SUBCHAPTER A—MISCELLANEOUS REGULATIONS

PART 301—INSTRUMENTS AND APPARATUS FOR EDUCATIONAL AND SCIENTIFIC INSTITUTIONS

AUTHORITY: Sec. 6(c), Pub. L. 89–651, 80 Stat. 897 (19 U.S.C. 1202).

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§ 301.1 General provisions.

(a) *Purpose.* This part sets forth the regulations of the Department of Commerce and the Department of the Treasury applicable to the duty-free importation of scientific instruments and apparatus by public or private nonprofit institutions.

(b) *Background.* (1) The Agreement on the importation of Educational, Scientific and Cultural Materials (Florence Agreement; ''the Agreement'') is a multinational treaty, contracted to by approximately 89 countries, which seeks to further the cause of peace through the freer exchange of ideas and knowledge across national boundaries, primarily by eliminating tariffs on certain educational, scientific and cultural materials.

(2) Annex D of the Agreement provides that scientific instruments and apparatus intended exclusively for educational purposes or pure scientific research use by qualified nonprofit institutions shall enjoy duty-free entry if instruments or apparatus of equivalent scientific value are not being manufactured in the country of importation.

(3) Pub. L. 89–651, the Educational, Scientific, and Cultural Materials Importation Act of 1966 (19 U.S.C. 1202; ''the Act''), implements the Agreement in the United States. Section 6(c) of the Act gives effect to Annex D of the Agreement. This section added tariff item 851.60 to the Tariff Schedules of the United States (TSUS) to provide for the duty-free importation of instruments and apparatus ''entered for the use of any nonprofit institution, whether public or private, established for educational or scientific purposes * * * if no instrument or apparatus of equivalent scientific value for the purposes for which the instrument or apparatus is intended to be used is being manufactured in the United States.'' Headnote 1 to Schedule 8, part 4, TSUS, was amended by Pub. L. 89–651 and provides for the use, disposition and transfer of articles and their repair components accorded duty-free entry under tariff items 851.60 and 851.65, respectively, and Headnote 6, added by Pub. L. 89–651, sets forth the duty-free procedures and responsibilities.

(c) *Summary of statutory procedures and requirements.* (1) Headnote 1 provides, among other things, that articles covered by tariff items 851.60 (scientific instruments and apparatus) and 851.65 (repair components therefor) must be exclusively for the use of the institutions involved and not for distribution, sale or other commercial use within five years after being entered. These articles may be transferred by a qualified nonprofit institution to another such institution without duty liability being incurred. However, if such article is transferred other than as provided by the preceding sentence, or is used for commercial purposes within five years after having been entered, duty shall be assessed in accordance with the procedures established in Headnote 1.

(2) Pursuant to Headnote 6 an institution desiring to enter an instrument or apparatus under tariff item 851.60 TSUS must file an application with the

Secretary of the Treasury (U.S. Customs Service) in accordance with these regulations. If the application is made in accordance with the regulations, notice of the application is published in the FEDERAL REGISTER to provide an opportunity for interested persons and government agencies to present views. The application is reviewed by the Secretary of Commerce (Director, Statutory Import Programs Staff) whose decision as to whether or not duty-free entry may be accorded the instrument is published in the FEDERAL REGISTER. An appeal of the final decision may be filed with the United States Court of Customs and Patent Appeals, on questions of law only, within 20 days after publication of the decision in the FEDERAL REGISTER.

(3) Repair components for instruments or apparatus admitted duty-free under tariff item 851.60 require no application and may be entered duty-free in accordance with the procedures prescribed in § 301.10.

(d) *Authority and delegations.* The Act authorizes the Secretaries of Commerce and the Treasury to prescribe joint regulations to carry out their functions under Headnote 6, TSUS. The Secretary of the Treasury has delegated authority to the Assistant Secretary for Enforcement and Operations, who has retained rulemaking authority and further delegated administration of the regulations to the Commissioner of the U.S. Customs Service. The authority of the Secretary of Commerce has been delegated to the Deputy Assistant Secretary for Import Administration who has retained rulemaking authority and further delegated administration of the regulations to the Director of the Statutory Import Programs Staff.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982]

§ 301.2 Definitions.

For the purposes of these regulations and the forms used to implement them:

(a) *Director* means the Director of the Statutory Import Programs Staff, International Trade Administration, U.S. Department of Commerce.

(b) *Customs* means the U.S. Customs Service and the ''The Commissioner'' means Commissioner of the U.S. Customs Service, or the official(s) designated to act on the Commissioner's behalf.

(c) *Customs Port* or *the Port* means the port where a particular claim has been or will be made for duty-free entry of a scientific instrument or apparatus under tariff item 851.60.

(d) *Entry* means entry of an instrument into the Customs territory of the United States for consumption or withdrawal of an instrument from a Customs bonded warehouse for consumption.

(e) *United States* includes only the several States, the District of Columbia and the Commonwealth of Puerto Rico.

(f) *Instrument* means only instruments and apparatus classifiable under the tariff items specified in headnote 6(a) of part 4 of Schedule 8. A combination of basic instrument or apparatus and accompanying accessories shall be treated as a single instrument provided that, under normal commercial practice, such combination is considered to be a single instrument and provided further that the applicant has ordered or, upon favorable action on its application, firmly intends to order the combination as a unit. Unless the context indicates otherwise, instrument or apparatus shall mean a foreign ''instrument or apparatus'' for which duty-free entry is sought under tariff item 851.60. Spare parts typically ordered and delivered with an instrument are also considered part of an instrument for purposes of these regulations. The term ''instruments'' shall not include:

(1) Materials or supplies used in the operation of instruments and apparatus such as paper, cards, tapes, ink, recording materials, expendable laboratory materials, apparatus that loses identity or is consumed by usage or other materials or supplies.

(2) Ordinary equipment for use in building construction or maintenance; or equipment for use in supporting activities of the institution, such as its administrative offices, machine shops, libraries, centralized computer facilities, eating facilities, or religious facilities; or support equipment such as copying machines, glass working apparatus and film processors.

(3) General purpose equipment such as air conditioners, electric typewriters, electric drills, refrigerators.

(4) General-purpose computers. Accessories to computers which are not eligible for duty-free treatment are also ineligible. Scientific instruments containing embedded computers which are to be used in a dedicated process or in instrument control, as opposed to general data processing or computation, are, however, eligible for duty-free consideration.

(5) Instruments initially imported solely for testing or review purposes which were entered under bond under tariff item 864.30, subject to the provisions of Headnote 1(a) of subpart C, part 5, schedule 8 TSUS and must be exported or destroyed within the time period specified in that headnote.

(g) *Domestic instrument* means an instrument which is manufactured in the United States. A domestic instrument need not be made exclusively of domestic components or accessories.

(h) *Accessory* has the meaning which it has under normal commercial usage. An accessory, whether part of an instrument or an attachment to an instrument, adds to the capability of an instrument. An accessory for which duty-free entry is sought under item 851.60 shall be the subject of a separate application when it is not an accompanying accessory.

(i) *Accompanying accessory* means an accessory for an instrument that is listed as an item in the same purchase order and that is necessary for accomplishment of the purposes for which the instrument is intended to be used.

(j) *Ancillary equipment* means an instrument which may be functionally related to the foreign instrument but is not operationally linked to it. Examples of ancillary equipment are vacuum evaporators or ultramicrotomes, which can be used to prepare specimens for electron microscopy. Further, equipment which is compatible with the foreign instrument, but is also clearly compatible with similar domestic instruments, such as automatic sampling equipment sold for use with a variety of mass spectrometers, will be treated as ancillary equipment. A separate application will be required for ancillary equipment even if ordered with the basic instrument.

(k) *Components* of an instrument means parts or assemblies of parts which are substantially less than the instrument to which they relate. A component enables an instrument to function at a specified minimum level, while an accessory adds to the capability of an instrument. Applications shall not be accepted for components of instruments that did not enter duty-free under tariff item 851.60 or for components of instruments being manufactured or assembled by a commercial firm or entity in the U.S. In determining whether an item is a component ineligible for duty-free consideration or an accessory eligible for such consideration, Customs shall take into account such factors as the item's complexity, novelty, degree of integration and pertinency to the research purposes to be performed by the instrument as a whole.

(l) *Produced for stock* means an instrument which is manufactured, on sale and available from a stock.

(m) *Produced on order* means an instrument which a manufacturer lists in current catalog literature and is able and willing to produce and have available without unreasonable delay to the applicant.

(n) *Custom-made* means an instrument which a manufacturer is willing and able to make to purchaser's specifications. Instruments resulting from a development effort are treated as custom-made for the purposes of these regulations. Also, a special-order variant of a produced on order instrument, with significant modifications specified by the applicant, may be treated as custom-made.

(o) *Same general category* means the category in which an instrument is customarily classified in trade directories and product-source lists, e.g., scanning electron microscope, mass spectrometer, light microscope, x-ray spectrometer.

(p) *Comparable domestic instrument* means a domestic instrument capable or potentially capable of fulfilling the applicant's technical requirements or intended uses, whether or not in the same general category as the foreign instrument.

(q) *Specifications* means the particulars of the structural, operational and performance characteristics or capabilities of a scientific instrument.

(r) *Guaranteed* specifications are those specifications which are an explicit part of the contractual agreement between the buyer and the seller (or which would become part of the agreement if the buyer accepted the seller's offer), and refer only to the minimum and routinely achievable performance levels of the instrument under specified conditions. If a capability is listed or quoted as a range (e.g., ''5 to 10 angstroms'') or as a minimum that may be exceeded (e.g., ''5 angstroms or better''), only the inferior capability may be considered the guaranteed specification. Evidence that specifications are ''guaranteed'' will normally consist of their being printed in a brochure or other descriptive literature of the manufacturer; being listed in a purchase agreement upon which the purchase is conditioned; or appearing in a manufacturer's formal response to a request for quote. If, however, no opportunity to submit a bid was afforded the domestic manufacturer or if, for any other reason, comparable guaranteed specifications of the foreign and domestic instruments do not appear on the record, other evidence relating to a manufacturer's ability to provide an instrument with comparable specifications may, at the discretion of the Director, be considered in the comparison of the foreign and domestic instruments' capabilities.

(s) *Pertinent* specifications are those specifications necessary for the accomplishment of the specific scientific research and/or science-related educational purposes described by the applicant. Specifications of features (even if guaranteed) which afford greater convenience, satisfy personal preferences, accommodate institutional commitments or limitations, or assure lower costs of acquisition, installation, operation, servicing or maintenance are not pertinent. For example, a design feature, such as a small number of knobs or controls on an instrument primarily designed for research purposes, would be a convenience. The ability to fit an instrument into a small room, when the required operations could be performed in a larger room, would be either a cost consideration or a matter of convenience and not a pertinent specification. In addition, mere difference in design (which would, for example, broaden the educational experience of students but not provide superior scientific capability) would not be pertinent. Also, unless the applicant demonstrates it is necessary for the accomplishment of its specific scientific purposes, the terms does not extend to such characteristics as size, weight, appearance, durability, reliability, complexity or (simplicity), ease of operation, ease of maintenance, productivity, versatility, ''state of the art'' design, specific design, or other such characteristics.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982]

§ 301.3 Application for duty-free entry of scientific instruments.

(a) *Who may apply.* An applicant for duty-free entry of an instrument under tariff item 851.60 must be a public or private nonprofit institution which is established for educational or scientific purposes and which has placed a bona fide order or has a firm intention to place a bona fide order for a foreign instrument within 60 days following a favorable decision on the institution's application.

(b) *Application forms.* Applications must be made on form ITA–338P which may be obtained from the Statutory Import Programs Staff, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230, or from the various District Offices of the U.S. Department of Commerce. (Approved by the Office of Management and Budget under control number 0625–0037.)

(c) *Where to apply.* Applications must be filed with the U.S. Customs Service, Department of the Treasury, at the address specified on page 1 of the form.

(d) Five copies of the form, including relevant supporting documents, must be submitted. One copy of the form shall be signed in the original by the person in the applicant institution under whose direction and control the foreign instrument will be used and who is familiar with the intended uses

of the instrument. The remaining four copies of the form may be copies of the original. Attachments should be fully identified and referenced to the question(s) on the form to which they relate.

(e) A single application (in the requisite number of copies) may be submitted for any quantity of the same type or model of foreign instrument provided that the entire quantity is intended to be used for the same purposes and provided that all units are included on a single purchase order. A separate application shall be submitted for each different type or model or variation in the type or model of instrument for which duty-free entry is sought even if covered by a single purchase order. Orders calling for multiple deliveries of the same type or model of instrument over a substantial period of time may, at the discretion of the Director, require multiple applications.

(f) Failure to answer completely all questions on the form in accordance with the instructions on the form or to supply the requisite number of copies of the form and supporting documents may result in delays in processing of the application while the deficiencies are remedied, return of the application without processing, or denial of the application without prejudice to resubmission. Any questions on these regulations or the application form should be addressed to the Director.

[47 FR 32517, July 28, 1982, as amended at 50 FR 11501, Mar. 22, 1985]

§ 301.4 Processing of applications by the Department of the Treasury (U.S. Customs Service).

(a) *Review and determination.* The Commissioner shall date each application when received by Customs. If the application appears to be complete, the Commissioner shall determine:

(1) Whether the institution is a nonprofit private or public institution established for research and educational purposes and therefore authorized to import instruments into the U.S. under tariff item 851.60. In making this determination the Commissioner will generally review the application to determine if the applicant has attached a copy of the letter from the Internal Revenue Service (IRS) granting the institution nonprofit status (exemption from Federal income tax) under section 501(c)(3) of the IRS Code or will determine if the institution is listed in a current edition of ''Cumulative List of Exempt Organizations'';

(2) Whether the instrument falls within the classes of instruments eligible for duty-free entry consideration under tariff item 851.60 (For eligible classes see Headnote 6(a), part 4, Schedule 8, TSUS); and

(3) Whether the instrument which is the subject of the application is intended for the exclusive use of the applicant institution and is not intended to be used for commercial purposes. For the purposes of this section, commercial uses would include, but not necessarily be limited to: Distribution or sale of the instrument by the applicant institution; any use by, or for the primary benefit of, a commercial entity; or use of the instrument for demonstration purposes in return for a fee or other valuable consideration. In making the above determination, the Commissioner may consider, among other things, whether the results of any research to be performed with the instrument will be fully and timely made available to the public. For the purposes of this section, use of an instrument for the treatment of patients is considered noncommercial.

If any of the Commissioner's determinations is in the negative, the application shall be found to be outside the scope of the Act and shall be returned to the applicant with a statement of the reason(s) for such findings.

(b) *Forwarding of applications to the Department of Commerce.* If the Commissioner finds the application to be within the scope of the Act and these regulations, the Commissioner shall (1) assign a number to the application and (2) forward one copy to the Secretary of the Department of Health and Human Services (HHS), and two copies, including the one that has been signed in the original, to the Director. The Commissioner shall retain one copy and return the remaining copy to the applicant stamped ''Accepted for Transmittal to the Department of Commerce.'' The applicant shall file the stamped copy of the form with the Port when formal entry of the article is made. If entry has already occurred

under a claim of tariff item 851.60, the applicant (directly or through his/her agent) shall at the earliest possible date supply the stamped copy to the Port. Further instructions for entering instruments are contained in §301.8 of the regulations.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982, as amended at 50 FR 11501, Mar. 22, 1985]

§ 301.5 Processing of applications by the Department of Commerce.

(a) *Public notice and opportunity to present views.* (1) Within 10 days of receipt of an application from the Commissioner, the Director shall make a copy available for public inspection during ordinary business hours of the Department of Commerce. Unless the Director determines that an application has deficiencies which preclude consideration on its merits (e.g., insufficient description of intended purposes to rule on the scientific equivalency of the foreign instrument and potential domestic equivalents), he shall publish in the FEDERAL REGISTER a notice of the receipt of the application to afford all interested persons a reasonable opportunity to present their views with respect to the question ''whether an instrument or apparatus of equivalent scientific value for the purpose for which the article is intended to be used is being manufactured in the United States.'' The notice will include the application number, the name and address of the applicant, a description of the instrument(s) for which duty-free entry is requested, the name of the foreign manufacturer and a brief summary of the applicant's intended purposes extracted from the applicant's answer to question 7 of the application. In addition, the notice shall specify the date the application was accepted by the Commissioner for transmittal to the Department of Commerce.

(2) If the Director determines that an application is incomplete or is otherwise deficient, he may request the applicant to supplement the application, as appropriate, prior to publishing the notice of application in the FEDERAL REGISTER. Supplemental information/material requested under this provision shall be supplied to the Director in two copies within 20 days of the date of the request and shall be subject to the certification contained in Question 11 of the form. Failure to provide the requested information on time shall result in a denial of the application without prejudice to resubmission.

(3) *Requirement for presentation of views (comments) by interested persons.* Any interested person or government agency may make written comments to the Director with respect to the question whether an instrument of equivalent scientific value, for the purposes for which the foreign instrument is intended to be used, is being manufactured in the United States. Except for comments specified in paragraph (a)(4) of this section, comments should be in the form of supplementary answers to the applicable questions on the application form. Comments must be postmarked no later than 20 days from the date on which the notice of application is published in the FEDERAL REGISTER. In order to be considered, comments and related attachments must be submitted to the Director in duplicate; shall state the name, affiliation and address of the person submitting the comment; and shall specify the application to which the comment applies. In order to preserve the right to appeal the Director's decision on a particular application pursuant to §301.6 of these regulations, a domestic manufacturer or other interested person must make timely comments on the application. Separate comments should be supplied on each application in which a person has an interest. However, brochures, pamphlets, printed specifications and the like, included with previous comments, if properly identified, may be incorporated by reference in subsequent comments. If the Director knows of the availability of a domestic instrument which may be comparable to the foreign instrument, he may: (i) Require the applicant to compare the domestic instrument with the foreign instrument; or (ii) compare the two instruments whether or not comments are received from a domestic manufacturer on the specific application.

(4) *Comments by domestic manufacturers.* Comments of domestic manufacturers opposing the granting of an application should:

(i) Specify the domestic instrument considered to be scientifically equivalent to the foreign article for the applicant's specific intended purposes and include documentation of the domestic instrument's guaranteed specifications and date of availability.

(ii) Show that the specifications claimed by the applicant in response to question 8 to be pertinent to the intended purpose can be equaled or exceeded by those of the listed domestic instrument(s) whether or not it has the same design as the foreign instrument; that the applicant's alleged pertinent specifications should not be considered pertinent within the meaning of § 301.2(s) of the regulations for the intended purposes of the instrument described in response to question 7 of the application; or that the intended purposes for which the instrument is to be used do not qualify the instrument for duty-free consideration under the Act.

(iii) Where the comments regarding paragraphs (a)(4)(i) and (a)(4)(ii) of this section relate to a particular accessory or optional device offered by a domestic manufacturer, cite the type, model or other catalog designation of the accessory device and include the specification therefor in the comments.

(iv) Where the justification for duty-free entry is based on excessive delivery time, show whether:

(A) The domestic instrument is as a general rule either produced for stock, produced on order, or custom-made and;

(B) An instrument or apparatus of equivalent scientific value to the article, for the purposes described in response to question 7, could have been produced and delivered to the applicant within a reasonable time following the receipt of the order.

(v) Indicate whether the applicant afforded the domestic manufacturer an opportunity to furnish an instrument or apparatus of equivalent scientific value to the article for the purposes described in response to question 7 and, if such be the case, whether the applicant submitted a formal invitation to bid that included the technical requirements of the applicant.

(5) *Untimely comments.* Comments must be made on a timely basis to ensure their consideration by the Director and the technical consultants, and to preserve the commenting person's right to appeal the Director's decision on an application. The Director, in his discretion, may entertain comments filed untimely to the extent that they contain factual information, as opposed to arguments, explanations or recommendations.

(6) *Provision of general comments.* A domestic manufacturer who does not wish to oppose duty-free entry of a particular application, but who desires to apprise the Director of the availability and capabilities of its instrument(s), may at any time supply documentation to the Director without reference to a particular application. Such documentation shall be routinely taken into account by the Director when applications involving comparable foreign instruments are received. The provision of general comments does not preserve the commentor's right to appeal the Director's decision on a particular application.

(7) *Provision of application to domestic manufacturers.* To facilitate timely comments, the Director may furnish copies of certain applications to domestic manufacturers who intend to comment on applications, provided:

(i) The manufacturer requests the service in writing;

(ii) The manufacturer provides copies of current company literature regarding the domestic instrument and its guaranteed capabilities; and

(iii) The manufacturer identifies the specific models or types of comparable foreign instrument(s) that it proposes to comment on. The Director may furnish for comment copies of the appropriate applications to the domestic manufacturer until the firm requests that the service be discontinued, provided the firm utilizes the service to supply written comments on applications. If the recipient of the service fails to avail itself of the opportunity to comment on appropriate applications for a period of one year, the Director may at his discretion discontinue the service. For reasons of cost and administrative burden, the service may be discontinued at the discretion of the Director. In such case the Director shall notify all recipients

of the service in writing of such discontinuance.

(b) *Additions to the record.* The Director may solicit from the applicant or from foreign or domestic manufacturers, and agents thereof, or any other person or Government agency considered by the Director to have competence on any issue pertaining to an application, any additional information the Director deems necessary to the rendering of a decision. The Director may attach such conditions and time limitations deemed appropriate upon the provision of such information and may draw appropriate inferences from a person's failure to provide the requested information.

(c) *Advice from technical consultants.*

(1) The Director shall consider any written advice from the Secretary of HHS, or his delegate, on the question whether a domestic instrument of equivalent scientific value to the foreign instrument, for the purposes for which the instrument is intended to be used, is being manufactured in the United States.

(2) After the comment period has ended (§ 301.5(a)(3)), the complete application and any comments received and related information are forwarded to the appropriate technical consultants for their written advice.

(3) The technical consultants are requested to provide their written recommendation within 30 days of the date of transmittal. The technical consultants relied upon for advice may include, but are not limited to, the National Institutes of Health (delegated the function by the Secretary of HHS), the National Bureau of Standards and the National Oceanographic and Atmospheric Administration.

(d) *Criteria for the determinations of the Department of Commerce*—(1) *Scientific equivalency.* (i) The determination of scientific equivalency shall be based on a comparison of the pertinent specifications of the foreign instrument with similar pertinent specifications of comparable domestic instruments (see § 301.2(s) for the definition of pertinent specification). Ordinarily, the Director will consider only those performance characteristics which are ''guaranteed specifications'' within the meaning of § 301.2(r) of this part. In no event, however, shall the Director consider performance capabilities superior to the manufacturer's guaranteed specifications or their equivalent. In making the comparison the Director may consider a reasonable combination of domestic instruments that combines two or more functions into an integrated unit if the combination of domestic instruments is capable of accomplishing the purposes for which the foreign instrument is intended to be used. If the Director finds that a domestic instrument possesses all of the pertinent specifications of the foreign instrument, he shall find that there is being manufactured in the United States an instrument of equivalent scientific value for such purposes as the foreign instrument is intended to be used. If the Director finds that the foreign instrument possesses one or more pertinent specifications not possessed by the comparable domestic instrument(s), the Director shall find that there is not being manufactured in the United States an instrument of equivalent scientific value to the foreign instrument for such purposes as the foreign instrument is intended to be used.

(ii) Programs that may be undertaken at some unspecified future date shall not be considered in the Director's comparison. In making the comparison, the Director shall consider only the instrument and accompanying accessories described in the application and determined eligible by the U.S. Customs Service. The Director shall not consider the planned purchase of additional accessories or the planned conversion of the article at some unspecified future time for such programs.

(iii) In order for the Director to make a determination with respect to the ''scientific equivalency'' of the foreign and domestic instruments, the applicant's intended purposes must include either scientific research or science-related educational programs. Instruments used exclusively for nonscientific purposes have no scientific value, thereby precluding the requisite finding by the Director with respect to ''whether an instrument or apparatus of equivalent scientific value to such article, for the purposes for which the article is intended to be used, is being

manufactured in the United States.'' In such cases the Director shall deny the application for the reason that the instrument has no scientific value for the purposes for which it is intended to be used. Examples of nonscientific purposes would be the use of an instrument in routine diagnosis or patient care and therapy (as opposed to clinical research); in teaching a nonscientific trade (e.g., printing, shoemaking, metalworking or other types of vocational training); in teaching nonscientific courses (e.g., music, home economics, journalism, drama); in presenting a variety of subjects or merely for presenting coursework, whether or not science related (e.g., video tape editors, tape recorders, projectors); and in conveying cultural information to the public (e.g., a planetarium in the Smithsonian Institution).

(2) *Manufactured in the United States.* An instrument shall be considered as being manufactured in the United States if it is customarily ''produced for stock,'' ''produced on order'' or ''custom-made'' within the United States. In determining whether a U.S. manufacturer is able and willing to produce an instrument, and have it available without unreasonable delay, the normal commercial practices applicable to the production and delivery of instruments of the same general category shall be taken into account, as well as other factors which in the Director's judgment are reasonable to take into account under the circumstances of a particular case. For example, in determining whether a domestic manufacturer is able to produce a custom-made instrument, the Director may take into account the production experience of the domestic manufacturer including (i) the types, complexity and capabilities of instruments the manufacturer has produced, (ii) the extent of the technological gap between the instrument to which the application relates and the manufacturer's customary products, (iii) the manufacturer's technical skills, (iv) the degree of saturation of the manufacturer's production capability, and (v) the time required by the domestic manufacturer to produce the instrument to the purchaser's specification. Whether or not the domestic manufacturer has field tested or demonstrated the instrument will not, in itself, enter into the decision regarding the manufacturer's ability to manufacture an instrument. Similarly, in determining whether a domestic manufacturer is willing to produce an instrument, the Director may take into account the nature of the bid process, the manufacturer's policy toward manufacture of the product(s) in question, the minimum size of the manufacturer's production runs, whether the manufacturer has bid similar instruments in the past, etc. Also, if a domestic manufacturer was formally requested to bid an instrument, without reference to cost limitations and within a leadtime considered reasonable for the category of instrument involved, and the domestic manufacturer failed formally to respond to the request, for the purposes of this section the domestic manufacturer would not be considered willing to have supplied the instrument.

(3) *Burden of proof.* The burden of proof shall be on the applicant to demonstrate that no instrument of equivalent scientific value for the purposes for which the foreign instrument is to be used is being manufactured in the United States. Evidence of applicant favoritism towards the foreign manufacturer (advantages not extended to domestic firms, such as additional lead time, know-how, methods, data on pertinent specifications or intended uses, results of research or development, tools, jigs, fixtures, parts, materials or test equipment) may be, at the Director's discretion, grounds for rejecting the application.

(4) *Excessive delivery time.* Duty-free entry of the instrument shall be considered justified without regard to whether there is being manufactured in the United States an instrument of equivalent scientific value for the intended purposes if excessive delivery time for the domestic instrument would seriously impair the accomplishment of the applicant's intended purposes. For purposes of this section, (i) except when objective and convincing evidence is presented that, at the time of order, the actual delivery time

would significantly exceed quoted delivery time, no claim of excessive delivery time may be made unless the applicant has afforded the domestic manufacturer an opportunity to quote and the delivery time for the domestic instrument exceeds that for the foreign instrument; and (ii) failure by the domestic manufacturer to quote a specific delivery time shall be considered a non-responsive bid (see §301.5(d)(2)). In determining whether the difference in delivery times cited by the applicant justifies duty-free entry on the basis of excessive delivery time, the Director shall take into account (A) the normal commercial practice applicable to the production of the general category of instrument involved; (B) the efforts made by the applicant to secure delivery of the instruments (both foreign and domestic) in the shortest possible time; and (C) such other factors as the Director finds relevant under the circumstances of a particular case.

(e) *Denial without prejudice to resubmission (DWOP).* The Director may, at any stage in the processing of an application by the Department of Commerce, DWOP an application if the application contains any deficiency which, in the Director's judgment, prevents a determination on its merits. The Director shall state the deficiences of the application in a letter to the applicant in making the provisional denial.

(1) The applicant has 60 days from the date of the DWOP to correct the cited deficiencies in the application unless a request for an extension of time for submission of the supplemental information has been received by the Director prior to the expiration of the 60-day period and is approved.

(2) The written request (letter or telegram) for an extension should indicate the reasons for the request and the amount of additional time needed. If granted, extensions of time will generally be limited to 30 days.

(3) Resubmissions must reference the application number of the earlier application. The resubmission shall be made by letter and filed in quadruplicate with the Director. The record of a resubmitted application shall include the original submission on file with the Department. Any new material or information contained in a resubmission, which should address the specific deficiencies cited in the DWOP letter, should be clearly labeled and referenced to the applicable question(s) on the application form. The resubmission should be signed and dated by the individual in the applicant institution who signed the original application or, in his/her absence, the individual in the applicant institution under whose direction and control the foreign instrument will be used and who is familiar with the intended uses of the instrument. The resubmission must be for the instrument covered by the original application unless the DWOP letter specifies to the contrary. The resubmission shall be subject to the certification contained in question 11 on the original application.

(4) If the applicant fails to resubmit within the applicable time period, the prior DWOP shall, irrespective of the merits of the case, result in a denial of the application.

(5) The Director shall use the postmark date of the fully completed resubmission in determining whether the resubmission was made within the allowable time period. Certified or registered mail, or some other means which can unequivocally establish the date of mailing, is recommended.

(6) The applicant may, at any time prior to the end of the resubmission period, notify the Director in writing that it does not intend to resubmit the application. Upon such notification, the application will be deemed to have been withdrawn. (See §301.5(g).)

(7) Information provided in a resubmission that, in the judgment of the Director, contradicts or conflicts with information provided in a prior submission, or is not a reasonable extension of the information contained in the prior submission, shall not be considered in making the decision on an application that has been resubmitted. Accordingly, an applicant may elect to reinforce an orginal submission by elaborating in the resubmission on the description of the purposes contained in a prior submission and may supply additional examples, documentation and/or other clarifying detail, but the applicant shall not introduce new purposes

or other material changes in the nature of the original application. The resubmission should address the specific deficiencies cited in the DWOP. The Director may draw appropriate inferences from the failure of an applicant to attempt to provide the information requested in the DWOP.

(8) In the event an applicant fails to address the noted deficiencies in the response to the DWOP, the Director may deny the application.

(9) Upon receipt of a responsive resubmission the Director shall publish a notice in the FEDERAL REGISTER citing the number of the earlier application, the name and address of the applicant institution, the instrument(s) involved, and any other information the Director deems relevant. The notice will also include the FEDERAL REGISTER citation for the original notice of application. Procedures applicable to comments on the processing of original applications shall thereafter apply.

(f) *Decisions on applications.* The Director shall prepare a written decision granting or denying each application. However, when he deems appropriate, the Director may issue a consolidated decision on two or more applications. The Director shall promptly forward a copy of the decision to each applicant institution and to the FEDERAL REGISTER for publication.

(g) *Withdrawal of applications.* The Director shall discontinue processing an application withdrawn by the applicant and shall publish notice of such withdrawal in the FEDERAL REGISTER. If at any time while its application is pending before the Director, either during the intital application or resubmission stage, an applicant cancels an order for the instrument to which the application relates or ceases to have a firm intention to order such instrument or apparatus, the institution shall promptly notify the Director. Such notification shall constitute a withdrawal. Withdrawals shall be considered as having been finally denied for purposes of § 301.7(c) below.

(h) Nothing in this subsection shall be construed as limiting the Director's discretion at any stage of processing to insert into the record and consider in making his decision any information in the public domain which he deems relevant.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982, as amended at 50 FR 11501, Mar. 22, 1985]

§ 301.6 Appeals.

(a) An appeal from any decision made pursuant to § 301.5(f) may be taken, in accordance with headnote 6(e) to part 4 of Schedule 8, only to the U.S. Court of Customs and Patent Appeals and only on questions of law, within 20 days after publication of the decision in the FEDERAL REGISTER. If at any time while its application is under consideration by the Court of Customs and Patent Appeals on an appeal from a finding by the Director an institution cancels an order for the instrument to which the application relates or ceases to have a firm intention to order such instrument, the institution shall promptly notify the court.

(b) An appeal may be taken by: (1) The institution which makes the application;

(2) A person who, in the proceeding which led to the decision, timely represented to the Secretary of Commerce in writing that he/she manufactures in the United States an instrument of equivalent scientific value for the purposes for which the instrument to which the application relates is intended to be used;

(3) The importer of the instrument, if the instrument to which the application relates has been entered at the time the appeal is taken; or

(4) An agent of any of the foregoing.

(c) Questions regarding appeal procedures should be addressed directly to the U.S. Court of Customs and Patent Appeals, Clerks' Office, Washington, DC 20439.

§ 301.7 Final disposition of an application.

(a) Disposition of an application shall be final when 20 days have elapsed after publication of the Director's final decision in the FEDERAL REGISTER (see § 301.6(a)) and no appeal has been taken pursuant to § 301.6 of these regulations, of if such appeal has been taken, when final judgment is made and entered by the Court.

(b) The Director shall notify the Customs Port when disposition of an application becomes final. If the Director has not been advised of the port of entry of the instrument, or if entry has not been made when the decision on the application becomes final, the Director shall notify the Commissioner of final disposition of the application.

(c) An instrument, the duty-free entry of which has been finally denied, may not be the subject of a new application from the same institution.

§ 301.8 Instructions for entering instruments through U.S. Customs under tariff item 851.60.

Failure to follow the procedures in this section may disqualify an instrument for duty-free entry notwithstanding an approval of an application on its merits by the Department of Commerce.

(a) *Entry procedures.* (1) An applicant desiring duty-free entry of an instrument may make a claim at the time of entry of the instrument into the Customs territory of the United States that the instrument is entitled to duty-free classification under tariff item 851.60.

(2) If no such claim is made the instrument shall be immediately classified without regard to tariff item 851.60, duty will be assessed, and the entry liquidated in the ordinary course.

(3) If a claim is made for duty-free entry under tariff item 851.60, the entry shall be accepted without requiring a deposit of estimated duties provided that a copy of the form, stamped by Customs as accepted for transmittal to the Department of Commerce in accordance with §301.4(b), is filed simultaneously with the entry.

(4) If a claim for duty-free entry under tariff item 851.60 is made but is not accompanied by a copy of the properly stamped form, a deposit of the estimated duty is required. Liquidation of the entry shall be suspended for a period of 180 days from the date of entry. On or before the end of this suspension period the applicant must file with the Customs Port a properly stamped copy of the form. In the event that the Customs Port does not receive a copy of the properly stamped form within 180 days the instrument shall be classified and liquidated in the ordinary course, without regard to tariff item 851.60.

(5) Entry of an instrument after the Director's approval of an application. Whenever an institution defers entry until after it receives a favorable final determination on the application for duty-free entry of the instrument, the importer shall file with the entry of the instrument (i) the stamped copy of the form, (ii) the institution's copy of the favorable final determination and (iii) proof that a bona fide order for the merchandise was placed on or before the 60th day after the favorable decision became final pursuant to §301.7 of these regulations. Liquidation in such case shall be made under tariff item 851.60.

(b) *Normal Customs entry requirements.* In addition to the above entry requirements mentioned in paragraph (a) of this section, the normal Customs entry requirements must be met. In most of the cases, the value of the merchandise will be such that the formal Customs entry requirements, which generally include the filing of a Customs entry bond, must be complied with. (For further information, see 19 CFR 142.3 and 142.4 (TD–221).)

(c) *Late filing.* Notwithstanding the preceding provisions of §301.8 any document, form, or statement required by regulations in this section to be filed in connection with the entry may be filed at any time before liquidation of the entry becomes final, provided that failure to file at the time of entry or within the period for which a bond was filed for its production was not due to willful negligence or fraudulent intent. Liquidation of any entry becomes conclusive upon all persons if the liquidation is not protested in writing in accordance with 19 CFR part 174, or the necessary document substantiating duty-free entry is not produced in accordance with 19 CFR 10.112, within 90 days after notice of liquidation. Upon notice of such final and conclusive liquidation, the Department of Commerce will cease the processing of any pending application for duty-free entry of the subject article. In all other respects, the provisions of this section do not apply to Department of Commerce

responsibilities and procedures for processing applications pursuant to other sections of these regulations.

(d) *Payment of duties.* The applicant will be billed for payment of duties when Customs determines that such payment is due.

§ 301.9 Uses and disposition of instruments entered under item 851.60, TSUS.

(a) An instrument granted duty-free entry may be transferred from the applicant institution to another eligible institution provided the latter institution agrees not to use the instrument for commercial purposes within 5 years of the date of entry of the instrument. In such cases title to the instrument must be transferred directly between the institutions involved. An institution transferring a foreign instrument entered under item 851.60 within 5 years of its entry shall so inform the Customs Port in writing and shall include the following information:

(1) The name and address of the transferring institution.

(2) The name and address of the transferee.

(3) The date of transfer.

(4) A detailed description of the instrument.

(5) The serial number of the instrument and any accompanying accessories.

(6) The entry number, date of entry, and port of entry of the instrument.

(b) Whenever the circumstances warrant, and occasionally in any event, the fact of continued use for 5 years for noncommercial purposes by the applicant institution shall be verified by Customs.

(c) If an instrument is transferred in a manner other than specified above or is used for commercial purposes within 5 years of entry, the institution for which such instrument was entered shall promptly notify the Customs officials at the Port and shall be liable for the payment of duty in an amount determined on the basis of its condition as imported and the rate applicable to it.

§ 301.10 Importation of repair components under item 851.65 for article previously entered under item 851.60.

(a) An institution which owns an instrument entered under tariff item 851.60 and desires to enter repair components for such instrument under tariff item 851.65 may do so without regard to the application procedures applicable to entries under item 851.60 provided the institution certifies to the customs official at the port of entry upon entry of such components that they are needed repair components for an instrument owned by that institution and previously entered and classified under tariff item 851.60.

(b) Instruments entered under item 851.60 and subsequently returned to the foreign manufacturer for repair, replacement or modification are not covered by tariff item 851.65, although they may, in certain circumstances, be considered non-dutiable under other Customs provisions (e.g., drawback within the specified period pursuant to 19 U.S.C. 1313(c)). Such instruments, if classified as dutiable by Customs, may nevertheless be made the subject of a new application under tariff item 851.60.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982]

PART 302 [RESERVED]

PART 303—WATCHES, WATCH MOVEMENTS AND JEWELRY PROGRAM

Subpart A—Watches and Watch Movements

Sec.