# CHAPTER III—INTERNATIONAL TRADE ADMINISTRATION, DEPARTMENT OF COMMERCE

SUBCHAPTER A—MISCELLANEOUS REGULATIONS

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## PART 300 [RESERVED]

## PART 301—INSTRUMENTS AND APPARATUS FOR EDUCATIONAL AND SCIENTIFIC INSTITUTIONS

Sec.



AUTHORITY: Sec. 6(c), Pub. L. 89–651, 80 Stat. 897, 899; Sec. 2402, Pub. L. 106–36, 113 Stat. 127, 168; 19 U.S.C. 1514(c)(3)); and Presidential Proclamation 7011, signed on June 30, 1997.

SOURCE: 47 FR 32517, July 28, 1982, unless otherwise noted.

### § 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, 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) The Annex D provisions are implemented for U.S. purposes in Subchapter X, Chapter 98, Harmonized Tariff Schedule of the United States (HTSUS).

(c) *Summary of statutory procedures and requirements.* (1) U.S. Note 1, Subchapter X, Chapter 98, HTSUS, provides, among other things, that articles covered by subheadings 9810.00.60 (scientific instruments and apparatus), 9810.00.65 (repair components therefor) and 9810.00.67 (tools for maintaining and testing the above), HTSUS, must be exclusively for the use of the institutions involved and not for distribution, sale, or other commercial use within five years after entry. These articles may be transferred to another qualified nonprofit institution, but any commercial use within five years of entry shall result in the assessment of applicable duties pursuant to §301.9(c).

(2) An institution wishing to enter an instrument or apparatus under tariff subheading 9810.00.60, HTSUS, must file an application with the Customs and Border Protection in accordance with the regulations in this section. 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) , who decides whether or not duty-free entry may be accorded the instrument and publishes the decision in the FEDERAL REGISTER. An appeal of the final decision may be filed with the U.S. Court of Appeals for the Federal Circuit, on questions of law only, within 20 days after publication in the FEDERAL REGISTER.

(3) Repair components for instruments or apparatus admitted duty-free under subheading 9810.00.60, HTSUS require no application and may be entered duty-free in accordance with the procedures prescribed in § 301.10.

(4) Tools specifically designed to be used for the maintenance, checking, gauging or repair of instruments or apparatus admitted under subheadings 9810.00.65 and 9810.00.67, HTSUS, 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 U.S. Note 6, Subchapter X, Chapter 98, HTSUS. The Secretary of the Treasury has delegated authority to the Assistant Secretary for Enforcement, who has retained rulemaking authority and further delegated administration of the regulations to the Commissioner of the Customs and Border Protection. The authority of the Secretary of Commerce has been delegated to the Assistant Secretary for Enforcement and Compliance 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, as amended at 66 FR 28832, May 25, 2001; 74 FR 30463, June 26, 2009; 78 FR 72571, Dec. 3, 2013]

### § 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) *The Commissioner* means Commissioner of Customs and Border Protection, or the official(s) designated to act on the Commissioner's behalf.

(c) *CBP 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 subheading 9810.00.60, HTSUS.

(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 instruments and apparatus specified in U.S. Note 6(a), Subchapter X, Chapter 98, HTSUS. 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. The term ''instrument'' also covers separable components of an instrument that are imported for assembly in the United States in such instrument where that instrument, due to its size, cannot feasibly be imported in its assembled state. The components, as well as the assembled instrument itself, must be classifiable under the tariff provisions listed in U.S. Note 6(a), Subchapter X, Chapter 98, HTSUS. See paragraph (k) of this section and § 301.3(f). Unless the context indicates otherwise, instrument or apparatus shall mean a foreign ''instrument or apparatus'' for which duty-free entry is sought under subheading 9810.00.60, HTSUS. 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 subheading 9813.00.30, HTSUS, subject to the provisions of U.S. Note 1(a), Subchapter XIII, Chapter 98, HTSUS, and must be exported or destroyed within the time period specified in that U.S. Note.

(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 subheading 9810.00.60, HTSUS shall be the subject of a separate application when it is not an accompanying accessory. The existing instrument, for which the accessory is being purchased, may be domestic or, if foreign, it need not have entered duty free under subheading 9810.00.60, HTSUS.

(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 a vacuum evaporator sold for use with an electron microscope, 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 subheading 9810.00.60, HTSUS 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 and Border Protection 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. The above notwithstanding, separable components of some instruments may be eligible for duty-free treatment. See paragraph (f) of this section.

(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, light microscope.

(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 nanometers'') 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. Performance results on a test sample run at the applicant's request may be cited as evidence for or against a guaranteed specification.

(s) *Pertinent* specifications are those specifications necessary for the accomplishment of the specific scientific research 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, characteristics such as size, weight, appearance, durability, reliability, complexity (or simplicity), ease of operation, ease of maintenance, productivity, versatility, ''state of the art'' design, specific design and compatibility with currently owned or ordered equipment are not pertinent unless the applicant demonstrates that the characteristic is necessary for the accomplishment of its scientific purposes.

[47 FR 32517, July 28, 1982; 47 FR 34368, Aug. 9, 1982, as amended at 66 FR 28832, May 25, 2001; 74 FR 30463, June 26, 2009]

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

(a) *Who may apply*. An applicant for duty-free entry of an instrument under subheading 9810.00.60, HTSUS 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, the Web site at *http://ia.ita.doc.gov/sips/index.html*, or from the

various District Offices of the U.S. Department of Commerce.

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

(d) Five copies of the form, including relevant supporting documents, must be submitted. One of these copies 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) An application for components of an instrument to be assembled in the United States as described in § 301.2(f) may be filed provided that all of the components for the complete, assembled instrument are covered by, and fully described in, the application. See also § 301.2(k).

(g) 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.

(Approved by the Office of Management and Budget under control number 0625–0037)

[47 FR 32517, July 28, 1982, as amended at 50 FR 11501, Mar. 22, 1985; 66 FR 28833, May 25, 2001; 74 FR 30463, June 26, 2009]

### § 301.4 Processing of applications by the Department of the Treasury (Customs and Border Protection).

(a) *Review and determination*. The Commissioner shall date each application when received by Customs and Border Protection. 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 subheading 9810.00.60, HTSUS. In making this determination, the Commissioner may require applicants to document their eligibility under this paragraph;

(2) Whether the instrument or apparatus falls within the classes of instruments eligible for duty-free entry consideration under subheading 9810.00.60, HTSUS. For eligible classes, see U.S. Note 6(a), Subchapter X, Chapter 98, HTSUS; and

(3) Whether the instrument or apparatus is 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, lease 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, price discount or other valuable consideration. Evaluation, modification or testing of the foreign instrument, beyond normal, routine acceptance testing and calibration, to enhance or expand its capabilities primarily to benefit the manufacturer in return for a discount or other valuable consideration, may be considered a commercial benefit. 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 subheading 9810.00.60, HTSUS , 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; 66 FR 28833, May 25, 2001; 74 FR 30463, June 26, 2009]

### § 301.5 Processing of applications by the Department of Commerce.

(a) *Public notice and opportunity to present views.* (1) Within 5 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 on the form. Failure to provide the requested information on time shall result in a denial of the application without prejudice to resubmission pursuant to paragraph (e) of this section.

(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.

(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 issued an 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. The Director, at his discretion, may take into account factual information contained in untimely comments.

(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 inform 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 taken into account by the Director when applications involving comparable foreign instruments are received. The provision of general comments does not preserve the provider's right to appeal the Director's decision.

(b) *Additions to the record.* The Director may solicit from the applicant, from foreign or domestic manufacturers, their agents, or any other person or Government agency considered by the Director to have related competence, any additional information the Director considers necessary to make a decision. The Director may attach conditions and time limitations

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 appropriate technical consultants for their advice.

(3) The technical consultants relied upon for advice include, but are not limited to, the National Institutes of Health (delegated the function by the Secretary of HHS), the National Institute of Standards and Technology 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 brings together 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, 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 Customs and Border Protection. The Director shall not consider the planned purchase of additional accessories or the planned adaptation of the article at some unspecified future time.

(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.

(5) *Processing of applications for components.* (i) The Director may process an application for components which are to be assembled in the United States into an instrument or apparatus which, due to its size, cannot be imported in its assembled state (see § 301.2(k)) as if it were an application for the assembled instrument. A finding by the Director that no equivalent instrument is being manufactured in the United States shall, subject to paragraph (d)(5)(ii) of this section, qualify all the associated components, provided they are entered within the period established by the Director, taking into account both the scientific needs of the importing institution and the potential for development of related domestic manufacturing capacity.

(ii) Notwithstanding a finding under paragraph (d)(5)(i) of this section that no equivalent instrument is being manufactured in the United States, the Director shall disqualify a particular component for duty-free treatment if the Director finds that the component is being manufactured in the United States.

(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 it contains any deficiency which, in the Director's judgment, prevents a determination on its merits. The Director shall state the deficiencies of the application in the DWOP letter to the applicant.

(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) If granted, extensions of time will generally be limited to 30 days.

(3) Resubmissions must reference the application number of the earlier submission. The resubmission may be made by letter to 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 on the application form. 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 made 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. Resubmission by fax, e-mail or other electronic means is acceptable provided an appropriate return number or address is provided in the transmittal. Resubmissions must clearly indicate the date of transmittal to the Director.

(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.

(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; 66 FR 28833, May 25, 2001; 74 FR 30463, June 26, 2009]

### § 301.6 Appeals.

(a) An appeal from a final decision made by the Director under § 301.5(f) may be taken in accordance with U.S. Note 6(e), Subchapter X, Chapter 98, HTSUS, only to the U.S. Court of Appeals for the Federal Circuit 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 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 Appeals for the Federal Circuit, Clerk's Office, Washington, DC 20439.

[47 FR 32517, July 28, 1982, as amended at 66 FR 28834, May 25, 2001]

### § 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 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 CBP 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,