Guidance for Industry, FDA Staff, and Third Parties

Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties

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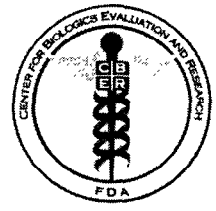

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Preface

Public Comment

Comments and suggestions regarding this document may be submitted at any time to the Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to "Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties." Comments may not be acted upon by the Agency until the document is next revised or updated.

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These documents are available on the FDA and CDRH Home Pages in text or PDF versions. The URL's 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. Rating Criteria Checklist (Checklist)
4. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 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

Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties

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 is intended to implement new section 704(g) of the Federal Food, Drug, and Cosmetic Act (FDCA or the act) by accrediting third parties (Accredited Persons) to conduct inspections of eligible manufacturers of Class II and Class III medical devices. Inspections by Accredited Persons will be conducted in essentially the same manner as those conducted by FDA. The Inspection by Accredited Persons Program will be conducted independent of third party inspections performed under the U.S./EC Mutual Recognition Agreement (MRA), http://www.fda.gov/cdrh/mra/introduction.html, currently in progress. However, some features of the two programs will be similar.

The Inspection by Accredited Persons Program will provide manufacturers an alternative to the traditional inspection by an FDA official. At the same time, it will allow FDA to utilize its inspectional resources in a more flexible manner.

This guidance provides information for those who are interested in the new program (Inspections by Accredited Persons), including:

- Persons who seek to be accredited to perform Quality System (QS) / Good Manufacturing Practice (GMP) inspections under the Federal Food, Drug and Cosmetic Act (the act);
- Medical device establishments subject to inspection under section 704 of the act; and
- FDA staff responsible for implementing the program.

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

- assess the quality system of eligible manufacturers of Class II and III devices under 21 CFR Part 820;
- determine compliance with other device requirements in the act and regulations; and
- prepare and submit reports to FDA, who makes the final compliance assessment.

Note: Although this guidance provides a general outline of the elements of the program that apply to establishments that may wish to use a third party inspector, **the focus of this document is on third parties who want to apply to become APs under this program.** FDA intends to issue additional guidance in the future that will provide establishments with more information about procedures for participating in this program.

This guidance represents the Agency's current thinking on the implementation of the Inspection by Accredited Persons Program under MDUFMA. MDUFMA requires FDA to "publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform" inspections of eligible manufacturers of Class II and Class III medical devices in lieu of FDA inspection. (Section 704(g)(2)). These criteria were published in the Federal Register on **[insert date notice will be published]** at **[insert FR cite]**. 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 are repeated in this guidance, as well as additional information that will assist with the implementation of this new program. Although guidances are generally non-binding and should be viewed only as the agency's recommendations, the portions of this document that repeat the criteria FDA will use to select APs (see Sections III.G-H, and IV.A-B below) have binding effect; therefore, the standard language that generally appears in FDA guidances stating that such documents constitute mere recommendations does not apply to these portions. However, with respect to the remainder of this document, the following standard language still applies:

> 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/cdrh/ombudsman/. 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/cber/inside/ombudsman.htm

II. Introduction

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

The FDCA established a requirement that FDA inspect manufacturers of Class II and III devices at least once every two years because Congress believed regular oversight would help ensure that appropriate manufacturing conditions and controls were in place to produce safe and effective products. (see Section 510(h) of the FDCA). The agency's ability to perform biennial inspections of all eligible establishments has diminished with decreasing resources and the significant growth of the medical device industry. 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 will be 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 requirements for medical devices were first authorized by the Medical Device Amendments of 1976 in section 520(f) of the act. As a result of this new authority to inspect medical device facilities, FDA published final regulations in July 1978, 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).

In developing the 1978 GMP regulation, FDA recognized that the medical device industry consists of manufacturers whose devices and manufacturing processes differ significantly. Therefore, the GMP regulation was designed to specify general requirements in areas of concern applicable to all manufacturers. Under the GMP regulation, FDA expects each manufacturer to develop a set of appropriate procedures for the manufacture of each device. FDA conducts inspections and evaluates these procedures to determine whether the manufacturer is complying with the regulation.

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. This section encourages FDA to work with foreign countries toward mutual recognition of the GMP and other regulations. This section also encourages 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, incorporating new requirements for preproduction design controls, supplier and service controls, and management controls. As part of this process, FDA attempted, to the extent possible, 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 Third Party Quality System Inspections?

U.S./EC Mutual Recognition Agreement

On June 20, 1997, the United States (U.S.) and the European Community (EC) signed a Mutual Recognition Agreement (MRA) which covers a variety of product sectors, including medical devices. The aim of this agreement is to facilitate transatlantic trade while reducing costs for compliance with regulatory requirements. This agreement became effective December 1, 1998 and initiated a three-year transition period during which time both sides have engaged in confidence-building activities. The confidence-building period has been extended to December 2003.

The medical device annex to the MRA covers the exchange of quality system evaluation/inspection reports for all medical devices and premarket notification (510(k)) reports for selected low-to-medium risk devices. An EU Conformity Assessment Body (CAB) can conduct inspections for all classes of devices and 510(k) evaluations based on FDA requirements for selected devices produced for the U.S. market. Similarly, a U.S. CAB can conduct a quality system evaluation based on EU requirements for all classes of devices or type-testing evaluation for selected devices produced for the EU market. See FDA's Guidance for Staff, Industry, and Third Parties for more information about the third-party programs established under the MRA.

Under the MRA, both the U.S. and the EU may eventually be able to save resources by relying on evaluations conducted by the other party, thereby saving overseas travel time and expense. CABs are required to participate in rigorous joint activities in order to demonstrate proficiency in conducting either FDA or EU evaluations. Based on such demonstrated proficiency, both parties expect to "normally endorse" evaluations conducted by the other party, while reserving the final decision making to themselves and reserving the right to conduct their own evaluations should significant deficiencies be found in any reports. As of this date, FDA has verified three European Union Conformity Assessment Bodies (EU CABs) to conduct independent inspections for FDA under the MRA.

D. How does the Medical Device User Fee and Modernization Act of 2002 Affect FDA Inspections?

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law by the President on October 26, 2002. Most provisions went into effect on that day, while other provisions have later effective dates and/or require implementing regulations.

Section 201 of MDUFMA establishes 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 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 requires that no more than 15 firms be accredited during the 12 months that follow the publication of this guidance. In addition, on or before October 26, 2003, FDA must make available on its web page a list of persons that have been accredited to conduct inspections of medical device establishments and the activities for which they are accredited. Therefore, in order to comply with this statutory timeframe, **FDA will not accept any applications for 2003 after August 25, 2003. Only applications for accreditation received by that date will be considered in the initial selection process**. MDUFMA requires FDA to inform those requesting accreditation, within 60 days of receipt, whether their application is adequate for review. (See section III.G. 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 accreditation, or a change in activities for which an AP was accredited.

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

A. What Are the Primary Features of the Program?

The primary purpose of an inspection by an AP is to evaluate the manufacturer's compliance with the Quality System regulation (21 CFR Part 820) and other FDA regulations and to submit the findings to FDA for final determination. In accordance with the requirements of section 704(g) of the act and based on FDA's experience with third parties under the MRA, the Inspection by APs Program includes features designed to maintain a high level of confidence in inspections by APs and to minimize risks to the public health. These include:

- Eligibility for inspection by APs is primarily limited to establishments whose most recent inspection was determined by FDA to be "No Action Indicated (NAI)" or "Voluntary Action Indicated (VAI)";
- Assessment, accreditation, and training of APs by FDA will occur before independent inspections by APs; APs **will not** be eligible to conduct independent inspections until they successfully complete FDA's training program and conduct a satisfactory performance inspection under FDA's observation;
- Qualifications for APs personnel will be to the level of FDA inspection personnel;
- Strict criteria exist to prevent conflicts of interest for APs;
- FDA retains responsibility for making the final compliance determination;
- 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 by APs Program; and
- FDA will monitor and evaluate APs' independence and compliance with section 704(g) of the act.

B. What Establishments are Eligible for Inspection by APs?

Not all device establishments are eligible for inspection by an AP. In order to be eligible to employ an AP in lieu of an inspection by FDA, establishments must meet the following basic criteria under section 704(g)(6)(A) of the act:

- The establishment's most recent inspection was classified by FDA as No Action Indicated (NAI) or Voluntary Action Indicated (VAI);
- The establishment submits a notice to FDA requesting clearance (approval) to use an AP and identifying the AP it intends to use, and FDA agrees to the use of the selected AP;
- The establishment markets a device in the United States *and* markets or intends to market a device in one or more foreign countries;
- The AP is certified, accredited, or otherwise recognized by one of the foreign countries in which the device is to be marketed;
- 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.

The intent of these provisions is to focus the use of third party inspections on manufacturers that operate in a global market and are likely to be subject to multiple inspection requirements.

C. How Do I Request An Inspection By An AP?

FDA will be issuing additional guidance with details about requesting a third party inspection. In general, however, the establishment will send a notice to the applicable Office of Compliance in CDRH or CBER requesting clearance (approval) to employ a specific third party to do a QSR inspection in lieu of a required FDA inspection. Under section 704(g)(6)(B)(i), FDA must respond within 30 days of receiving an establishment's notice requesting clearance to employ an AP to conduct an inspection. If FDA fails to respond to a notice within 30 days, the establishment is deemed to have clearance to use the AP it selected.

FDA's response to a notice may include:

- Approval to use the selected AP;
- Denial of clearance to use the selected AP; or
- A request for additional information concerning:
    - compliance data showing whether the establishment has consistently complied with QS/GMP requirements and promptly corrected any problems; this data must include complete reports of inspections or other quality control audits made during the preceding two years, as well as other compliance data FDA deems necessary. The establishment is responsible for providing this information to FDA; and/or
    - the relationship between the establishment and the AP, including information on previous inspections of the manufacturer or any related manufacturers. FDA may request this information from either the establishment or the AP.

When FDA requests additional information, the statute requires FDA to either provide or deny clearance to use the selected AP within 60 days of receiving the additional information. If FDA denies the request, the reasons for denial will be stated. If FDA does not respond, the selection is deemed to have been accepted.

D. What Can I Do If FDA Denies My Request To Use an AP?

If FDA denies an establishment's request for clearance (approval) to use an AP to do an inspection in lieu of an FDA inspection, the establishment may:

- Request a review of FDA's decision within 30 days of receiving FDA's decision. This review will be conducted by a person designated by FDA and will begin within 30 days of the request for review.

If FDA rejects an establishment's selection of an AP, the establishment may:

- Submit another notice, selecting a different AP. This notice is treated in the same manner as an original request;
- Request a review of FDA's decision within 30 days of receiving FDA's decision. This review will be conducted by a person designated by FDA and will begin within 30 days of the request for review.

If an establishment is inspected by an AP and receives an Official Action Indicated (OAI) determination from FDA following the inspection, the act provides at section 704(g)(6)(C) that the establishment becomes ineligible to use an AP again until:

- The establishment meets the basic (5) criteria under Section III B above for eligibility for inspection by AP;

- FDA issues a "written statement" upon request that the OAI violations have been resolved; and
- Upon petition of the establishment or on FDA's own initiative, FDA informs the establishment that it has clearance to use an AP for inspections. If the establishment submits a petition, FDA must by law respond within 30 days.

Participation in the program is entirely voluntary. Eligible manufacturers may utilize an AP or continue to have FDA perform inspections.

E. Are There Limits to the Number of AP Inspections that Can Be Performed?

MDUFMA sets limits on the number of AP inspections that can be performed. In general, an AP may not perform more than two consecutive inspections of a particular establishment unless the establishment petitions FDA for and receives a waiver. (Section 704(g)(6)(A)(iv)(I)). This provision of MDUFMA is intended to ensure periodic inspections by FDA. As depicted on the chart below, there are two paths for approval of a waiver petition allowing continued use of APs to conduct inspections: one requires explicit FDA approval, the other is deemed granted.

FDA may grant the petition if	*The petition is "deemed to be granted" if*
• The petition states a commercial reason for the waiver; • FDA determines the public health would be served by a waiver; and • FDA inspected the establishment within the past four years.	• The petition states a commercial reason for the waiver; • FDA has not determined that the public health would be served by granting the waiver;[1] • Within 18 months of the last inspection, the establishment requested an FDA inspection; and • FDA did not inspect the establishment within 30 months of the last inspection.

F. How Can I Become an AP?

FDA will use 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. The FDA also utilized the TPRB to verify the qualifications of EU CABs under the U.S./EC MRA. EU CABs perform a scope of work similar to the APs for inspection.

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

[1] Although MDUFMA currently includes this language as written, there is a technical amendment to MDUFMA pending which, if passed, will clarify the language of this factor by deleting the word "not."

section IV. B of this document. FDA may accredit up to 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 consider applications from both domestic and foreign persons. To facilitate timely review, applications and communications should be in English.

- MDUFMA requires FDA to post on its Internet site by October 26, 2003 a list of persons that have been accredited by the agency. To meet this statutory timeframe, FDA **will cease accepting applications for 2003 on August 25, 2003.**
- If FDA requests clarification or additional information, such information should be received no later than September 25, 2003. Please note that applicants filing very close to the application acceptance deadline will have limited time to provide additional information in response to any TPRB concerns.

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, and any limitations in the APs' scope of work.

G. 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 supervision.

Minimum Requirements

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

1. You may 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/ohrms/dockets/yellow/yellotoc.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. 321 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;
- has available to its personnel clear, written instructions for duties and responsibilities with respect to inspections;
- has 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
- has 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, including the FDA Internet websites, and the CDRH Facts-On-Demand system. 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 must have 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)). 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, the most 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/ohrms/dockets/yellow/yellotoc.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 in which they had **performed contract work** (e.g., conformity assessment body audit, laboratory testing, or AP inspection) within the last 12 months;

g. 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;

h. the fees charged or accepted are contingent or based upon the recommendation 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 APs 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 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.

H. 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. The FDA will train no more than three employees per AP at the training to be held by the agency in January 2004. FDA strongly encourages each AP to send at least two employees to the training, in recognition of the potential for employee attrition. APs with multiple sites engaged in FDA inspectional activities should request permission from FDA to send one representative from each site, not to exceed a total of 5 representatives from each AP. This training is 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 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 for specific dates and locations. Please note that you must register separately for the training session and the examination. AAMI's training schedule for 2004 will not be posted until late 2003.

      A copy of each trainee's certificate of successful completion of the AAMI training should be submitted to FDA prior to attending the portion of the training conducted by FDA.

   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

      FDA plans to conduct training sessions on January 12 – 16, 2004 in the Washington, DC Metropolitan area. The approved AP will not have to pay for the training, although they will be expected to pay any travel costs incurred by their trainees.

FDA will make a final decision on rating and ranking 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 by October, 2003 will be eligible to attend the training. Applicants should identify under section IV. D. "Technical Competence" in this guidance, the names of the employee(s) that have either successfully completed this training or those that will be nominated to participate in this training.

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 accord 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**-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 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 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.

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-conformities 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 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.

Training for APs will be "modeled" after the training program FDA put in place for EU CABs under the MRA Implementation Plan. (see

http://www.fda.gov/cdrh/mra/guidance/mraprocedure.html for additional information about that program)

EU CABs that have been accredited as APs, whose personnel have previously successfully completed the required classroom 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 inspections. However, FDA does recommend that the AP send a representative to the FDA Investigator Training (See III.H.1.c above) as an update. Personnel trained by FDA under the MRA program who do not attend the current training will review a videotaped FDA presentation on evidence development.

FDA will provide APs with information on its 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/cdrh/, 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.

I. How Will APs Be Monitored?

The CDRH Office of Compliance (OC) will monitor APs for inspections relating to devices regulated by CDRH and the CBER Office of Compliance and Biologics Quality (OCBQ) will do so for inspections relating to devices regulated by CBER. Those two offices together with the ORA Office of Regional Operations (ORO) will perform an evaluation based on the first three independent inspections by the AP. 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.

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 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.**

J. 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 actions it has taken to ensure that it has followed the prevention of conflict of interest requirements of the AP program at the end of each year.

Because the statute requires FDA to monitor each request from a particular 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 particular companies.

If FDA 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 the appearance of an undue financial influence.

K. What Inspection Records Are to Be Submitted to FDA?

APs will need to prepare an FDA prescribed 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/ora/inspect_ref/iom/exhibits/x510b.html. FDA will provide instruction in the preparation of a list of observations and the report at the FDA training course. See Regulatory Procedures Manual: http://www.fda.gov/ora/compliance_ref/rpm_new2/ for timeframes for submitting reports.

At the conclusion of the inspection, when deficiencies have been observed, the AP Inspector lists all significant objectionable conditions observed and presents 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 no later than three weeks following the last day of the inspection. As required by section 704(g)(7)(B), the 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 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 of the AP's recommendation.

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, we will begin our review only after we receive the necessary information. The need for translations will also impede FDA endorsement.

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. This will be a topic of discussion at the FDA training.

L. How will APs and FDA Treat Confidential Information?

The AP must protect trade secret and confidential commercial or financial information, and must treat as private personal identifier information in records such as adverse event reports, except that such information may be made available to FDA. FDA recommends that any contract between an AP and an establishment include a provision that specifies protection of trade secret and confidential commercial or financial 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 or confidential commercial or financial 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/foi/foia2.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.

Note also that 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 financial information, or information that is otherwise exempt from public disclosure by law.

M. 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.

In accordance with section 704(g)(5) of the act, an AP must make these records available upon request to an officer or employee of FDA at all reasonable times and FDA may view, copy, or verify these records.

In addition, an AP should retain the following records for at least three years following submission of a review to FDA:

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.

N. What Fees May an AP Assess?

An AP may assess a reasonable fee for services. The fee for an inspection is a matter to be determined by contract between an AP and the device establishment to be inspected. FDA will consider the fee to present a conflict of interest if it is contingent or based on the type of recommendation made by the AP.

O. Can FDA Withdraw AP Accreditation?

In accordance with section 704(g)(5) of the act, 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. Before FDA withdraws AP accreditation, we will notify the AP and provide an opportunity for an informal hearing. FDA may at its discretion suspend the accreditation of the AP during the pendency of this process.

P. Did MDUFMA Change the Prohibited Acts Section of the act?

Section 301 of the act was amended by adding the following prohibited acts:

- 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.

Q. How Do Manufacturers Identify an AP?

Manufacturers should access the CDRH Home Page at: http://www.fda.gov/cdrh 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 training has been successfully completed. The list will reflect the status of APs. Manufacturers should see section III B of this guidance 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 should apply to the TPRB. Detailed information about the application process is set forth below. FDA will inform those requesting accreditation, within 60 days of receipt of the application, whether their application is adequate for review. MDUFMA limits to 15 the number of applicants that can be accredited during the first year of the program.

A. How Will FDA Evaluate the AP Application?

1. The TPRB Chairman will e-mail the applicant's contact person, within 24 hours of receipt of the AP application, acknowledging receipt.

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

3. 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 if additional information is needed.

4. If the application is deficient, FDA will identify its shortcomings and advise the applicant so it may submit additional information within the 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 no later than September 25, 2003.

5. If the application is adequate, FDA will file it for full review, rating and ranking by the TPRB. The rating criteria checklist (see Appendix 3) will be used to assess the relevant qualifications and competence of persons applying to become APs. The agency has assigned a weight (5, 15 or 20) to each of eight elements. The eight elements are addressed in the next section, IV. B., What are the Contents of an AP Application. The weight of the element is based on how essential the information is in determining if the applicant is suitable to perform Quality System / Good Manufacturing Practices (QS/GMP) inspections on behalf of FDA. Each member of the TPRB will assess each of the eight elements and will vote a "quality level" score from 0 to 4 (0 = Unsatisfactory, 2 = Satisfactory, 4 = Exceeds) for each element. The final Quality Level Score will be determined by a majority vote of the TPRB. Quality Level Score x Weight = Element Score. The eight element scores will be totaled to

yield an "Application Rating" (maximum rating attainable is 400). The TPRB will then rank the applications (highest application rating first).

6. If more than 15 applicants seeking accreditation satisfy the minimum requirements, FDA will accredit the 15 applicants that have the highest scores. If fewer than 15 persons are initially accredited, additional applications will be considered during the 12 months that follow the publication of this guidance. Persons seeking accreditation that are not among the 15 highest ranking applications can reapply 12 months after the publication of this guidance and persons who did not previously apply may also apply 12 months after publication of this guidance.

7. FDA may deny the request for accreditation if we determine that the application does not meet the criteria established for APs or scores lower than the 15 highest rated applications received by August 25, 2003 (see Appendix 3).

8. FDA will stop accepting applications on August 25, 2003. FDA plans to publish on its web site the List of Persons Accredited for Inspections on or before October 26, 2003.

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, G, 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); and 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 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;

- Specify 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 applicant should submit a copy of the written policies, procedures and sample certification/compliance statements established to prevent conflicts of interest. MDUFMA requires that the AP and its employees (including contract employees) involved in the performance of inspections and the preparation and approval of reports be free from conflicts of interest and the appearance of conflicts of interest that might affect the inspection process. 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. In accordance with section 704(g)(3)(E), APs will annually make available to the public the extent to which the AP complies with conflict of interest requirements.

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 15-17 of this guidance for a discussion of conflict of interest concerns.

3. Technical Competence

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

programs, the QS regulation, and general auditing principles). The description should include documentation of the ability of the team to recognize, collect and identify evidence of non-compliance and adequately communicate with the manufacturer regarding the inspection;

- Documentation that personnel involved in inspections have broad quality systems knowledge and are qualified in accordance with generally accepted quality assurance standards, (e.g., ISO 10011-2 or 21 CFR 820) and capable of functioning in accordance with the relevant parts of these standards;

- Documentation of training plan to assure 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 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

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

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. AP Quality System

FDA will consider the following factors to determine whether the applicant has established an adequate quality system to ensure compliance with FDA policies and procedures relevant to inspections:

- 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 that resources are available for conducting such 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 APs 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?

Send applications to become an AP to the following address by a method such as registered mail that returns to you proof of delivery. Submit 10 complete copies, with all attachments, to the address below and keep a complete copy for your files.

Anthony Rodgers, Chairman
Third Party Recognition Board (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850 USA

D. Can I Request Reconsideration Of A TPRB Decision?

A written request for **reconsideration of a decision** by the TPRB should be addressed to:

John Stigi
Director, Division of Small Manufacturers, International and Consumer Assistance
Center for Devices and Radiological Health (HFZ-220)
Food and Drug Administration
1350 Piccard Drive
Rockville, Maryland 20850
e-mail: jfs@cdrh.fda.gov

V. How Can I Obtain Additional Information?

Interested parties can obtain additional information on the Inspections by APs Program under the MDUFMA through the FDA or CDRH Home Pages and/or on 3.5" IBM formatted disks. To request a copy of these documents on disk, FAX a request to the Division of Small Manufacturers, International, and Consumers Assistance, Attention: Publications, at 301-443-8818 or telephone 301-443-6597 ext. 114.

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/cdrh. 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/cdrh/modact/soc917.pdf

2. Model Conflict of Interest Policy; http://www.fda.gov/cdrh/mdufma/mcipolicy.html

3. AP Inspection Program Rating Criteria Checklist; http://www.fda.gov/cdrh/mdufma/aprating.html

4. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.); http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm

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

6. Title 21, Code of Federal Regulations, Parts 1-1271; http://www.fda.gov/cdrh/devadvice/365.html

7. FDA Compliance Program 7382.845, Inspection of Medical Device Manufacturers; http://www.fda.gov/cdrh/comp/7382_845.pdf

8. Investigations Operations Manual; http://www.fda.gov/ora/inspect_ref/iom/

9. Guide to Inspection of Quality Systems (Quality System Inspection Technique); http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.HTM

10. Guidelines for the Regulatory Auditing of Quality Systems for Medical Device Manufacturers – Global Harmonization Task Force (GHTF) SG-4 (99) 28 http://www.ghtf.org/sg4/inventorysg4/99-28genreq.pdf