

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date	2-28-01
Publication Date	3-1-01
Certifier	Skese

Food and Drug Administration

[Docket No. 01D-0044]

Medical Devices Draft Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver." FDA is issuing this draft guidance to propose alternative criteria for obtaining CLIA waiver to the criteria proposed by the Health Care Financing Administration (HCFA) and the Centers for Disease Control and Prevention (CDC). This draft guidance is neither final nor in effect at this time.

DATES: Submit written comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register.]*

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets

in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1243.

SUPPLEMENTARY INFORMATION:

I. Background

FDA assumes primary responsibility for performing the CLIA complexity categorization functions that includes requests for waiver. Responsibility for determining whether a particular device is waived was transferred from the CDC to FDA on January 21, 2000. At the same time, HCFA is responsible for financial management operations of the CLIA program. In the **Federal Register** of September 13, 1995 (60 FR 47534), HCFA and CDC published a notice of proposed rulemaking that proposed criteria for obtaining CLIA waiver (the 1995 proposed rule). FDA believes, based on its interpretation of the legislative history and the changes to the CLIA statute enacted by Congress on November 21, 1997, as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA), that alternative criteria to the criteria proposed by HCFA and CDC can be used to determine whether a device can be waived. HCFA, CDC, and FDA are continuing to discuss whether the criteria contained in this guidance appropriately reflect the intent of the statute. In an effort to get additional perspective on these criteria, this draft guidance will be discussed at the Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting to obtain their advice and recommendations. FDA is publishing this draft guidance so that it can be presented and discussed at the February 7 and 8, 2001, CLIAC meeting. FDA remains committed to ensuring an open, consistent, reliable process that all parties can understand and comment on as we take steps to finalize a rule.

Because FDA believes the agency will have to repropose a regulation to clarify waiver criteria, we think it will be some time before a final rule is codified. If this draft guidance is made final,

the agency would propose alternative waiver criteria that may continue in the interim (based on comments received on this draft guidance) until a reproposal of the regulation to clarify waiver criteria is published.

II. Significance of Guidance

FDA bases the recommendations in this draft guidance document on our interpretation of the law, our review experience with CLIA complexity reviews, and our interactions with stakeholders throughout the transition of this program from CDC to FDA. One of the interactions with stakeholders was in the form of an open public workshop on August 14 and 15, 2000. We are still evaluating the comments from this workshop. We intend to reevaluate and revise this draft guidance, as circumstances warrant, based on these and future comments. The recommendations in this draft guidance are different from the recommendations made by HCFA and CDC in their 1995 proposed rule. As stated in this draft guidance, FDA will continue to review requests for waiver that follow the criteria contained in the 1995 proposed rule; however, we will also review requests for waiver that follow the criteria contained in this draft guidance document. The most significant difference between the criteria proposed by CDC and HCFA, and the criteria outlined in this draft guidance, is that this draft guidance allows studies that compare the performance of the device in the hands of untrained users with the performance of the device in the hands of laboratory professionals to demonstrate accuracy.

This draft guidance represents the agency's current thinking on criteria for obtaining CLIA waiver. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

The agency has adopted good guidance practices regulations (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance is issued as a Level 1 draft guidance consistent with the GGP regulations.

III. Electronic Access

In order to receive the draft guidance entitled "Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1147) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the draft document entitled "Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLCIA) Criteria for Waiver," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. "Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver" is available at <http://www.fda.gov/cdrh>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/14/01

~~February 14, 2001~~
February 14, 2001.

98

Linda S. Kahan

Linda S. Kahan,
Deputy Director for Regulations Policy,
Center for Devices and Radiological Health.

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Suzette N. Reese