons on their advisory board. The surgeons all thought the design was terrific. Subsequently, the manufacturer invited two experienced operating room nurses to participate in the final design review. During the course of the review, it became apparent that while surgeons may be the customers, nurses are the primary users of the device, and no one up to that point had consulted with any nurses. The nurses at the design review didn't like some of the features of the design. After some further market survey, the manufacturer decided to make changes to the design to accommodate these concerns. It was unfortunate (and expensive) in this case that the user requirements were not considered until late in the development cycle, but the design review was ultimately very successful.

Independence. The formal design review should include at least one individual who does not have direct responsibility for the design stage under review. In a small company, complete independence is very difficult to obtain. Within the context of formal design reviews, the practical solution is simply to ensure a fresh perspective, based on the principle that those who are too close to the design may overlook design errors. Thus, reviewers will often be from the same organization as the developers, but they should not have been significantly involved in the activities under review. As discussed in the following section, the formal design review procedures play a large role in assuring independent and objective reviews.

DESIGN REVIEW PROCEDURES. The manufacturer should have documented formal design review procedures addressing the following:

- Evaluation of the design (including identification of concerns, i.e., issues and potential problems with the design)
- Resolution of concerns

- Implementation of corrective actions

Evaluation of the design. Many formal design reviews take the form of a meeting. At this meeting, the designer(s) may make presentations to explain the design implementation, and persons responsible for verification activities may present their findings to the reviewers. Reviewers may ask for clarification or additional information on any topic, and add their concerns to any raised by the presenters. This portion of the review is focused on finding problems, not resolving them.

There are many approaches to conducting design review meetings. In simple cases, the technical assessor and reviewer may be the same person, often a project manager or engineering supervisor, and the review meeting is a simple affair in the manager's office. For more elaborate reviews, detailed written procedures are desirable to ensure that all pertinent topics are discussed, conclusions accurately recorded, and action items documented and tracked.

There is a dangerous tendency for design review meetings to become adversarial affairs. The reputation of the designers tends to be linked to the number of discrepancies found, causing the designers to become defensive, while the reviewers score points by finding weaknesses in the design. The resulting contest can be counterproductive. An added complication is the presence of invited guests, often clinicians, who are expected to provide the user perspective. These reviewers are often very reluctant to ask probing questions, especially if they sense that they may become involved in a conflict where all the rules and relationships are not evident.

These difficulties can be avoided by stating the goals and ground rules for conducting the formal design review clearly at the outset. While the designers are in the best position to explain the best features of the design, they are also most likely to be aware of the design's weaknesses. If the designers and reviewers are encouraged to work together to systematically explore problems and find solutions, the resultant design will be improved and all parties will benefit from the process. Participants must be encouraged to ask questions, avoid making assumptions, and think critically. The focus must be on the design, not the participants.

Not all formal design reviews involve meetings. For extremely simple designs or design changes, it may be appropriate to specify a procedure in which review materials are distributed or circulated among the reviewers for independent assessment and approval. However, such a procedure negates the benefits of synergy and teamwork, and should be considered only in cases where the design issues are limited in scope and well defined.

Resolution of concerns. The reviewers consider concerns raised during the evaluation portion of the formal design review and decide on an appropriate disposition for each one. There is wide variation in the way companies implement decision-making processes. In some cases, the reviewers play an advisory role to the engineering manager or other company official, who directs the formal design review and ultimately selects a course of

action. In other cases, the reviewers are given limited or broad authority to make decisions and commit resources to resolve problems. The approach used should be documented.

In the real world, reviews often leave unresolved issues. Therefore, review procedures should include a process for resolving differences, and provide reviewers with enough leeway to make practical decisions while protecting the integrity of the process.

Implementation of corrective actions. Not all identified concerns result in corrective actions. The reviewers may decide that the issue is erroneous or immaterial. In most cases, however, resolution involves a design change, a requirements change, or a combination of the two. If the solution is evident, the reviewers may specify the appropriate corrective action; otherwise, an action item will be assigned to study the problem further. In any case, action items and corrective actions are normally tracked under the manufacturer's change control procedures.

RELATIONSHIP OF DESIGN REVIEW TO VERIFICATION AND VALIDATION. In practice, design review, verification, and validation overlap one another, and the relationship among them may be confusing. As a general rule, the sequence is: verification, review, validation, review.

In most cases, verification activities are completed prior to the design review, and the verification results are submitted to the reviewers along with the other design output to be reviewed. Alternatively, some verification activities may be treated as components of the design review, particularly if the verification activity is complex and requires multidisciplinary review.

Similarly, validation typically involves a variety of activities, including a determination that the appropriate verifications and reviews have been completed. Thus, at the conclusion of the validation effort, a review is usually warranted to assure that the validation is complete and adequate.

SECTION F. DESIGN VERIFICATION

I. REQUIREMENTS

§ 820.30(f) Design verification.

- Each manufacturer shall establish and maintain procedures for verifying the device design.
- Design verification shall confirm that the design output meets the design input requirements.
- The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the Design History File.

Cross-reference to ISO 9001:1994 and ISO/DIS 13485 section 4.4.7 Design verification.

I. DEFINITIONS

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

§ 820.3(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).

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

III. DISCUSSION AND POINTS TO CONSIDER

Verification and validation are associated concepts with very important differences. Various organizations have different definitions for these terms. Medical device

manufacturers are encouraged to use the terminology of the quality system requirements in their internal procedures.

To illustrate the concepts, consider a building design analogy. In a typical scenario, the senior architect establishes the design input requirements and sketches the general appearance and construction of the building, but associates or contractors typically elaborate the details of the various mechanical systems. Verification is the process of checking at each stage whether the output conforms to requirements for that stage. For example: does the air conditioning system deliver the specified cooling capacity to each room? Is the roof rated to withstand so many newtons per square meter of wind loading? Is a fire alarm located within 50 meters of each location in the building?

At the same time, the architect has to keep in mind the broader question of whether the results are consistent with the ultimate user requirements. Does the air conditioning system keep the occupants comfortable throughout the building? Will the roof withstand weather extremes expected at the building site? Can the fire alarm be heard throughout the building? Those broader concerns are the essence of validation.

In the initial stages of design, verification is a key quality assurance technique. As the design effort progresses, verification activities become progressively more comprehensive. For example, heat or cooling delivery can be calculated and verified by the air conditioning designer, but the resultant air temperature can only be estimated. Occupant comfort is a function not only of delivered air temperature, but also humidity, heat radiation to or from nearby thermal masses, heat gain or loss through adjacent windows, etc. During the latter design phases, the interaction of these complex factors may be considered during verification of the design.

Validation follows successful verification, and ensures that each requirement for a particular use is fulfilled. Validation of user needs is possible only after the building is built. The air conditioning and fire alarm performance may be validated by testing and inspection, while the strength of the roof will probably be validated by some sort of analysis linked to building codes which are accepted as meeting the needs of the user—subject to possible confirmation during a subsequent severe storm.

Validation is the topic of Section G of this guidance document. The remainder of this section focuses on verification principles.

TYPES OF VERIFICATION ACTIVITIES. Verification activities are conducted at all stages and levels of device design. The basis of verification is a three-pronged approach involving tests, inspections, and analyses. Any approach which establishes conformance with a design input requirement is an acceptable means of verifying the design with respect to that requirement. In many cases, a variety of approaches are possible.

Complex designs require more and different types of verification activities. The nature of verification activities varies according to the type of design output. The intent of this guidance document is not to suggest or recommend verification techniques which should

be performed by device manufacturers. Rather, the manufacturer should select and apply appropriate verification techniques based on the generally accepted practices for the technologies employed in their products. Many of these practices are an integral part of the development process, and are routinely performed by developers. The objective of design controls is to ensure adequate oversight by making verification activities explicit and measuring the thoroughness of their execution. Following are a few examples of verification methods and activities.

- Worst case analysis of an assembly to verify that components are derated properly and not subject to overstress during handling and use.
- Thermal analysis of an assembly to assure that internal or surface temperatures do not exceed specified limits.
- Fault tree analysis of a process or design.
- Failure modes and effects analysis.
- Package integrity tests.
- Biocompatibility testing of materials.
- Bioburden testing of products to be sterilized.
- Comparison of a design to a previous product having an established history of successful use.

For some technologies, verification methods may be highly standardized. In other cases, the manufacturer may choose from a variety of applicable methods. In a few cases, the manufacturer must be creative in devising ways to verify a particular aspect of a design.

Some manufacturers erroneously equate production testing with verification. Whereas verification testing establishes conformance of design output with design input, the aim of production testing is to determine whether the unit under test has been correctly manufactured. In other words, production testing is designed to efficiently screen out manufacturing process errors and perhaps also to detect infant mortality failures. Typically, a small subset of functional and performance tests accomplish this objective with a high degree of accuracy. Therefore, production testing is rarely, if ever, comprehensive enough to verify the design. For example, a leakage test may be used during production to ensure that a hermetically-sealed enclosure was properly assembled. However, the leakage test may not be sensitive enough to detect long-term diffusion of gas through the packaging material. Permeability of the packaging material is an intrinsic property of the material rather than an assembly issue, and would likely be verified using a more specialized test than is used during production.

DOCUMENTATION OF VERIFICATION ACTIVITIES. Some verification methods result in a document by their nature. For example, a failure modes and effects analysis produces a table listing each system component, its postulated failure modes, and the effect of such failures on system operation.

Another self-documenting verification method is the traceability matrix. This method is particularly useful when the design input and output are both documents; it also has great utility in software development. In the most common form of the traceability matrix, the input requirements are enumerated in a table, and references are provided to each section in the output documents (or software modules) which address or satisfy each input requirement. The matrix can also be constructed "backwards," listing each feature in the design output and tracing which input requirement bears on that feature. This reverse approach is especially useful for detecting hidden assumptions. Hidden assumptions are dangerous because they often lead to overdesign, adding unnecessary cost and complexity to the design. In other cases, hidden assumptions turn out to be undocumented design input requirements which, once exposed, can be properly tracked and verified.

However, many verification activities are simply some sort of structured assessment of the design output relative to the design input. When this is the case, manufacturers may document completion of verification activities by linking these activities with the signoff procedures for documents. This may be accomplished by establishing a procedure whereby each design output document must be verified and signed by designated persons. The presence of the reviewers' signatures on the document signifies that the design output has been verified in accordance with the signoff procedure.

SECTION G. DESIGN VALIDATION

I. REQUIREMENTS

§ 820.30(g) Design validation.

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

Cross-reference to ISO 9001:1994 and ISO/DIS 13485 section 4.4.8 Design validation.

II. DEFINITIONS

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

§ 820.3(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).

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

III. DISCUSSION AND POINTS TO CONSIDER

Whereas verification is a detailed examination of aspects of a design at various stages in the development, design validation is a cumulative summation of all efforts to assure that the design will conform with user needs and intended use(s), given expected variations in components, materials, manufacturing processes, and the use environment.

VALIDATION PLANNING. Planning for validation should begin early in the design process. The performance characteristics that are to be assessed should be identified, and validation methods and acceptance criteria should be established. For complex designs, a schedule of validation activities and organizational or individual responsibilities will facilitate maintaining control over the process. The validation plan should be reviewed for appropriateness, completeness, and to ensure that user needs and intended uses are addressed.

VALIDATION REVIEW. Validation may expose deficiencies in the original assumptions concerning user needs and intended uses. A formal review process should be used to resolve any such deficiencies. As with verification, the perception of a deficiency might be judged insignificant or erroneous, or a corrective action may be required.

VALIDATION METHODS. Many medical devices do not require clinical trials. However, all devices require clinical evaluation and should be tested in the actual or simulated use environment as a part of validation. This testing should involve devices which are manufactured using the same methods and procedures expected to be used for ongoing production. While testing is always a part of validation, additional validation methods are often used in conjunction with testing, including analysis and inspection methods, compilation of relevant scientific literature, provision of historical evidence that similar designs and/or materials are clinically safe, and full clinical investigations or clinical trials.

Some manufacturers have historically used their best assembly workers or skilled lab technicians to fabricate test articles, but this practice can obscure problems in the manufacturing process. It may be beneficial to ask the best workers to evaluate and critique the manufacturing process by trying it out, but pilot production should simulate as closely as possible the actual manufacturing conditions.

Validation should also address product packaging and labeling. These components of the design may have significant human factors implications, and may affect product performance in unexpected ways. For example, packaging materials have been known to cause electrostatic discharge (ESD) failures in electronic devices. If the unit under test is delivered to the test site in the test engineer's briefcase, the packaging problem may not become evident until after release to market.

Validation should include simulation of the expected environmental conditions, such as temperature, humidity, shock and vibration, corrosive atmospheres, etc. For some classes

of device, the environmental stresses encountered during shipment and installation far exceed those encountered during actual use, and should be addressed during validation.

Particular care should be taken to distinguish among customers, users, and patients to ensure that validation addresses the needs of all relevant parties. For a consumer device, the customer, user, and patient may all be the same person. At the other extreme, the person who buys the device may be different from the person who routinely uses it on patients in a clinical setting. Hospital administrators, biomedical engineers, health insurance underwriters, physicians, nurses, medical technicians, and patients have distinct and sometimes competing needs with respect to a device design.

VALIDATION DOCUMENTATION. Validation is a compilation of the results of all validation activities. For a complex design, the detailed results may be contained in a variety of separate documents and summarized in a validation report. Supporting information should be explicitly referenced in the validation report and either included as an appendix or available in the design history file.

SECTION H. DESIGN TRANSFER

I. REQUIREMENTS

§ 820.30(h) Design transfer.

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

Cross reference to ISO 9001:1994 and ISO/DIS 13485 section 4.2.3(c) Quality planning.

II. DISCUSSION AND POINTS TO CONSIDER

Production specifications must ensure that manufactured devices are repeatedly and reliably produced within product and process capabilities. If a manufactured device deviates outside those capabilities, performance may be compromised. Thus, the process of encapsulating knowledge about the device into production specifications is critical to device quality.

The level of detail necessary to accomplish this objective varies widely, based on the type of device, the relationship between the design and manufacturing organizations, and the knowledge, experience, and skills of production workers. In some cases, devices are produced by contract manufacturers who have no involvement in the development and little or no contact with the designers. At the other extreme, some devices are hand-crafted by skilled artisans with extensive knowledge about the use of the product.

One normally associates the term “production specifications” with written documents, such as assembly drawings, component procurement specifications, workmanship standards, manufacturing instructions, and inspection and test specifications. While these types of documents are widely employed in medical device production, other equally acceptable means of conveying design information exist, and manufacturers have the flexibility to employ these alternate means of communication as appropriate. For example, each of the following could constitute “production specifications” within the meaning of the quality system requirements:

- documentation (in electronic format as well as paper)
- training materials, e.g., manufacturing processes, test and inspection methods
- digital data files, e.g., programmable device files, master EPROM, computer-aided manufacturing (CAM) programming files
- manufacturing jigs and aids, e.g., molds, sample wiring harness to be duplicated

Historically, shortcomings in the production specifications tend to be manifested late in the product life cycle. When the design is new, there is often intensive interaction between the design and production teams, providing ample opportunity for undocumented information flow. Later, as production experience is gained, some decoupling often occurs between design and production teams. In addition, key personnel may leave, and their replacements may lack comparable training, experience, or institutional knowledge.

Particular care should be taken when the product involves new and unproved manufacturing processes, or established processes which are new to the manufacturer. It may not be possible to determine the adequacy of full-scale manufacturing on the basis of successfully building prototypes or models in a laboratory and testing these prototypes or models. The engineering feasibility and production feasibility may be different because the equipment, tools, personnel, operating procedures, supervision and motivation could be different when a manufacturer scales up for routine production.

No design team can anticipate all factors bearing on the success of the design, but procedures for design transfer should address at least the following basic elements.

- First, the design and development procedures should include a qualitative assessment of the completeness and adequacy of the production specifications.
- Second, the procedures should ensure that all documents and articles which constitute the production specifications are reviewed and approved.
- Third, the procedures should ensure that only approved specifications are used to manufacture production devices.

The first item in the preceding list may be addressed during design transfer. The second and third elements are among the basic principles of document control and configuration management. As long as the production specifications are traditional paper documents, there is ample information available to guide manufacturers in implementing suitable procedures. When the production specifications include non-traditional means, flexibility and creativity may be needed to achieve comparable rigor.

SECTION I. DESIGN CHANGES

I. REQUIREMENTS

§ 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.

Cross-reference to ISO 9001:1994 and ISO/DIS 13485 section 4.4.9 Design changes.

II. DISCUSSION AND POINTS TO CONSIDER

There are two principal administrative elements involved in controlling design changes:

- Document control—enumeration of design documents, and tracking their status and revision history. Throughout this section, the term "document" is used in an inclusive sense to mean all design documents, drawings, and other items of design input or output which characterize the design or some aspect of it.
- Change control—enumeration of deficiencies and corrective actions arising from verification and review of the design, and tracking their resolution prior to design transfer.

For a small development project, an adequate process for managing change involves little more than documenting the design change, performing appropriate verification and validation, and keeping records of reviews. The main objectives are ensuring that:

- corrective actions are tracked to completion;
- changes are implemented in such a manner that the original problem is resolved and no new problems are created; or if new problems are created, they are also tracked to resolution; and
- design documentation is updated to accurately reflect the revised design.

For projects involving more than two persons, coordination and communication of design changes become vitally important. In other words, manufacturers should take steps to avoid the common situation where, for example, Jon and Marie agree to a make a change but neglect to inform Pat of their decision.

Medical device manufacturers are usually quite comfortable with the processes of document control and change control with respect to managing manufacturing documents. The principles of these processes are reviewed in the following paragraphs. Subsequently, we will explore how these may be applied to design activities.

DOCUMENT CONTROL. The features of a manufacturing document control system typically include the following:

- Documents should be identified (i.e., named and numbered) in accordance with some logical scheme which links the documents to the product or component they describe or depict and illuminates the drawing hierarchy.
- A master list or index of documents should be maintained which presents a comprehensive overview of the documentation which collectively defines the product and/or process.
- Approval procedures should be prescribed which govern entry of documents into the document control system.
- A history of document revisions should be maintained.
- Procedures for distributing copies of controlled documents and tracking their location should be prescribed.
- Files of controlled documents should be periodically inventoried to ensure that the contents are up to date.
- A person or persons should be assigned specific responsibility to oversee and carry out these procedures. It is desirable that the document control system be administered by a person who is not directly involved with developing or using the documents. For a small manufacturer, document control might be a part-time job for a technician or clerical staff person. More typically, one or more librarians or full-time clerical or paraprofessional employees are required to administer the system.
- There should be a procedure for removal and deletion of obsolete documents.

CHANGE CONTROL. Manufacturing change control is usually implemented using a set of standardized procedures similar to the following:

- A change request might be originated by a developer, manager, reviewer, marketing representative, user, customer, quality assurance representative, or production personnel, and identifies a design problem which the requester believes should be corrected. Change requests are typically reviewed following the manufacturer's prescribed review process, and the request might be rejected, deferred, or accepted.
- If a change request is accepted and corrective action is straightforward, a change order might be issued on the spot to implement the change. The change order pertains to an explicitly identified document or group of documents, and specifies the detailed revision of the document content which will fix the identified problem.
- Often, the change request results in an assignment to developers to further study the problem and develop a suitable corrective action. If the change is extensive, wholesale revision of affected documents may be warranted in lieu of issuing change orders.
- Change requests and change orders should be communicated to all persons whose work might be impacted by the change.

- It may not be practical to immediately revise documents affected by a change order. Instead, the common practice is to distribute and attach a copy of the change order to each controlled copy of the original document.
- Change control procedures should incorporate review and assessment of the impact of the design change on the design input requirements and intended uses.
- A mechanism should be established to track all change requests and change orders to ensure proper disposition.
- Change control procedures are usually administered by the document control staff.

APPLICATION OF DOCUMENT AND CHANGE CONTROLS TO DESIGN. The design control system has to be concerned with the creation and revision of documents, as well as the management of finished documents. Additional mechanisms are required to provide needed flexibility while preserving the integrity of design documentation. These additional mechanisms are embodied in the procedures for review and approval of various documents.

It is important that the design change procedures always include re-verifying and re-validating the design. Fortunately, most design changes occur early in the design process, prior to extensive design validation. Thus, for most design changes, a simple inspection is all that is required. The later in the development cycle that the change occurs, the more important the validation review becomes. There are numerous cases when seemingly innocuous design changes made late in the design phase or following release of the design to market have had disastrous consequences.

For example, a manufacturer encountered problems in the field with a valve sticking in a ventilator due to moisture in the breathing circuit. The problem was resolved by slightly increasing the weight of the disc. Since the change was minor, minimal testing was performed to verify the change. Subsequently, when the revised valves entered production, significant numbers of valves began failing. Investigation revealed that the heavier disc was causing the valve cage to separate due to higher inertia. This failure mode was more serious than the original sticking problem, and resulted in a safety recall.

SECTION J. DESIGN HISTORY FILE (DHF)

I. REQUIREMENTS

§ 820.30(j) Design history file.

- Each manufacturer shall establish and maintain a DHF for each type of device.
- The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

Cross-reference to ISO 9001:1994 and ISO/DIS 13485 section 4.16 Control of quality records.

II. DEFINITIONS

§ 820.3(e) *Design history file* (DHF) means a compilation of records which describes the design history of a finished device.

III. DISCUSSION AND POINTS TO CONSIDER

There is no specific requirement in ISO 9001 or ISO 13485 for a design history file. However, in order to market a medical device in the United States, a manufacturer must comply with the U. S. Food and Drug Administration (FDA) quality system regulation, which requires a design history file. For this reason, some guidance is provided on the U. S. FDA design history file.

Other national regulations require some form of documentation and records. Product documentation required by Canada, Europe, and Japan contain certain elements of the U. S. FDA design history file requirements without requiring all the elements to be compiled in a file.

Virtually every section of the design control requirements specifies information which should be recorded. The compilation of these records is sometimes referred to as the design history file. Throughout this guidance document, suggestions are made when warranted as to the form and content of documents contained in the design history file.

The primary beneficiary of the device history file is the device manufacturer. For example, in one case, a microprocessor-controlled enteral feeding pump was reported to be behaving erratically in the field. Some of the symptoms pointed to software problems. But the manufacturer admitted that they did not possess a copy of the software source code for the product. The software had been developed by a contractor who had delivered only a master EPROM (memory chip) which was duplicated by the manufacturer to install the

software in each machine. The contractor had subsequently withdrawn following a contractual dispute, leaving the manufacturer with no rights to the source code developed by the contractor, and no practical way to maintain the software. For this and other reasons, the product was the subject of a mandatory recall and all known units were collected and destroyed.

This is admittedly an extreme case, but many similar cases have been documented in which the manufacturer lacked design information necessary to validate a design and maintain it throughout the product life cycle. This occurs for the most innocent of reasons—contracts expire, companies reorganize, employees move on to new projects or new jobs. Even when the designer is available, he or she may forget why a particular decision was made years, months, or even weeks before. Since design decisions often directly affect the well-being of device users and patients, it is to the manufacturer's benefit to maintain the knowledge base which forms a basis for the product design.

Except for small projects, it is unusual for all design history documents to be filed in a single location. For example, many design engineers maintain laboratory notebooks which are typically retained in the engineers' personal files. In addition, the design history may include memoranda and electronic mail correspondence which are stored at various physical locations. Quality system plans applicable to a development project may reside in the quality assurance department, while the chief engineer may be responsible for maintaining design and development plans. These diverse records need not be consolidated at a single location. The intent is simply that manufacturers have access to the information when it is needed. If a manufacturer has established procedures for multiple filing systems which together satisfy that intent, there is no need to create additional procedures or records.

As an example of the level of detail which may be entailed, some manufacturers have policies covering laboratory notebooks. Manufacturers typically find that without such written procedures, a breakdown in communications eventually occurs, resulting in a loss of control. These procedures might address the following points.

- Laboratory notebooks are the property of the manufacturer, not the individual.
- A separate notebook is to be maintained for each project, and surrendered to the engineering librarian at the conclusion of the engineer's active participation in the project.
- Laboratory notebooks are to be surrendered if the employee leaves the company.
- Product development supervisors shall review employees' laboratory notebooks at specified intervals to ensure that records are complete, accurate, and legible.

There are no requirements on the location or organization of the design history file. In some cases, especially for simple designs, the designer will assemble and maintain the entire design history file. For larger projects, a document control system will likely be established for design documents, and these files will likely be maintained in some central location, usually within the product development department.

Based on the structure (or lack thereof) of the product development organization, more or less extensive controls will be required. For example, company policy should state unequivocally that all design history documentation is the property of the manufacturer, not the employee or contractor. Design and development contracts should explicitly specify the manufacturer's right to design information and establish standards for the form and content of design documentation. Finally, certain basic design information may be maintained in a single project file in a specified location. This may include the following:

- Detailed design and development plan specifying design tasks and deliverables.
- Copies of approved design input documents and design output documents.
- Documentation of design reviews.
- Validation documentation.
- When applicable, copies of controlled design documents and change control records.

END OF DOCUMENT: DCGD.DOC (Microsoft Word 7.0) or DCGD.PDF (Adobe Acrobat format)