

Comments to Draft Guidance for Industry and FDA Staff:

Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications

Forwarded to:

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Reference:

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Comments: Number 1:

From page 29 (of the draft guidance), V. Labeling for Waived Devices...

You should include your proposed labeling, including Quick Reference Instructions, package insert, and outer labels, in your waiver application.

There are two situations where this does not work...

- a) Some devices are automatically reviewed for waiver categorization following clearance of the 510(k).
- b) Some devices will not be marketed if they don't receive a waived categorization.

Devices may not, however, state (in the labeling) that the device is waived until it has been determined to be waived, therefore, the 510(k) submission must not have any statements about the device being waived. This means there must be two sets of labeling. This creates confusion and burdensome cost.

Comments: Number 2:

From page 35 (of the draft guidance), Appendix A, Package Insert...

Information on reporting test system problems to the manufacturer and/or FDA.

A statement that users should notify CMS of device problems.

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Reports should go to the manufacturer ONLY. The manufacturer is required by regulation to assess the situation for further action (such as reporting to the FDA).

If a generic statement regarding the FDA or CMS is included, it will go unheeded by the user.

If a detailed statement regarding the contact information for FDA or CMS is included, this contact information must be monitored for changes (at such time, all existing labeling would be obsolete and would require revision, at great cost).

Comments: Number 3:

From page 34 (of the draft guidance), Appendix A, Package Insert...

...a statement that a certificate of CLIA waiver is required to perform the test in a waived setting, and information on how users can obtain a certificate.

These items are requirements of the waived laboratory as monitored by CLIA. They are not the responsibility of the manufacturer. To include the information regarding certification (in a package insert) is burdensome and costly, particularly if the information changes and newer revisions of all inserts are required.

Comments: Number 4:

From page 35 (of the draft guidance), Appendix A, Package Insert...

Study results demonstrating how the test compares to a known method, traceable to a reference method, if applicable.

A brief description and summary of the results of the waiver studies.

This information would go (essentially) unnoticed. It would, however, add cost to the preparation of the insert. Any facility that truly needed this information could contact the manufacturer (from the info given on the insert) to gain the full, proper studies.

Comments: Number 5:

Regarding the requirement for the Quick Reference Instructions...

CLIA (through this guidance document) requests a QRI. Has CLIA reviewed the product liability issues before issuing such a request? The use of a QRI versus a well-designed manual or insert raises a liability question.

Comments: Number 6:

From page 19 (of the draft guidance), Selection of the Comparative Method...

For some analytes, there is no internationally recognized reference method. Should the manufacturer contact CLIA prior to the preparation of studies to ensure that the methodologies will be accepted?

Comments: Number 7:

From page 16 (of the guidance), Clinical Study Sites and Participants...

In some instances, the test requirements are not practical for the tests performed. The number of sites and the number of samples may be difficult and costly to manage.

Could a study with lesser sites and/or samples be acceptable is deemed appropriate?

Would studies from foreign countries be acceptable?