

articles regulated under the act and have no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor;

3. Shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation;

4. Shall not engage in the design, manufacture, promotion, or sale of articles regulated under the act;

5. Shall operate in accordance with generally accepted professional and ethical business practices and agree in writing that, at a minimum, it will:

(a) Certify that the reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with the act, and recommendations made during an inspection or at an inspection's closing meeting;

(b) Limit work to that for which competence and capacity are available;

(c) 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;

(d) Respond promptly and attempt to resolve complaints regarding its activities for which it is accredited;

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 the officers and employees of the person, have maintained compliance with requirements relating to financial conflicts of interest.

#### B. Additional Criteria

In addition to the minimum requirements specified at section 704(g)(3) of the act for becoming an AP, this notice also establishes the following additional criteria:

##### 1. Personnel Qualifications

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

(a) Whether personnel have demonstrated 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 part 11 and parts 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 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 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 Web sites, 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 also 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)

An AP must be impartial and free from any commercial, financial, and other pressures that might present a COI or an appearance of a COI. 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 COI, including conflicts that their contractors or individual contract employees may have.

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

a. The AP is owned, operated, or controlled by a manufacturer, supplier or vendor of any article regulated under the act. Please 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, compact disk 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 (see section II.B.3.a of this document);

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 section II.B.3.a of this document);

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 section II.B.3.a of this document);

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 AP's responsibility to assure that the contractor meets the same criteria for freedom from COI as the AP and its personnel.

In addition to conducting inspections as an AP, an AP may also conduct other activities, such as objective laboratory testing of products regulated under the act or assessment of conformance to