



6747 '00 SEP 12 P2:03

Rec'd 9/12/00  
H.K.H

September 29, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

Reference: Docket No. 98N-0331

UL has reviewed the July 18, 2000 Federal Register Notice published at 65 FR 44540 (and the related Draft Guidance) and offers the following comments. For brevity and clarity the term Accredited Person is abbreviated as AP.

1. 65 FR 44541, middle column: Draft Guidance, page 6 --

1.1 An AP can only review a Class II device under the new pilot program if the AP applies to the Third Party Review Board for inclusion of these devices on the AP's device list (per draft guidance page 19). There is no express requirement that the AP must perform a prior review of a "same or similar medical specialty area" in order to include a device on the AP's device list. However, item 1) on draft guidance page 6 requires an AP to perform a prior review in a "same or similar medical specialty area" before undertaking a review under the new pilot program. We question how an AP can request inclusion of a device on its device list when it may not have performed a prior review in a "same or similar medical specialty area"; and conversely we question how an AP can be required to perform a prior review in a "same or similar medical specialty area" when the AP's device list includes the device. A manufacturer will be misled when it consults the database to determine whether an AP is eligible to review a device when in fact the AP may not review the device even though it appears on the AP's list of eligible devices.

1.2 Under the current program and under the new pilot program an AP must have FDA training in the administrative conduct of a review, and staff performing the review must have competence in the technologies involved regardless of the device Class and availability of guidance. It appears the intent of item 1) on draft guidance page 6 is to ensure that an AP undertaking a review under the new pilot program has the competence and experience to review the 510(k) and perform the administrative functions. The criteria of having the AP completing a prior review in a "same or similar medical specialty area" may restrict an AP from performing a review even though it has appropriate competence and experience. In order to allow greater flexibility, we suggest that additional options be included in item 1) whereby an AP may contact CDRH for authorization to perform the review.

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- 1.3 An Accredited Person must ensure that staff performing reviews are qualified and ensure that supervisory control over the 510(k) program is exercised. The means by which an Accredited Person accomplishes these must be acceptable to the FDA for delineating the conduct of reviews of Class II devices without specific guidance (draft guidance page 19).
- 1.4 The conduct of such reviews will necessarily involve coordination between the Accredited Person and the FDA not only during the initial review phases but also throughout the review. Therefore, the identification of pertinent issues and review criteria will evolve during the review, and documentation of such discussions should be submitted to FDA as intended by the draft guidance page 16 item 3.
- 1.5 In view of the above, we suggest that the criteria of draft guidance page 6 items 1), 2) and 3) be revised, and the paragraph after item 3) be revised. Following are revision suggestions with old text lined out and new text underlined.

FDA now intends to encourage more widespread use of the third party program by accepting reviews from Accredited Persons of devices for which there is no device-specific review guidance under the following circumstances. An Accredited Person may review a Class II device that does not have device-specific guidance if:

- 1) The Accredited Person has previously completed three successful 510(k) reviews ~~under the third party program of Class II devices with specific guidance or Class I devices.~~ This should include at least one 510(k) review that was in the same or similar medical specialty area as the device the Accredited Person now intends to review, or the Accredited Person should make a case to the appropriate CDRH ODE Branch Chief for authorization to undertake the review. ~~The prior 510(k) reviews can be for Class II devices that have device-specific guidance or for Class I devices;~~
- 2) The Accredited Person Contacts the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief (or designee) before initiating a 510(k) review for a Class II device that does not have a device-specific guidance to confirm that the Accredited Person meets the criteria in paragraph 1 above for review and to identify pertinent issues and review criteria related to this type of device; and
- 3) The Accredited Person prepares a summary documenting the ODE discussions and submits the summary of those discussions to ODE of the pertinent issues and review criteria that develop during the review, and submits the summary to ODE with the final submittal materials.

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The discussion and summary would not be binding on the agency or the Accredited Person. The pre-submission discussions and the creation of a record of those discussions by the Accredited Person documenting the rationale and development of review criteria will help FDA ensure the consistency and timeliness that can be provided by device-specific guidances of such reviews. In addition, the FDA may utilize such documentation to ensure consistency in its own interactions with different Accredited Persons and regular submitters. Moreover, the record of these discussions review criteria development will help FDA determine whether there is a need to issue device-specific guidance and could facilitate future development of those documents.

2. Draft Guidance, page 16, item 3 -- With reference to our comments under 1.2 and 1.4 above, we suggest that item 3 be revised to state:
3. If the Accredited Person is reviewing a product that is not the subject of device-specific guidance, they should submit a statement that the Accredited Person has previously completed three successful 510(k) reviews under the third party program, identification of the 510(k) that was in the same or similar medical specialty area as the device it has reviewed, and a copy of the summary of the pre-submission discussion discussion(s) that occurred with the appropriate branch chief or designee, including statements supporting eligibility to perform the review by confirming that the Accredited Person had previously completed three successful 510(k) reviews of Class II devices with specific guidance or Class I devices, and either (a) identify a 510(k) review that was in the same or similar medical specialty area, or (b) restate the case made to the CDRH ODE Branch Chief with a copy of the ODE authorization to undertake the review.

UL appreciates the opportunity to review and comment on the Draft Guidance, and we look forward to helping make the new pilot program successful. We hope you find our comments helpful.

Respectfully,

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