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

APPENDIXES C–F TO SUBPART B OF PART 26 [RESERVED]

Subpart C—``Framework'' Provisions

§ 26.60 Definitions.

(a) The following terms and definitions shall apply to this subpart only:

(1) *Designating Authority* means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this part.

(2) *Designation* means the identification by a designating authority of a conformity assessment body to perform conformity assessment procedures under this part.

(3) *Regulatory Authority* means a government agency or entity that exercises a legal right to control the use or sale of products within a party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

(b) Other terms concerning conformity assessment used in this part shall have the meaning given elsewhere in this part or in the definitions contained in ''Guide 2: Standardization and Related Activities—General Vocabulary of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC)'' (ISO/IEC Guide 2) (1996 edition), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the International Organization for Standardization, 1, rue de Varembé, Case postale 56, CH–1211 Genève 20, Switzerland, or on the Internet at ''http://www.iso.ch'' or may be examined at the Food and Drug Administration's Medical Library, 5600 Fishers Lane, rm. 11B–40, Rockville, MD 20857, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. In the event of an inconsistency between the ISO/IEC Guide 2 and definitions in this part, the definitions in this part shall prevail.

§ 26.61 Purpose of this part.

This part specifies the conditions by which each party will accept or recognize results of conformity assessment procedures, produced by the other party's conformity assessment bodies (CAB's) or authorities, in assessing conformity to the importing party's requirements, as specified on a sector-specific basis in subparts A and B of this part, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the parties with regard to conformity assessment for all products covered under this part. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the party alleging its market access has been denied may, within 90 days of such consultation, invoke its right to terminate the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived, in accordance with § 26.80.

§ 26.62 General obligations.

(a) The United States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by the other party's conformity assessment bodies (CAB's) and/or authorities.

(b) The European Community (EC) and its Member States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the EC and its Member States, produced by the other party's CAB's and/or authorities.

(c) Where sectoral transition arrangements have been specified in subparts A and B of this part, the obligations in paragraphs (a) and (b) of this section will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure

conformity to the satisfaction of the receiving party, with applicable legislative, regulatory, and administrative provisions of that party, equivalent to the assurance offered by the receiving party's own procedures.

§ 26.63 General coverage of this part.

(a) This part applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this part.

(b) Subparts A and B of this part may include:

(1) A description of the relevant legislative, regulatory, and administrative provisions pertaining to the conformity assessment procedures and technical regulations;

(2) A statement on the product scope and coverage;

(3) A list of designating authorities;

(4) A list of agreed conformity assessment bodies (CAB's) or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;

(5) The procedures and criteria for designating the CAB's;

(6) A description of the mutual recognition obligations;

(7) A sectoral transition arrangement;

(8) The identity of a sectoral contact point in each party's territory; and

(9) A statement regarding the establishment of a Joint Sectoral Committee.

(c) This part shall not be construed to entail mutual acceptance of standards or technical regulations of the parties and, unless otherwise specified in subpart A or B of this part, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

§ 26.64 Transitional arrangements.

The parties agree to implement the transitional commitments on confidence building as specified in subparts A and B of this part.

(a) The parties agree that each sectoral transitional arrangement shall specify a time period for completion.

(b) The parties may amend any transitional arrangement by mutual agreement.

(c) Passage from the transitional phase to the operational phase shall proceed as specified in subparts A and B of this part, unless either party documents that the conditions provided in such subpart for a successful transition are not met.

§ 26.65 Designating authorities.

The parties shall ensure that the designating authorities specified in subpart B of this part have the power and competence in their respective territories to carry out decisions under this part to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies (CAB's).

§ 26.66 Designation and listing procedures.

The following procedures shall apply with regard to the designation of conformity assessment bodies (CAB's) and the inclusion of such bodies in the list of CAB's in subpart B of this part:

(a) The designating authority identified in subpart B of this part shall designate CAB's in accordance with the procedures and criteria set forth in subpart B of this part;

(b) A party proposing to add a CAB to the list of such bodies in subpart B of this part shall forward its proposal of one or more designated CAB's in writing to the other party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in subpart B of this part of the proposed CAB or CAB's shall take effect; and

(d) In the event that the other party contests on the basis of documented evidence the technical competence or compliance of a proposed CAB, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such CAB shall not be included on the list of CAB's in subpart B of this part. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the