Guidance for Staff, Industry, and
U.S./EU Conformity Assessment Bodies

# Implementation Plan for the Mutual Recognition Agreement between the European Union and the United States of America: Procedure for Joint Confidence Building

# Medical Device Annex
## Version 7 June 29, 2000

***Draft Guidance – Not for Implementation***

**This guidance document is being distributed for comment purposes only.**
**Draft released for comment on October 3, 2000**

**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:

For 30 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, 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. To expedite the review process, if possible, FDA requests that you send a copy of your comments to the contact person, Christine Nelson by e-mail; mcn@cdrh.fda.gov or in writing to CDRH Liaison for MRA Implementation (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Drive, Rockville, MD 20850. Comments should be identified with the title of this document "Implementation Plan for the Mutual Recognition Agreement between the European Union and the United States of America: Procedure for Joint Confidence Building – Medical Device Annex."

## Additional Copies:

Additional copies are available from the World Wide Web, on the CDRH MRA home page: http://www.fda.gov/cdrh/mra .

*Draft - Not for Implementation*

# Guidance for Staff, Industry, and U.S./EU Conformity Assessment Bodies

# Implementation Plan for the Mutual Recognition Agreement between the European Union and the United States of America:

# Procedure for Joint Confidence Building[1]

# Medical Device Annex
# Version 7 June 29, 2000

[1] This document is intended to provide guidance. This document was developed by the FDA and the European Commission. This current draft represents the European Commission's (EC's) latest edits. FDA will be providing comments to the EC and proposing certain changes that are described in the "FDA Concerns" section of this document. This document 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 document, "Mutual Recognition Agreement between the European Union and the United States of America: Confidence building programme: Procedure for joint confidence building " was prepared jointly by the FDA and the European Commission (EC). The current draft, Version 7, dated June 29, 2000, reflects the latest EC edits and has not been accepted by the Food and Drug Administration (FDA). FDA has several concerns that need to be addressed before this document becomes final. FDA's concerns are described below. FDA will provide its comments and any relevant comments received from stakeholders to the European Commission.

This document is not intended to be an international agreement under the Vienna Convention on the Law of Treaties, nor is this document intended to meet the criteria for clearance by the U.S. Department of State under its Circular 175 procedure. Once this guidance document is finalized, FDA will make a good faith effort to carry out the activities, subject, of course, to availability of resources.

FDA Concerns

2.0 Definitions

The FDA proposes adding the following note and definitions to clarify the terminology used in this document:

Note: as used in this document the term:

- **'joint inspection/audit'** refers to a series of audits starting with a collaborative audit, followed by a modified performance audit and a full performance audit.

  **— 'collaborative audit'** means an inspection in which the Experienced Auditor/Trainer is the lead auditor and the CAB Trainee participates in the inspection.

  — **'modified performance audit'** means an inspection in which the CAB Trainee leads the inspection to the extent possible and the Experienced Auditor/Trainer observes, evaluates, and provides assistance and guidance as needed to the CAB Trainee

  — **'full performance audit'** means an inspection in which the CAB Trainee conducts the inspection and the Experienced Auditor/Trainer observes and evaluates the CAB Trainee and does not provide assistance or guidance."

5.1 Auditor training

The FDA proposes modifying the last sentence in this section with the italicized text as follows:

> "CAB Trainees who complete these programmes and are assessed under the CAB training system to be competent will conduct a full performance inspection and *will* be observed, evaluated, and found successful by the CAB, DA, *and importing party."*

It is essential that FDA participate in evaluating the competence of EU CAB 's and their auditors. FDA is required by statutory obligations to conduct a thorough and comprehensive assessment of CABs and their auditors who are performing work on behalf of FDA.

6.0 Product evaluation

The FDA proposes modifying the section on product evaluation, which currently says, "Procedures to be developed." FDA has developed procedures for conducting 510(k) reviews and wishes to have these procedures referenced in this document. The proposed addition can be accomplished by using two boxes, one for the FDA procedures for EU CABs and one for the EU procedures for US CABs.

| EU | US |
|---|---|
| 6.1 **510(k) Reviewer Training**<br><br>• CABs shall ensure that personnel who review 510(k) submissions are trained in FDA requirements, regulations, and procedures.<br>• At least one employee of the CAB shall attend FDA training on 510(k) review, such as that offered in October 1998 and August 1999, before the CAB accepts 510(k)'s for review. Additional CAB personnel will be trained through either the FDA-offered training or CAB-managed programs.<br><br>6.2 **Product Scope**<br><br>• CABs will accept 510(k)'s for review only for those devices covered by the scope of the MRA (Device Annex, Appendix 2) and consistent with U.S. laws governing third-party review of 510(k)'s, in particular, section 523 of the Federal Food, Drug, and Cosmetic | Procedure to be developed. |

| | |
|---|---|
| Act. CABs will not review 510(k)'s for Class III devices, or for Class II devices that are permanently implantable, life sustaining or supporting, or that requires clinical data in a 510(k).<br><br>6.3 **510(k) review criteria, procedures, and documentation**<br><br>• (see 7.5 of "Overview" document) | |

8.3 CAB Assessments

FDA proposes the following language for the last section of this document:

> "DA's are expected to advise the importing party of scheduled assessments of their CABs. If the DA cannot conduct the assessment as scheduled, it is agreed that the importing party can conduct the assessment independently. If there are reasonable grounds for concern over potential risk to public health, the importing party reserves the right to conduct an independent assessment of a CAB and will notify and invite the DA to participate."

FDA is required by statutory obligations to conduct a thorough and comprehensive assessment of CABs who are performing work on behalf of FDA. FDA understands that DAs may not always be able to conduct assessments according to schedules, but it is essential that FDA not be hampered in conducting assessments of CABs, particularly in instances where FDA has information indicating a potential risk to public health.

Addition of web sites:

FDA has added to this document web sites for each document mentioned. FDA added web sites to make it easier for people who review and comment on this document to gain access to supporting documents referenced here. FDA has made no other changes to this document.

# Procedure for joint confidence building for the medical device annex to the Mutual Recognition Agreement between the European Community and the United States of America

## 1.0 Introduction

This document should be read in conjunction with the document "Mutual Recognition Agreement between the European Union and the United States of America: Confidence Building Programme: Overview, Medical Device Annex".

## 2.0 Definitions

**CAB designation assessment**

A systematic and independent examination by the DA to determine whether a legal entity, its organisation, competence, quality management and related activities comply with defined requirements and that its arrangements are implemented effectively and are suitable to achieve the objectives.

Note: As used in the MRA and this document the term 'inspection' refers to the audit of a manufacturer's quality system and 'assessment' refers to the evaluation of a Conformity Assessment Body (CAB).

**CAB Trainee (also an auditor)**

An auditor, employed or authorised by the CAB, with relevant qualifications and competence to perform audits or specified parts of such audits by the CAB, established under the EU/US MRA implementation plan.

**Experienced Auditor/Trainer**

As used in this document a person nominated by the Importing Party to observe/train/evaluate an auditor (CAB Trainee) from the CAB during a joint inspection/audit.

**Mutual Recognition Agreement (MRA)**

In the context of this document Mutual Recognition Agreement (MRA) means the agreement on mutual recognition between the United States of America and the European Community and specifically the sectoral annex on medical device. Ref OJ L31 1999/78/EC

## 3.0 Aim of Confidence building activities

### 3.1 Purpose

The purpose of confidence building is for the parties to obtain sufficient evidence to make judgements concerning the equivalence of Conformity Assessment Bodies (CABs) of the other party with respect to their ability to perform quality systems and product evaluations for the other party. The purpose is also to enable the Designating Authorities (DAs) to establish and exercise their capability for designation, monitoring, suspension, removal of suspension or withdrawal of CABs.

### 3.2 Collaboration

- The Food and Drug Administration (FDA), the Commission of the European Communities (CEC), and the DAs recognize that co-operation and collaboration are essential to the successful implementation of the MRA.
- The FDA, CEC, and the DAs will work together to propose to the Joint Sector Committee (JSC) CABs that will participate in the MRA's transition period. The Joint Committee (JC) will make the formal listing of CABs. The FDA, CEC and the DAs shall exchange information to ensure that their respective regulatory requirements/criteria are understood by the CABs, their DAs and regulatory authorities.
- The FDA, CEC and the DAs will work with potential CABs to facilitate their participation in and their successful completion of the designation process.

## 4.0 CAB designation assessment information exchange.

- The DAs will supply supporting evidence for the proposed CABs to the importing party. This will include a 2-3-page summary of their review of the CAB’s application and the completed checklist cross-referenced against the criteria of the other party.
- The parties will verify particular requirements as appropriate, for example conflicts of interest, and in respect of these may request from the DAs supporting evidence prior to the CABs conducting independent quality systems audits or product evaluation. A copy of communications with the DAs may be sent to the relevant CAB.

## 5.0 Inspection/audit of manufacturer’s quality systems

### 5.1 Auditor training

- CABs shall ensure that auditors who conduct inspections/audits are trained in the importing party’s requirements/regulations and procedures.

- The CAB's auditors participating in the initial 1-3 joint inspections /audits are required to participate in classroom training programmes established by the Importing Party, followed by the joint inspection/audit programme, and to successfully complete the Full Performance Inspection/Audit.

Examples of acceptable classroom training:

| EU CAB | US CAB |
|---|---|
| AAMI GMP Quality systems and industry practices. | Establishing compliance with the medical device directive as presented in April 1999. |
| FDA training as offered in August 1999. | Course with a similar content as the one above. |
| In house training based on the above. | In house training based on the above. |
| Videotapes of FDA training. | |

Other courses may be added as appropriate.

- Subsequently, additional CAB auditors may be trained, through either the same programme as initial auditors or CAB managed programmes.
- CAB managed training programmes may involve, as trainers, auditors who have successfully completed both the above-cited courses (or their equivalent) and the Collaborative, Modified, and Full Performance inspection/audits. CAB Trainees who complete these programmes and are assessed under the CAB training system to be competent will conduct a full performance inspection and must be observed, evaluated, and found successful by the CAB and the DA.

## 5.2 Joint inspections/audits

### 5.2.1 General

- The Importing Parties will provide the experienced auditor/trainer to observe/train/evaluate CABs during the joint inspections/audits.
- Inspections/audits carried out, as part of the collaborative inspection/audit programme will be considered as valid audits for regulatory purposes.
- During the CAB joint inspection/audit the experienced auditor/trainer will remain responsible for the outcome of the inspection/audit and circumstances may require the experienced auditor/trainer to take the lead.

### 5.2.2 US CABs

The procedure used for the joint audits performed by the US CABs will follow that described in the document on observed audits prepared by Study Group 4 of the GHTF (document reference SG(99)26) PDF:www.ghtf.org/sg4/inventorysg4/99-26confbuild.pdf Word: www.ghtf.org, click on Study Group 4, click on "Proposed Documents"

### 5.2.3 EU CABs

The procedure used for joint inspections performed for the EU CABs will follow the appropriate parts described in the Compliance Programme 7382.845 Inspection of Medical Device Manufacturers, PDF: www.fda.gov/cdrh/comp/7382_845.pdf or Text: www.fda.gov/cdrh/comp/7382.845.html and Quality Systems Inspection (QSIT) Guide to Inspections of Quality Systems, PDF: www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF
Text: www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.HTM. As soon as the GHTF SG4 documents are evaluated and accepted for operational use by the FDA they will be applied under the MRA.

## 5.3. Joint audit programme

The following collaborative and performance audits will enable the CAB to both become familiar with and then demonstrate compliance with, the procedures of the other party for conducting quality systems audits. The following model is adopted for field training of the CAB auditor.

### 5.3.1 Collaborative Inspection/Audit

- A CAB trainee and an experienced auditor/trainer will conduct a collaborative inspection/audit of the manufacturers quality system.
- The respective DA will be invited to observe at the audit.
- The experienced auditor/trainer will be the lead auditor during the collaborative inspection/audit and prepare the list of non-conformities, if applicable and the audit report.
- As a training exercise the CAB trainee should prepare a practice list of non-conformities, whether or not actual deficiencies are noted based on scenarios provided by the experienced auditor/trainer and should also prepare an audit report.
- The experienced auditor/trainer will provide an informal assessment of the trainee's performance for the trainee, CAB and the DA.

### 5.3.2 Modified Performance Audit

- A CAB trainee and an experienced auditor/trainer will conduct a modified performance inspection/audit of the manufacturers quality system.
- The respective DA will be invited to observe.
- An experienced auditor/trainer will observe and evaluate the CAB trainee's performance during the audit using established performance criteria.

- The experienced auditor/trainer will also provide the CAB trainee with assistance during the audit.
- The CAB trainee will prepare the list of non-conformities, if applicable, to be presented to the manufacturer and a full inspection/audit report under the supervision of the experienced auditor/trainer.
- If no non conformities were observed the CAB trainee will prepare a list of non conformities based on scenarios provided by the experienced auditor/trainer for training purposes.
- The experienced auditor/trainer will provide an assessment of the trainee's performance with recommendations as appropriate to the trainee, CAB and the DA.

### 5.3.3 Full Performance Inspection/Audit

- A CAB trainee will perform independently a full performance inspection /audit of the manufacturers quality system and prepare a list of non-conformities, if applicable, and a full inspection/audit report.
- The respective DA will be invited to observe.
- An experienced auditor will observe and evaluate the CAB trainee using established performance criteria.
- The experienced auditor will not provide assistance during full performance inspection/audits.
- A full performance inspection/audit can be converted to a modified performance inspection/audit when the trainee has failed to demonstrate competence.
- The experienced auditor will provide an assessment of the trainee's performance with recommendations as appropriate to the trainee, CAB and the DA.

## 5.4 Inspection/Audit Reports

### 5.4.1 EU CAB reports

- EU CAB auditors must prepare an FDA prescribed establishment inspection report using the format defined in the Investigations Operations Manual subchapter 590 (http://www.fda.gov/ora/inspect_ref/iom/C5a.html) and a FDA form 483 list of observations (non-conformities) (http://www.fda.gov/ora/inspect_ref/iom/exhibits/510b.html) if applicable. The CAB auditor directs the report to CAB management for review and as appropriate preliminary endorsement. CAB management directs the preliminary endorsed report to the FDA contact point.
- As soon as the GHTF SG4 documents are evaluated and accepted for operational use by the FDA they will be applied under the MRA.

- The report and any clarification requested by the FDA must be supplied in English. Any documents collected from the manufacturers may be in the operational/working language used in the manufacturer's premises.

### 5.4.2 US CAB reports

- The US CAB inspector/auditor must prepare an audit report in a suitable format such as described in the GHTF SG4 guidance document.
- The US CAB's report should be in the language as agreed upon between the NB and its DA, the CAB and the manufacturer. In cases where the NB requests additional information, this information may be in the operational/working language, which is used in the manufacturer's premises.

## 5.5 Scheduling

- The DAs to be kept informed of the proposed inspections/audits and this should be sufficiently in advance to allow them time to make a decision on their need to attend and to schedule their participation.

## 5.6 Completion of CAB auditor training

After successfully completing the joint inspection/audit programme and subject to the CAB meeting the other applicable criteria, e.g. Confidence building programme – overview, section 6.2, the trainee CAB auditor can proceed to full unsupervised inspections/audits.

The CAB is responsible for effectively managing all aspects of the full performance and independent inspections/audits of manufacturer's quality system carried out by its auditors. Thid will include management, training and selection of suitable auditors, monitoring their activities, cheking and approving audit reports prepared by the auditor to be issued by the CAB.

# 6.0 Product evaluation

Procedure to be developed.

# 7.0 Activities at the end of the transitional period

Activities at the end of the transitional period will be the subject of a separate document.

## 8.0 Role of Designating Authorities

### 8.1 Establishing Designating Authorities (DAs) capability to monitor CABs

- During the confidence-building period each DA or its designee is expected to participate in recommended training exercises, workshops and seminars in order to develop the knowledge and expertise to adequately monitor the CABs proposed under its authority. This monitoring activity will be carried out to ensure that the CAB continues to meet the designation criteria, its procedures are carried out and documented, and that appropriate conformity assessment decisions are made and recorded.
- The CAB will be monitored by its DA to ensure that feedback information provided by the Importing Party during conformity assessment activities is evaluated and as appropriate used to develop competence and/or effectiveness.
- The CAB will be assessed by the DA at least annually to confirm that it is operating the planned management system,
- The DA is expected, as a part of its monitoring activity, to observe inspections/audits of manufacturers quality systems conducted by CAB audit teams. Ideally DAs will observe at least two inspections/audits per CAB during the confidence building period. The actual number will depend upon the volume of inspections/audits that CABs conduct during the MRA's Transitional Period. For the purposes of this plan, monitoring includes the review of information collected by the DA and decisions taken (e.g. to continue designation, suspension and removal of suspension or withdrawal of designation).
- The DA is expected to use performance criteria jointly developed by the Importing Parties and provide results of their assessments to the other Importing Party.

### 8.2 Joint Assessments.

As part of the confidence building activities the parties will work together collaboratively. Joint assessments of CABs may be performed and include observing audits of manufacturers conducted by CAB auditors. Ideally these joint assessments will typically include at least two per CAB. The actual number will depend upon the volume of inspections and the number of CAB auditors participating for any one CAB during the MRAs transitional period.

### ~~8.3 CAB Assessments~~

~~DA's are expected to advise the other party of scheduled assessments of their CABs. While joint assessments are preferred, the importing party may conduct independent assessments of CABs if justified and the exporting DA is not available.~~