

## Food and Drug Administration, HHS

## § 26.1

SOURCE: 63 FR 60141, Nov. 6, 1998, unless otherwise noted.

### § 26.0 General.

This part substantially reflects relevant provisions of the framework agreement and its sectoral annexes on pharmaceutical good manufacturing practices (GMP's) and medical devices of the "Agreement on Mutual Recognition Between the United States of America and the European Community" (the MRA), signed at London May 18, 1998. For codification purposes, certain provisions of the MRA have been modified for use in this part. This modification is done for purposes of clarity only and shall not affect the text of the MRA concluded between the United States and the European Community (EC), or the rights and obligations of the United States or the EC under that agreement. Whereas the parties to the MRA are the United States and EC, this part is relevant only to the Food and Drug Administration's (FDA's) implementation of the MRA, including the sectoral annexes reflected in subparts A and B of this part. This part does not govern implementation of the MRA by the EC, which will implement the MRA in accordance with its internal procedures, nor does this part address implementation of the MRA by other concerned U.S. Federal agencies. For purposes of this part, the terms "party" or "parties," where relevant to FDA's implementation of the MRA, should be considered as referring to FDA only. If the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly, using appropriate administrative procedures.

### Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

#### § 26.1 Definitions.

(a) *Enforcement* means action taken by an authority to protect the public from products of suspect quality, safety, and effectiveness or to assure that products are manufactured in compliance with appropriate laws, regulations, standards, and commitments

made as part of the approval to market a product.

(b) *Equivalence* of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. Equivalence does not require that the respective regulatory systems have identical procedures.

(c) *Good Manufacturing Practices* (GMP's). [The United States has clarified its interpretation that under the MRA, paragraph (c)(1) of this section has to be understood as the U.S. definition and paragraph (c)(2) as the EC definition.]

(1) GMP's mean the requirements found in the legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(2) GMP's are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subpart, GMP's include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization/product authorization or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification in the EC).

(d) *Inspection* means an onsite evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP's and/or commitments made as part of the approval to market a product.

(e) *Inspection report* means the written observations and GMP's compliance assessment completed by an authority listed in appendix B of this subpart.

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(f) *Regulatory system* means the body of legal requirements for GMP's, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

[63 FR 60141, Nov. 6, 1998; 64 FR 16348, Apr. 5, 1999]

### § 26.2 Purpose.

The provisions of this subpart govern the exchange between the parties and normal endorsement by the receiving regulatory authority of official good manufacturing practices (GMP's) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the parties, which is the cornerstone of this subpart.

### § 26.3 Scope.

(a) The provisions of this subpart shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community (EC) before products are marketed (hereafter referred to as "preapproval inspections") as well as during their marketing (hereafter referred to as "postapproval inspections").

(b) Appendix A of this subpart names the laws, regulations, and administrative provisions governing these inspections and the good manufacturing practices (GMP's) requirements.

(c) Appendix B of this subpart lists the authorities participating in activities under this subpart.

(d) Sections 26.65, 26.66, 26.67, 26.68, 26.69, and 26.70 of subpart C of this part do not apply to this subpart.

### § 26.4 Product coverage.

(a) The provisions of this subpart will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the European Community (EC)) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both parties as listed in appendix B of this subpart.

(b) Human blood, human plasma, human tissues and organs, and veteri-

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nary immunologicals (under 9 CFR 101.2, "veterinary immunologicals" are referred to as "veterinary biologicals") are excluded from the scope of this subpart. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals, and medicinal gases are also excluded during the transition phase; their situation will be reconsidered at the end of the transition period. Products regulated by the Food and Drug Administration's Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research as devices are not covered under this subpart.

(c) Appendix C of this subpart contains an indicative list of products covered by this subpart.

[63 FR 60141, Nov. 6, 1998, as amended at 70 FR 14980, Mar. 24, 2005]

### § 26.5 Length of transition period.

A 3-year transition period will start immediately after the effective date described in § 26.80(a).

### § 26.6 Equivalence assessment.

(a) The criteria to be used by the parties to assess equivalence are listed in appendix D of this subpart. Information pertaining to the criteria under European Community (EC) competence will be provided by the EC.

(b) The authorities of the parties will establish and communicate to each other their draft programs for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programs will be carried out, as deemed necessary by the regulatory authorities, for post- and preapproval inspections and for various product classes or processes.

(c) The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the parties will ensure that efforts are made to save resources.

(d) Equivalence assessment for authorities added to appendix B of this subpart after the effective date described in § 26.80(a) will be conducted as

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described in this subpart, as soon as practicable.

### § 26.7 Participation in the equivalence assessment and determination.

The authorities listed in appendix B of this subpart will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

### § 26.8 Other transition activities.

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

### § 26.9 Equivalence determination.

(a) Equivalence is established by having in place regulatory systems covering the criteria referred to in appendix D of this subpart, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e.g., postapproval or preapproval) or product classes or processes.

(b) The parties will document insufficient evidence of equivalence, lack of opportunity to assess equivalence or a determination of nonequivalence, in sufficient detail to allow the authority being assessed to know how to attain equivalence.

### § 26.10 Regulatory authorities not listed as currently equivalent.

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

### § 26.11 Start of operational period.

(a) The operational period shall start at the end of the transition period and

its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

(b) In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, the Food and Drug Administration (FDA) will accept for normal endorsement (as provided in § 26.12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the parties will agree on procedures for exercising this option.

(c) In the European Community (EC), the qualified person will be relieved of responsibility for carrying the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC (see appendix A of this subpart) provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the World Health Organization Certification Scheme on the Quality of Medicinal Products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

### § 26.12 Nature of recognition of inspection reports.

(a) Inspection reports (containing information as established under § 26.8), including a good manufacturing practice (GMP) compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of

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material inconsistencies or inadequacies in an inspection report, quality defects identified in the postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing party may request clarification from the authority of the exporting party which may lead to a request for reinspection. The authorities will endeavor to respond to requests for clarification in a timely manner.

(b) Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

### § 26.13 Transmission of postapproval inspection reports.

Postapproval good manufacturing practice (GMP) inspection reports concerning products covered by this subpart will be transmitted to the authority of the importing country within 60-calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90-calendar days of the request.

### § 26.14 Transmission of preapproval inspection reports.

(a) A preliminary notification that an inspection may have to take place will be made as soon as possible.

(b) Within 15-calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the European Community (EC), requests will be sent directly to the relevant authority, with a copy to the European Agency for the Evaluation of Medicinal Products (EMA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

(c) Reports of preapproval inspections will be sent within 45-calendar days of the request that transmitted the appropriate information and detailed the precise issues to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

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### § 26.15 Monitoring continued equivalence.

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections; and the conduct of common training sessions.

### § 26.16 Suspension.

(a) Each party has the right to contest the equivalence of a regulatory authority. This right will be exercised in an objective and reasoned manner in writing to the other party.

(b) The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the Joint Sectoral Committee determines that verification of equivalence is required, it may be carried out jointly by the parties in a timely manner, under § 26.6.

(c) Efforts will be made by the Joint Sectoral Committee to reach unanimous consent on the appropriate action. If agreement to suspend is reached in the Joint Sectoral Committee, an authority may be suspended immediately thereafter. If no agreement is reached in the Joint Sectoral Committee, the matter is referred to the Joint Committee as described in § 26.73. If no unanimous consent is reached within 30 days after such notification, the contested authority will be suspended.

(d) Upon the suspension of authority previously listed as equivalent, a party is no longer obligated to normally endorse the inspection reports of the suspended authority. A party shall continue to normally endorse the inspection reports of that authority prior to suspension, unless the authority of the receiving party decides otherwise based on health or safety considerations. The suspension will remain in effect until unanimous consent has been reached by the parties on the future status of that authority.

### § 26.17 Role and composition of the Joint Sectoral Committee.

(a) A Joint Sectoral Committee is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who each will have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment, which must be agreed by both parties, of the equivalence of the respective authorities;

(2) Developing and maintaining the list of equivalent authorities, including any limitation in terms of inspecting type or products, and communicating the list to all authorities and the Joint Committee;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that an authority may be no longer equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

(d) The Joint Sectoral Committee shall meet at the request of either party and, unless the cochaIRS otherwise agree, at least once each year. The Joint Committee will be kept informed of the agenda and conclusions of meetings of the Joint Sectoral Committee.

#### § 26.18 Regulatory collaboration.

(a) The parties and authorities shall inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to appendix B of this subpart.

#### § 26.19 Information relating to quality aspects.

The authorities will establish an appropriate means of exchanging information on any confirmed problem reports, corrective actions, recalls, rejected import consignments, and other regulatory and enforcement problems for products subject to this subpart.

#### § 26.20 Alert system.

(a) The details of an alert system will be developed during the transitional period. The system will be maintained in place at all times. Elements to be considered in developing such a system are described in appendix E of this subpart.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, recalls, counterfeiting, and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

#### § 26.21 Safeguard clause.

Each party recognizes that the importing country has a right to fulfill its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. This includes the suspension of the distribution, product detention at the border of the importing country, withdrawal of the batches and any request for additional information or inspection as provided in § 26.12.

#### APPENDIX A TO SUBPART A OF PART 26— LIST OF APPLICABLE LAWS, REGULATIONS, AND ADMINISTRATIVE PROVISIONS

##### 1. For the European Community (EC):

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036. EC documents may be viewed on the European Commission Pharmaceuticals Units web site at <http://dg3.eudra.org>.]

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation, or administrative action relating to proprietary medicinal products as extended, widened, and amended. Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, as widened and amended.

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.

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Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Council Regulation EEC No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use.

Guide to Good Distribution Practice (94/C 63/03).

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV.

### 2. For the United States:

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents, except the FDA Compliance Program Guidance Manual, may be viewed on FDA's Internet web site at <http://www.fda.gov>.]

Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act. Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1–99, Parts 200–299, Parts 500–599, and Parts 600–799.

Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.

### APPENDIX B TO SUBPART A OF PART 26— LIST OF AUTHORITIES

1. For the United States: In the United States, the regulatory authority is the Food and Drug Administration.

2. For the European Community: In the European Community, the regulatory authorities are the following:

Belgium: Inspection générale de la Pharmacie, Algemene Farmaceutische Inspectie.

Denmark: Laegemiddelstyrelsen.

Germany: Bundesministerium für Gesundheit für immunologicals: Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines.

Greece: Εθνικός Οργανισμός Φαρμάκων, Ministry of Health and Welfare, National Drug Organization (E.O.F).

Spain: For medicinal products for human use: Ministerio de Sanidad y Consumo, Subdirección General de Control Farmacéutico. For medicinal products for

veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA), Dirección General de la Producción Agraria.

France: For medicinal products for human use: Agence du Médicament. For veterinary medicinal products: Agence Nationale du Médicament Vétérinaire.

Ireland: Irish Medicines Board.

Italy: For medicinal products for human use: Ministero della Sanità, Dipartimento Farmaci e Farmacovigilanza. For medicinal products for veterinary use: Ministero della Sanità, Dipartimento alimenti e nutrizione e sanità pubblica veterinaria-Div. IX.

Luxembourg: Division de la Pharmacie et des Médicaments.

Netherlands: Staat der Nederlanden.

Austria: Bundesministerium für Arbeit, Gesundheit und Soziales.

Portugal: Instituto da Farmácia e do Medicamento (INFARMED).

Finland: Lääkelaitos/Läkemedelsverket (National Agency for Medicines).

Sweden: Läkemedelsverket-Medical Products Agency.

United Kingdom: For human use and veterinary (non-immunologicals): Medicines Control Agency. For veterinary immunologicals: Veterinary Medicines Directorate.

European Community: Commission of the European Communities. European Agency for the Evaluation of Medicinal Products (EMEA).

### APPENDIX C TO SUBPART A OF PART 26— INDICATIVE LIST OF PRODUCTS COVERED BY SUBPART A

Recognizing that precise definition of medicinal products and drugs are to be found in the legislation referred to above, an indicative list of products covered by this arrangement is given below:

—human medicinal products including prescription and nonprescription drugs;

—human biologicals including vaccines, and immunologicals;

—veterinary pharmaceuticals, including prescription and nonprescription drugs, with the exclusion of veterinary immunologicals (Under 9 CFR 101.2 “veterinary immunologicals” are referred to as “veterinary biologicals”);

—premixes for the preparation of veterinary medicated feeds (EC), Type A medicated articles for the preparation of veterinary medicated feeds (United States);

—intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals (United States)/starting materials (EC).

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**APPENDIX D TO SUBPART A OF PART 26—  
CRITERIA FOR ASSESSING EQUIVA-  
LENCE FOR POST- AND  
PREAPPROVAL**

**I. Legal/Regulatory authority and structures and procedures providing for post- and preapproval:**

- A. Appropriate statutory mandate and jurisdiction.
- B. Ability to issue and update binding requirements on GMP's and guidance documents.
- C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.
- D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.
- E. Substantive current good manufacturing requirements.
- F. Accountability of the regulatory authority.
- G. Inventory of current products and manufacturers.
- H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by subpart A of this part.

**II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.**

**III. Administration of the regulatory authority:**

- A. Standards of education/qualification and training.
- B. Effective quality assurance systems measures to ensure adequate job performance.
- C. Appropriate staffing and resources to enforce laws and regulations.

**IV. Conduct of inspections:**

- A. Adequate preinspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.
- B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.
- C. Adequate postinspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of followup inspections and other activities where appropriate, assurance of preservation and retrieval of records.

**V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.**

**VI. Effective use of surveillance systems:**

- A. Sampling and analysis.
- B. Recall monitoring.
- C. Product defect reporting system.
- D. Routine surveillance inspections.
- E. Verification of approved manufacturing process changes to marketing authorizations/approved applications.

**VII. Additional specific criteria for preapproval inspections:**

- A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the regulatory authorities' capabilities.
- B. Preinspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.
- C. Ability to verify chemistry, manufacturing, and control data supporting an application is authentic and complete.
- D. Ability to assess and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.
- E. Ability to verify conformity of the onsite processes and procedures with those described in the application.
- F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

**APPENDIX E TO SUBPART A OF PART 26—  
ELEMENTS TO BE CONSIDERED IN DE-  
VELOPING A TWO-WAY ALERT SYS-  
TEM**

**1. Documentation**

- Definition of a crisis/emergency and under what circumstances an alert is required
- Standard Operating Procedures (SOP's)
- Mechanism of health hazards evaluation and classification
- Language of communication and transmission of information

**2. Crisis Management System**

- Crisis analysis and communication mechanisms
- Establishment of contact points
- Reporting mechanisms

**3. Enforcement Procedures**

- Followup mechanisms
- Corrective action procedures

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### 4. Quality Assurance System

—Pharmacovigilance programme  
—Surveillance/monitoring of implementation of corrective action

### 5. Contact Points

For the purpose of subpart A of this part, the contact points for the alert system will be:

#### A. For the European Community:

the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone 44-171-418 8400, Fax 418-8416.

#### B. For the United States :

Biologics: Director, Office of Compliance and Biologics Quality (HFM-600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301-827-6190, fax: 301-594-1944.

Human Drugs: Director, Office of Compliance, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, phone: 301-796-3100, fax: 301-847-8747.

Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV-200), MPN II, 7500 Standish Pl., Rockville, MD 20855-2773, phone: 301-827-6644, fax: 301-594-1807.

[63 FR 60141, Nov. 6, 1998, as amended at 69 FR 48775, Aug. 11, 2004; 74 FR 13112, Mar. 26, 2009]

## Subpart B—Specific Sector Provisions for Medical Devices

### § 26.31 Purpose.

(a) The purpose of this subpart is to specify the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.

(b) This subpart is intended to evolve as programs and policies of the parties evolve. The parties will review this subpart periodically, in order to assess progress and identify potential enhancements to this subpart as Food and Drug Administration (FDA) and European Community (EC) policies evolve over time.

### § 26.32 Scope.

(a) The provisions of this subpart shall apply to the exchange and, where appropriate, endorsement of the fol-

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lowing types of reports from conformity assessment bodies (CAB's) assessed to be equivalent:

(1) Under the U.S. system, surveillance/postmarket and initial/preapproval inspection reports;

(2) Under the U.S. system, premarket (510(k)) product evaluation reports;

(3) Under the European Community (EC) system, quality system evaluation reports; and

(4) Under the EC system, EC type examination and verification reports.

(b) Appendix A of this subpart names the legislation, regulations, and related procedures under which:

(1) Products are regulated as medical devices by each party;

(2) CAB's are designated and confirmed; and

(3) These reports are prepared.

(c) For purposes of this subpart, equivalence means that: CAB's in the EC are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner equivalent to those conducted by FDA; and CAB's in the United States are capable of conducting product and quality systems evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CAB's.

### § 26.33 Product coverage.

(a) There are three components to this subpart each covering a discrete range of products:

(1) *Quality System Evaluations.* U.S.-type surveillance/postmarket and initial/preapproval inspection reports and European Community (EC)-type quality system evaluation reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(2) *Product Evaluation.* U.S.-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the U.S. system as Class I/Class II-Tier 2 medical devices which are listed in appendix B of this subpart.

(3) *Postmarket Vigilance Reports.* Postmarket vigilance reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.