

§ 26.37

independence, as identified in Appendix A of this subpart. The list shall be accompanied by supporting evidence. Designated CAB's will be listed in Appendix D of this subpart for participation in the confidence building activities once confirmed by the importing party. Nonconfirmation would have to be justified based on documented evidence.

§ 26.37 Confidence building activities.

(a) At the beginning of the transitional period, the Joint Sectoral Group will establish a joint confidence building program calculated to provide sufficient evidence of the capabilities of the designated conformity assessment bodies (CAB's) to perform quality system or product evaluations to the specifications of the parties.

(b) The joint confidence building program should include the following actions and activities:

(1) Seminars designed to inform the parties and CAB's about each party's regulatory system, procedures, and requirements;

(2) Workshops designed to provide the parties with information regarding requirements and procedures for the designation and surveillance of CAB's;

(3) Exchange of information about reports prepared during the transition period;

(4) Joint training exercises; and

(5) Observed inspections.

(c) During the transition period, any significant problem that is identified with a CAB may be the subject of cooperative activities, as resources allow and as agreed to by the regulatory authorities, aimed at resolving the problem.

(d) Both parties will exercise good faith efforts to complete the confidence building activities as expeditiously as possible to the extent that the resources of the parties allow.

(e) Both the parties will each prepare annual progress reports which will describe the confidence building activities undertaken during each year of the transition period. The form and content of the reports will be determined by the parties through the Joint Sectoral Committee.

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§ 26.38 Other transition period activities.

(a) During the transition period, the parties will jointly determine the necessary information which must be present in quality system and product evaluation reports.

(b) The parties will jointly develop a notification and alert system to be used in case of defects, recalls, and other problems concerning product quality that could necessitate additional actions (e.g., inspections by the parties of the importing country) or suspension of the distribution of the product.

§ 26.39 Equivalence assessment.

(a) In the final 6 months of the transition period, the parties shall proceed to a joint assessment of the equivalence of the conformity assessment bodies (CAB's) that participated in the confidence building activities. CAB's will be determined to be equivalent provided they have demonstrated proficiency through the submission of a sufficient number of adequate reports. CAB's may be determined to be equivalent with regard to the ability to perform any type of quality system or product evaluation covered by this subpart and with regard to any type of product covered by this subpart. The parties shall develop a list contained in Appendix E of this subpart of CAB's determined to be equivalent, which shall contain a full explanation of the scope of the equivalency determination, including any appropriate limitations, with regard to performing any type of quality system or product evaluation.

(b) The parties shall allow CAB's not listed for participation in this subpart, or listed for participation only as to certain types of evaluations, to apply for participation in this subpart once the necessary measures have been taken or sufficient experience has been gained, in accordance with § 26.46.

(c) Decisions concerning the equivalence of CAB's must be agreed to by both parties.

§ 26.40 Start of the operational period.

(a) The operational period will start at the end of the transition period after the parties have developed the list of conformity assessment bodies (CAB's)

found to be equivalent. The provisions of §§ 26.40, 26.41, 26.42, 26.43, 26.44, 26.45, and 26.46 will apply only with regard to listed CAB's and only to the extent of any specifications and limitations contained on the list with regard to a CAB.

(b) The operational period will apply to quality system evaluation reports and product evaluation reports generated by CAB's listed in accordance with this subpart for the evaluations performed in the respective territories of the parties, except if the parties agree otherwise.

§ 26.41 Exchange and endorsement of quality system evaluation reports.

(a) Listed European Community (EC) conformity assessment bodies (CAB's) will provide FDA with reports of quality system evaluations, as follows:

(1) For preapproval quality system evaluations, EC CAB's will provide full reports; and

(2) For surveillance quality system evaluations, EC CAB's will provide abbreviated reports.

(b) Listed U.S. CAB's will provide to the EC Notified Body of the manufacturer's choice:

(1) Full reports of initial quality system evaluations;

(2) Abbreviated reports of quality systems surveillance audits.

(c) If the abbreviated reports do not provide sufficient information, the importing party may request additional clarification from the CAB.

(d) Based on the determination of equivalence in light of the experience gained, the quality system evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in a report, quality defects identified in postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the importing party may request clarification from the exporting party which may lead to a request for reinspection. The parties will endeavor to respond to requests for clarification in a timely manner.

Where divergence is not clarified in this process, the importing party may carry out the quality system evaluation.

§ 26.42 Exchange and endorsement of product evaluation reports.

(a) European Community (EC) conformity assessment bodies (CAB's) listed for this purpose will, subject to the specifications and limitations on the list, provide to FDA 510(k) premarket notification assessment reports prepared to U.S. medical device requirements.

(b) U.S. CAB's will, subject to the specifications and limitations on the list, provide to the EC Notified Body of the manufacturer's choice, type examination, and verification reports prepared to EC medical device requirements.

(c) Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies, inadequacies, or incompleteness in a product evaluation report, or other specific evidence of serious concern in relation to product safety, performance, or quality. In such cases, the importing party may request clarification from the exporting party which may lead to a request for a reevaluation. The parties will endeavor to respond to requests for clarification in a timely manner. Endorsement remains the responsibility of the importing party.

§ 26.43 Transmission of quality system evaluation reports.

Quality system evaluation reports covered by § 26.41 concerning products covered by this subpart shall be transmitted to the importing party within 60-calendar days of a request by the importing party. Should a new inspection be requested, the time period shall be extended by an additional 30-calendar days. A party may request a new inspection, for cause, identified to the other party. If the exporting party cannot perform an inspection within a specified period of time, the importing