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REPLIES TO QUESTIONNAIRE ON IMPORT LICENSING PROCEDURES

UNITED STATES

Addendum

Information on import licensing procedures of the United States submitted in response to the questionnaire annexed to document L/5106, has been made available to contracting parties in documents L/5131 and L/5131/Add.1. The following notification describes the procedures maintained by:

1. United States Nuclear Regulatory Commission in respect of nuclear facilities and materials, and
2. Department of Health and Human Services, Public Health Service, Food and Drugs Administration in respect of biological products.

The information reproduced below supplements the data previously submitted by the United States:

1. United States Nuclear Regulatory Commission: Nuclear Facilities and Materials

Outline of systems

1. Nuclear Regulatory Commission regulations governing import licences are published in 10 CFR 110.^{1/} They are based upon the Atomic Energy Act of 1954, as amended, and Title II of the Energy Reorganization Act of 1974, as amended. The regulations apply to all persons in the United States other than for the import of nuclear material or technology by the Department of Energy or Defense under authority of Sections 54, 57b, 64, 82, 91, 144b and 144c of the Atomic Energy Act.

"Import" is defined as an import into the United States. Sub-part D of the regulations gives instructions for making applications for specific licences. Paragraph 10 CFR 110.34 specifically covers the requirements for import licences. There is no prescribed form for this application, the usual submission being in the form of a letter.

^{1/} A copy of this document is available for reference in the Technical and Other Barriers to Trade Division, Room 1070, Centre William Rappard.

Purposes and coverage of the licensing

2. The list of items under NRC import licensing authority is found in Appendix A to 10 CFR 110.
3. The system applies to goods originating in and coming from all countries.
4. The licensing is not intended to restrict quantity or value of imports. The primary purposes for licensing controls over imports are related to health and safety matters, to controls over possession, use, distribution, manufacture and transport, and to considerations of inimicality to the common defence and security of the United States.

Alternative methods of accomplishing the purposes of import licensing are considered and, to the extent these other methods are acceptable, import licensing regulations reflect these alternatives. For example, paragraph 10 CFR 110.11 exempts nuclear equipment source material and by-product material from specific licensing requirements when other acceptable conditions apply. In addition, elimination of certain specific import licence requirements for special nuclear material is currently under review.

5. As mentioned in reply No. 1, the NRC regulations in 10 CFR 110 are issued pursuant to the Atomic Energy Act of 1954, as amended, and Title II of the Energy Reorganization Act of 1974, as amended. The Nuclear Nonproliferation Act of 1978 also applies, but for exports only, and does not directly affect import licensing requirements. The legislation defines the products and facilities subject to licensing controls with minimum discretion in definitions left to administrative determination.

Procedures

6. Products are not restricted as to quantity or value of imports; therefore, this question is not applicable.

7(a) There is no fixed period for submission of a licence application in advance of importation, other than the times prescribed in 10 CFR 110 required for public notice of receipt of the application. (See 10 CFR 110.70 and 10 CFR 110.82.) The Commission does have the prerogative for granting specific exemptions from the regulations in 10 CFR 110 under certain conditions (see 10 CFR 110.10) and this prerogative has been exercised on occasions to grant licences within a short period of time.

(b) A specific licence would rarely be granted immediately upon request. The applicant should anticipate a review period of three to six weeks from date of application.

(c) There are no limitations as to the period of the year during which the licence application or importation may be made.

(d) For materials and equipment subject to Nuclear Regulatory Commission licensing authority, the NRC is the only agency with which the importer must correspond. On occasions, the NRC will refer applications to other interested Federal agencies for input into the licensing process (usually to the Departments of State and Energy), although the final licensing responsibility remains with NRC. Because the Department of Commerce also has licensing responsibilities for many items which are nuclear-related or dual-use in nature, NRC co-ordinates general policy and some specific cases with that Department.

8. No import licence has been refused, to date. It is unlikely one would be refused for reasons other than failure to meet the ordinary (statutory) criteria. Reasons for refusal to issue would be made known to an applicant and there would be rights of appeal. The avenues open to the applicant are given in Sub-parts H, I, J, K and L of 10 CFR 110.

9. Not specified

Documentational and other requirements for application of licence

10. Information required in applications is set out in 10 CFR 110.34. There is no prescribed form. The usual submission is in letter form. The importer may support his application with other documents of his choosing. NRC may request additional information, if necessary, to conduct the licensing review required by applicable statutes.

11. The NRC does not require any documents for the importation, other than the import authorization itself (licence). However, the customary import forms required by other government agencies will be necessary (Customs Service and the Department of Commerce documents, for example). There are certain reporting requirements when the transfer of nuclear material is involved, but these are not related to the import authorization.

12. There is no fee or administrative charge.

13. There is no deposit or advance payment required.

Conditions on licensing

14. An import licence is usually valid for a period of one year from the date of issuance but the validity date can be for a longer period if the applicant so requests and the NRC agrees. The licence expiration date will be extended, in almost all cases, upon request by the licensee.

15. There is no penalty for failure to use a licence.

16. A licence may be transferred or assigned to another person only with the approval of the Commission by licence amendment.

17. Licences often are conditioned with respect to transportation requirements, security provisions, notification requirements.

Other procedural requirements

18. Because the materials most often imported under NRC licences are considered hazardous and frequently are of strategic significance, other administrative arrangements are necessary in conjunction with their transportation. These arrangements may involve such things as physical protection, special handling procedures for health and safety purposes, or advance notice of pending receipt; however, these requirements are not part of the import authorization itself. They are general requirements placed on persons who transfer or receive specific types of materials, whether the shipment is a domestic one or from abroad.

19. The formalities for obtaining foreign currencies or its availability are not specified.

2. Department of Health and Human Services, Public Health
Service - Food and Drug Administration:
Biological Products

Outline of systems

1. Biological products and establishments are subject to licensing under Section 351 of the Public Health Service Act which requires the obtaining of both an establishment and product licence by the domestic or foreign manufacturer prior to introduction of the product for marketing in inter-State commerce. The statutory authority is Section 351 of the Public Health Service Act (42 USC 262).

The following comments provided in answer to the questionnaire annexed to document L/5106 are based upon the singular licensing system for both foreign and domestic manufacturers.

Purposes and coverage of the licensing

2. All biological products intended for use in man are licensed under Section 351 of the Public Health Service Act and included in the current Licensed Establishments and Products book, Publication No. FDA 81-9003.¹

3. A computer printed listing includes the currently licensed foreign establishments and the products they are authorized to import.

¹ A copy of this document is available for reference in the Technical and Other Barriers to Trade Division, Room 1070, Centre William Rappard.

4. Licensing does not restrict the quantity or value of imports. Its purpose is to assure that safe, pure, potent and effective biological products only are introduced for marketing in the country. Consideration of alternative methods has not been deemed necessary.

5. The statutory authority for licensing of biological products is Section 351 of the Public Health Service Act (42 USC 262). All products defined by the statute or by regulations (21 CFR 600.3)¹ promulgated thereunder require licensure. It is not possible for the Government (or the executive branch) to abolish the system without legislative approval.

Procedures

6. No biological products are under the restrictions as to the quantity or value of imports.

7(a) Application for product licensure may be applied for after the manufacturer has documented that the product is safe and effective. If such documentation and required data are complete at time of filing, approval can usually be accomplished following (1) an establishment inspection, (2) satisfactory testing of the product(s) and (3) administrative review of the application. No biological products may be imported until a licence is issued and a licence cannot be issued until safety and efficacy have been demonstrated. There is no provision for an abbreviated approval procedure for licensing of biological products.

(b) No. See answer to question 7(a) above.

(c) No

(d) The Bureau of Biologics of the Food and Drug Administration has the sole responsibility for the approval of biological product licences intended for use in man. No other administrative organs are required for the approval of imported biological products except for products of animal origin. See the response to question No. 18 - other procedural requirements.

8. It is the practice of the Bureau of Biologics to reject an initial submission of an application by a manufacturer if it is determined to be incomplete to such an extent that a technical and regulatory review cannot be performed. Also, after the initial submission, if a manufacturer fails to submit additional data and information needed for licensure, the Bureau will put the manufacturer on notice that his application will be placed in the Inactive Files unless he responds with the requested information and data within sixty days. Normally it is the practice of the Bureau to give the applicant every opportunity to obtain a licence, and so long as the manufacturer is making a sincere effort toward that goal, the Bureau will

¹ A copy of this document is available for reference in the Technical and Other Barriers to Trade Division, Room 1070, Centre William Rappard.

keep the licence application file open. However, 21 CFR 601.4(b) provides for the rejection of applications through the administrative procedure known as "denial of licence" and provides for an appeal mechanism.^{1/}

Eligibility of importers to apply for licence

9. All persons, firms and institutions are eligible to apply for licensure without restriction, provided they are the manufacturers of the product intended to be imported.

Documentational and other requirements for application of licence

10. A description regarding what is required to be submitted by the manufacturer for application for a biological product or establishment licence is included in 21 CFR 601.2.^{1/}

Importers may act only as distributors of the licensed products in the country, but cannot perform any steps in the manufacture of the product.

11. For licensed biological products, documentation (i.e. Labelling) that the product holds a valid United States licence and a Bureau of Biologics' lot release document (if the specific product is subject to lot release by the Food and Drug Administration).

12. There is no licensing fee or administrative charge for the importation of biological products.

13. There is no deposit or advance payment required with the issue of licences.

Conditions of licensing

14. A licence for a biological establishment or product remains valid until revoked at the request of the manufacturer or by reason of cause if such establishment or product does not meet current standards. The manufacturer is required to inform the agency of changes in products or establishments and the agency is required to perform annual inspections to validate the status of each firm.

15. In certain instances, revocation procedures may be instituted if the manufacturer fails to continue the production of the licensed product such that a meaningful inspection cannot be performed by the agency.

16. No. The holder of each licence (manufacturer) must demonstrate the capability to prepare a safe, pure and potent product.

^{1/}A copy of this document is available for reference in the Technical and Other Barriers to Trade Division, Room 1070, Centre William Rappard.

17. There are no quantitative restrictions on biological products. Proof of safety and efficacy as well as adequate manufacturing facilities and labelling are the major determinants for licensure.

Other procedural requirements

18. Yes. If biological products of animal origin (i.e. made from animals and intended for use in man) are to be imported, they must be accompanied by a Department of Agriculture, Animal Health Division permit as described in 21 CFR 12.23(d).¹

19. Not applicable

¹ A copy of this document is available for reference in the Technical and Other Barriers to Trade Division, Room 1070, Centre William Rappard.

