

exclusively. Owners of eligible projects may choose tenant-specific RA or operating assistance, but may not utilize both programs in the same project. The objective of this program is to provide assistance toward the cost of operating the project so that rents may be set at rates that are affordable to very low and low-income migrant farmworkers.

(1) *Project eligibility requirements.* To be eligible for the operating assistance program, projects must be:

(i) Off-farm labor housing projects financed under section 514 or section 516 serving migrant farmworkers exclusively (projects serving both migrant and year-round farmworker households are *not* eligible); and

(ii) Eligible for the Agency's rental assistance (RA) program as defined in paragraph II B of exhibit E of subpart C of part 1930 of this chapter.

(2) *Tenant eligibility requirements.* To be eligible for operating assistance rents, tenants must meet the RA eligibility requirements of paragraph II A of exhibit E of subpart C of part 1930 of this chapter.

(3) *Operating assistance limits.* The amount of operating assistance requested by the owner must be based on the project's actual income and expenses and must be approved by the Agency. In no instance may the annual amount of operating assistance exceed 90 percent of the project's annual operating costs.

(4) *Owner responsibilities—(i) Request for operating assistance program.*

Owners of off-farm migrant housing projects may request operating assistance by submitting a request on a form provided by the Agency. The request must include a budget in the format prescribed by the Agency and prepared in accordance with Agency instructions. The budget must include:

(A) Estimated project operating costs, including authorized expenditures such as reserve deposits.

(B) Proposed rental rates to generate sufficient funds for project operating costs, taking into consideration all other sources of project income.

(C) Estimated rental income from tenants, based on a tenant contribution of 30 percent of the average adjusted monthly income of migrant farmworker households in the area. The average adjusted monthly income of migrant farmworker households will be determined as follows:

(1) For existing RHS-financed projects that have been in operation for at least one year, owners will use the average adjusted monthly household income for each unit-size (1-, 2-, 3-bedroom, etc.) based on the prior year's Multi-Family Tenant File System (MTFS) data.

(2) For new projects, owners will use the average adjusted monthly household income for each unit-size, based on the prior year's MTFS data for a like-type property in the same or similar area, as provided by the Agency. Owners may request authorization to use other reliable income data if available.

(D) Estimated operating assistance, calculated as the difference between estimated project income and estimated project operating costs. The annual amount of operating assistance may not exceed 90 percent of the annual operating costs.

(ii) *Requesting operating assistance payments.* Each month, owners will submit a project worksheet for interest credit and rental or operating assistance on a form provided by the Agency. The amount of operating assistance requested each month will be one-twelfth of the annual amount approved by the Agency.

(iii) *Verifying tenant income eligibility.* Owners are responsible for verifying tenant income in accordance with § 1944.182(a). Only very low or low-income households are eligible for the operating assistance rents. Income-eligible households with incomes above low must pay the full rent.

(iv) *Reporting requirements.—(A) Tenant certification.* Owners and tenants will complete a tenant certification, on a form provided by the Agency, to document tenant income and eligibility. Tenant certification forms need not be submitted to the Agency but must be maintained, along with income verifications, for at least 3 years. The tenant files must be available for the Agency's review upon request. The owner will use the income information, along with the project's actual expense figures, to complete the next year's operating assistance request.

(B) *Project worksheet.* Each month, the borrower will submit to the Agency a project worksheet for interest credit and rental or operating assistance on a form provided by the Agency, in accordance with paragraph XIII C2f (2) of exhibit B of subpart C of part 1930 of this chapter.

(C) *Budgets.* Prior to the beginning of the project's fiscal year, owners must submit an annual planning budget in accordance with paragraph XIII C2a of exhibit E of subpart C of part 1930 of this chapter, on a form provided by the Agency. The budget must reflect actual income and expenses for at least 9 months of the current fiscal year and the proposed income and expenses for the coming year. Owners must include a summary report showing the income of tenants served on a form provided by the Agency. If warranted by the actual

income of tenants served, a request for rent change should be included, following the guidance in paragraph XIII C2b of exhibit E of subpart C of part 1930 of this chapter. After the first full year of operation, owners will use the actual year-end budget figures to make appropriate adjustments to the amount of operating assistance requested.

Dated: October 20, 2000.

Jill Long Thompson,

Under Secretary, Rural Development.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AF74

Medical Use of Byproduct Material— Specialty Boards and Medical Specialty Boards: Solicitation

AGENCY: Nuclear Regulatory Commission.

ACTION: Solicitation.

SUMMARY: The Nuclear Regulatory Commission (NRC) is beginning a new process to recognize specialty boards and medical specialty boards (whose diplomates would fulfill the training and experience requirements for an authorized medical physicist, authorized nuclear pharmacist, authorized user, and/or a Radiation Safety Officer) by listing the boards on an NRC website instead of including the names of boards in 10 CFR Part 35, "Medical Use of Byproduct Material." The NRC is taking this action in anticipation of a revision to its regulations governing the medical use of byproduct material. Any board that is interested in being recognized by the NRC should submit a letter certifying that its certification process would meet the draft final training and experience requirements for an authorized medical physicist, authorized nuclear pharmacist, authorized user, and/or a Radiation Safety Officer.

DATES: The solicitation process begins November 2, 2000.

ADDRESSES: Documents related to the proposed rule may be examined through September 22, 2000, at the NRC Public Document Room and electronically at <http://ruleforum.llnl.gov>. Beginning September 25, 2000, the NRC Public Document Room will be located at 11555 Rockville Pike, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Sam Jones, Office of Nuclear Material Safety

and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-6198, e-mail SZJ@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is in the final stages of revising its medical use regulations in 10 CFR Part 35, "Medical Use of Byproduct Material." The proposed rule revising Part 35 was published August 13, 1998 (63 FR 43516). It is anticipated that the Commission will publish the final rule in the **Federal Register** in Spring 2001 with an effective date 6 months after publication. As part of this revision, the regulatory text would not include the names of the specific boards whose diplomates automatically fulfill the training and experience requirements for an authorized medical physicist, authorized nuclear pharmacist, authorized user and a Radiation Safety Officer. Rather, the NRC will recognize certification boards that require individuals to complete the training and experience requirements specified in the regulatory text. This change is being made to eliminate the need for a rulemaking each time a board is added or deleted. Once recognized, the board's name will be placed on the list of recognized boards to be maintained on the NRC website. NRC expects to begin listing the names of boards on an NRC website prior to the effective date of the final rule.

This document serves as notification to all specialty boards of NRC's intent to initiate the recognition process immediately. If any board is interested in being recognized by the NRC, the board should submit a letter to Dr. Donald A. Cool, Director, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001. The letter should list each training and experience section of the rule for which the board believes that their diplomates should be deemed to have met the requirements. Section II and Section III of the **SUPPLEMENTARY INFORMATION** should assist a board in preparing its letter. Section II lists all training requirements for which NRC plans to recognize board certification as meeting the requirements. Section III is a copy of the draft final regulatory text that lists the training and experience criteria for an authorized medical physicist, authorized nuclear pharmacist, authorized user and a Radiation Safety Officer.

The board's letter should clearly state that an individual must have completed the training and experience required by

a particular section prior to receiving board certification. For example, if a board would like to be recognized under 10 CFR 35.390. "Training for use of unsealed byproduct material for which a written directive is required," the letter should state: "(the name of the organization) has reviewed 10 CFR 35.390 and has determined that our certification process requires an individual to meet all the requirements in paragraph (b) of this section prior to being certified by our board." The letter should be dated and signed by the chief executive of the board.

II. Training Requirements for Which NRC Plans To Recognize Board Certification

The following are the titles of the specific sections in the draft final regulations that contain the specific training and experience requirements for a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, and authorized user:

- 35.50 Training for Radiation Safety Officer.
- 35.51 Training for an authorized medical physicist.
- 35.55 Training for an authorized nuclear pharmacist.
- 35.190 Training for uptake, dilution, and excretion studies.
- 35.290 Training for imaging and localization studies.
- 35.390 Training for use of unsealed byproduct material for which a written directive is required.
- 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries).
- 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries).
- 35.490 Training for use of manual brachytherapy sources.
- 35.491 Training for ophthalmic use of strontium-90.
- 35.590 Training for use of sealed sources for diagnosis.
- 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

III. Draft Final Regulatory Text—Training and Experience

This section contains draft final regulatory text for the sections listed under section II. This regulatory text is presented here for use by boards that are interested in being recognized by NRC.

Section 35.50 Training for Radiation Safety Officer

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety

Officer as provided in § 35.24 to be an individual who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of didactic training in the following areas—

- (A) Radiation physics and instrumentation;
- (B) Radiation protection;
- (C) Mathematics pertaining to the use and measurement of radioactivity;
- (D) Radiation biology; and
- (E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material involving the following—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material; and

(2) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or

(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

Section 35.51 Training for an authorized medical physicist

The licensee shall require the authorized medical physicist to be an individual who—

(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution

that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51 or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

Section 35.55 Training for an authorized nuclear pharmacist

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who—

(a) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas—

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving—

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Section 35.190 Training for uptake, dilution, and excretion studies

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed

byproduct material for the uses authorized under § 35.100 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under §§ 35.290 or 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies; the training and experience must include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.190, § 35.290, or § 35.390 or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

Section 35.290 Training for imaging and localization studies

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390 or equivalent Agreement State requirements; or

(c)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies; the training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

Section 35.390 Training for use of unsealed byproduct material for which a written directive is required

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material

requiring a written directive; the training and experience must include—

(i) Classroom and laboratory training in the following areas—

- (A) Radiation physics and instrumentation;
- (B) Radiation protection;
- (C) Mathematics pertaining to the use and measurement of radioactivity;
- (D) Chemistry of byproduct material for medical use; and
- (E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve—

- (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
- (C) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
- (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
- (F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
- (G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131¹;

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements.

The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

Section 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(1) or (2), § 35.394, or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include—

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of byproduct material for medical use; and
- (v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.392, § 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve—

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- (vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level

of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).

Section 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)

Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Is an authorized user under § 35.390(a), § 35.390(b), for uses listed in § 35.390(b)(1)(ii)(G)(2), or equivalent Agreement State requirements; or

(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include—

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of byproduct material for medical use; and
- (v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), § 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve—

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- (vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

¹ Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).

Section 35.490 Training for use of manual brachytherapy sources

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity; and
(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving—

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining running inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification, signed by a preceptor authorized user who

meets the requirements in § 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

Section 35.491 Training for ophthalmic use of strontium-90

Except as provided in § 35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy; the training must include—

(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity; and
(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, § 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Section 35.590 Training for use of sealed sources for diagnosis

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device; the training must include—

(1) Radiation physics and instrumentation;
(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Training in the use of the device for the uses requested.

Section 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who—

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity; and
(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution, involving—

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

Dated at Rockville, Maryland this 20th day of October, 2000.

For the Nuclear Regulatory Commission.
Josephine M. Piccone,
*Acting Director, Division of Industrial and
 Medical Nuclear Safety, NMSS.*
 [FR Doc. 00-27940 Filed 11-1-00; 8:45 am]
 BILLING CODE 7590-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-CE-77-AD]

RIN 2120-AA64

Airworthiness Directives; Pilatus Aircraft LTD Model PC-6 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to all Pilatus Aircraft LTD (Pilatus) Model PC-6 airplanes that are equipped with a certain stabilizer trim actuator. The proposed AD would require you to inspect the lower lug of the actuator for cracks, damage, or distortion; verify that the staked bearing is correctly installed in the bore of the lug; and repair any cracked, damaged, or distorted parts and reassemble any incorrectly installed staked bearing, as necessary. The proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Switzerland. The actions specified by the proposed AD are intended to detect and correct damage, distortion, or cracks in the lower lug assembly, which could result in failure of the lower lug. Such failure could lead to loss of the stabilizer trim actuator with consequent loss of control of the airplane.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before December 8, 2000.

ADDRESSES: Submit comments in triplicate to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-CE-77-AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Pilatus Aircraft Ltd., Customer Liaison Manager, CH-6371 Stans, Switzerland;

telephone: +41 41 619 65 09; facsimile: +41 41 610 33 51. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT:

Roman T. Gabrys, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4141; facsimile: (816) 329-4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

How Do I Comment on the Proposed AD?

The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments in triplicate to the address specified under the caption **ADDRESSES**. The FAA will consider all comments received on or before the closing date. We may amend the proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of the proposed AD action and determining whether we need to take additional rulemaking action.

Are There Any Specific Portions of the Proposed AD I Should Pay Attention To?

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of the proposed rule that might suggest a need to modify the rule. You may examine all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each FAA contact with the public that concerns the substantive parts of the proposed AD.

We are re-examining the writing style we currently use in regulatory documents, in response to the Presidential memorandum of June 1, 1998. That memorandum requires federal agencies to communicate more clearly with the public. We are interested in your comments on whether the style of this document is clearer, and any other suggestions you might have to improve the clarity of FAA communications that affect you. You can get more information about the Presidential memorandum and the plain language initiative at <http://www.plainlanguage.gov>.

How Can I Be Sure FAA Receives My Comment?

If you want us to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write "Comments to Docket No. 99-CE-77-AD." We will date stamp and mail the postcard back to you.

Discussion

What Events Have Caused This Proposed AD?

The Federal Office for Civil Aviation (FOCA), which is the airworthiness authority for Switzerland, recently notified the FAA that an unsafe condition may exist on all Pilatus Model PC-6 airplanes that are equipped with a stabilizer trim actuator, part number (P/N) 978.73.18.101, 978.73.18.102, or 978.73.18.103 (Electomech P/N EM-483-1, 483-2, or 483-3). The FOCA reports an incident of a cracked, damaged, and distorted lower lug of the horizontal stabilizer trim actuator. Analysis of this incident reveals that the staked bearing was loose, which caused excessive wear and failure of the actuator lower lug.

What Are the Consequences If the Condition Is Not Corrected?

Damage, distortion, or cracks in the lower lug assembly, if not detected and corrected, could result in failure of this part. Such failure could lead to loss of the stabilizer trim actuator with consequent loss of control of the airplane.

Is There Service Information That Applies to This Subject?

Pilatus has issued Service Bulletin No. 178, dated September 29, 1999.

What Are the Provisions of This Service Bulletin?

The service bulletin:

- includes procedures for inspecting the lower lug of the actuator for cracks, damage, or distortion, and assuring that the staked bearing is correctly installed in the bore of the lug; and
- specifies repairing any cracked, damaged, or distorted parts, as necessary, and reassembling any incorrectly installed staked bearing.

What Action Did the FOCA Take?

The FOCA classified this service bulletin as mandatory and issued Swiss AD HB 99-507, dated October 1, 1999, in order to assure the continued airworthiness of these airplanes in Switzerland.