

General Principles of Software Validation; Final Guidance for Industry and FDA Staff

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**This document supersedes the draft document, "General Principles of
Software Validation, Version 1.1, dated June 9, 1997.**

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**U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research**

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance which involve the Center for Devices and Radiological Health (CDRH), contact Stewart Crumpler at (301) 594-4659 or email esc@cdrh.fda.gov.

For questions regarding the use or interpretation of this guidance which involve the Center for Biologics Evaluation and Research (CBER) contact Jerome Davis at (301) 827-6220 or email davis@cber.fda.gov.

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General Principles of Software Validation

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

SECTION 1. PURPOSE

This guidance outlines general validation principles that the Food and Drug Administration (FDA) considers to be applicable to the validation of medical device software or the validation of software used to design, develop, or manufacture medical devices. This final guidance document, Version 2.0, supersedes the draft document, *General Principles of Software Validation, Version 1.1*, dated June 9, 1997.

SECTION 2. SCOPE

This guidance describes how certain provisions of the medical device Quality System regulation apply to software and the agency's current approach to evaluating a software validation system. For example, this document lists elements that are acceptable to the FDA for the validation of software; however, it does not list all of the activities and tasks that must, in all instances, be used to comply with the law.

The scope of this guidance is somewhat broader than the scope of validation in the strictest definition of that term. Planning, verification, testing, traceability, configuration management, and many other aspects of good software engineering discussed in this guidance are important activities that together help to support a final conclusion that software is validated.

This guidance recommends an integration of software life cycle management and risk management activities. Based on the intended use and the safety risk associated with the software to be developed, the software developer should determine the specific approach, the combination of techniques to be used, and the level of effort to be applied. While this guidance does not recommend any specific life cycle model or any specific technique or method, it does recommend that software validation and verification activities be conducted throughout the entire software life cycle.

Where the software is developed by someone other than the device manufacturer (e.g., off-the-shelf software) the software developer may not be directly responsible for compliance with FDA

regulations. In that case, the party with regulatory responsibility (i.e., the device manufacturer) needs to assess the adequacy of the off-the-shelf software developer's activities and determine what additional efforts are needed to establish that the software is validated for the device manufacturer's intended use.

2.1. APPLICABILITY

This guidance applies to:

- Software used as a component, part, or accessory of a medical device;
- Software that is itself a medical device (e.g., blood establishment software);
- Software used in the production of a device (e.g., programmable logic controllers in manufacturing equipment); and
- Software used in implementation of the device manufacturer's quality system (e.g., software that records and maintains the device history record).

This document is based on generally recognized software validation principles and, therefore, can be applied to any software. For FDA purposes, this guidance applies to any software related to a regulated medical device, as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) and by current FDA software and regulatory policy. This document does not specifically identify which software is or is not regulated.

2.2. AUDIENCE

This guidance provides useful information and recommendations to the following individuals:

- Persons subject to the medical device Quality System regulation
- Persons responsible for the design, development, or production of medical device software
- Persons responsible for the design, development, production, or procurement of automated tools used for the design, development, or manufacture of medical devices or software tools used to implement the quality system itself
- FDA Investigators
- FDA Compliance Officers
- FDA Scientific Reviewers

2.3. THE LEAST BURDENSOME APPROACH

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments

to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at:

<http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html>.

2.4. REGULATORY REQUIREMENTS FOR SOFTWARE VALIDATION

The FDA's analysis of 3140 medical device recalls conducted between 1992 and 1998 reveals that 242 of them (7.7%) are attributable to software failures. Of those software related recalls, 192 (or 79%) were caused by software defects that were introduced when changes were made to the software after its initial production and distribution. Software validation and other related good software engineering practices discussed in this guidance are a principal means of avoiding such defects and resultant recalls.

Software validation is a requirement of the Quality System regulation, which was published in the Federal Register on October 7, 1996 and took effect on June 1, 1997. (See Title 21 Code of Federal Regulations (CFR) Part 820, and 61 Federal Register (FR) 52602, respectively.) Validation requirements apply to software used as components in medical devices, to software that is itself a medical device, and to software used in production of the device or in implementation of the device manufacturer's quality system.

Unless specifically exempted in a classification regulation, any medical device software product developed after June 1, 1997, regardless of its device class, is subject to applicable design control provisions. (See of 21 CFR §820.30.) This requirement includes the completion of current development projects, all new development projects, and all changes made to existing medical device software. Specific requirements for validation of device software are found in 21 CFR §820.30(g). Other design controls, such as planning, input, verification, and reviews, are required for medical device software. (See 21 CFR §820.30.) The corresponding documented results from these activities can provide additional support for a conclusion that medical device software is validated.

Any software used to automate any part of the device production process or any part of the quality system must be validated for its intended use, as required by 21 CFR §820.70(i). This requirement applies to any software used to automate device design, testing, component acceptance, manufacturing, labeling, packaging, distribution, complaint handling, or to automate any other aspect of the quality system.

In addition, computer systems used to create, modify, and maintain electronic records and to manage electronic signatures are also subject to the validation requirements. (See 21 CFR §11.10(a).) Such computer systems must be validated to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

Software for the above applications may be developed in-house or under contract. However, software is frequently purchased off-the-shelf for a particular intended use. All production

and/or quality system software, even if purchased off-the-shelf, should have documented requirements that fully define its intended use, and information against which testing results and other evidence can be compared, to show that the software is validated for its intended use.

The use of off-the-shelf software in automated medical devices and in automated manufacturing and quality system operations is increasing. Off-the-shelf software may have many capabilities, only a few of which are needed by the device manufacturer. Device manufacturers are responsible for the adequacy of the software used in their devices, and used to produce devices. When device manufacturers purchase "off-the-shelf" software, they must ensure that it will perform as intended in their chosen application. For off-the-shelf software used in manufacturing or in the quality system, additional guidance is included in Section 6.3 of this document. For device software, additional useful information may be found in FDA's *Guidance for Industry, FDA Reviewers, and Compliance on Off-The-Shelf Software Use in Medical Devices*.

2.4. QUALITY SYSTEM REGULATION VS PRE-MARKET SUBMISSIONS

This document addresses Quality System regulation issues that involve the implementation of software validation. It provides guidance for the management and control of the software validation process. The management and control of the software validation process should not be confused with any other validation requirements, such as process validation for an automated manufacturing process.

Device manufacturers may use the same procedures and records for compliance with quality system and design control requirements, as well as for pre-market submissions to FDA. This document does not cover any specific safety or efficacy issues related to software validation. Design issues and documentation requirements for pre-market submissions of regulated software are not addressed by this document. Specific issues related to safety and efficacy, and the documentation required in pre-market submissions, should be addressed to the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH) or to the Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER). See the references in Appendix A for applicable FDA guidance documents for pre-market submissions.

SECTION 3. CONTEXT FOR SOFTWARE VALIDATION

Many people have asked for specific guidance on what FDA expects them to do to ensure compliance with the Quality System regulation with regard to software validation. Information on software validation presented in this document is not new. Validation of software, using the principles and tasks listed in Sections 4 and 5, has been conducted in many segments of the software industry for well over 20 years.

Due to the great variety of medical devices, processes, and manufacturing facilities, it is not possible to state in one document all of the specific validation elements that are applicable. However, a general application of several broad concepts can be used successfully as guidance for software validation. These broad concepts provide an acceptable framework for building a comprehensive approach to software validation. Additional specific information is available from many of the references listed in Appendix A.

3.1. DEFINITIONS AND TERMINOLOGY

Unless defined in the Quality System regulation, or otherwise specified below, all other terms used in this guidance are as defined in the current edition of the FDA *Glossary of Computerized System and Software Development Terminology*.

The medical device Quality System regulation (21 CFR 820.3(k)) defines "establish" to mean "define, document, and implement." Where it appears in this guidance, the words "establish" and "established" should be interpreted to have this same meaning.

Some definitions found in the medical device Quality System regulation can be confusing when compared to commonly used terminology in the software industry. Examples are requirements, specification, verification, and validation.

3.1.1 Requirements and Specifications

While the Quality System regulation states that design input requirements must be documented, and that specified requirements must be verified, the regulation does not further clarify the distinction between the terms "requirement" and "specification." A **requirement** can be any need or expectation for a system or for its software. Requirements reflect the stated or implied needs of the customer, and may be market-based, contractual, or statutory, as well as an organization's internal requirements. There can be many different kinds of requirements (e.g., design, functional, implementation, interface, performance, or physical requirements). Software requirements are typically derived from the system requirements for those aspects of system functionality that have been allocated to software. Software requirements are typically stated in functional terms and are defined, refined, and updated as a development project progresses. Success in accurately and completely documenting software requirements is a crucial factor in successful validation of the resulting software.

A **specification** is defined as “a document that states requirements.” (See 21 CFR §820.3(y).) It may refer to or include drawings, patterns, or other relevant documents and usually indicates the means and the criteria whereby conformity with the requirement can be checked. There are many different kinds of written specifications, e.g., system requirements specification, software requirements specification, software design specification, software test specification, software integration specification, etc. All of these documents establish “specified requirements” and are design outputs for which various forms of verification are necessary.

3.1.2 Verification and Validation

The Quality System regulation is harmonized with *ISO 8402:1994*, which treats “verification” and “validation” as separate and distinct terms. On the other hand, many software engineering journal articles and textbooks use the terms “verification” and “validation” interchangeably, or in some cases refer to software “verification, validation, and testing (VV&T)” as if it is a single concept, with no distinction among the three terms.

Software verification provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all of the specified requirements for that phase. Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated. Software testing is one of many verification activities intended to confirm that software development output meets its input requirements. Other verification activities include various static and dynamic analyses, code and document inspections, walkthroughs, and other techniques.

Software validation is a part of the design validation for a finished device, but is not separately defined in the Quality System regulation. For purposes of this guidance, FDA considers software validation to be “**confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.**” In practice, software validation activities may occur both during, as well as at the end of the software development life cycle to ensure that all requirements have been fulfilled. Since software is usually part of a larger hardware system, the validation of software typically includes evidence that all software requirements have been implemented correctly and completely and are traceable to system requirements. A conclusion that software is validated is highly dependent upon comprehensive software testing, inspections, analyses, and other verification tasks performed at each stage of the software development life cycle. Testing of device software functionality in a simulated use environment, and user site testing are typically included as components of an overall design validation program for a software automated device.

Software verification and validation are difficult because a developer cannot test forever, and it is hard to know how much evidence is enough. In large measure, software validation is a matter of developing a “level of confidence” that the device meets all requirements and user expectations for the software automated functions and features of the device. Measures such as defects found in specifications documents, estimates of defects remaining, testing coverage, and other techniques are all used to develop an acceptable level of confidence before shipping the

product. The level of confidence, and therefore the level of software validation, verification, and testing effort needed, will vary depending upon the safety risk (hazard) posed by the automated functions of the device. Additional guidance regarding safety risk management for software may be found in Section 4 of FDA's *Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices*, and in the international standards *ISO/IEC 14971-1* and *IEC 60601-1-4* referenced in Appendix A.

3.1.3 IQ/OQ/PQ

For many years, both FDA and regulated industry have attempted to understand and define software validation within the context of process validation terminology. For example, industry documents and other FDA validation guidance sometimes describe user site software validation in terms of installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). Definitions of these terms and additional information regarding IQ/OQ/PQ may be found in FDA's *Guideline on General Principles of Process Validation*, dated May 11, 1987, and in FDA's *Glossary of Computerized System and Software Development Terminology*, dated August 1995.

While IQ/OQ/PQ terminology has served its purpose well and is one of many legitimate ways to organize software validation tasks at the user site, this terminology may not be well understood among many software professionals, and it is not used elsewhere in this document. However, both FDA personnel and device manufacturers need to be aware of these differences in terminology as they ask for and provide information regarding software validation.

3.2. SOFTWARE DEVELOPMENT AS PART OF SYSTEM DESIGN

The decision to implement system functionality using software is one that is typically made during system design. Software requirements are typically derived from the overall system requirements and design for those aspects in the system that are to be implemented using software. There are user needs and intended uses for a finished device, but users typically do not specify whether those requirements are to be met by hardware, software, or some combination of both. Therefore, software validation must be considered within the context of the overall design validation for the system.

A documented requirements specification represents the user's needs and intended uses from which the product is developed. A primary goal of software validation is to then demonstrate that all completed software products comply with all documented software and system requirements. The correctness and completeness of both the system requirements and the software requirements should be addressed as part of the design validation process for the device. Software validation includes confirmation of conformance to all software specifications and confirmation that all software requirements are traceable to the system specifications. Confirmation is an important part of the overall design validation to ensure that all aspects of the medical device conform to user needs and intended uses.

3.3. SOFTWARE IS DIFFERENT FROM HARDWARE

While software shares many of the same engineering tasks as hardware, it has some very important differences. For example:

- The vast majority of software problems are traceable to errors made during the design and development process. While the quality of a hardware product is highly dependent on design, development and manufacture, the quality of a software product is dependent primarily on design and development with a minimum concern for software manufacture. Software manufacturing consists of reproduction that can be easily verified. It is not difficult to manufacture thousands of program copies that function exactly the same as the original; the difficulty comes in getting the original program to meet all specifications.
- One of the most significant features of software is branching, i.e., the ability to execute alternative series of commands, based on differing inputs. This feature is a major contributing factor for another characteristic of software – its complexity. Even short programs can be very complex and difficult to fully understand.
- Typically, testing alone cannot fully verify that software is complete and correct. In addition to testing, other verification techniques and a structured and documented development process should be combined to ensure a comprehensive validation approach.
- Unlike hardware, software is not a physical entity and does not wear out. In fact, software may improve with age, as latent defects are discovered and removed. However, as software is constantly updated and changed, such improvements are sometimes countered by new defects introduced into the software during the change.
- Unlike some hardware failures, software failures occur without advanced warning. The software's branching that allows it to follow differing paths during execution, may hide some latent defects until long after a software product has been introduced into the marketplace.
- Another related characteristic of software is the speed and ease with which it can be changed. This factor can cause both software and non-software professionals to believe that software problems can be corrected easily. Combined with a lack of understanding of software, it can lead managers to believe that tightly controlled engineering is not needed as much for software as it is for hardware. In fact, the opposite is true. **Because of its complexity, the development process for software should be even more tightly controlled than for hardware, in order to prevent problems that cannot be easily detected later in the development process.**
- Seemingly insignificant changes in software code can create unexpected and very significant problems elsewhere in the software program. The software development

process should be sufficiently well planned, controlled, and documented to detect and correct unexpected results from software changes.

- Given the high demand for software professionals and the highly mobile workforce, the software personnel who make maintenance changes to software may not have been involved in the original software development. Therefore, accurate and thorough documentation is essential.
- Historically, software components have not been as frequently standardized and interchangeable as hardware components. However, medical device software developers are beginning to use component-based development tools and techniques. Object-oriented methodologies and the use of off-the-shelf software components hold promise for faster and less expensive software development. However, component-based approaches require very careful attention during integration. Prior to integration, time is needed to fully define and develop reusable software code and to fully understand the behavior of off-the-shelf components.

For these and other reasons, software engineering needs an even greater level of managerial scrutiny and control than does hardware engineering.

3.4. BENEFITS OF SOFTWARE VALIDATION

Software validation is a critical tool used to assure the quality of device software and software automated operations. Software validation can increase the usability and reliability of the device, resulting in decreased failure rates, fewer recalls and corrective actions, less risk to patients and users, and reduced liability to device manufacturers. Software validation can also reduce long term costs by making it easier and less costly to reliably modify software and revalidate software changes. Software maintenance can represent a very large percentage of the total cost of software over its entire life cycle. An established comprehensive software validation process helps to reduce the long-term cost of software by reducing the cost of validation for each subsequent release of the software.

3.5 DESIGN REVIEW

Design reviews are documented, comprehensive, and systematic examinations 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. While there may be many informal technical reviews that occur within the development team during a software project, a formal design review is more structured and includes participation from others outside the development team. Formal design reviews may reference or include results from other formal and informal reviews. Design reviews may be conducted separately for the software, after the software is integrated with the hardware into the system, or both. Design reviews should include examination of development plans, requirements specifications, design specifications, testing plans and procedures, all other documents and activities associated with the project, verification results from each stage of the defined life cycle, and validation results for the overall device.

Design review is a primary tool for managing and evaluating development projects. For example, formal design reviews allow management to confirm that all goals defined in the software validation plan have been achieved. The Quality System regulation requires that at least one formal design review be conducted during the device design process. However, it is recommended that multiple design reviews be conducted (e.g., at the end of each software life cycle activity, in preparation for proceeding to the next activity). Formal design review is especially important at or near the end of the requirements activity, before major resources have been committed to specific design solutions. Problems found at this point can be resolved more easily, save time and money, and reduce the likelihood of missing a critical issue.

Answers to some key questions should be documented during formal design reviews. These include:

- Have the appropriate tasks and expected results, outputs, or products been established for each software life cycle activity?
- Do the tasks and expected results, outputs, or products of each software life cycle activity:
 - ✓ Comply with the requirements of other software life cycle activities in terms of correctness, completeness, consistency, and accuracy?
 - ✓ Satisfy the standards, practices, and conventions of that activity?
 - ✓ Establish a proper basis for initiating tasks for the next software life cycle activity?

SECTION 4. PRINCIPLES OF SOFTWARE VALIDATION

This section lists the general principles that should be considered for the validation of software.

4.1. REQUIREMENTS

A documented software requirements specification provides a baseline for both validation and verification. The software validation process cannot be completed without an established software requirements specification (Ref: 21 CFR 820.3(z) and (aa) and 820.30(f) and (g)).

4.2. DEFECT PREVENTION

Software quality assurance needs to focus on preventing the introduction of defects into the software development process and not on trying to “test quality into” the software code after it is written. Software testing is very limited in its ability to surface all latent defects in software code. For example, the complexity of most software prevents it from being exhaustively tested. **Software testing is a necessary activity. However, in most cases software testing by itself is not sufficient to establish confidence that the software is fit for its intended use.** In order to establish that confidence, software developers should use a mixture of methods and techniques to prevent software errors and to detect software errors that do occur. The “best mix” of methods depends on many factors including the development environment, application, size of project, language, and risk.

4.3. TIME AND EFFORT

To build a case that the software is validated requires time and effort. Preparation for software validation should begin early, i.e., during design and development planning and design input. The final conclusion that the software is validated should be based on evidence collected from planned efforts conducted throughout the software lifecycle.

4.4. SOFTWARE LIFE CYCLE

Software validation takes place within the environment of an established software life cycle. The software life cycle contains software engineering tasks and documentation necessary to support the software validation effort. In addition, the software life cycle contains specific verification and validation tasks that are appropriate for the intended use of the software. This guidance does not recommend any particular life cycle models – only that they should be selected and used for a software development project.

4.5. PLANS

The software validation process is defined and controlled through the use of a plan. The software validation plan defines “what” is to be accomplished through the software validation effort. Software validation plans are a significant quality system tool. Software validation plans specify areas such as scope, approach, resources, schedules and the types and extent of activities, tasks, and work items.

4.6. PROCEDURES

The software validation process is executed through the use of procedures. These procedures establish “how” to conduct the software validation effort. The procedures should identify the specific actions or sequence of actions that must be taken to complete individual validation activities, tasks, and work items.

4.7. SOFTWARE VALIDATION AFTER A CHANGE

Due to the complexity of software, a seemingly small local change may have a significant global system impact. When any change (even a small change) is made to the software, the validation status of the software needs to be re-established. **Whenever software is changed, a validation analysis should be conducted not just for validation of the individual change, but also to determine the extent and impact of that change on the entire software system.** Based on this analysis, the software developer should then conduct an appropriate level of software regression testing to show that unchanged but vulnerable portions of the system have not been adversely affected. Design controls and appropriate regression testing provide the confidence that the software is validated after a software change.

4.8. VALIDATION COVERAGE

Validation coverage should be based on the software’s complexity and safety risk – not on firm size or resource constraints. The selection of validation activities, tasks, and work items should be commensurate with the complexity of the software design and the risk associated with the use of the software for the specified intended use. For lower risk devices, only baseline validation activities may be conducted. As the risk increases additional validation activities should be added to cover the additional risk. Validation documentation should be sufficient to demonstrate that all software validation plans and procedures have been completed successfully.

4.9. INDEPENDENCE OF REVIEW

Validation activities should be conducted using the basic quality assurance precept of “independence of review.” Self-validation is extremely difficult. When possible, an independent evaluation is always better, especially for higher risk applications. Some firms contract out for a third-party independent verification and validation, but this solution may not

always be feasible. Another approach is to assign internal staff members that are not involved in a particular design or its implementation, but who have sufficient knowledge to evaluate the project and conduct the verification and validation activities. Smaller firms may need to be creative in how tasks are organized and assigned in order to maintain internal independence of review.

4.10. FLEXIBILITY AND RESPONSIBILITY

Specific implementation of these software validation principles may be quite different from one application to another. The device manufacturer has flexibility in choosing how to apply these validation principles, but retains ultimate responsibility for demonstrating that the software has been validated.

Software is designed, developed, validated, and regulated in a wide spectrum of environments, and for a wide variety of devices with varying levels of risk. FDA regulated medical device applications include software that:

- Is a component, part, or accessory of a medical device;
- Is itself a medical device; or
- Is used in manufacturing, design and development, or other parts of the quality system.

In each environment, software components from many sources may be used to create the application (e.g., in-house developed software, off-the-shelf software, contract software, shareware). In addition, software components come in many different forms (e.g., application software, operating systems, compilers, debuggers, configuration management tools, and many more). The validation of software in these environments can be a complex undertaking; therefore, it is appropriate that all of these software validation principles be considered when designing the software validation process. The resultant software validation process should be commensurate with the safety risk associated with the system, device, or process.

Software validation activities and tasks may be dispersed, occurring at different locations and being conducted by different organizations. However, regardless of the distribution of tasks, contractual relations, source of components, or the development environment, the device manufacturer or specification developer retains ultimate responsibility for ensuring that the software is validated.

SECTION 5. ACTIVITIES AND TASKS

Software validation is accomplished through a series of activities and tasks that are planned and executed at various stages of the software development life cycle. These tasks may be one time occurrences or may be iterated many times, depending on the life cycle model used and the scope of changes made as the software project progresses.

5.1. SOFTWARE LIFE CYCLE ACTIVITIES

This guidance does not recommend the use of any specific software life cycle model. Software developers should establish a software life cycle model that is appropriate for their product and organization. The software life cycle model that is selected should cover the software from its birth to its retirement. Activities in a typical software life cycle model include the following:

- Quality Planning
- System Requirements Definition
- Detailed Software Requirements Specification
- Software Design Specification
- Construction or Coding
- Testing
- Installation
- Operation and Support
- Maintenance
- Retirement

Verification, testing, and other tasks that support software validation occur during each of these activities. A life cycle model organizes these software development activities in various ways and provides a framework for monitoring and controlling the software development project. Several software life cycle models (e.g., waterfall, spiral, rapid prototyping, incremental development, etc.) are defined in FDA's *Glossary of Computerized System and Software Development Terminology*, dated August 1995. These and many other life cycle models are described in various references listed in Appendix A.

5.2. TYPICAL TASKS SUPPORTING VALIDATION

For each of the software life cycle activities, there are certain "typical" tasks that support a conclusion that the software is validated. However, the specific tasks to be performed, their order of performance, and the iteration and timing of their performance will be dictated by the specific software life cycle model that is selected and the safety risk associated with the software application. For very low risk applications, certain tasks may not be needed at all. However, the software developer should at least consider each of these tasks and should define and document which tasks are or are not appropriate for their specific application. The following discussion is generic and is not intended to prescribe any particular software life cycle model or any particular order in which tasks are to be performed.

5.2.1. Quality Planning

Design and development planning should culminate in a plan that identifies necessary tasks, procedures for anomaly reporting and resolution, necessary resources, and management review requirements, including formal design reviews. A software life cycle model and associated activities should be identified, as well as those tasks necessary for each software life cycle activity. The plan should include:

- The specific tasks for each life cycle activity;
- Enumeration of important quality factors (e.g., reliability, maintainability, and usability);
- Methods and procedures for each task;
- Task acceptance criteria;
- Criteria for defining and documenting outputs in terms that will allow evaluation of their conformance to input requirements;
- Inputs for each task;
- Outputs from each task;
- Roles, resources, and responsibilities for each task;
- Risks and assumptions; and
- Documentation of user needs.

Management must identify and provide the appropriate software development environment and resources. (See 21 CFR §820.20(b)(1) and (2).) Typically, each task requires personnel as well as physical resources. The plan should identify the personnel, the facility and equipment resources for each task, and the role that risk (hazard) management will play. A configuration management plan should be developed that will guide and control multiple parallel development activities and ensure proper communications and documentation. Controls are necessary to ensure positive and correct correspondence among all approved versions of the specifications documents, source code, object code, and test suites that comprise a software system. The controls also should ensure accurate identification of, and access to, the currently approved versions.

Procedures should be created for reporting and resolving software anomalies found through validation or other activities. Management should identify the reports and specify the contents, format, and responsible organizational elements for each report. Procedures also are necessary for the review and approval of software development results, including the responsible organizational elements for such reviews and approvals.

Typical Tasks – Quality Planning

- Risk (Hazard) Management Plan
- Configuration Management Plan
- Software Quality Assurance Plan
 - Software Verification and Validation Plan

- Verification and Validation Tasks, and Acceptance Criteria
 - Schedule and Resource Allocation (for software verification and validation activities)
 - Reporting Requirements
- Formal Design Review Requirements
- Other Technical Review Requirements
- Problem Reporting and Resolution Procedures
- Other Support Activities

5.2.2. Requirements

Requirements development includes the identification, analysis, and documentation of information about the device and its intended use. Areas of special importance include allocation of system functions to hardware/software, operating conditions, user characteristics, potential hazards, and anticipated tasks. In addition, the requirements should state clearly the intended use of the software.

The software requirements specification document should contain a written definition of the software functions. It is not possible to validate software without predetermined and documented software requirements. Typical software requirements specify the following:

- All software system inputs;
- All software system outputs;
- All functions that the software system will perform;
- All performance requirements that the software will meet, (e.g., data throughput, reliability, and timing);
- The definition of all external and user interfaces, as well as any internal software-to-system interfaces;
- How users will interact with the system;
- What constitutes an error and how errors should be handled;
- Required response times;
- The intended operating environment for the software, if this is a design constraint (e.g., hardware platform, operating system);
- All ranges, limits, defaults, and specific values that the software will accept; and
- All safety related requirements, specifications, features, or functions that will be implemented in software.

Software safety requirements are derived from a technical risk management process that is closely integrated with the system requirements development process. Software requirement specifications should identify clearly the potential hazards that can result from a software failure in the system as well as any safety requirements to be implemented in software. The consequences of software failure should be evaluated, along with means of mitigating such failures (e.g., hardware mitigation, defensive programming, etc.). From this analysis, it should be possible to identify the most appropriate measures necessary to prevent harm.

The Quality System regulation requires a mechanism for addressing incomplete, ambiguous, or conflicting requirements. (See 21 CFR 820.30(c).) Each requirement (e.g., hardware, software,

user, operator interface, and safety) identified in the software requirements specification should be evaluated for accuracy, completeness, consistency, testability, correctness, and clarity. For example, software requirements should be evaluated to verify that:

- There are no internal inconsistencies among requirements;
- All of the performance requirements for the system have been spelled out;
- Fault tolerance, safety, and security requirements are complete and correct;
- Allocation of software functions is accurate and complete;
- Software requirements are appropriate for the system hazards; and
- All requirements are expressed in terms that are measurable or objectively verifiable.

A software requirements traceability analysis should be conducted to trace software requirements to (and from) system requirements and to risk analysis results. In addition to any other analyses and documentation used to verify software requirements, a formal design review is recommended to confirm that requirements are fully specified and appropriate before extensive software design efforts begin. Requirements can be approved and released incrementally, but care should be taken that interactions and interfaces among software (and hardware) requirements are properly reviewed, analyzed, and controlled.

Typical Tasks – Requirements

- Preliminary Risk Analysis
- Traceability Analysis
 - Software Requirements to System Requirements (and vice versa)
 - Software Requirements to Risk Analysis
- Description of User Characteristics
- Listing of Characteristics and Limitations of Primary and Secondary Memory
- Software Requirements Evaluation
- Software User Interface Requirements Analysis
- System Test Plan Generation
- Acceptance Test Plan Generation
- Ambiguity Review or Analysis

5.2.3. Design

In the design process, the software requirements specification is translated into a logical and physical representation of the software to be implemented. The software design specification is a description of what the software should do and how it should do it. Due to complexity of the project or to enable persons with varying levels of technical responsibilities to clearly understand design information, the design specification may contain both a high level summary of the design and detailed design information. The completed software design specification constrains the programmer/coder to stay within the intent of the agreed upon requirements and design. A

complete software design specification will relieve the programmer from the need to make ad hoc design decisions.

The software design needs to address human factors. Use error caused by designs that are either overly complex or contrary to users' intuitive expectations for operation is one of the most persistent and critical problems encountered by FDA. Frequently, the design of the software is a factor in such use errors. Human factors engineering should be woven into the entire design and development process, including the device design requirements, analyses, and tests. Device safety and usability issues should be considered when developing flowcharts, state diagrams, prototyping tools, and test plans. Also, task and function analyses, risk analyses, prototype tests and reviews, and full usability tests should be performed. Participants from the user population should be included when applying these methodologies.

The software design specification should include:

- Software requirements specification, including predetermined criteria for acceptance of the software;
- Software risk analysis;
- Development procedures and coding guidelines (or other programming procedures);
- Systems documentation (e.g., a narrative or a context diagram) that describes the systems context in which the program is intended to function, including the relationship of hardware, software, and the physical environment;
- Hardware to be used;
- Parameters to be measured or recorded;
- Logical structure (including control logic) and logical processing steps (e.g., algorithms);
- Data structures and data flow diagrams;
- Definitions of variables (control and data) and description of where they are used;
- Error, alarm, and warning messages;
- Supporting software (e.g., operating systems, drivers, other application software);
- Communication links (links among internal modules of the software, links with the supporting software, links with the hardware, and links with the user);
- Security measures (both physical and logical security); and
- Any additional constraints not identified in the above elements.

The first four of the elements noted above usually are separate pre-existing documents that are included by reference in the software design specification. Software requirements specification was discussed in the preceding section, as was software risk analysis. Written development procedures serve as a guide to the organization, and written programming procedures serve as a guide to individual programmers. As software cannot be validated without knowledge of the context in which it is intended to function, systems documentation is referenced. If some of the above elements are not included in the software, it may be helpful to future reviewers and maintainers of the software if that is clearly stated (e.g., There are no error messages in this program).

The activities that occur during software design have several purposes. Software design evaluations are conducted to determine if the design is complete, correct, consistent,

unambiguous, feasible, and maintainable. Appropriate consideration of software architecture (e.g., modular structure) during design can reduce the magnitude of future validation efforts when software changes are needed. Software design evaluations may include analyses of control flow, data flow, complexity, timing, sizing, memory allocation, criticality analysis, and many other aspects of the design. A traceability analysis should be conducted to verify that the software design implements all of the software requirements. As a technique for identifying where requirements are not sufficient, the traceability analysis should also verify that all aspects of the design are traceable to software requirements. An analysis of communication links should be conducted to evaluate the proposed design with respect to hardware, user, and related software requirements. The software risk analysis should be re-examined to determine whether any additional hazards have been identified and whether any new hazards have been introduced by the design.

At the end of the software design activity, a Formal Design Review should be conducted to verify that the design is correct, consistent, complete, accurate, and testable, before moving to implement the design. Portions of the design can be approved and released incrementally for implementation; but care should be taken that interactions and communication links among various elements are properly reviewed, analyzed, and controlled.

Most software development models will be iterative. This is likely to result in several versions of both the software requirement specification and the software design specification. All approved versions should be archived and controlled in accordance with established configuration management procedures.

Typical Tasks – Design

- Updated Software Risk Analysis
- Traceability Analysis - Design Specification to Software Requirements (and vice versa)
- Software Design Evaluation
- Design Communication Link Analysis
- Module Test Plan Generation
- Integration Test Plan Generation
- Test Design Generation (module, integration, system, and acceptance)

5.2.4. Construction or Coding

Software may be constructed either by coding (i.e., programming) or by assembling together previously coded software components (e.g., from code libraries, off-the-shelf software, etc.) for use in a new application. Coding is the software activity where the detailed design specification is implemented as source code. Coding is the lowest level of abstraction for the software development process. It is the last stage in decomposition of the software requirements where module specifications are translated into a programming language.

Coding usually involves the use of a high-level programming language, but may also entail the use of assembly language (or microcode) for time-critical operations. The source code may be either compiled or interpreted for use on a target hardware platform. Decisions on the selection of programming languages and software build tools (assemblers, linkers, and compilers) should include consideration of the impact on subsequent quality evaluation tasks (e.g., availability of debugging and testing tools for the chosen language). Some compilers offer optional levels and commands for error checking to assist in debugging the code. Different levels of error checking may be used throughout the coding process, and warnings or other messages from the compiler may or may not be recorded. However, at the end of the coding and debugging process, the most rigorous level of error checking is normally used to document what compilation errors still remain in the software. If the most rigorous level of error checking is not used for final translation of the source code, then justification for use of the less rigorous translation error checking should be documented. Also, for the final compilation, there should be documentation of the compilation process and its outcome, including any warnings or other messages from the compiler and their resolution, or justification for the decision to leave issues unresolved.

Firms frequently adopt specific coding guidelines that establish quality policies and procedures related to the software coding process. Source code should be evaluated to verify its compliance with specified coding guidelines. Such guidelines should include coding conventions regarding clarity, style, complexity management, and commenting. Code comments should provide useful and descriptive information for a module, including expected inputs and outputs, variables referenced, expected data types, and operations to be performed. Source code should also be evaluated to verify its compliance with the corresponding detailed design specification. Modules ready for integration and test should have documentation of compliance with coding guidelines and any other applicable quality policies and procedures.

Source code evaluations are often implemented as code inspections and code walkthroughs. Such static analyses provide a very effective means to detect errors before execution of the code. They allow for examination of each error in isolation and can also help in focusing later dynamic testing of the software. Firms may use manual (desk) checking with appropriate controls to ensure consistency and independence. Source code evaluations should be extended to verification of internal linkages between modules and layers (horizontal and vertical interfaces), and compliance with their design specifications. Documentation of the procedures used and the results of source code evaluations should be maintained as part of design verification.

A source code traceability analysis is an important tool to verify that all code is linked to established specifications and established test procedures. A source code traceability analysis should be conducted and documented to verify that:

- Each element of the software design specification has been implemented in code;
- Modules and functions implemented in code can be traced back to an element in the software design specification and to the risk analysis;
- Tests for modules and functions can be traced back to an element in the software design specification and to the risk analysis; and
- Tests for modules and functions can be traced to source code for the same modules and functions.

Typical Tasks – Construction or Coding

- Traceability Analyses
 - Source Code to Design Specification (and vice versa)
 - Test Cases to Source Code and to Design Specification
- Source Code and Source Code Documentation Evaluation
- Source Code Interface Analysis
- Test Procedure and Test Case Generation (module, integration, system, and acceptance)

5.2.5. Testing by the Software Developer

Software testing entails running software products under known conditions with defined inputs and documented outcomes that can be compared to their predefined expectations. It is a time consuming, difficult, and imperfect activity. As such, it requires early planning in order to be effective and efficient.

Test plans and test cases should be created as early in the software development process as feasible. They should identify the schedules, environments, resources (personnel, tools, etc.), methodologies, cases (inputs, procedures, outputs, expected results), documentation, and reporting criteria. The magnitude of effort to be applied throughout the testing process can be linked to complexity, criticality, reliability, and/or safety issues (e.g., requiring functions or modules that produce critical outcomes to be challenged with intensive testing of their fault tolerance features). Descriptions of categories of software and software testing effort appear in the literature, for example:

- NIST Special Publication 500-235, *Structured Testing: A Testing Methodology Using the Cyclomatic Complexity Metric*;
- NUREG/CR-6293, *Verification and Validation Guidelines for High Integrity Systems*;
- and
- IEEE Computer Society Press, *Handbook of Software Reliability Engineering*.

Software test plans should identify the particular tasks to be conducted at each stage of development and include justification of the level of effort represented by their corresponding completion criteria.

Software testing has limitations that must be recognized and considered when planning the testing of a particular software product. Except for the simplest of programs, software cannot be exhaustively tested. Generally it is not feasible to test a software product with all possible inputs, nor is it possible to test all possible data processing paths that can occur during program execution. There is no one type of testing or testing methodology that can ensure a particular software product has been thoroughly tested. Testing of all program functionality does not mean all of the program has been tested. Testing of all of a program's code does not mean all necessary functionality is present in the program. Testing of all program functionality and all

program code does not mean the program is 100% correct! Software testing that finds no errors should not be interpreted to mean that errors do not exist in the software product; it may mean the testing was superficial.

An essential element of a software test case is the expected result. It is the key detail that permits objective evaluation of the actual test result. This necessary testing information is obtained from the corresponding, predefined definition or specification. A software specification document must identify what, when, how, why, etc., is to be achieved with an engineering (i.e., measurable or objectively verifiable) level of detail in order for it to be confirmed through testing. The real effort of effective software testing lies in the definition of what is to be tested rather than in the performance of the test.

A software testing process should be based on principles that foster effective examinations of a software product. Applicable software testing tenets include:

- The expected test outcome is predefined;
- A good test case has a high probability of exposing an error;
- A successful test is one that finds an error;
- There is independence from coding;
- Both application (user) and software (programming) expertise are employed;
- Testers use different tools from coders;
- Examining only the usual case is insufficient;
- Test documentation permits its reuse and an independent confirmation of the pass/fail status of a test outcome during subsequent review.

Once the prerequisite tasks (e.g., code inspection) have been successfully completed, software testing begins. It starts with unit level testing and concludes with system level testing. There may be a distinct integration level of testing. A software product should be challenged with test cases based on its internal structure and with test cases based on its external specification. These tests should provide a thorough and rigorous examination of the software product's compliance with its functional, performance, and interface definitions and requirements.

Code-based testing is also known as structural testing or "white-box" testing. It identifies test cases based on knowledge obtained from the source code, detailed design specification, and other development documents. These test cases challenge the control decisions made by the program; and the program's data structures including configuration tables. Structural testing can identify "dead" code that is never executed when the program is run. Structural testing is accomplished primarily with unit (module) level testing, but can be extended to other levels of software testing.

The level of structural testing can be evaluated using metrics that are designed to show what percentage of the software structure has been evaluated during structural testing. These metrics are typically referred to as "coverage" and are a measure of completeness with respect to test selection criteria. The amount of structural coverage should be commensurate with the level of risk posed by the software. Use of the term "coverage" usually means 100% coverage. For example, if a testing program has achieved "statement coverage," it means that 100% of the