

preserving a prudent loan making program.

The Agency is revising the definition of "single enterprise" to provide that any individual crop which constitutes a basic part of the applicant's total farming operation will be considered a single enterprise. Loan eligibility will be based on a 30 percent loss to an individual enterprise. The maximum loss loan entitlement will be the sum of production losses to all enterprises.

This change is necessary to respond to the extreme financial stress of many farmers affected by repetitive natural disasters. By basing the determination of loan eligibility on single crops, more applicants will be permitted to qualify for loan assistance.

The Agency is also relaxing the requirement for the handling of nonessential assets. The existing EM Instructions require that such assets be mortgaged and/or assigned to FmHA and sold no later than one year from the date of loan closing, if not sold prior to loan closing. The intent of this requirement was to reduce the amount of loan assistance needed by applying the sale proceeds to the loan account when the assets were sold.

The Agency is revising the nonessential asset section of the regulations by removing the requirement that borrowers sell nonessential assets. The revision will require applicants to pledge such assets as security for the emergency loans. Historically the requirement to sell nonessential assets has been difficult to administer. The Agency has concluded that the elimination of this requirement would not harm the Government, but instead would benefit the public by reducing the administrative cost associated with requiring the liquidation of nonessential assets.

List of Subjects in 7 CFR Part 1945

Agriculture, Disaster assistance.

Therefore, chapter XVIII, title 7, Code of Federal Regulations, is amended as follows:

PART 1945—EMERGENCY

1. The authority citation for part 1945 continues to read as follows:

Authority: 7 U.S.C. 1989; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart D—Emergency Loan Policies, Procedures and Authorizations

2. Section 1945.154 is amended by revising the first sentence in paragraph (a)(13)(i), revising paragraphs (a)(13)(i)(A) through (a)(13)(i)(C), redesignating paragraphs (a)(13)(i)(D) through (a)(13)(i)(J) as (a)(13)(i)(E)

through (a)(13)(i)(K), adding a new paragraph (a)(13)(i)(D), and revising newly redesignated paragraphs (a)(13)(i)(E), (J) and (K) to read as follows:

§ 1945.154 Definitions and abbreviations.

(a) * * *

(13) * * *

(i) *Single enterprise.* Any single crop or livestock enterprise which constitutes a basic part of an applicant's total farming operation. * * *

(A) Individual cash crops, i.e., wheat is an individual crop, corn is an individual crop, and soybeans is an individual crop.

(B) Individual vegetable crops, i.e., carrots is an individual crop, tomatoes is an individual crop, and radishes is an individual crop.

(C) Individual fruit crops, i.e., apples is an individual crop, oranges is an individual crop, and grapefruit is an individual crop.

(D) Individual nut crops, i.e., walnuts is an individual crop, almonds is an individual crop, and pecans is an individual crop.

(E) Individual feed crops, i.e., alfalfa is an individual feed crop, and corn is an individual feed crop when fed to an applicant's own livestock. A livestock enterprise must be a basic part of the farming operation in order for the feed crops to be considered as a basic enterprise in determining eligibility based on production losses to feed crops.

* * * * *

(J) Any aquaculture operation; and

(K) Any other operations (i.e., trees grown for timber).

* * * * *

3. Section 1945.156 is amended by revising paragraph (b)(3) to read as follows:

§ 1945.156 The test for credit and certification requirements for availability of credit elsewhere.

* * * * *

(b) * * *

(3) *Use of nonessential assets (both farm and nonfarm) when seeking other credit.* When an EM loan(s) will be made, after other lenders have declined to provide needed credit to the applicant, the County Supervisor will, as a condition of loan approval, require the applicant, and the owner(s) of the entity to list all assets (both essential and nonessential) and to pledge the nonessential assets to FmHA as security for the proposed loan. This security will be in addition to the security required pursuant to § 1945.169 of this subpart.

4. Section 1945.163 is amended by revising the first sentence of paragraph (a)(2)(iv) to read as follows:

§ 1945.163 Determining qualifying losses, eligibility for EM loan(s) and the maximum amount of each.

* * * * *

(a) * * *

(2) * * *

(iv) The gross dollar value of production losses will be computed for all crops and all livestock enterprises that suffered losses due to the disaster, by calculating the value of the disaster year's production and subtracting that amount from the calculated value of the normal production. * * *

5. Section 1945.200 is revised to read as follows:

§ 1945.200 OMB control number.

The reporting and recordkeeping requirements contained in this regulation have been approved by the Office of Management and Budget and have been assigned OMB control number 0575-0090. Public reporting burden for this collection of information is estimated to vary from 10 minutes to 1 hour per response, with an average of .58 hours per response including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250; and to the Office of Management and Budget, Paperwork Reduction Project (OMB #0575-0090), Washington, DC 20503.

Dated: May 21, 1991.

David T. Chen,

Acting Administrator, Farmers Home Administration.

[FR Doc. 91-13018 Filed 5-30-91; 8:45 am]

BILLING CODE 3410-07-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

RIN 3150-AD 95

Return of Topaz Reactor to Soviet Union

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations pertaining to import and export of nuclear equipment and material to permit the return of the Topaz II Reactor System to the Union of Soviet Socialist Republics (USSR). The Topaz II was imported into the United States pursuant to an import license issued by the NRC on January 4, 1991. This rulemaking action permits the export of Topaz II, which is owned by the Government of the USSR, without issuance of a license by the NRC.

EFFECTIVE DATE: May 31, 1991.

FOR FURTHER INFORMATION CONTACT:

Joseph F. Scinto or Joanna M. Becker, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; Telephone (301) 492-1740.

SUPPLEMENTARY INFORMATION:

In January 1991, the Topaz II Reactor System, a space reactor developed and owned by the USSR, was imported into the United States under an NRC import license, at the behest of the Department of Defense (DOD), for exhibit at a Space Nuclear Power Symposium in Albuquerque, New Mexico, and inspection and study by DOD. The reactor was imported without fuel, coolant or moderator and is non-operating. It is possessed in the United States by Sandia National Laboratory, a prime contractor of the Department of Energy exempt from facility license requirements by NRC regulations in 10 CFR 50.11.

The Topaz II Reactor System, while in the United States, is subject to the provisions of those sections of the Atomic Energy Act applicable to utilization facilities, including sections 101 and 104.

Section 101 reads as follows:

Sec. 101. Licensed Required.—It shall be unlawful, except as provided in section 91, for any person within the United States to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, use, import, or export any utilization or production facility except under and in accordance with a license issued by the Commission pursuant to section 103 or 104.

Section 104d. provides, in pertinent part:

Sec. 104 Medical Therapy and Research and Development

d. No license under this section may be given to any person for activities which are not under or within the jurisdiction of the United States, except for the export of production or utilization facilities under terms of an agreement for cooperation arranged pursuant to section 123 or except under the provisions of section 109. * * *

Section 11.cc. of the Atomic Energy Act of 1954, as amended, defines "utilization facility", in pertinent part, as

Any equipment or device, except an atomic weapon, determined by rule of the Commission to be capable of making use of special nuclear material in such quantity as to be of significance to the common defense and security, or in such a manner as to affect the health and safety of the public, or peculiarly adapted for making use of atomic energy in such quantities as to be of significance to the common defense and security or in a manner as to affect the health and safety of the public. * * *

Commission regulations in 10 CFR 50.2 define "utilization facility" as

Any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233.

Commission regulations in 10 CFR 110.2 define "utilization facility" as

Any nuclear reactor, "other than one that is a production facility, and the following major components of a nuclear reactor * * *

Although presently unfueled, the Topaz II Reactor is a reactor peculiarly adapted to making use of atomic energy and was imported under NRC import license No. IR 90002, issued January 4, 1991. This license contained a condition to the effect that it would "become effective only upon written acknowledgement, by an authorized representative of the Union of Soviet Socialist Republics, that any export from the United States of the TOPAZ II Reactor System must meet the requirements of the U.S. Atomic Energy Act of 1954, as amended. Under the law, at present, these requirements include the need for an Agreement for Cooperation in the Peaceful Uses of Atomic Energy." The authorized representative of the USSR acknowledged this condition. There is currently no such Agreement for Cooperation. However, the Soviet agency which developed and owns the Topaz II Reactor System desires its return to the Soviet Union.

Although capable of making use of special nuclear material and peculiarly adapted for making use of atomic energy, taking into account the absence of fuel, moderator or coolant, the intended short stay and limited use as a model for exhibition purposes in the United States, and its return in the near future to the country of origin, the Commission has determined that, in connection with the export of the device, the Topaz II Reactor System imported under NRC License No. IR90002 is not a "utilization facility" and is amending the definition of that term in 10 CFR 110.2. Thus, this device may

be exported without issuance of a Commission export license.

Since this matter involves a device which is the property of the Soviet Government transferred for exhibition purposes to the Department of Energy and involves a matter of interest to the Department of Defense and the Department of State, the Commission has determined that this amendment involves a foreign affairs function of the United States. Thus, the notice and comment provisions of the Administrative Procedure Act do not apply, pursuant to 5 U.S.C. 553(a)(1).

Environmental Impact: Categorical Exclusion

The NRC has determined that, pursuant to §§ 51.10 and 51.22(c)(1) of this chapter, the amendments to part 110 which follow require neither an environmental impact statement nor an environmental assessment.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget under approval number 3150-0036.

Regulatory Analysis

Adoption of these amendments is necessary in order to enable return of the Topaz II Reactor System to the Soviet Union. No other NRC regulatory actions or alternative actions by other agencies, to the best of the Commission's knowledge, address this matter nor, in view of the desired time frame, are any alternative courses of action feasible. It is not expected to result in any increased regulatory burden.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The final rule does not impose additional obligations on the public.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule, and, therefore, a backfit analysis is not required for this final rule because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalty, Export, Import, Incorporation by reference, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 110.

PART 110—EXPORT AND IMPORT OF NUCLEAR EQUIPMENT AND MATERIAL

1. The authority citation for part 110 continues to read as follows:

Authority: Secs. 51, 53, 54, 57, 63, 64, 65, 81, 82, 103, 104, 109, 111, 126, 127, 128, 129, 161, 181, 182, 183, 187, 189, 68 Stat. 929, 930, 931, 932, 933, 936, 937, 948, 953, 954, 955, 956, as amended, (42 U.S.C. 2071, 2073, 2074, 2077, 2092-2095, 2111, 2112, 2133, 2134, 2139, 2139a, 2141, 2154-2158, 2201, 2231-2233, 2237, 2239); sec. 201, 68 Stat. 1242, as amended (42 U.S.C. 5841).

Section 110.1(b)(2) also issued under Pub. L. 96-92, 93 Stat. 710 (22 U.S.C. 2403). Section 110.11 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152) and secs. 54c and 57d, 88 Stat. 473, 475 (U.S.C. 2074). Section 110.27 also issued under sec. 309(a), Pub. L. 99-440. Section 110.50(b)(3) also issued under sec. 123, 92 Stat. 142 (42 U.S.C. 2153). Section 110.51 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 110.52 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236). Sections 110.80-110.113 also issued under 5 U.S.C. 552, 554. Sections 110.30-110.35 also issued under 5 U.S.C. 553.

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 110.20-110.29, 110.50, and 110.120-110.129 also issued under secs. 161 b and i, 68 Stat. 948, 949, as amended (42 U.S.C. 2201 (b) and (i)); and §§ 110.7a and 110.53 are also issued under sec. 161(o), 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. The definition of "utilization facility" in § 110.2 is revised to read as follows:

§ 110.2 Definitions.

Utilization facility means any nuclear reactor, other than one that is a production facility, and the following major components of a nuclear reactor:

- (1) Pressure vessels designed to contain the core of a nuclear reactor;
- (2) Primary coolant pumps;
- (3) Fuel charging or discharging machines; and
- (4) Control rods.

A utilization facility does not include the steam turbine generator portion of a

nuclear power plant. For purposes of export from the United States under the jurisdiction of the Nuclear Regulatory Commission, a utilization facility does not include the Topaz II Reactor System owned by the Union of Soviet Socialist Republics and imported into the United States pursuant to NRC License No. IR90002, issued January 4, 1991.

3. Section 110.5 is revised to read as follows:

§ 110.5 Licensing requirements.

Except as provided under subpart B of this part and the definition of utilization facility in § 110.2 of this part, no person may export any nuclear equipment or material listed in § 110.8 and § 110.9, or import any nuclear equipment or material listed in § 110.9a, unless authorized by a general or specific license issued under this part.

Dated at Rockville, MD, this 24th day of May, 1991.

For the Nuclear Regulatory Commission,
Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 91-12908 Filed 5-30-91; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF THE TREASURY**Customs Service****19 CFR Part 101**

[T.D. 91-47]

Changes in the Customs Service Field Organization; Apalachicola, Carrabelle, and Port St. Joe, FL

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule, correction.

SUMMARY: In T.D. 91-47, published on May 16, 1991 (56 FR 22641), 19 CFR part 101 was amended to remove Apalachicola and Carrabelle, Florida from the list of ports of entry, and to change Port St. Joe, Florida from a port of entry to a Customs station. This document corrects errors which appeared in the Authority citation as well as a typographical error in that document.

EFFECTIVE DATE: July 15, 1991.

FOR FURTHER INFORMATION CONTACT: Joseph O'Gorman, Office of Inspection and Control, 202-566-9425.

PART 101—GENERAL PROVISIONS [CORRECTED]

In FR Doc. 91-11634, on page 22642, in the first column the following corrections are made.

1. Authority: The Authority citation for part 101 should read "Authority: 5 U.S.C. 301, 19 U.S.C. 2, 66, 1202 (General Note 8, Harmonized Tariff Schedule of the United States) 1623, 1624."

§ 101.3 [Corrected]

2. The date of issuance of E.O. 7818 relating to Port St. Joe, Florida, should read "Feb. 17, 1938" instead of "Feb. 17, 1983."

Dated: May 24, 1991.

Kathryn C. Peterson,
Chief, Regulations and Disclosure Law Branch.

[FR Doc. 91-12825 Filed 5-30-91; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket Nos. 88p-0179, 88p-0173, 88p-0136]

Food and Drug Administration**21 CFR PART 878****Medical Devices; Reclassification and Codification of Nonabsorbable Poly (Ethylene Terephthalate) Surgical Suture, Nonabsorbable Polypropylene Surgical Suture, and Nonabsorbable Polyamide Surgical Suture**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued orders in the form of letters to a manufacturer reclassifying the nonabsorbable poly(ethylene terephthalate) surgical suture, nonabsorbable polypropylene surgical suture, and nonabsorbable polyamide surgical suture, from class III to class II. The orders are being codified in the Code of Federal Regulations as specified herein.

DATES: The reclassifications were effective February 15, 1990, for the nonabsorbable polyamide surgical suture, and July 5, 1990, for the nonabsorbable poly(ethylene terephthalate) surgical suture and the nonabsorbable polypropylene surgical suture. These codifications become effective (July 1, 1991).

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-4874.

SUPPLEMENTARY INFORMATION: On May 4 and 10, 1988, and April 7, 1988, FDA

filed the reclassification petitions submitted by Advanced Biosearch Associates, Danville, CA 94526-4617, on behalf of United States Surgical Corp. (U.S. Surgical), Norwalk, CT 06856, requesting reclassification of the nonabsorbable poly(ethylene terephthalate) surgical suture, nonabsorbable polyamide surgical suture, and the nonabsorbable polypropylene surgical suture from class III to class II.

FDA consulted with the General and Plastic Surgery Devices Panel (the Panel). The Panel, during an open public meeting on October 20, 1988, recommended that FDA reclassify nonabsorbable polypropylene surgical suture and the nonabsorbable poly(ethylene terephthalate) surgical suture from class III into class II.

On June 24, 1988, the Panel recommended that FDA reclassify the nonabsorbable polypropylene surgical suture from class III into class II. FDA fully considered the Panel's recommendation, and reviewed various statements offered by persons who opposed U.S. Surgical's petitions for reclassification of the nonabsorbable polypropylene surgical suture, the nonabsorbable poly(ethylene terephthalate) surgical suture, and the nonabsorbable polypropylene surgical suture. FDA concluded that these generic types of devices, and all devices substantially equivalent to them should be reclassified from class III to class II.

After reviewing all data in the petition and presented before the Panel, and after considering the Panel's recommendation, FDA, based on the information set forth, ordered the reclassification of the nonabsorbable polypropylene surgical suture, the nonabsorbable poly(ethylene terephthalate) surgical suture, and the nonabsorbable polypropylene surgical suture from class III to class II. On July 5, 1990, FDA sent to the petitioner letters (orders) which reclassified the nonabsorbable polypropylene surgical suture and the poly(ethylene terephthalate) surgical suture, and substantially equivalent devices of these generic types, from class III to class II. On February 15, 1990, FDA sent the petitioner a letter (order) which reclassified the nonabsorbable polyamide surgical suture, and substantially equivalent devices within the reclassified generic type, from class III to class II. As required by 21 CFR 860.134 (b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of these generic types. In addition, FDA is codifying the reclassification of these devices by

adding §§ 878.5000, 878.5010, and 878.5020 to subpart E.

The agency has determined under 21 CFR 25.24 (a)(8) and (e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

After considering the economic consequences of approving this reclassification, FDA certifies that this final rule requires neither a regulatory impact analysis as specified in Executive Order 12291 nor an analysis under the Regulatory Flexibility Act (Pub. L. 96-354). This reclassification will not have a significant economic impact on a substantial number of small entities. All manufacturers of nonabsorbable poly(ethylene terephthalate) surgical suture, nonabsorbable polypropylene surgical suture, and nonabsorbable polyamide surgical suture will no longer be required to comply with the premarket approval requirement in section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) and, therefore, will not be subject to the costs of such compliance.

There are no offsetting costs that manufacturers would incur from reclassification into class II other than those associated with meeting a standard, once established. The magnitude of the economic savings attributable to this reclassification is dependent upon the number of premarket approval studies that would have been required of the manufacturers had reclassification not occurred. This savings may not be reliably calculated to permit an accurate quantification of the economic savings.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under this Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New §§ 878.5000, 878.5010, and 878.5020 are added to subpart E to read as follows:

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

(a) *Identification.* Nonabsorbable poly(ethylene terephthalate) surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component and is indicated for use in soft tissue approximation. The poly(ethylene terephthalate) surgical suture meets U.S.P. requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(b) *Classification.* Class II.

§ 878.5010 Nonabsorbable polypropylene surgical suture.

(a) *Identification.* Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.

(b) *Classification.* Class II.

§ 878.5020 Nonabsorbable polyamide surgical suture.

(a) *Identification.* Nonabsorbable polyamide surgical suture is a nonabsorbable, sterile, flexible thread prepared from long-chain aliphatic polymers Nylon 6 and Nylon 6,6 and is indicated for use in soft tissue approximation. The polyamide surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. monograph for nonabsorbable surgical sutures; it may be monofilament or multifilament in form; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.

(b) *Classification.* Class II.

Dated: May 20, 1991.

Ronald G. Chesemore,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 91-12954 Filed 5-30-91; 8:45 am]

BILLING CODE 4160-01-M