Guidance for Staff, Industry and Third Parties

Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Small Manufacturers Assistance
Office of Health and Industry Programs

Preface

Public Comment:

Comments and suggestions may be submitted at any time for Agency consideration to John Stigi, Director, Division of Small Manufacturers Assistance, Food and Drug Administration, 1350 Piccard Drive (HFZ-220), Room 130C, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact John Stigi at 301-443-6597 (telephone) or 301-443-8818 (FAX).

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Additional Copies: World Wide Web/CDRH home page: http://www.fda.gov/cdrh/modact/eurma.pdf. In addition, copies can be obtained on 3.5" IBM formatted disks. To request a copy on disk, FAX a request to DSMA, Attention: Publications at 301-443-8818.

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Guidance for Staff, Industry and Third Parties Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)

I. Purpose

The purpose of this document[1] is to provide guidance for the Center for Devices and Radiological Health (CDRH), the European Community and third parties in implementing the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA).

II. Introduction

On June 20, 1997, the United States of America (U.S.) and the European Community (EC) completed negotiation of the MRA. It covered, in its sectoral annexes, a variety of products including telecommunication equipment, recreational craft, pharmaceuticals, and medical devices. The MRA specifies the conditions by which each party will accept or recognize results of conformity assessments performed by the other party's conformity assessment bodies or authorities. Each party will be assessing products for conformity to the importing party's requirements.

The MRA was signed in London on May 18, 1998, and will enter into force as to FDA regulated products (pharmaceutical and medical devices) on December 7, 1998. FDA published a final rule on the provisions of the MRA that affect FDA regulated products, in 63 FR 60122 (November 6, 1998). FDA is publishing this guidance to communicate FDA's current thinking on implementation of the MRA program, and the procedures involved, and to give adequate prior notice to third parties who might desire to participate in the MRA program.

[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

The Medical Devices Annex specifies the conditions under which each party will accept the results of medical device quality system-related evaluations and inspections and premarket evaluations as conducted by listed conformity assessment bodies (CABs) and to provide for other cooperative activities. It extends to the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices.

The Medical Devices Annex sets out a three stage process leading up to normal endorsement of each party's conformity assessment results. First, each party will designate conformity assessment bodies (CABs) to perform the specified evaluations within that party's territory. Second, after confirming the eligibility of the designated CABs, the parties will place the names of the CABs on Appendix 4 to the Medical Devices Annex ("listing" of the CABs) and each party will proceed to assess the performance of the other party's listed CABs during a three-year confidence-building period. Finally, the parties will jointly assess which bodies have demonstrated proficiency to be found equivalent or acceptable and then proceed to the operational period of the MRA during which time the parties expect to normally endorse the reports of those CABs.

In this document, FDA is explaining its understanding of the process necessary to implement the MRA and is announcing the procedures that are being followed to designate third parties to participate in the confidence-building period as CABs. Third parties will be recommended to the European Commission by FDA as U.S. CABs for the purpose of performing evaluations to the Medical Devices Directives. Their evaluation would include activities such as: EC quality system evaluations (ISO 9001 and ISO 13485) and product type-examination and verification evaluations, for U.S. medical devices produced for export to the EC[2]. U.S. CABs will be recommended through the U.S. Department of Commerce, National Institute of Standards and Technology (NIST) pursuant to its National Voluntary Conformity Assessment System Evaluation (NVCASE) program. FDA will make the final decision on the qualifications of the bodies to be designated as well as their subsequent status as listed or equivalent. EC Regulatory Authorities (the European Commission in cooperation with EC Member States) will separately announce the process for designation of EC CABs to perform premarket evaluation under section 510(k) and quality system evaluations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the Act) for EC medical devices produced for export to the United States.

III. Outline of the Anticipated U.S./EC MRA Third Party Program

A. Purpose and Nature of Program

[2] The European Community consists of the following member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

The Medical Devices Annex covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. An EC CAB, therefore, could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices for compliance with FDA requirements. Similarly, a U.S. CAB could conduct quality system evaluations for all classes of devices and product type-examination and verification for selected devices for compliance with EC requirements. In addition, an alert system would be set up during the transition period and maintained thereafter enabling FDA and EC to notify each other when there is an immediate danger to public health. As part of that system, FDA and EC will also notify each other of any confirmed problem reports, corrective actions, or recalls.

The purpose of the U.S./EC MRA Third Party Program is to implement that part of the Medical Devices Annex dealing with conformity assessment by U.S. and EC CABs for medical device premarket evaluations and quality system evaluations. The MRA may 1) be an important means of facilitating movement between the U.S. and EC of medical devices important to human health; 2) enhance public health by allowing better use of scarce FDA resources; 3) enhance harmonization of U.S. and EC regulatory systems; and 4) permit FDA to better leverage its regulatory resources to focus on manufacturers located in other countries.

Under the MRA, both the U.S. and the EC may eventually be able to save resources by utilizing evaluations of manufacturers conducted by the other party, thereby saving resources, including overseas travel time and expense. However, CABs will be required to participate in rigorous joint activities in order to demonstrate their proficiency in conducting FDA and EC evaluations. Based on demonstrated proficiency of CABs, both FDA and EC are expected 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.

The following points explain highlights of the program that is to be implemented under the MRA:

- Participation in the program will be voluntary. Manufacturers may continue to apply directly to FDA for U.S. market access and to the EC Notified Bodies for market access in the EC. Although participation in the program is voluntary, when CABs or manufacturers elect to participate in the MRA activities, they will, of course, need to abide by the MRA and applicable requirements (U.S. or EC), including, FDA's final rule on the MRA in 63 FR 60122 (November 6, 1998).

- FDA and EC will exchange lists of designated CABs to be considered by each party. Following confirmation of the qualifications of these designated CABs, FDA will hold training for the designated EC CABs. After training, FDA will be prepared to receive reports from designated EC CABs during the confidence-building period.

- The purpose of the EC CAB assessment report will be to evaluate a manufacturer's premarket notification [(510(k))] for an eligible device, document the review, and provide to FDA assessment reports with respect to the initial classification of that device. EC CABs may also perform quality system evaluations and submit reports to

FDA regarding compliance with the Agency's Quality Systems Regulation, Medical Device Reporting (MDR) Regulation, Corrections and Removal Regulation, and Tracking Regulation as it applies to all medical devices. However, FDA's evaluation of 510(k) review and performance of quality system evaluations by EC CABs under the MRA will be limited to EC Member State manufacturers for devices intended for export to the U.S.

- Similarly, U.S. CABs may perform product type-examinations and verifications for certain medical devices and submit evaluation reports to EC Notified Bodies of the manufacturer's choice. In addition, U.S. CABs may perform quality system evaluations and submit reports to EC Notified Bodies for determination of compliance with the Medical Device Directives as they apply to all medical devices. EC evaluation of product type-examination and verification and quality system evaluations by U.S. CABs under the MRA will be limited to U.S. manufacturers for devices intended for export to the EC.

- U.S. and EC CABs will need to be knowledgeable of documents named in Appendix 1 of the Medical Devices Annex. In addition, U.S. CABs can consult ISO 9001, Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation, and Servicing; and ISO 13485, Quality Systems - Medical Devices - Particular Requirements for the Application of ISO 9001, for quality system evaluations. EC CABs can consult the FDA guidance documents listed in Section IV of this guidance for information about 510(k) evaluations and quality system evaluations.

- FDA expects the material to be submitted by a designated EC CAB, the processing of these materials by FDA, and records maintained upon completion of a 510(k) review to be the same under this U.S./EC MRA program and the Accredited Persons program being implemented under the FDA Modernization Act of 1997. The Accredited Person program is addressed in the guidance document, "Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997" (see Section IV).

- Materials to be included in reports to be submitted by EC CABs regarding quality system evaluations will include identification of records reviewed and observations. The specific materials to be submitted by a designated EC CAB, the processing of these materials by FDA, and records to be maintained upon completion of a quality system evaluation will be addressed in the guidance document, "EC Audit Reports for FDA" (under development). During the three-year confidence building period, EC CABs are to submit full reports of quality system evaluations. The CDRH Office of Compliance will receive and process quality system evaluation reports from EC CABs in a manner similar to the process used for foreign inspection reports received from FDA inspectors.

- FDA intends to utilize the NVCASE program as administered by NIST to recognize accreditation bodies that will assess potential U.S. CABs for the purpose of performing EC quality system evaluations and product type-examinations and verifications for U.S.

medical devices produced for export to the EC. In the event that no accreditation bodies are recognized, FDA will request NIST to perform the assessment of potential CABs.

- Designated EC and U.S. CABs will be expected to ensure that fees imposed for services shall be commensurate with the services provided.

Each party will be expected to maintain, to the extent required under its laws, the confidentiality of information exchanged under this arrangement. In particular, under the terms of the MRA, neither party shall disclose to the public, or permit a CAB to disclose to the public, information exchanged under this arrangement that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation. The parties and CABs may, upon exchanging information, designate the portions of the information that it considers to be exempt from disclosure. Under the MRA, FDA and EC shall take all precautions reasonably necessary to protect information exchanged under this arrangement from unauthorized disclosure.

B. National Voluntary Conformity Assessment Evaluation (NVCASE)

Under the NVCASE program, the National Institute of Standards and Technology (NIST) of the Department of Commerce will evaluate U.S. based accreditation bodies that are to provide assurances to a foreign government that qualifying CABs meet that government's requirements and can provide results that are acceptable to that government. NIST will accept requests under the NVCASE program only when (1) directed by U.S. law, (2) requested by another U.S. government agency, or (3) requested to respond to a specific U.S. industrial or technical need relative to a mandatory foreign technical requirement, if it has been determined after public consultation that there is no suitable alternative available and there is evidence that significant public disadvantage would result from the absence of any alternative. It should be noted that NIST has stated it will not operate in product areas covered by other government agencies unless such assistance is requested by the Agency.

The driving force behind the creation of NVCASE was the impending negotiations between the U.S. and EC, which officially began in 1994 culminating in the U.S./EC MRA discussed in this document. Prior to these negotiations, the EC indicated that it would enter into such agreements only if the U.S. could offer government assurances that designated conformity assessment programs satisfied criteria for conformity assessment activities mandated by the EC under an MRA. NIST then proposed a program to satisfy the EC's request by publishing a notice in the FEDERAL REGISTER on July 23, 1993 [58 FR 39486]. The final rule establishing this program was published in the FEDERAL REGISTER on April 22, 1994 [59 FR 19129].

This NVCASE program will be operated on a cost reimbursable basis and will be open for voluntary participation by any U.S. based accreditation body falling within the program's scope. All evaluation activities rely on the use of generic requirements based on standards and other guidelines. NIST will rely on substantial advice and technical assistance from all parties interested in developing program requirements. In preparing program documentation, NIST will seek public input.

Each U.S. applicant interested in being evaluated as an accreditation body under this program should submit an application to NIST along with a fee. The application should include relevant information based on generic requirements and specified criteria. After review of an application, NIST will conduct an on-site assessment and may request supplementary materials. NIST will conduct a final review and recognize each accreditation body that, in turn, will assess potential U.S. CABs seeking to be designated under the MRA, to assess medical devices produced for the EC market. NIST will maintain a list of all recognized accreditation bodies (see Section IV).

C. Devices to be Eligible for CAB Evaluation

Under the MRA, quality system evaluation reports will be exchanged for all devices and premarket evaluation reports will be exchanged for all U.S. Class I devices and Class II Tier 2 devices not exempt from premarket notification and listed in Appendix 2, Table 1 of the Medical Devices Annex. However, the U.S. has modified the list of eligible devices to be the same as the devices eligible for Accredited Person review under the FDA Modernization Act of 1997 to the extent that these products are regulated as medical devices by the EC.

D. Qualifications of CABs

EC CABs

Designation and listing of EC CABs for the purpose of conducting quality system evaluations and premarket 510(k) evaluations will be conducted in accord with Article 6 of the Medical Devices Annex. Appendix 1 of the Medical Devices Annex sets forth requirements for EC CABs, including knowledge of:

1. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 et seq.;
2. The Public Health Service Act, 42, U.S.C. §§ 201 et seq.;
3. Regulations of the United States Food and Drug Administration found at 21 CFR, in particular, parts 800 to 1299; and
4. Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program, 61, FEDERAL REGISTER 14,789-14,796 (April 3,1996).

These documents are available on the FDA and CDRH Home Pages (see Section IV).

Prospective EC CABs should contact EC Regulatory Authorities, not FDA, for further information. Following designation and listing, the EC CABs can expect to be monitored through surveillance audits at intervals determined by the FDA.

In addition to the minimum requirements for EC CABs set forth in the MRA, FDA expects that:

To be considered as a designated EC CAB, an applicant should demonstrate that it has the appropriate qualifications and facilities to conduct competent 510(k) evaluations and/or quality system evaluations and have instituted effective controls to prevent any conflict of interest or appearance of conflict of interest that might affect the review process.

For purposes of performing quality system evaluations, EC CABs should meet the criteria established in, "Information to be Considered to be Designated as a European Conformity Assessment Body for Purposes of Conducting Surveillance/Postmarket and Initial/Preapproval Quality System (GMP) Audits" (under development), and should have knowledge of:

1. FDA Investigations Operations Manual, Chapter 5 - Establishment Inspections for Procedures for Conducting Inspections/Audits;

2. Compliance Program 7382.830 - Inspection of Medical Device Manufacturers (May 4, 1995) [Please note that this compliance program is being revised to incorporate guidance for enforcement of new FDA regulations for medical devices and their manufacturers. The revised compliance program will be made available for public comment.]; and

3. Compliance Program 7382.830A - Sterilization of Medical Devices (October 1, 1989) [Please note that this compliance program is being revised to incorporate new guidance. The revised compliance program will be made available for public comment.]

For purposes of performing competent 510(k) evaluations, EC CABs should have knowledge of:

1) "Premarket Notification 510(k) - Regulatory Requirements for Medical Devices" (August 1995);
2) "In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions" (January 1997);
3) "Guidance on the Recognition and Use of Consensus Standard (February 1998); and
4) "Determination of Intended Use for 510(k) Devices - Guidance for Industry and CDRH Staff" (January 1998).

These documents are available on the FDA Home Page (see Section IV).

In addition, FDA expects EC CABs to have the following qualifications:

1. <u>Personnel Qualifications</u>

CABs should have sufficient personnel, with the necessary education, training, skills, and experience, to evaluate 510(k)s in those categories of devices it accepts for evaluation and/or to perform quality systems evaluations. Several factors with respect to personnel qualifications will be considered. These include whether the CAB:

a) has established, documented, and executed policies and procedures to ensure that 510(k) evaluations and/or quality system evaluations are performed by qualified

personnel, and will maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the technical review of 510(k) or quality system evaluations;

b) has clear, written instructions for duties and responsibilities with respect to 510(k) evaluations and/or quality system evaluations available to its personnel;
c) has employed personnel who, as a whole, are qualified in all of the scientific and quality system disciplines addressed by the 510(k)s that the CAB accepts for evaluation and for the quality systems it contracts to evaluate;
d) has identified at least one individual who is responsible for providing supervision over 510(k) evaluations and quality system evaluations and who has sufficient authority and competence to assess the quality and acceptability of these evaluations; and
e) is prepared to conduct technically competent 510(k) or quality system evaluations at the time of requesting designation.

Information on the general education and experience FDA requires of its scientific review personnel is included in Appendix A to this document, "Qualification Standards for FDA Reviewers". CABs may adopt these criteria as one means of ensuring that its personnel having primary responsibility for review of a 510(k) for a Class I device have appropriate education and experience. A CAB may develop and apply alternative criteria that result in personnel having education and experience necessary and appropriate to evaluate 510(k)s and perform quality system evaluations.

For appropriate review of a particular Class II device, FDA expects specialized education or experience consistent with assuring a technically competent review.

2. Facilities

CABs should have the capability to interface with FDA electronic data systems. At a minimum, this would include a computer system with a modem and an independent facsimile machine.

3. Prevention of Conflicts of Interest

FDA will expect CABs to be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of conflict of interest. FDA believes the CAB should have established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest. Although it is not feasible to identify all of the circumstances that would raise concerns about conflicts of interest, the most common conditions that would indicate a potential conflict of interest are:

a) the CAB is owned, operated, or controlled by a device manufacturer or distributor;
b) the CAB or any of its personnel involved in 510(k) evaluations or quality system evaluations has an ownership or other financial interest in any medical device, device manufacturer, or distributor;

c) the CAB or any of its personnel involved in 510(k) evaluations or quality system evaluations participates in the design, manufacture, or distribution of any medical device;
d) the CAB or any of its personnel involved in 510(k) evaluations or quality system evaluations provides consultative services to any device manufacturer or distributor regarding any specific devices;
e) the CAB or any of its personnel involved in 510(k) evaluations or quality system evaluations participates in the preparation of any 510(k) and/or quality system consultation;
f) the fee charged or accepted by the CAB is contingent or based upon the type of recommendation made; or
g) the CAB uses in the evaluation of a 510(k) or in the quality system evaluation, personnel who were employed within the last twelve months by the firm who submitted the 510k for evaluation or requested a quality system evaluation.

A CAB may assess a fee for its services and conduct other activities, such as objective testing of devices, if the services and activities do not affect the impartiality of 510(k) evaluations or quality system evaluations.

Where a CAB uses the services of a contractor, the CAB is responsible for the contracted work. The CAB is to assure that the contractor meets the CABs established criteria for freedom from conflicts of interest.

Information on the conflict of interest standards FDA applies to its personnel is included in Appendix B to this document, "Standards of Ethical Conduct for Employees of the Executive Branch". A CAB may adopt these standards as one means of safeguarding its operations against conflicts of interest.

4. Training

CABs should assure that they will have designated individuals attend FDA and/relevant EC training for CABs.

U.S. CABs

Designation and listing of U.S. CABs for purposes of conducting premarket and quality system evaluations will be conducted in accord with Article 6 of the Medical Devices Annex. Appendix 1, paragraph 1 of the Medical Devices Annex sets forth requirements for U.S. CABs, including knowledge of:

1. Council Directive 90385/EEC of 20 June 1990 on active implantable medical devices - OJ No. L 189, 20.7.1990,p.17. Conformity assessment procedures.

   * Annex 2 (with the exception of section 4)
   * Annex 4
   * Annex 5

2. Council Directive 9342/EEC of 14 June 1993 on Medical Devices - OJ No. L 169, 12.7.1993, p.l. Conformity assessment procedures.

    * Annex 2 (with the exception of section 4)
    * Annex 3
    * Annex 4
    * Annex 5
    * Annex 6

Assessment of prospective U.S. CABs will be conducted under the NVCASE program. FDA has requested that NIST's NVCASE program be used to recognize accreditation bodies to assess potential U.S. CABs for the MRA. NIST will employ NVCASE to recognize one or more accreditation bodies that, in turn, will assess U.S. CABs seeking to be designated under the MRA. In the event that no accreditation bodies are recognized, FDA will request NIST to perform the assessment of potential CABs. Prospective U.S. CABs and accreditation bodies should contact NIST for additional information (see Section IV).

E. Training

FDA conducted training for EC CABs on October 14-16, 1998, in the Washington, D.C. area to address premarket notification (510(k)) review. Additional 510(k) training will be provided as needed. The primary emphasis of this training was on how to conduct and document an appropriate review of a 510(k).

Additional training for EC CABs on quality system evaluation will occur at regular intervals. FDA will issue a notice in the Federal Register announcing the dates of such training. Quality system evaluation training will include training on the following: Quality System Regulation, Medical Device Reporting Regulation, Corrections and Removal Regulation, Tracking Regulation, General Food and Drug Law, Evidence Development, FDA Compliance Programs, Investigations Operations, and other related topics.

FDA believes that quality system evaluation training can occur through a combination of outside training courses and FDA-sponsored training. Organizations interested in conducting training on any of the above topics, for purposes of the US/EC MRA, should contact CDRH immediately (see Section V for contact information). FDA generally will consider training courses to be adequate if they include a "tested" course exam for determination of successful completion. FDA will then notify the European Commission and those EC CABs that are participants in MRA activities of courses that will satisfy FDA requirements and any additional information needed.

Designated US CABs will likewise be advised of appropriate training by the EC, after the EC has announced its plans for such training.

IV. Obtaining Additional Information

Persons interested in obtaining a copy of the documents may do so using the World Wide Web (WWW). CDRH maintains an entry on the World Wide Web for easy access to information, including text, graphics, and files that may be downloaded to a PC with access to the Web. 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. Currently available documents for third party programs under the MRA are listed below:

1. Council Directive 90/385/EEC of June 20, 1990 on Active Implantable Medical Devices OJ No. L189, 20.7.1990, P17. Conformity assessment procedures, Annexes 2, 4 and 5. (only available on disk)

2. Council Directive 93/42/EEC of June 14, 1993 on Medical Devices OJ NO. L169, 12.7.1993, p.l, Annexes 2-6. (only available on disk)

3. FEDERAL REGISTER Notice [59 FR 19129] Establishment of the National Voluntary Conformity Assessment System Evaluation Program. (only available on disk)

The following documents are available through FDA/CDRH Home Pages or the NIST Home Page:

1) Agreement on Mutual Recognition Agreements between the United States of America and the European Community (www.fda.gov under "International" menu item)

2) Premarket Notification 510(k) Regulatory Requirements/for Medical Devices (August, 1995) (www.fda.gov/cdrh/manual/510kprt1.html) (also available on disk)

3) In Vitro Diagnostic Products: Guidance for the Preparation of 510(k) Submissions (January, 1997) (www.fda.gov/cdrh/manual/ivdmanul.html) (also available on disk)

4) Medical Device Quality Systems Manual: A Small Entity Compliance Guide (December, 1996) (www.fda.gov/cdrh/dsma/gmp_man.html) (also available on disk)

5) Determination of Intended Use for 510(k) Devices - Guidance for Industry and CDRH Staff (January, 1998) (www.fda.gov/cdrh/modact/K981.html)

6) Guidance on the Recognition and Use of Consensus Standards (February, 1998) (www.fda.gov/cdrh/modact/K982.html)

7) Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997 (www.fda.gov/cdrh)

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

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

10) FDA Investigations Operations Manual (www.fda.gov at the "Field Operations" menu item)

11) Compliance Program 7382.830 - Inspection of Medical Device Manufacturers (May 4, 1995) (www.fda.gov at the "Field Operations" menu item).

12) Compliance Program 7382.830A - Sterilization of Medical Devices (October 1, 1989) (www.fda.gov at the "Field Operations" menu item)

13) Regulations of the United States Food and Drug Administration found at 21 C.F.R., in particular, Parts 800-1299. (http://www.fda.gov/cdrh/devadvice/800to1299.html

14) Background Information on NVCASE (http://ts.nist.gov/ts/htdocs/210/216/nvcase.htm)

Information on the aforementioned documents related to MRA can also be obtained through the FDA or CDRH Home Page 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 Assistance, Attention: Publications, at 301-443-8818.

V. Contact Persons

John Stigi, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850, telephone, 301-443-6597 or FAX, 301-443-8818 for further information regarding the MRA third party program.

Robert L. Gladhill, National Institute of Standards and Technology, NN, 282 Gaithersburg, Maryland 20899, telephone, 301-975-4273 or FAX 301-963-2871 for further information regarding the process for being assessed as a U.S. CAB.