

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 the additional information described at section II.B.6.f of the document, Contractors);

- 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 noncompliance 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 part 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.

#### (d) 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.

#### (e) 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.

#### (f) 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.

#### (g) 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.

#### (h) 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 as private information about specific patient identifiers in records such as adverse event reports, except that such information may be made available to FDA.

### III. The Guidance

We are also issuing a guidance entitled "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,"