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

September 4, 2001

To whom it may concern:

Attached are my comments to Docket No. 01D-0262, "Guidance for FDA Reviewers, Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments, Draft Guidance."

Sincerely,

Diane Gubernot
Scientific Reviewer
FDA/CBER/OBRR/DETTD

01D-0262

C 1

Re: Docket No. 01D-0262

I. Introduction

Do we also want to include HIV diagnostic and viral load assay instruments? These are also reviewed by CBER.

E. Labeling

Add: Training Manual, Maintenance Procedures Manual (not just calibration maintenance), and Instrument trouble-shooting guide. Also, if the instrument is to be marketed with a particular assay, include the product insert(s)

Insert- Level of Concern of Software

Because instruments are usually run by software, and because this document includes requirements for validation and verification, the level of concern of the software is necessary. If this is outside the scope of this document, the Guidance for FDA Reviewers and Industry "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" should be referenced so that the firm includes all pertinent software information in the submission.

J. Functional Requirements

1. Add: specimen traceability

5. Add: all error handling messages (not just sampling errors). Also include if any reagent controls or calibrators are manufactured and/or distributed specifically for this instrument's calibration/quality control procedures.

6. Should this cross-reference also include a trace to tests performed for each requirement?

K. Design and Development

3. Add: and Off-the-shelf software

7. "Test methodology" is unclear. Does this refer to the assay? This point seems to be hardware related with the exception of this requirement. Also add: barcode specifications.

L. Hazard Analysis

2. Add: 3) Include all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the device. 4) Consider the entire system including necessary and optional accessories and sub-systems. 5) Human factors issues and user interfaces should also be considered.

5. Add labeling and training as possible mitigations.

M. Validation

First paragraph should be re-written to clearly state the goal of verification and validation and specify the documents which are required to be submitted. I suggest: " Verification, validation and testing are performed to demonstrate the requirements were met and to substantiate labeling claims for test kit reagent compatibility for all of the different instrument(s) and/or computer hardware/software configurations. The following documentation should be submitted:"

1. Functional testing is not necessarily done at the unit level. It should probably be described as its own point or under system level testing. Verification at the unit level includes structural testing and code walkthroughs. Functional tests, including stress testing, are performed at the system level (black-box testing). Functional tests should include intended uses, as well as: fault, alarm, hazard testing; error, range checking and boundary value testing; special algorithm testing; and testing of device peripherals. Off the shelf software also needs to be qualified.

2. Populated Decision tables should be defined. It is unclear exactly what the guidance is requiring. It appears that this may not apply to all instruments.

4. Beta testing. Add: Include any unforeseen hazards that were encountered with the software and hardware, including operator errors.

5. Add: Please provide a list of any unresolved anomalies in the software or firmware. Assure these anomalies are communicated to the user.

Barcode Reader validation needs to be included in this Validation section.

General Comments: Should this guidance document have definitions and explanations for each stage in the development process? For example, should we explain why a hazard analysis is necessary? CDRH guidance for software in Medical Devices contains

detailed explanations of software development and is an informative, user-friendly document. It also provides references. Do we want this document to be similar in that respect?

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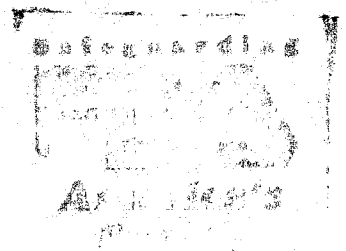

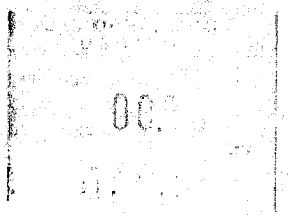

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