The FDA Reauthorization Act of 2017 (FDARA), signed into law on August 18, 2017, amended several sections of the Federal Food, Drug, and Cosmetic Act. This document was developed and issued prior to the enactment of FDARA, and certain sections may no longer be current as a result. FDA is assessing how to revise this document to represent our current thinking on this topic. For more information please contact CDRH-FDARA@fda.hhs.gov.

Guidance for Industry, FDA Staff, and Third Parties

Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria

Document issued on: August 6, 2009

This document supersedes "Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria," issued on October 4, 2004.

The information collection provisions in this guidance have been approved under OMB control number 0910-0510. This approval expires 08/31/2019. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

For questions regarding this document contact the Medical Device Single Audit Program (MDSAP) Team by e-mail at mdsap@fda.hhs.gov. For questions regarding the application of this guidance to devices regulated by the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach and Development, at - 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biological Evaluation and Research
Third Party Implementation Team

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. When submitting comments, please refer to Docket No. FDA-2003-D-0304 (formerly Docket No. 2003D-0117). Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089702.htm, or http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089721.pdf. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1200) to identify the guidance you are requesting.

Additional copies of this guidance document are also available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach and Development (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm

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Appendices:

These documents are available on the FDA and CDRH Home Pages in text or PDF versions. The URLs are included in **Section V** of this guidance.

1. Standards of Ethical Conduct for Employees of the Executive Branch
2. Model Conflict of Interest (COI) Policy
3. AP Inspection Program Rating Criteria Checklist (Checklist)
4. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
5. The Public Health Service Act (42 U.S.C. 201 et seq.)
6. Title 21, Code of Federal Regulations, Parts 1-1271
7. FDA Compliance Program 7382.845, Inspection of Medical Device Manufacturers
8. Investigations Operations Manual
9. Guide to Inspections of Quality Systems (Quality System Inspection Technique)
10. Guidelines for the Regulatory Auditing of Quality Systems for Medical Device Manufacturers – Global Harmonization Task Force (GHTF) SG-4 (99) 28

Guidance for Industry, FDA Staff, and Third Parties

Inspection by Accredited Persons Under the Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. What is the Purpose of this Guidance?

This guidance addresses section 704(g) of the Federal Food, Drug, and Cosmetic Act (FDCA or the act) (21 U.S.C. 374(g)(2)) which concerns the accreditation of third parties (Accredited Persons) to conduct inspections of eligible manufacturers of class II and class III medical devices

Under the Accredited Persons Program (AP Program), manufacturers may elect to have third parties that have been accredited by FDA conduct some of their inspections instead of FDA. This program will allow manufacturers greater control over the timing of their inspections and, in cases where the APs are recognized by regulatory authorities of other countries, may reduce the total number of inspections required. At the same time, it will allow FDA to leverage its inspectional resources.

For those who are interested in the AP program, this guidance provides information about the following:

- Persons who seek to be accredited to perform Quality System (QS) / Good Manufacturing Practice (GMP) inspections under the act;
- FDA staff responsible for implementing the AP program.

For purposes of this guidance, an AP is a third party recognized by FDA to:

- perform the equivalent of an FDA QS inspection of eligible manufacturers of class II and III devices under 21 CFR Part 820 and
- prepare and submit reports to FDA, which makes the final compliance classification.

Note: **The focus of this document is on third parties who want to apply to become APs under this program.** "Manufacturer's Notification Of The Intent To Use An Accredited Person Under The Accredited Persons Inspection Program Authorized By Section 228 Of The Food and Drug Administration Amendments Act of 2007 (FDAAA)" available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm, provides establishments with information about procedures for participating in this program.

This guidance represents the Agency's current thinking on the Accredited Persons Program under the Medical Device and User Fee Modernization Act (MDUFMA) and FDAAA. MDUFMA required FDA to publish in the Federal Register the criteria to be used by the agency to accredit or deny accreditation. (Section 704(g) (2)) (21 U.S.C. 374(g)(2)). These criteria were published in the Federal Register on April 28, 2003 at 68 FR 22400. On October 4, 2004, FDA published revised accreditation criteria in the Federal Register (69 FR 59250) to incorporate changes to MDUFMA made by the Medical Devices Technical Corrections Act (MDTCA)(Public Law 108-214) which was signed into law on April 1, 2004. Under section 704(g) (2) of the act, (21 U.S.C. 374(g)(2)), the published criteria are binding on those persons who apply to become APs under this program.

The criteria for APs that FDA published in the Federal Register under the authority of section 704(g)(2) of the act, (21 U.S.C. 374(g)(2)), are repeated in this guidance, along with additional information that will assist with the implementation of this program.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that FDA believes need to be addressed by participants in this program. In developing the guidance, FDA carefully considered the relevant statutory criteria. FDA also considered the burden that may be incurred in complying with the guidance and addressing the issues we have identified. FDA believes that we have considered the least burdensome approach to resolving the issues presented in this guidance document. If, however, you believe that there is a less burdensome way to address the issues, please contact us. You may send your comments to the contact person listed in the preface of this guidance. Also, comprehensive information on dispute resolution at Center for Devices and Radiological Health (CDRH) is listed on the CDRH Ombudsman's web page: http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOmbudsman/default.htm.

Information on dispute resolution for Center for Biologics Evaluation and Research (CBER) regulated devices is listed on the CBER web site at:
http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm122881.htm

II. Introduction

A. Why Are Medical Device Establishments Subject to Mandatory Inspections?

Section 510(h) of the FDCA states that every establishment engaged in the manufacture of a class II and III device and registered under section 510 shall be inspected by one or more designated employees or by an accredited person at least once in every two year period. Over the years, the Agency has reengineered its inspection policy and work plans to embrace a risk based approach that targets limited resources to inspections that will best protect the public health. The AP inspection program established by MDUFMA and revised under FDAAA is another tool the Agency and stakeholders can use to leverage resources by permitting qualified independent third parties to perform certain biennial inspections.

B. What is the Quality System / Good Manufacturing Practice (GMP) Regulation?

The GMP regulations for medical devices were first authorized by the Medical Device Amendments of 1976 under section 520(f) of the act. In July 1978, FDA published final regulations prescribing GMP requirements for the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of medical devices. This regulation became effective in December 1978 and was codified in Title 21 of the Code of Federal Regulations, Part 820 (21 CFR Part 820). Under the GMP regulation, FDA required each manufacturer to develop a set of appropriate procedures for the manufacture of each device.

In November 1990, the Safe Medical Devices Act (SMDA) amended section 520(f) of the act to give FDA the authority to add preproduction design controls to the GMP regulation. The SMDA also added a new section 803 to the act, which encouraged FDA to work with foreign countries toward mutual recognition of the GMP and other regulations. This section also encouraged any revision of the GMP regulation to be consistent with the requirements contained in applicable international standards.

In October 1996, FDA published the Quality System regulation (QS regulation), which revised the 1978 GMP regulation, to incorporate new requirements for preproduction design controls, supplier and service controls, and management controls. As part of this process, FDA took steps to harmonize the QS regulation with the international standard ISO 13485:1996, Quality Systems, Medical Devices, Supplementary Requirements to ISO 9001:1994.

C. What is FDA's Experience with AP Quality System Inspections?

The FDA has over 5 years of experience using APs to perform Quality System inspections of FDA regulated establishments. The AP program was first implemented with the passage of the MDUFMA. Since 2003, the FDA has accredited 16 organizations, conducted classroom training

for over 60 AP auditors, and participated in joint inspections/audits with over 40 AP auditors. Auditors for the 16 accredited organizations have successfully conducted over 90 inspections in lieu of inspections by FDA personnel.

D. How do the Medical Device User Fee and Modernization Act of 2002 and the Food and Drug Administration Amendments Act (FDAAA) of 2007 Affect FDA Inspections?

Section 201 of MDUFMA established a new subsection "g" to section 704 (Factory Inspection) of the act, which requires FDA to accredit third parties (APs) to perform inspections of eligible manufacturers of class II or III devices. **This is a voluntary program. While all firms remain subject to inspection by FDA, eligible manufacturers have the option of being inspected voluntarily by an AP.** However, inspections by APs are limited by the act to manufacturers who meet the conditions described in section III B of this document.

MDUFMA required that no more than 15 firms be accredited during the first year of the AP Program. On October 26, 2003, FDA posted on its web page a list of 15 APs who would be eligible to perform inspections for FDA after successfully completing the Tier 1 and Tier 2 requirements. These included FDA's training program and the conduct of a satisfactory performance inspection under FDA's observation. On April 28, 2004, FDA began accepting new applications under section 704(g) of the act (21 U.S.C. 374(g)(2)). FDA must inform those requesting accreditation whether their application is adequate for review within 60 days of receipt of their request. (See section III.C. for qualifications to become accredited.) The list of APs will be updated periodically but no later than one month after a new accreditation, the withdrawal of an accreditation, or a change in activities for which an AP was accredited (21 U.S.C. 374(g)(4)).

The Food and Drug Administration Amendments Act (FDAAA) of 2007 was signed into law by the President on September 27, 2007. FDAAA streamlined the Accredited Person for Inspection Program by eliminating the requirement that a device establishment must seek prior FDA approval for a Third Party Inspection. See related guidance, Guidance for Industry, FDA Staff, and FDA-Accredited Third Parties Manufacturer's Notification Of The Intent To Use An Accredited Person Under The Accredited Persons Inspection Program Authorized By Section 228 Of The Food and Drug Administration Amendments Act of 2007 (FDAAA), regarding notification to FDA of the use of an Accredited Person. In addition, FDAAA eliminated the limit of two consecutive Third Party inspections unless FDA granted a waiver. FDAAA also added a provision permitting an establishment to voluntarily submit reports by a Third Party assessing conformance with an ISO standard identified by FDA in a public notice. Such reports will not substitute for an FDA inspection, but FDA may use them when establishing risk-based inspection priorities. (21 U.S.C. 374(g)(7)(F)).

III. What is the Inspection by Accredited Persons (AP) Program?

A. What Are the Primary Features of the Program?

The program permits APs to perform the equivalent of an FDA QS inspection and to submit the findings to FDA for final inspectional classification. In accordance with the requirements of section 704(g) of the act, (21 U.S.C. 374(g)), an inspection under the AP program includes features designed to maintain a high level of confidence in inspections conducted by APs and to minimize risks to the public health. These features include the following:

- Eligibility for inspection by APs is primarily limited to establishments whose most recent inspection was classified by FDA as either "No Action Indicated (NAI)" or "Voluntary Action Indicated (VAI)" (704(g)(6)(A)(i)) (21 U.S.C. 347(g)(6)(A)(i));
- Assessment, accreditation, and training of APs by FDA will occur before APs conduct independent inspections; APs **will not** be eligible to conduct independent inspections until they successfully complete FDA's training program and perform a satisfactory inspection under FDA's observation (704(g)(2)) (21 U.S.C. 347(g)(2)) (69 FR 59251);
- Qualifications for APs' personnel will be equivalent to that of FDA personnel (704(g)(2)) (21 U.S.C. 374(g)(2)) (69 FR 59251);
- Strict criteria exist to prevent conflicts of interest for APs (704(g)(3)(E)) (21 U.S.C.374(g)(3)) (69 FR 59252);
- FDA retains responsibility for making the final compliance classification of the inspection (702(g)(7)(A)) (21 U.S.C. 374(g)(7))A));
- Provisions for FDA to make onsite visits on a periodic basis to each AP to audit performance and inspect records, correspondence, and other materials relating to the inspection under the AP program (704(g)(5)(A)(i)) (21 U.S.C. (g)(5)(i)); and
- FDA will monitor and evaluate each AP's independence and compliance with section 704(g) of the act (704(g)(2)) (21 USC 3.7.4. (g)(2)) (69 FR 59253).

B. How Can I Become an AP?

FDA uses the Third Party Recognition Board (TPRB) to accredit persons to conduct inspections of medical device establishments under MDUFMA. In 1998, the FDA established the TPRB to accredit persons under section 523 of the act.

Applications to become an AP under MDUFMA's Inspection by Accredited Persons Program should be submitted to the TPRB. Information on how to submit an application is provided at section IV.B of this document. FDA accredited 15 firms in the first year of the program. Organizations may apply to be an AP for the inspection of all eligible establishments or limit their scope to specific types of devices. FDA will accredit only applicants with qualified personnel (technically competent) and who meet stringent conflict of interest standards. FDA will accept applications from both domestic and foreign persons. To facilitate timely review, applications and communications should be in English.

MDUFMA required FDA to post on its Internet site a list of persons that have been accredited by the Agency. To meet this statutory timeframe, FDA posted the first list of 15 accredited persons on October 26, 2003.

FDA will maintain a list of APs eligible to conduct inspections on the CDRH Home Page. This list will include the name, contact person, address, telephone number, e-mail address, status (e.g., foreign certifications, eligibility to do independent inspections, etc.), and any limitations in the APs' scope of work.

C. What Qualifications Are Necessary to Become an AP?

Only those applicants that demonstrate that their organization has the relevant qualifications and competence to perform inspections and that they have instituted effective controls to prevent any conflict of interest or appearance of conflict of interest that might affect the inspection outcome may be accredited. In addition, before APs can conduct independent inspections, they will need to successfully complete classroom training and qualifying inspections performed under FDA's observation.

Minimum Requirements

As specified at section 704(g)(3) of the act, (21 U.S.C. 374(g)(3)), to be accredited, the applicant must, at a minimum, meet the following general requirements:

1. You are not be a Federal Government employee;
2. You must be an independent organization not owned or controlled by a manufacturer, supplier, or vendor of **articles regulated under the act** and have no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor;

   Please see http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm079670.htm for examples of firms that are regulated by FDA and would, therefore, create a conflict. This includes manufacturers of radiation-emitting electronic products such as televisions, microwave ovens, CD players, laser printers, industrial lasers, as well as food, drugs, biologics, cosmetics, veterinary products, and medical devices.
3. You must be a legally constituted entity permitted to conduct the activities for which you seek accreditation;
4. You must not engage in the design, manufacture, promotion, or sale of **articles regulated under the act;**
5. You must operate in accordance with generally accepted professional and ethical business practices and agree in writing that at a **minimum** you will:
   i. certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with this act, and recommendations made during an inspection or at an inspection's closing meeting;
   ii. limit work to that for which competence and capacity are available;

iii. treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the FDA;

iv. promptly respond and attempt to resolve complaints regarding your activities for which you are accredited; and

v. protect against the use of any officer or employee of the AP to conduct inspections who has a financial conflict of interest **regarding any product regulated under the act**, and annually make available to the public disclosures of the extent to which the AP and officers and employees have maintained compliance with requirements relating to financial conflicts of interest.

Additional Criteria

In addition to the minimum requirements described above, FDA will also consider the following criteria when selecting APs:

1. Personnel.

   FDA expects APs to have sufficient personnel, with the necessary education, training, skills and experience to review records and perform inspections. We will consider several factors when evaluating personnel. These include:

   a. whether personnel have knowledge of:

   - the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);
   - the Public Health Service Act (42 U.S.C. 201 et seq.);
   - regulations implementing these statutes, particularly 21 CFR Parts 11 and 800-1271, with special emphasis on Parts 11, 801, 803, 806, 807, 809, 814, 820 and 821;
   - FDA Compliance Program 7382.845, Inspection of Medical Device Manufacturers;
   - Guide to Inspection of Quality Systems: Quality System Inspection Technique (QSIT); and
   - FDA Investigations Operations Manual, Chapter 5-Establishment Inspection.

   b. whether the applicant has:

   - established, documented, and executed policies and procedures to ensure that inspections are performed by qualified personnel, and whether it will maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the performance of inspections;
   - available to its personnel clear, written instructions for duties and responsibilities with respect to inspections;

- identified personnel who, as a whole, are qualified in all of the quality system disciplines for the inspections under the AP's scope of work; and

- identified at least one individual who is responsible for providing supervision over inspections and who has sufficient authority and competence to assess the quality and acceptability of inspection reports.

2. Infrastructure

   APs need the capability to interface with FDA's electronic data systems and the FDA Internet websites. At a minimum, this would entail a computer system with a modem and an independent facsimile machine. FDA will rely extensively on the use of our electronic systems for timely dissemination of guidance documents to APs and other interested parties.

   APs need physical security and safeguards for protecting trade secret and confidential commercial or financial information, as well as personal identifier information in medical records, such as adverse event reports, that would reveal the identity of individuals if disclosed.

3. Prevention of Conflicts of Interest (COI)

   MDUFMA requires that APs be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of a conflict of interest (section 704(g)(3)) (21 U.S.C. 374(g)(3)). To that end, when deciding whether to accredit a person, we will consider whether they have established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest, including conflicts that contractors or individual contract employees may have.

   Although it is not feasible to identify all of the circumstances that would raise concerns about conflicts of interest in this document, common conditions that indicate an actual or a potential conflict of interest are:

   a. the AP is owned, operated, or controlled by a manufacturer, supplier or vendor of **any article regulated under the act**; See http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm079670.htm for examples of firms that are regulated by FDA and, therefore, would create a conflict. This includes manufacturers of radiation-emitting electronic products such as televisions, microwave ovens, CD players, laser printers, industrial lasers, as well as foods, drugs, biologics, cosmetics, veterinary products, and medical devices.

   b. the AP has any ownership or financial interest in any product, manufacturer, supplier or vendor regulated under the act;

   c. any personnel of the AP involved in inspections or **their spouse or minor children** have an ownership or other financial interest regarding **any product regulated under the act** (**see link at 3 a. above**);

d. the AP or any of its personnel involved in inspections participates in the design, manufacture, promotion or sale of **any product regulated under the act**;

e. the AP or any of its personnel involved in inspections provides consultative services to any manufacturer, supplier, or vendor of products regulated under the act (**see link at 3 a. above**);

f. any personnel of the AP involved in the inspection process participates in an inspection of a firm **they were employed by** within the last 12 months;

g. the fees charged or accepted are contingent or based upon the observations in the report made by the AP.

When the AP uses the services of a contractor in connection with an inspection, it is responsible for the work of the contractor and its personnel. It will be the AP's responsibility to assure that the contractor meets the same criteria for freedom from conflicts of interest as the AP and its personnel.

In addition to conducting inspections as an AP, you may also conduct other activities, such as objective laboratory testing of products regulated under the act or assessment of conformance to standards, **if those other activities do not affect the impartiality of inspections**. Examples of conflicted laboratory testing, activities an AP **may not** perform, are those tests linked to the manufacturing process and which are usually performed by manufacturers such as routine quality production tests, validation/verification studies, and quality assurance related testing.

Information on the conflict of interest standards FDA applies to its own personnel is included in Appendix 1, "Standards for Ethical Conduct for Employees of the Executive Branch." An AP may adopt these standards, utilize the Model Conflict of Interest Policy FDA has provided (see Appendix 2), or explain alternative equivalent procedures that will safeguard operations against conflicts of interest.

D. If I Am Approved as an AP, What Additional Training Will Be Required Before I Can Do Inspections and Who Will Provide that Training?

If you are approved to be an AP, you will be asked to designate employees to participate in classroom training and joint qualifying inspections. FDA conducted the initial training program for AP auditors in January 2004. FDA will periodically provide either "face to face" or electronic training of AP auditors. Training for new AP auditors consists of a two-tiered program as follows:

1. **Tier one** will include formal classroom training. 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 conducts

this training throughout the United States and in foreign countries. See AAMI web site at http://www.aami.org/meetings/ for specific dates and locations. A copy of each trainee's certificate of successful completion of the AAMI training should be submitted to FDA's Third Party Recognition Board.

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

c. FDA Investigator Training, which will include training by FDA on:
   - Food and Drug law,
   - Advanced QSIT,
   - FDA inspectional procedures,
   - FDA policies and device regulations, and
   - Evidence development.

Those trainees who successfully pass the test given at the end of each Tier one training session will qualify for the second tier of training.

2. **Tier two** of the training will include successful completion of three joint inspections with FDA. Joint inspections will be carried out in accordance with 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 include:

a. **Collaborative Inspection**-An FDA investigator or under certain circumstances, a qualified AP auditor, will be the lead investigator. The AP trainee will act primarily as an observer. The FDA investigator will prepare a list of any non-conformities and an inspection report. The trainee will prepare a "practice" list of non-conformities 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 non-conformities to be presented to the establishment and an inspection report. The FDA investigator will review the list of non-conformities 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 non-conformity to be presented to the facility and an inspection report. The FDA investigator will review the list of non-conformities 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 whether the trainee is qualified to perform independent inspections.

The criteria FDA will use to evaluate the joint inspections will be addressed during the FDA training sessions.

FDA will provide APs with information on the Agency's inspection procedures, criteria, general guidance, and any additional training programs. Also, APs may access the FDA's Office of Regulatory Affairs (ORA) Home Page, http://www.fda.gov/ora/, the Center for Devices and Radiological Health (CDRH) Home Page, http://www.fda.gov/MedicalDevices/, and the Center for Biologics Evaluation and Research (CBER) Home Page, http://www.fda.gov/cber/ for general information on regulatory guidance and on MDUFMA. APs may also access existing guidance documents specific to FDA inspections listed in Section V of this document.

E. How Will APs be Monitored?

The CDRH Office of Compliance (OC) will monitor AP inspections relating to devices regulated by CDRH. The CBER Office of Compliance and Biologics Quality (OCBQ) will monitor inspections relating to devices regulated by CBER. These two offices, together with the ORA Office of Regional Operations (ORO), will perform an evaluation of each AP based on the first three independent inspections. Subsequently, FDA will audit APs on a periodic and "for cause" basis. The APs must continue to demonstrate technical competency in order to maintain accreditation. (Section 704(a)(5)(A))

FDA will inspect the APs' facilities to assure they have maintained records and are operating in accordance with procedures as specified in their application and section 704(g)(7) of the act. In addition, **FDA will monitor inspections conducted by APs and may periodically accompany them on an inspection or perform an audit of an AP-inspected facility.**

F. How will FDA Address Concerns about the Independence of APs?

As discussed above, each AP will be expected to demonstrate that there are no actual or perceived conflicts of interest and that there are procedures in place to ensure that the AP will maintain its freedom from conflicts of interest. In addition, the statute requires each AP to publish at the end of each year the actions it has taken to ensure that it has followed the prevention of conflict of interest requirements of the AP program.

Because the statute requires FDA to monitor each request from an establishment to use a particular AP, the agency will have the ability to stop inspections by APs who may have developed inappropriate business relationships with certain companies. If FDA's monitoring of the program reveals that manufacturers are developing business relationships with APs that call into question the independence or objectivity of the AP, FDA will consider implementing a process that limits the submitter's choice of APs for a specific inspection. Business relationships that may undermine the independence or objectivity of an AP include contracts between a manufacturer and an AP that represent a significant share of the AP's income such that continuation or termination of the

contract may create undue financial influence or at least the appearance of such influence. Where there is evidence of a financial conflict of interest between the AP and the owner or operator of the inspected device establishment, FDA may take steps to withdraw the AP's accreditation in accordance with section 704(g)(5) of the act.

G. What Inspection Records Are to be Submitted to FDA?

APs are required to prepare inspection reports in the form and manner designated by FDA (21 U.S.C. 374(g)(7)(A)). APs will need to prepare an FDA prescribed inspection report, using the format defined in the Investigations Operations Manual (IOM), http://www.fda.gov/ora/inspect_ref/iom/ subchapters 559 and 590. Also see List of Observations, http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf. FDA will provide instruction in the preparation of a list of observations (non-conformities) and the inspection report at the FDA training course. See Regulatory Procedures Manual, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm for timeframes for submitting reports.

At the conclusion of the inspection, when non-conformities have been observed, the AP will list all significant non-conformities observed and present them in writing to notify the manufacturer's top management of significant objectionable conditions. Each observation is discussed with the firm's most responsible person at the facility. In addition, the AP inspector will prepare and send a report to FDA and the manufacturer's designated representative at the same time, but not later than three weeks following the last day of the inspection. As required by section 704(g)(7)(B), the inspection report, at a minimum shall:

- identify the persons responsible for compliance with the QS regulation;
- include the date(s) of the inspection;
- include the scope of the inspection;
- describe in detail each observation identified and presented in writing to the establishment's management at the conclusion of the inspection;
- identify other matters that relate or that may influence compliance with the act;
- describe any recommendations made to the establishment during the inspection or at the inspection's closing meeting; and
- describe any promised corrective actions or other discussions with management at the conclusion of the inspection.

FDA expects the APs' reports and any clarifying information requested by FDA to be provided in English. Any documents collected from the manufacturer may be in the operational or working language used in the manufacturer's facility. However, the time necessary to translate the firm's documents may delay FDA's endorsement.

FDA may not be able to evaluate and classify an inspection report submitted by an AP if the information discussed above is not included. If information necessary for the agency's review is not included, the review will begin only after we receive the necessary information.

If at any time during an inspection the AP discovers a condition that it believes could cause or contribute to an unreasonable risk to public health, the AP must report the problem to FDA immediately. 21 U.S.C. 374(g)(7)(E). This will be a topic of discussion at the FDA training.

H. How will APs and FDA Treat Confidential Information?

The AP must protect from public disclosure trade secret, confidential commercial or financial information, and private personal identifier information in records, such as in adverse event reports, except that such information may be made available to FDA. 21 U.S.C. 374(g)(3)(E)(iii) FDA recommends that any contract between an AP and an establishment include a provision that specifies the protection of all such information.

FDA will determine the releasability of inspection records and information collected from the manufacturer and submitted to FDA by an AP in accordance with applicable disclosure laws, including the Freedom of Information Act (5 U.S.C. 552) , the Trade Secrets Act (18 U.S.C. 1905), section 301(j) of the Act (21 U.S.C. 331(j)) and FDA regulations implementing these statutes. For information on FDA treatment of confidential information and definitions of what constitutes trade secret, confidential commercial or financial information, and private personal identifier information, see the FDA regulations implementing the Freedom of Information Act in 21 CFR Part 20. See also FDA's FOI web page at http://www.fda.gov/RegulatoryInformation/foi/default.htm

In general, inspection records and information collected from the manufacturer and submitted to FDA by APs will be available for disclosure by FDA after the agency has issued a compliance decision, unless such information is exempt from disclosure by law.

Information submitted by an AP to obtain approval for participation in the program will be available for disclosure by FDA except to the extent it constitutes trade secret, confidential commercial or personal privacy, or information that is otherwise exempt from public disclosure by law.

I. What Records Should an AP Maintain?

At a minimum, an AP should maintain records that support the initial and continuing qualifications to be an AP. These records include:

1. Documentation of the training and qualifications of the AP and the employees of the AP involved in performance of inspections and review of reports, as well as written instruction for duties and responsibilities of inspection personnel;
2. The procedures used by the AP for handling confidential information;
3. The compensation arrangements made by the AP;
4. The procedures used by the AP to identify and avoid conflicts of interest and resolve any conflicts or complaints;

5. The procedures used by the AP to make inspection assignments as well as the names of employees (regular, contract, and supervisory) who conducted the inspection and its review.

FDA may take appropriate measures to ensure that an AP continues to meet accreditation standards, 21 U.S.C. 374(g)(5)(A)(ii)). Accordingly, an AP must make these records available upon request to an officer or employee of FDA at all reasonable times, FDA may view, copy, or verify these records.

In addition, an AP should retain the following records for at least three years following its submission of an inspection report to FDA and the inspected device establishment:

1. Copies of the inspection records, information collected from the manufacturer, reviews and associated correspondence; and
2. Information on the identity, COI certification/compliance statement, and qualifications of all personnel who contributed to the inspection or to the review and approval of records submitted to FDA and to the manufacturer.

J. What Fees May an AP Assess?

Compensation for an AP must be determined by agreement between the AP and the device establishment to be inspected. (21 U.S.C. 374(g)(8)). FDA will consider the fee to present a conflict of interest if it is contingent or based on the observations in the report made by the AP.

K. Can FDA Withdraw AP Accreditation?

In accordance with section 704(g)(5) of the act, (21 U.S.C. 374(g)(5)), FDA may withdraw accreditation when an AP is substantially not in compliance with the standards of accreditation, poses a threat to the public health, or fails to act in a manner consistent with the act or where FDA determines that there is a financial conflict of interest between the AP and the owner or operator of a device establishment that the AP has inspected. Before FDA withdraws an AP's accreditation, the Agency will notify the AP and provide an opportunity for an informal hearing. FDA may, at its discretion, suspend the accreditation of the AP prior to the outcome of the accreditation withdrawal process.

L. Does the Law Describe Additional Prohibited Acts Applicable to APs?

Section 301(gg) of the act describes the following prohibited acts (21 U.S.C. 331(gg)):

- The knowing failure of an AP to immediately notify FDA of a condition noted during an AP inspection that could cause or contribute to an unreasonable risk to the public health;
- The knowing inclusion by an AP of false information in an inspection report; and
- The knowing failure of an AP to include material facts in such a report

M. How Do Manufacturers Identify an AP?

Manufacturers should access the CDRH Home Page at: http://www.fda.gov/MedicalDevices/ for a list of APs and the name and address of each AP's contact. The listed APs are not eligible to perform inspections under section 704 (g) of the act until FDA determines that all required training has been successfully completed. The list will reflect the status of APs. Manufacturers should see section III. B of this document for information about eligibility to participate in this program.

IV. What is the Format and Content of an AP's Initial Application?

Persons wishing to become APs under section 704(g)(2) of the act (21 U.S.C. 374(g)(2)) should apply to the TPRB. Detailed information about the application process is described below. FDA will inform those requesting accreditation, within 60 days of receipt of the application, whether their application is adequate for review.

A. How Will FDA Evaluate the AP Application?

1. FDA will e-mail the applicant's contact person to acknowledge receipt. Generally, this will be within 24 hours of receipt of the AP application.

2. Members of the TPRB will perform an initial review to determine whether the request for accreditation addresses the information in section IV. B of this document and is adequate for review by the full TPRB.

3. FDA will advise the contact individual via e-mail whether the request is adequate for review or whether additional information is needed. Generally, this will occur within 60 days after the receipt of such request for accreditation.

4. If the AP application is deficient, FDA will identify its shortcomings and advise the applicant accordingly so it may submit additional information within designated time period. FDA may deem the application incomplete and deny the request for accreditation if the applicant fails to respond to a request for additional information in a timely manner. All information submitted to FDA in response to any requests for additional information should be received by the date indicated in the FDA's request.

5. If the application is adequate, FDA will file it for full review, rating, and ranking. FDA uses a rating criteria checklist to assess the relevant qualifications and competence of persons applying to become APs. (See Appendix 3.)

6. FDA may deny the request for accreditation if we determine that the application does not meet the criteria established for APs.

7. FDA plans to update the list of Persons Accredited for Inspections published on its web site within 30 days of accrediting or withdrawing accreditation of an AP.

B. What Are the Contents of an AP Application?

Applicants should include the information described below to demonstrate that they meet the qualifications addressed in section III. C of this document entitled, "What Qualifications are Necessary to Become an AP?" In addition, the rating details for information submitted in the application are included in Appendix 3**. The AP may want to include the rating criteria checklist as a coversheet to the application with all applicable documented sections of the application cross-referenced next to the criteria under the right hand column of the checklist, "Where document is found in AP application". Using the checklist this way can help ensure timely and efficient review of the information you have submitted to establish your qualifications.**

1. Administrative Information

- Application in English;
- Name and address of the organization seeking accreditation;
- Telephone number and e-mail address of the contact person. The contact person should be the individual to whom questions about the content of the application may be addressed and to whom a letter of determination and general correspondence will be directed;
- Name and title of the most responsible individual at the AP. Foreign applicants may wish to identify an authorized representative located within the United States who will serve as the AP's contact with FDA;
- Name and title of the most responsible individual at the parent organization, if applicable;
    - Brief description of the applicant, including:
    - type of organization (e.g., not-for-profit institution, commercial business, other type of organization);
    - size of organization (number of employees);
    - organizational charts showing the relationship of the organization involved in the AP inspection program and its relationship with parent or affiliate companies;
    - number of years in operation;
    - nature of work (e.g., conformity assessment testing or certification laboratory);

- sufficient information regarding ownership, operation, and control of the organization to assess its degree of independence from manufacturers and distributors of products regulated under the act.

Please include your annual report or, if it is available electronically on the internet, please include the appropriate web site address. **If the applicant's organization has offices in numerous locations, please be specific and identify those locations that would participate in the AP inspection process for your firm.** Applicants may include all locations under one application if they will operate under the same processes and procedures for AP inspections. Include curriculum vitae (CVs) for all supervisory personnel and explain where supervisory oversight will be located;

- List of countries that have certified, accredited or recognized the applicant for quality system or GMP inspections/auditing and the date of such certification, accreditation, or recognition;

- Specification of any accreditation for assessment of quality systems that you may have, such as accreditation to ISO/IEC Guide 62. If you are accredited to standards other then Guide 62, please provide copies of the standards in English.

- Activities for which the AP seeks accreditation. This includes a list identifying the devices the applicant seeks to inspect. Applicants may simply state "all devices" or identify the devices they wish removed from their scope of work by classification panel or by classification name (e.g., Except Cardiovascular Devices under 21 CFR Part 870 or Except 21 CFR 870.3620; 870.3630; 870.3640; and 870.3670).

FDA will assess this section of the application according to information in section 1, "Administrative Information" of the rating criteria checklist (Appendix 3).

2. Prevention of Conflict of Interest

The AP and its employees (including contract employees) involved in the performance of inspections and the preparation and approval of reports must be free from conflicts of interest and the appearance of conflicts of interest that might affect the inspection process (21 U.S.C. 374(g)(2)) (69 FR 59252). No personnel of an AP involved in inspections, nor their spouses or minor children, may have ownership of or other financial interest in any product regulated under the act (21 U.S.C. 374(g)(2)) (69 FR 59252) In accordance with section 704(g)(3)(E), (21 U.S.C. 374(g)(3)(E)) APs will annually make available to the public the extent to which the AP complies with conflict of interest requirements.

The applicant should submit a copy of the written policies, procedures and sample certification/compliance statements established to prevent conflicts of interest.

FDA will assess this section of the application according to information in section 2, "Conflict Of Interest", in the rating criteria checklist (Appendix 3). An applicant's documentation of conformity with the Model Conflict of Interest Policy (see Appendix 2), or

similar procedures or standards, will carry significant weight in the rating process. See pages 8 - 9 of this document for a discussion of conflict of interest concerns.

3. Technical Competence

An AP must assure that competence and capacity are available for all work performed (21 U.S.C. 374(g)(3)(E)(ii)).

FDA will consider several factors with respect to personnel qualifications and the preparedness of the applicant to conduct technically competent inspections. The applicant should document these factors in its application and include:

- The written policies and procedures established to ensure that manufacturers are inspected by qualified personnel;

- The written instructions for the duties and responsibilities of personnel, including inspectors, with respect to the inspection of device manufacturing facilities;

- The written personnel qualification standards established to ensure that inspectors and other designated personnel are qualified in all of the regulatory and technical disciplines needed to effectively inspect for compliance with FDA's regulatory requirements for medical devices;

- The documentation (e.g., CVs) to establish that the inspectors and other involved non-supervisory personnel meet the established criteria for qualified personnel. This includes documentation of knowledge, education, training, skills, abilities and experience, including specialized education and experience needed for the inspection of manufacturers' facilities;

- The documentation (e.g., CVs) to establish that the supervisor(s) of inspectors have sufficient authority and meet the established criteria for qualified supervisory personnel. This includes documentation of knowledge, education, training, skills, abilities and experience, including any specialized education and experience needed to supervise the inspection and review records prepared by inspectors;

- A description of the applicant's management structure and that of any contractor used for inspection work. The application should describe the position of the individual(s) providing supervision within the management structure and explain how that structure provides for the supervision of the inspectors and other personnel involved in the inspection process. (If the applicant plans to utilize contractors, please address additional information required in section IV. B. 6. of this guidance and section 6 of the rating criteria, Appendix 3);

- A description of the inspection team. This includes documentation for any members of the team who may already have training and experience relevant to the assessment of compliance with FDA's regulatory requirements for medical devices (e.g., compliance

- Documentation that personnel involved in inspections have basic quality systems knowledge and are qualified in accordance with generally accepted quality assurance standards, (e.g., ISO 13485 or 21 CFR Part 820) and capable of functioning in accordance with the relevant parts of these standards;

- Documentation of training plan to assure continued technical competence;

- Documentation of records that demonstrate the appropriate experience and training of each inspector.

FDA will assess this section of the application according to information in section 3, "Technical Competence" of the rating criteria checklist (Appendix 3). Technical competence and the thoroughness with which the requirements are addressed will carry significant weight in the rating process.

4. Resources

The operations of an AP must be in accordance with generally accepted professional business practices. (21 U.S.C. 374(g)(3)(E)).

The applicant should identify what reference materials are available to inspectors and other personnel involved in inspections, (e.g., the act, regulations, manuals, standards). Also, the application should identify equipment and resources available that will enable the inspector to perform technical and administrative tasks. At a minimum, this should include a computer system with a modem and an independent facsimile machine. FDA will rely extensively on the use of our electronic systems for timely dissemination of guidance documents to APs and other interested parties.

APs should have physical security and safeguards in place for protecting trade secret and confidential commercial and financial information, as well as personal identifier information in medical records, such as adverse event reports, that would reveal the identity of individuals if disclosed.

FDA will assess this section of the application according to information in section 4, "Resources" in the rating criteria checklist (Appendix 3).

5. Confidentiality

An AP must treat information received as confidential or financial information or trade secret information. (21 U.S.C. (g)(3)(E)(iii)).

The applicant should include established procedures to ensure confidentiality of reports and all information obtained during an inspection. These should address aspects of authorized disclosure and the procedures by which the applicant maintains confidentiality between itself and the manufacturer. In addition, the applicant should describe the procedures through which the applicant's personnel and any contractors are made aware of confidentiality requirements.

FDA will assess this section of the application according to information in section 5, "Confidentiality" of the rating criteria checklist (Appendix 3).

6. Contractors

An AP must limit work to that for which competence and capacity are available, and must protect against the use of officers and employees who have a financial conflict of interest. (21 U.S.C. 374(g)(3)(E)(ii), (v).

FDA will consider several factors to determine whether the applicant ensures that contractors are properly qualified, utilized, and monitored. Special emphasis will be placed on personnel qualifications and preparedness to conduct technically competent inspections, and on conflict of interest controls. The applicant should document these factors in the application and include:

- The written policies and procedures established to ensure that contractors conform to the same requirements (e.g., education, training, and experience) that would apply to the applicant if it were performing the inspection or aspects of the inspection contracted. These policies and procedures should ensure that the contractor conducts inspections in accordance with the same procedures under which the applicant operates. The applicant should include assurances that it will maintain documentary evidence that the contractor has the necessary technical competence and resources to carry out contracted activities;

- Written policies and procedures documenting that the applicant will not contract the overall responsibility for reviewing the results of the inspections;

- Documentation of an agreement delineating the duties, responsibilities, and accountability of the contractor; and

- The written policies and procedures for establishing a register of qualified contractors.

FDA will assess this section of the application according to information in section 6, "Contractors" of the rating criteria checklist (Appendix 3).

7. Quality System of the AP

AP inspections must be in the form and manner designated by FDA, which takes into account the goals of international harmonization of quality systems standards. (21 U.S.C. 374(g)(7)(A).

FDA will consider the following factors to determine whether the applicant has adequately assured compliance with these FDA inspections, policies, and procedures:

- The applicant should establish a **documented** quality system to ensure that there are processes and procedures in place to demonstrate compliance with section 704(g) of the act;

- The policies and procedures the applicant follows are adequate to maintain control of all quality system documentation and to ensure that a current version is available at all locations; and

- The policies and procedures for internal auditing to ensure the quality system is implemented effectively and those resources are available for conducting these internal audits.

FDA will assess this section of the application according to information in section 7, "Quality System of the AP" of the rating criteria checklist (Appendix 3).

8. Certification Agreement Statement

The applicant should provide a copy of a documented statement, which will be signed by the most responsible individual, certifying that:

- The AP has appropriate policies and procedures to meet FDA's conflict of interest provisions, has the appropriate staff and procedures in place to ensure technical competence for conducting inspections under section 704(g) of the act, and has the quality system in place to ensure acceptable and consistent inspections;

- Where the AP uses the services of a contractor for Quality System (QS)/GMP inspections, the AP should also certify that its contractor(s) meets the AP's established criteria for freedom from conflicts of interest and technical competence;

- The AP consents to FDA inspection and copying of all records, correspondence, and other materials relating to any inspections conducted by the AP under this program, including records on personnel, education, training, skills, and experience and all documentation on prevention of conflicts of interest, including certification/compliance statements; and

- The AP will protect trade secret and confidential commercial or financial information, and will treat information about specific patient identifiers in records, such as adverse event reports, as private, except that such information may be made available to FDA.

This information is included in section 8, "Certification/Agreement Statement" of the rating criteria checklist (Appendix 3).

C. Where Do I Send an Application to Become an AP?

Please email your question/request to the MDSAP Team by email at mdsap@fda.hhs.gov

D. Can I Request Reconsideration of a TPRB Decision?

Please email your question/request to the MDSAP Team by email at mdsap@fda.hhs.gov

V. How Can I Obtain Additional Information?

Interested parties can obtain additional information on the Inspection by Accredited Persons Program through the FDA or CDRH Home Pages. To request a copy of these documents, FAX a request to the Division of Small Manufacturers, International, and Consumers Assistance, Attention: Publications, at 301-847-8149 or telephone 301-796-5859.

Also, persons interested in obtaining a copy of the documents listed below may do so using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a PC with access to the Internet. The FDA Home Page may be accessed at http://www.fda.gov and the CDRH Home Page may be accessed at http://www.fda.gov/MedicalDevices.

http://www.fda.gov/MedicalDevices. The appendices of this guidance also list currently available documents for third-party programs under MDUFMA.

Appendices 1 - 10 are available on the FDA and CDRH Home Pages:

1. Standards of Ethical Conduct for Employees of the Executive Branch; http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM136692.pdf

2. Model Conflict of Interest Policy; http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm109485.pdf

3. AP Inspection Program Rating Criteria Checklist; http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm148991.htm

4. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm

5. The Public Health Service Act (42 U.S.C. 201 et seq.); http://www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm

6. Title 21, Code of Federal Regulations, Parts 1-1271; http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

7. FDA Compliance Program 7382.845, Inspection of Medical Device Manufacturers; http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073174.htm

8. Investigations Operations Manual; http://www.fda.gov/ICECI/Inspections/IOM/default.htm

9. Guide to Inspection of Quality Systems (Quality System Inspection Technique); http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm

10. Guidelines for the Regulatory Auditing of Quality Systems for Medical Device Manufacturers – Global Harmonization Task Force (GHTF) SG-4 (99) http://www.ghtf.org/documents/sg4/99-28genreq.pdf