Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 928

[Docket No. FV–96–928–2]

Papayas Grown in Hawaii; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible growers of Hawaiian papayas to determine whether they favor continuance of the marketing order regulating the handling of papayas grown in the production area.

DATES: The referendum will be conducted from July 1 through July 26, 1996. The representative production period is from July 1, 1994, through June 30, 1995.

ADDRESSES: Copies of the text of the aforesaid marketing order may be obtained from the office of the referendum agent at 2202 Monterey Street, Suite 102B, Fresno, California 93721, or the Office of the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2525–S, Washington, D.C., 20090–6456.

FOR FURTHER INFORMATION CONTACT: Martin J. Engeler, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, 2202 Monterey Street, Suite 102B, Fresno, California, 93721; telephone: (209) 487–5901; or Charles L. Rush, Marketing Order Administration Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, room 2522–S, P.O. Box 96456, Washington, D.C. 20090–6456; telephone: (202) 720–2431.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 928 (7 CFR Part 928), hereinafter referred to as the ''order,'' and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act,'' it is hereby directed that a referendum be conducted to ascertain whether continuance of the order is favored by growers. The referendum shall be conducted during the period July 1 through July 26, 1996, among growers in the production area. Only growers who were engaged in the production of papayas during the period July 1, 1994, through June 30, 1995, may participate in the continuance referendum.

The Secretary of Agriculture has determined that continuance referenda are an effective means for ascertaining whether growers favor continuation of marketing order programs. The Secretary would consider termination of the order if less than two-thirds of the growers voting in the referendum and growers of less than two-thirds of the volume of papayas represented in the referendum favor continuance. In evaluating the merits of continuance versus termination, the Secretary would not only consider the results of the continuance referendum. The Secretary would also consider all other relevant information concerning the operation of the order and the relative benefits and disadvantages to growers, handlers, and consumers in order to determine whether continued operation of the order would tend to effectuate the declared policy of the Act.

In any event, section 608c(16)(B) of the Act requires the Secretary to terminate an order whenever the Secretary finds that a majority of all growers favor termination, and such majority produced for market more than 50 percent of the commodity covered under such order.

The order requires that a referendum be held every 6 years to determine whether growers favor continuance of their marketing order program. The most recent referendum was held in May 1993. The next referendum was scheduled for 1999. However, due to concerns regarding the operation of the order including program compliance, the Department has determined that a referendum should be held at this time to ascertain whether growers favor continuance of the order.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 38), the ballot materials to be used in the referendum herein ordered have been submitted to and approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581–0102. It has been estimated that it will take an average of 20 minutes for each of the approximately 400 growers of papayas to participate in the voluntary referendum balloting. Ballots postmarked after July 26, 1996 will not be included in the vote tabulation.

Martin J. Engeler, California Marketing Field Office, Fruit and Vegetable Division, Agricultural Marketing Service, USDA, is hereby designated as the referendum agent of the Secretary of Agriculture to conduct such referendum. The procedure applicable to the referendum shall be the ''Procedure for the Conduct of Referenda in Connection With Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended'' (7 CFR Part 900.400 *et seq.*).

Ballots will be mailed to all known growers and may also be obtained from the referendum agent and from his appointees at the above address.

List of Subjects in 7 CFR Part 928

Marketing agreements, Papayas, Reporting and recordkeeping requirements.

Authority: Agricultural Marketing Agreement Act of 1937, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

Dated: June 24, 1996.

Michael V. Dunn,

Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 96–16431 Filed 6–26–96; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM–35–14]

IsoStent, Inc., Receipt of a Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and

requests public comment on a petition for rulemaking filed by IsoStent, Inc. The petition has been docketed by the Commission and assigned Docket No. PRM–35–14. The petitioner requests that the NRC amend its regulations by adding a new section to address permanently implanted intraluminal stents, including phosphorus-32 and strontium-89 radioisotope stents. These stents would be permanently implanted in the patient's vessels and arteries. The petitioner also requests that the NRC add a new section to specify training and experience requirements for qualified physicians responsible for placing radioisotope stents in patients. The petitioner believes the suggested amendments would address an innovative approach for the treatment of stenotic arteries and vessels with low-activity, beta-emitting stents.

DATES: Submit comments by September 10, 1996. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except to those comments received on or before this date.

ADDRESSES: For a copy of the petition, write: Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Attention: Docketing and Service Branch.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm on Federal workdays.

For information on sending comments by electronic format, see ''Electronic Access,'' under the Supplementary Information section of this notice.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: 301–415–7163 or Toll Free: 800–368–5642, or E-mail MTL@NRC.GOV.

SUPPLEMENTARY INFORMATION:

Receipt of Petition for Rulemaking

The NRC received the IsoStent, Inc., petition for rulemaking on May 10, 1996. The petition is dated May 9, 1996, and was docketed as PRM–35–14 on May 20, 1996.

Background

The petitioner states that preliminary data indicates that stents, combined with a low-activity, beta-emitting source (less than 3 microcuries per millimeter of length), may significantly reduce restenosis of the vessel following therapeutic intervention. The petitioner refers to a source that estimates total societal costs of restenosis in the United States is somewhere between $800 million and $2 billion a year.

The petitioner states that it is important to ensure that the stents are appropriately classified and regulated because radioactive stents could significantly benefit the healthcare system and the quality of life of patients suffering from restenosis of the vessel following therapeutic intervention. The petitioner believes, after reviewing existing NRC regulations pertaining to the medical uses of byproduct materials, that a new section is necessary to address permanently implanted radioisotope intraluminal stents. The petitioner states that standard coronary stents, 15 millimeters in length, would contain less than 20 microcuries (740 kBq) of beta-emitting isotope, and longer and larger diameter stents for other anatomical sites would contain less than 3 microcuries of beta-emitting isotope per millimeter of length.

Petitioner's Suggested Amendments

The petitioner requests that the NRC amend its regulations by adding a new section that would be applicable to permanently implanted intraluminal stents. The new section would govern stents that include phosphorus-32 and strontium-89 radioisotope sealed sources. These sealed sources would have removable contamination of less than 1 percent of the total device activity. The petitioner further requests a new section be created on training and experience requiring the stents to be placed in the patient by a licensed physician who—

(1) Is certified either by the American Board of Radiology in diagnostic radiology with additional specialization in intravascular radiology or by the American Board of Internal Medicine with special competence in cardiology; and

(2) Has received 8 hours of classroom and laboratory training in the basic handling of beta-emitting sources.

Discussion of the Petition

The petitioner states that the existing regulations do not include phosphorus-32 and strontium-89 as sealed sources for medical therapeutic use. Therefore, the petitioner believes that these sources would be regulated under sources used for traditional brachytherapy. The petitioner believes this category is not appropriate to control low-activity, beta-emitting stents for the following reasons:

1. Training and Competency Requirements.

Low-activity, beta-emitting stents differ significantly from those sources that are used for traditional brachytherapy. Traditional brachytherapy sources have higher activity and require significant dose calculations. To be used safely, traditional brachytherapy sources require extensive knowledge in radiobiology, radiation physics, and radiation protection. Low-activity beta-emitting stents do not require this same level of radiation expertise because they have significantly lower radioactivity levels and are permanently implanted devices that do not require any calculation of dose or dwell time.

Under current NRC regulations, any procedure using a source defined under § 35.400 would require the supervision of a certified radiation oncologist. Stents are currently prescribed and implanted by physicians trained in cardiovascular specialties. Once given required training in the proper handling of these low dose-rate, beta-emitting sources, these physicians could safely and effectively implant radioactive stents. Access to low-activity, beta-emitting stents should be allowed for those physicians who are already certified for stent implantation specialties. Requiring the additional oversight of a radiation oncologist for these stent applications could potentially limit the accessibility of this technology and add significant cost to each procedure. Such a requirement would unnecessarily burden the medical system.

2. Safety Requirements

Low-activity, beta-emitting stents can be shielded with approximately 1 centimeter of plastic material and have half-lives of less than two months, and, when shielded, should not pose a significant hazard to the public or medical staff. The radioactive stent remains within the shield until it is passed into the patient by means of a stent delivery catheter. Once in the patient, these beta-emitters are shielded by the patient's tissues, and because of their shorter half-lives, do not represent a significant long-term risk to the public or to medical personnel. A precedent for the release of patients with such short half-life sources has been set with sources such as iodine-125 seeds having a 60-day half-life and 10^3 to 10^4 times higher activity per seed, as well as with the more penetrating photon radiation.

3. Facility Licensing Requirements

Medical facilities without a broad-scope license also should have access to low-activity, beta-emitting stents, as do facilities with a broad-scope license under current regulations. There are a large number of medical facilities that currently implant stents, but do not meet these licensing requirements. Therefore, maintaining these requirements also could limit the accessibility of this technology.

The petitioner believes that these suggested changes would have a potentially large benefit to patients and the healthcare system.

Electronic Access

Comments may be submitted electronically in either ASCII text or WordPerfect format (version 5.1 or later) by calling the NRC Electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on the petition for rulemaking also are available, as practical, for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC rulemaking subsystem on FedWorld can be accessed directly by dialing the toll free number 800–303–9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT–100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the ''Rules Menu'' option from the ''NRC Main Menu.'' Users will find the ''FedWorld Online User's Guides'' particularly helpful. Many NRC subsystems and data bases also have a ''Help/Information Center'' option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld also can be accessed by a direct-dial telephone number for the main FedWorld BBS, 703–321–3339, or by using Telnet via Internet: fedworld.gov. If using 703–321–3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the ''Regulatory, Government Administration and State Systems,'' then selecting ''Regulatory Information Mall.'' At that point, a menu will be displayed that has an option ''U.S. Nuclear Regulatory Commission'' that will take the user to the NRC online main menu. The NRC online area also can be accessed directly by typing ''/go nrc'' at a FedWorld command line. If NRC is accessed from FedWorld's main menu, the user may return to FedWorld by selecting the ''Return to FedWorld'' option from the NRC online main menu. However, if NRC is accessed at FedWorld by using NRC's toll-free number, the user will have full access to all NRC systems, but will not have access to the main FedWorld system.

If FedWorld is contacted using Telnet, the user will see the NRC area and menus, including the Rules Menu. Although the user will be able to download documents and leave messages, he or she will not be able to write comments or upload files (comments). If FedWorld is contacted using FTP, all files can be accessed and downloaded, but uploads are not allowed. Only a list of files will be shown without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is available. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the World Wide Web, like FTP, that mode only provides access for downloading files and does not display the NRC Rules Menu.

For more information on NRC bulletin boards, call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555–0001, telephone 301–415–5780; E-mail AXD3@nrc.gov.

Single copies of this petition for rulemaking may be obtained by written request or telefax (301–415–5144) from the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, Mail Stop T6–D59, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001. Certain documents related to this petition for rulemaking, including comments received, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the Electronic Bulletin Board established by NRC for this petition for rulemaking as indicated above.

Dated at Rockville, Maryland, this 21st day of June 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 96–16397 Filed 6–26–96; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 95–AWP–40]

Proposed Establishment of Class E Airspace; Coolidge, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Class E airspace area at Coolidge, AZ. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 23 and a VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME) to RWY 05 has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Coolidge Municipal Airport, Coolidge, AZ.

DATES: Comments must be received on or before July 29, 1996.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, Operations Branch, AWP–530, Docket No. 95–AWP–40, Air Traffic Division, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009.

The official docket may be examined in the Office of the Assistant Chief Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business at the Office of the Manager, Operations Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: William Buck, Airspace Specialist, Operations Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261, telephone (310) 725—6556..

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory