CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Guidance Development

(Includes Special Controls Guidance Documents)

CONTENTS

PURPOSE

This document summarizes the Center for Devices and Radiological Health's (CDRH) guidance development process.

BACKGROUND

Standard operating procedures for developing guidance documents were developed with the participation of CDRH staff and management before taking effect on July 31, 2010. The procedures were developed to improve CDRH processes for the development of guidance documents, consistent with CDRH's FY 2010 Strategic Priorities document, Strategy 1.2. Improve Guidance and Regulation Development.

DEFINITIONS

CDRH Fiscal Year Guidance Agenda – The CDRH Fiscal Year Guidance Agenda is the list of guidance documents CDRH is considering for development and may issue during the fiscal year. CDRH is not required to issue every guidance document on the agenda and may issue guidance documents not on the agenda. At the beginning of every fiscal year, the agenda is made publicly-available on the FDA website.

CDRH Guidance List – The CDRH Guidance List is the list of guidance documents CDRH is actively developing. This list is available to CDRH staff in the CDRH Guidance and Regulations Development eRoom.

CDRH Guidance Development Work Plan – The CDRH Guidance Development Work Plan is a document that identifies estimated timelines for development, review, clearance, and issuance of a guidance document. The Guidance Workgroup is responsible for creating and updating the Guidance Development Work Plan.

CDRH Guidance Program Email Address – The CDRH guidance program email address (Outlook name: CDRH-OCD-Guidance Distribution) should be used anytime a document is sent to the Deputy Center Director for Policy (DCDP). The use of this email address will ensure all members of the OCD guidance program are aware of the request for review. The CDRH guidance program email address is accessed by the DCDP, and others in OCD.

Classification Regulation – Classification regulations include initial classification regulations , de novo classification regulations, and reclassification regulations associated with a special controls guidance document. The development process for classification regulations and associated special controls guidance documents fall within the scope of this guidance development process.

Expedited Guidance Document – An expedited guidance document is a guidance document identified by the Center Director or the Deputy Director for Policy as high priority. Expedited guidance documents have an abbreviated review period.

GGP Conformance and Clearance Sheet – The GGP Conformance and Clearance Sheet is a form that documents the drafting, review, and clearance process of a guidance document. The lead Office GGP representative is responsible for initiating, maintaining, and updating this form.

Guidance Initiation Form – New guidance documents must be initiated using the Guidance Initiation Form (GIF), a document that describes basic information about a proposed new guidance document to permit a determination of whether Center resources should be devoted to development of the proposed guidance document. Submission of a GIF is required for all CDRH guidance documents. The form contains high level concepts, such as the issues the guidance document would address and *how* it would address those issues. Any CDRH employee may complete the Guidance Initiation Form. The GIF must be reviewed and a favorable decision to proceed with guidance development must be made by (i) all Offices from which

significant resources will be needed to develop the guidance document and (ii) the Deputy Center Director for Policy.

Guidance Summary Paper – The Guidance Summary Document is an optional document intended to assist the Guidance Workgroup in developing the content of a guidance document and foreseeing any issues that, unless addressed in advance, may interfere with the development of the guidance document. For certain guidance documents, however, documenting the important concepts and potential legal, policy, and scientific issues may be useful to facilitate development of the guidance document. The Senior Champion, with input from the Guidance Workgroup, should decide whether to prepare a Guidance Summary Document.

Guidance Workgroup – The Guidance Workgroup is comprised of individuals who collectively possess the expertise necessary to develop the guidance document. Each guidance workgroup will have a **"Core" Workgroup** and an assigned **Senior Champion.** Additional participation can be sought as needed. Workgroup participants are identified in the table below.

Table 1. Composition of the Guidance Workgroup

Core Workgroup Members	**Additional Workgroup Members (REPRESENTATION AS NEEDED)**
• Lead Office GGP Representative (for ODE, this will be a regulatory advisor) • Subject Matter Expert(s) (SME) • Senior Champion • Writer (the guidance writer is often, but not always, the SME. The guidance writer may also be the OCD Policy Advisor or an ODE regulatory advisor)	• Regulations Staff Representative • CDRH Center and Office Representative • OCD Policy Advisor • CDRH PRA Expert/Liaison • FDA PRA Representative • FDA Staff Level OCC Representative • FDA Economics Representative (Special Control guidances only) • Representative from Other Centers

Senior Champion – The Senior Champion is an individual responsible for resolving/elevating roadblocks and policy issues that may arise during guidance development. The lead Office, DCDP, or Center Director appoints the Senior Champion. This role should reside with someone of sufficient authority to effectively champion a document, such as an Office, Deputy Office or Division Director.

Special Controls Guidance Documents (SCGD) – A SCGD is a guidance document identified as a special control in a classification regulation for a class II device.

GUIDANCE DEVELOPMENT PROCEDURES

Part I. Initiation

Submission of a GIF is required for all CDRH draft guidance documents. A new guidance document is proposed by the submission of a GIF to the CDRH general guidance email address. The GIF must be cleared through all offices for which significant resources will be needed to develop the guidance document and the Deputy Center Director for Policy (DCDP) (or designee).

Part II. Development

The key steps in developing a guidance document are formation of the guidance working group, developing the concept of the guidance document, and writing the guidance document. Accompanying forms to track the process and checklists should be initiated at this stage.

1. Formation of the Guidance Workgroup

The lead Office is responsible for staffing the Guidance Workgroup, which always includes the core group members.

2. Developing Guidance Document Concept and Content

Once the Guidance Workgroup has been identified, members should meet to develop agreement on the content of the guidance and an estimated timeline for developing the guidance. The Guidance Summary Paper may be used to guide the group's discussion and to document key decisions.

3. Writing the Guidance

The Subject Matter Expert or Regulatory/Policy Staff may write the guidance depending upon the subject matter area the guidance document will address. In some instances, the writing is a collaborative effort with other members of the workgroup writing significant portions of the guidance.

Part III. Initial Internal Guidance Review and Clearance

Guidance document reviewers at each step of the initial internal (CDRH) guidance review and clearance process review the document and provide comments and revisions, if any.

Part IV. Initial External Review and Clearance

Guidance document reviewers at each step of the initial external review and clearance process review the document and provide comments.

Initial External guidance review is intended to identify and address all significant issues within the purview of the external component that must be resolved prior to issuance. "Part V. Final Guidance Review and Clearance" is intended to confirm that identified issues have been addressed by CDRH.

Part V. Final Guidance Review and Clearance

Final guidance review and clearance is intended to confirm that substantive issues identified in "Part V. Initial External Review and Clearance" have been be addressed by CDRH and to indicate official clearance for the guidance document by each internal and external component involved in the review and clearance of the document.

Part VI. Guidance Issuance and Web Posting

Level 2 Guidance Documents should be sent for posting to the CDRH web page when "Part III. Initial Internal Guidance Review and Clearance" is complete. Level 1 Guidance Documents should be posted to coincide with the *Federal Register* display date for the Notice of Availability.

Part VII. Finalizing a Draft Guidance

The goal of the guidance development process is to create a final guidance upon which FDA and industry can rely. The process is not complete, until a final guidance is issued. Within 30 days of the closing of the public comment period on a draft guidance document, the lead Office GGP representative should initiate the finalization of that guidance. "Part I. Initiation" and "Part II. Development" of this SOP do not apply to the finalization of a draft document.

Finalizing a Draft Upon Which Public comments Were Received

Finalization of a Draft Guidance requires collecting and evaluating public comments received on the draft and making revisions if necessary. After public comments have been collected, reviewed, evaluated and addressed, the workgroup should proceed to "Part III. Initial Internal Guidance Review and Clearance."

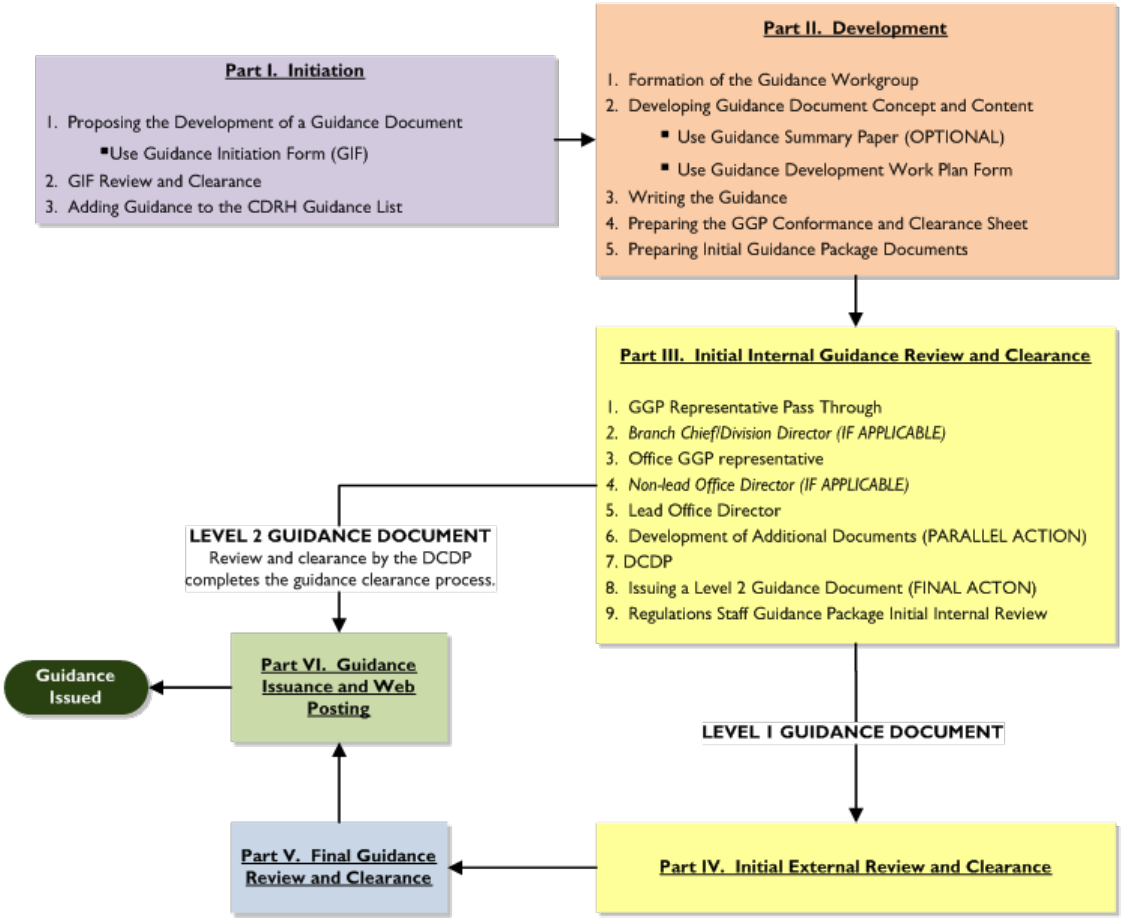
Finalizing a Draft Upon Which No Public comments Were Received

If the comment period on the draft guidance closed with no public comments received, a streamlined review and clearance process should be applied. When no public comments were received on a draft guidance, the final guidance can often be published with little or no modification. Initial review and clearance of the document is not necessary, proceed directly to "Part V. Final Guidance Review and Clearance."

Part VIII. Withdrawing Guidance

On occasion, a draft or final guidance should be withdrawn because the policy in the guidance no longer applies. If you wish to initiate the withdrawal of a draft or final guidance, send an email explaining why the guidance should be withdrawn to the Associate Director for Policy (ADP), copying the DCDP. The ADP, will decide whether to remove the guidance from the CDRH guidance page. Upon approval of the request the guidance will be removed from the FDA website. However, the guidance title will remain on the website with a note indicating that the document has been withdrawn.

FLOW CHART



EFFECTIVE DATE

This standard operating procedure (SOP) is effective upon date of publication.