

standards, if those other activities do not affect the impartiality of inspections. Examples of conflicted laboratory testing, i.e., activities an AP may not perform, are routine quality production tests, validation/verification studies, and quality assurance-related testing.

Information on the COI standards FDA applies to its own personnel is included in appendix 1 of the guidance entitled "Standards for Ethical Conduct for Employees of the Executive Branch." An AP may adopt these standards, utilize the model COI policy FDA has provided as another appendix to the guidance, or demonstrate how alternative equivalent procedures will safeguard against COI.

4. Training

An AP will not be eligible to conduct independent inspections until they have successfully completed the classroom training required by FDA and conducted a satisfactory performance inspection under FDA observation. Firms identified on the FDA's list of APs to perform inspections will designate employees to participate in the classroom training and joint qualifying inspections. FDA will train no more than three employees per AP during the training sessions to be held by FDA in January 2004. FDA strongly encourages each AP to send at least two employees to the training, in recognition of employee attrition. APs with multiple sites engaged in FDA inspectional activities should request permission from the agency to send one representative from each site, not to exceed a total of five representatives from each AP.

Training for APs will be "modeled" after training of European Union Conformity Assessment Bodies (EU CABs) under the Mutual Recognition Agreement (MRA) Implementation Plan. (See <http://www.fda.gov/cdrh/mra/guidance/mraprocedure.html>.) EU CABs that have been accredited as APs and whose personnel have successfully completed the required training and/or joint inspections under the MRA program should state this in their application. If confirmed by FDA, the AP will not be required to have a representative repeat the classroom training or joint qualifying inspections. However, FDA does recommend that the AP send a representative to the FDA Investigator Training module as an update. Personnel trained by FDA under the MRA program who do not attend the current training will need to review a videotaped FDA presentation on evidence development.

The FDA training will consist of a two tiered program.

Tier one will include formal classroom training for AP inspectional staffers (trainees). At a minimum this will include:

a. The Association for the Advancement of Medical Instrumentation (AAMI) GMP/ Quality System: Requirements and Industry Practice (or equivalent). AAMI will be conducting this training throughout the United States and in Frankfurt, Germany in 2003; see AAMI web site at <http://www.aami.org/meetings/courses/gmp.html>¹ for specific dates and locations. Please note that you must register separately for the training session and the examination. The AAMI training schedule for 2004 will not be posted until late 2003.

b. FDA's Quality System Inspection Technique (QSIT) training module.

c. FDA Investigator Training, which will include training on:

- Food and drug law,
- Advanced QSIT,
- FDA inspectional procedures,
- FDA policies and device regulations and
- Evidence development.

FDA plans to conduct its training sessions from January 12 through 16, 2004, in the Washington, DC metropolitan area. FDA will make a final decision on applications in early October 2003, and plans to advise applicants and post the list of APs on the Internet in mid-October. Each applicant to this program should make tentative plans to send appropriate representatives to the FDA Investigator Training. However, only those applicants that are confirmed as APs in October will be eligible to attend the training. Applicants should advise FDA in their AP application of the names of the employee(s) that have either successfully completed this training or those who will be nominated to participate in this training. AP trainees will not qualify to enter the second tier, unless they successfully pass a test at the end of each tier one training session.

The second tier will involve the completion of three joint inspections, during which FDA and the AP will address the relevant parts of Compliance Program 7382.845—Inspection of Medical Device Manufacturers and the QSIT guidance—Guide to Inspection of Quality Systems. The three joint inspections will include:

(a) Collaborative Inspection—The FDA investigator will be the lead inspector and the AP trainee will act

primarily as an observer. The FDA investigator will prepare a list of any nonconformities and an inspection report. The trainee will prepare a "practice" list of nonconformities and an inspection report.

(b) Modified Performance Inspection—Using established criteria, the FDA investigator will observe and evaluate the trainee performance of an inspection and may provide assistance. The trainee will prepare a list of any nonconformities to be presented to the facility and an inspection report. The FDA investigator will review the list of nonconformities and provide feedback before it is presented. In addition, the FDA investigator will review the inspection report and, if necessary, write an addendum to supplement the inspection report.

(c) Full Performance Inspection—The AP trainee will perform an independent inspection and will be observed and evaluated by the FDA investigator using established criteria. The FDA investigator may not provide assistance to the trainee. The trainee will prepare a list of any nonconformities to be presented to the facility and an inspection report. The FDA investigator will review the list of nonconformities and provide feedback before it is presented. In addition, the FDA investigator will review the inspection report and, if necessary, write an addendum to supplement the inspection report. The FDA investigator's evaluation of the trainee and recommendation will be presented to the FDA Office of Regulatory Affairs (ORA) certifier in the FDA Division of Human Resource Development who will determine if the trainee is qualified to perform independent inspections.

The criteria FDA will use to evaluate the joint inspections will be addressed at the FDA training sessions to be held in January 2004.

5. Evaluation of the AP Application

(a) The Third Party Recognition Board (TPRB) Chairman will e-mail the applicant's contact person, within 24 hours of receipt of the AP application, acknowledging receipt.

(b) Members of the TPRB will perform an initial review to determine if the request for accreditation addresses the information set forth below in section II.B.6 of this document, Contents of an AP Application, and is adequate for review by the full TPRB.

(c) The TPRB Chairman will advise the contact individual, via e-mail, within 60 days after the receipt of such request for accreditation, whether the request is adequate for review by the TPRB or whether additional information is needed.

¹ FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.