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Documents Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
Room 1061 (HFA-305)
5600 Fishers Lane
Rockville, MD 20852

Re: Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act

Dear Madam or Sir:

Underwriters Laboratories, Inc., respectfully submits the following comments on the referenced guidance document:

1. Page 5, Section I, "The Inspection by Accredited Persons (AP) Program will be conducted independent of third party inspections performed..."

   This sentence does not make sense. One of the purposes of the AP Program is to reduce regulatory burden on medical device manufacturers who market globally. This would occur, for example, if the AP FDA inspection were held simultaneously with another inspection required for marketing in another country. However, combining AP inspections with audits as a US CAB, under the MRA, would be prohibited by this sentence. That was not the intent of the law. Perhaps FDA means that the accreditation of participants in the two programs will be independent. In that case the following wording is suggested:

   > "The accreditation of third parties under the Inspection by Accredited Persons (AP) Program will be independent of the accreditation of third parties under the US/EC Mutual Recognition Agreement (MRA)..."

2. Page 9, Section III, Part A, "The primary purpose of an inspection by an AP is to evaluate the manufacturer's compliance with the Quality Systems regulation (21 CFR Part 820) and other FDA regulations and..." (Emphasis added.)

   This goes well beyond the intent of the law. The AP program under MDUFMA was intended to relieve the pressure on scarce FDA resources by authorizing the use of third parties to conduct routine inspections of manufacturers to the Quality Systems Regulation (QSR). This was because it is reasonable to expect that third party auditors, already

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trained to assess compliance with ISO 13485, would with little additional training be qualified to assess compliance with the QSR, which is harmonized to ISO 13485. Conducting inspections to assess conformity with other regulations was not part of this intent. This additional requirement is not part of a "routine" inspection and would demand considerable additional training.

This does not mean that an AP inspector should not be aware of FDA law and regulations and be able to address situations that may come up during a QRS inspection. Any issue that could compromise the public health should be reported to FDA. Our auditors currently have such responsibility without the AP program. The AP auditors should not be expressly required to assess conformity to other regulations and their audit report should only explicitly cover compliance with the QSR.

We suggest that FDA deletes the phrase, "and other regulations."

3. Page 10, Section III, Part B, fifth bullet, "The establishment submits a statement that the laws of one of the countries in which the device is to be marketed recognizes an inspection of the establishment by FDA."

   Although this sentence is an exact quote from the law, this is an impossible statement to make. No country currently recognizes an establishment inspection by FDA.

4. Page 11, Section III, Part C, first open bullet, "compliance data showing whether the establishment has consistently complied with QS/GMP requirements and promptly corrected any problems; this data must include complete reports...The establishment is responsible for providing this information to FDA..." (Emphasis added.)

   The establishment is never provided a complete report of a QSR or GMP inspection. They are only given a summary (on a Form 483), and thus cannot provide the information to FDA. FDA maintains these records and may review them at any time.

   We suggest that FDA deletes the term "complete."

5. Page 11, Section III, Part C, second open bullet, "...information on previous inspections of the manufacturer or any related manufacturers. FDA may request this information from either the establishment or the AP."

   Again, manufacturers will only have a summary of any previous inspections by the manufacturer. These would be maintained by the AP, if they did the inspection, or by another third party if the AP did not perform the inspection. Also, in practice, the manufacturer may not have ready access to information on inspections of related manufacturers. (We assume that the term "related" means a facility within the same global corporation.) In many corporations, separate companies under the same corporate umbrella choose their regulatory service organizations independently. For example, one very large corporation with headquarters in Chicago has three different notified bodies,

and one in Minneapolis has even more. Such companies would also likely have APs to match up with their notified bodies in the different locations.

We suggest the following wording:

> "the relationship between the establishment and the AP, including information on previous inspections of the manufacturer by the AP or, if available, information on inspections of manufacturers under the same corporate umbrella by the AP. If the information is unavailable to the manufacturer, FDA may request this information from the AP."

6. Page 16, Section III, Part G, Paragraph 3f, "any personnel of the AP involved in the inspection process participates in an inspection of a firm in which they had **performed contract work** (e.g., conformity assessment body audit, laboratory testing, or AP inspection) within the last 12 months..."

   This requirement goes well beyond the law, which already requires that an AP may do no more that two inspections in a row, except in special circumstances. This latter requirement was inserted into the bill partly to assure that the AP did not become too familiar with the client's quality management system and such that problems were missed. The additional restriction goes well beyond that intent

   Further, this additional restriction poses an undue burden on the AP and its auditors. Most AP candidates audit their clients on a three-year cycle, performing surveillance audits at six or twelve month intervals. Not all of the QMS is explored in detail during any one audit; parts of the system may only be sampled. A plan is developed through which the entire QMS is assessed in detail over the three-year cycle. This additional restriction placed upon the AP would require the typical AP to change auditors every twelve to 24 months, depending on where in the audit cycle the FDA audit occurred. Although the AP candidates would probably change auditors periodically anyway, they would do this after a complete audit cycle because the logistics are much simpler and the transition to a new auditor is much easier.

   If it is the intent of the FDA to have the APs change auditors periodically, why not make that the requirement, instead of arbitrarily imposing an artificial and unnecessary requirement?

   We suggest replacing paragraph 3f with:

   > "any particular AP inspector conducts more than two sequential FDA inspections."

7. Page 18, Section III, Part G, Paragraph 2, "Tier two of the training will include successful completion of three joint inspections with FDA..."

The implications of this sentence and the succeeding paragraphs are that every AP inspector must receive three witnessed audits to be qualified. This requirement is not consonant with the statement in the paragraph on P. 7 regarding the least burdensome approach as it is extremely burdensome on both the AP and the FDA. FDA could be faced with witnessing hundreds of audits over the next year, just for 15 AP candidates! This would not be consistent with the law's intent of easing FDA's inspectional burden. Note that requiring every auditor to pass three witnessed inspections is also not consistent with the approach taken for the EU CABs under the MRA, where only the CAB must undergo three witnessed inspections.

While it is true that training in the law and how FDA expects an inspection to be done are extensive and ought to be taken by each AP auditor, all of the AP auditors are already extremely well-trained and experienced in auditing and audit procedures. Further, all of our other accreditors are satisfied to witness and qualify one lead auditor and to assess our procedures for qualifying additional auditors (auditing us periodically).

It would be sufficient (and least burdensome on both the APs and FDA) for FDA to witness three inspections with a single AP auditor. That auditor could then qualify other auditors within the AP by witnessing their inspections. FDA could require that the AP have procedures in place to qualify additional inspectors and could review those procedures as part of the AP accreditation process. FDA would always retain the right to inspect the AP and its records to assure that auditors were properly being qualified.

This would also be consistent with how the FDA treats the EU CABs that are currently authorized to perform FDA inspections in the EU.

We suggest changing paragraph 2 to read:

> "Tier two of the training will include successful completion of three joint inspections with FDA. At least one candidate from each AP must complete tier two training. Those who are so qualified may qualify additional inspectors within the AP who have completed tier one training. The AP shall establish procedures for qualifying additional inspectors under the AP Program and shall include these procedures in their application.
>
> Joint inspections will be carried out..."

Sincerely,

Harvey Rudolph, Ph.D.
Global Program Manager
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