

(B) Written notice from the Social Security Administration that the combination of name and social security account number submitted for the employee does not match Social Security Administration records; or

(C) Written notice from the Department of Homeland Security that the immigration status document or employment authorization document presented or referenced by the employee in completing Form I-9 was assigned to another person, or that there is no agency record that the document was assigned to any person.

(2)(i) An employer who receives the notice from SSA described in paragraph (1)(1)(iii)(B) of this section will not be deemed to have constructive knowledge that the employee is an unauthorized alien if—

(A) The employer takes reasonable steps, within 14 days, to attempt to resolve the discrepancy; such steps may include:

(1) Checking the employer's records promptly after receiving the notice, to determine whether the discrepancy results from a typographical, transcribing, or similar clerical error, and if so, correcting the error(s), informing the Social Security Administration of the correct information (in accordance with the letter's instructions, if any; otherwise in any reasonable way), verifying with the Social Security Administration that the employee's name and social security account number, as corrected, match in Social Security Administration records, and making a record of the manner, date, and time of such verification; and

(2) If no such error is found, promptly requesting the employee to confirm that the name and social security account number in the employer's records are correct—and, if they are correct according to the employee, requesting the employee to resolve the discrepancy with the Social Security Administration, such as by visiting a Social Security Administration office, bringing original documents or certified copies required by SSA, which might include documents that prove age, identity, and citizenship or alien status, and other documents that may be relevant, such as those that prove a name change, or, if the employee states that the employer's records are in error, taking the actions to correct, inform, verify, and make a record described in paragraph (1)(2)(i)(A)(1) of this section; and

(B) In the event that, within 60 days of receiving the notice, the employer does not verify with the Social Security Administration that the employee's name matches in the Social Security Administration's records a number

assigned to that name and that the number is valid for work or is valid for work with DHS authorization (and, with respect to the latter, verify the authorization with DHS), the employer takes reasonable steps, within an additional 3 days, to verify the employee's employment authorization and identity, such as by following the verification procedure specified in paragraph (1)(2)(iii) of this section.

(ii) An employer who receives the notice from DHS described in paragraph (1)(1)(iii)(C) of this section will not be deemed to have constructive knowledge that the employee is an unauthorized alien if—

(A) The employer takes reasonable steps, within 14 days of receiving the notice, to attempt to resolve the question raised by DHS about the immigration status document or the employment authorization document; and

(B) In the event that, within 60 days of receiving the notice, the employer does not verify with DHS that the document was assigned to the employee, the employer takes reasonable steps, within an additional 3 days, to verify the employee's employment authorization and identity, such as by following the verification procedure specified in paragraph (1)(2)(iii) of this section.

(iii) The verification procedure referenced in paragraphs (1)(2)(i)(B) and (1)(2)(ii)(B) of this section is as follows:

(A) The employer completes a new Form I-9 for the employee, using the same procedures as if the employee were newly hired, as described in § 274a.2(a) and (b) of this part, except that—

(1) Both Section 1—"Employee Information and Verification"—and Section 2—"Employer Review and Verification"—of the new Form I-9 should be completed within 63 days of receiving the notice referred to in paragraph (1)(1)(iii)(B) or (C) of this section;

(2) No document containing the social security account number or alien number that is the subject of a written notice referred to in paragraph (1)(1)(iii)(B) or (C) of this section, and no receipt for an application for a replacement of such document, may be used to establish employment authorization or identity or both; and

(3) No document without a photograph may be used to establish identity or both identity and employment authorization; and

(B) The employer retains the new Form I-9 with the prior Form(s) I-9 for the same period and in the same manner as if the employee were newly hired at

the time the new Form I-9 is completed, as described in § 274a.2(b) of this part.

(3) Knowledge that an employee is unauthorized may not be inferred from an employee's foreign appearance or accent. Nothing in this definition should be interpreted as permitting an employer to request more or different documents than are required under section 274A(b) of the Act or to refuse to honor documents tendered that on their face reasonably appear to be genuine and to relate to the individual, except a document about which the employer has received a notice described in paragraph (1)(1)(iii) of this section and with respect to which the employer has received no verification as described in paragraph (1)(2)(i)(B) or (1)(2)(ii)(B) of this section.

Dated: June 8, 2006.

**Michael Chertoff,**

*Secretary.*

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**BILLING CODE 4410-10-P**

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## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 35

[Docket No. PRM-35-19]

#### William Stein III, M.D.; Receipt of Petition for Rulemaking

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Petition for rulemaking; Notice of receipt.

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**SUMMARY:** The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by William Stein III, M.D. (petitioner). The petition has been docketed by the NRC and has been assigned Docket No. PRM-35-19. The petitioner is requesting that the NRC amend the regulations that govern medical use of byproduct material concerning training for parenteral administration of certain radioactive drugs used to treat cancer. The petitioner believes that these regulations do not adequately consider the training necessary for a class of physicians, namely medical oncologists and hemotologists, to qualify as an Authorized User (AU) physician to administer these drugs. The petitioner requests that the regulations be amended to clearly codify an 80-hour training and experience requirement as appropriate and sufficient for physicians desiring to attain AU status for these unsealed byproduct materials.

**DATES:** Submit comments by August 28, 2006. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

**ADDRESSES:** You may submit comments by any one of the following methods. Please include the following number (PRM-35-19) in the subject line of your comments. Comments on petitions submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including personal information such as social security numbers and birth dates in your submission.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Rulemaking and Adjudications staff.

E-mail comments to: [SECY@nrc.gov](mailto:SECY@nrc.gov). If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking Web site at <http://ruleforum.llnl.gov>. Address comments about our rulemaking website to Carol Gallagher, (301) 415-5905; (e-mail [cag@nrc.gov](mailto:cag@nrc.gov)). Comments can also be submitted via the Federal eRulemaking Portal <http://www.regulations.gov>.

Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

Publicly available documents related to this petition may be viewed electronically on the public computers located at the NRC Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC rulemaking website at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999 are also available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC

PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov).

For a copy of the petition, write to Michael T. Lesar, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

**FOR FURTHER INFORMATION CONTACT:**

Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-415-7163 or Toll-Free: 1-800-368-5642 or E-mail: [MTL@NRC.Gov](mailto:MTL@NRC.Gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

The NRC has received a petition for rulemaking dated March 20, 2006, submitted by William Stein III, M.D. (petitioner). The petitioner requests that the NRC amend 10 CFR part 35, "Medical Use of Byproduct Material." Specifically, the petitioner requests that a requirement be added to 10 CFR part 35 or that 10 CFR 35.396 be revised to define and specify the number of classroom and laboratory training hours appropriate and sufficient for physicians who seek AU status limited to parenteral administrations of Sm-153-lexidronam (Quadramet), I-131-tositumomab (Bexxar), and Y-90-ibritumomab tiuxetan (Zevalin).

The petitioner believes the current regulations are burdensome and deficient. The NRC has determined that the petition meets the threshold sufficiency requirements for a petition for rulemaking under 10 CFR 2.802. The petition has been docketed as PRM-35-19. The NRC is soliciting public comment on the petition for rulemaking.

**Discussion of the Petition**

The petitioner states that the training and experience requirements for physicians who seek AU status for parenteral administration of Quadramet, Bexxar, and Zevalin to treat certain cancers should reflect current requirements in 10 CFR 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)," and not those currently in 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive." The petitioner believes that the requirements in 10 CFR 35.396 are too restrictive and unnecessarily burdensome because they require 700

hours of training and board-certification in radiation oncology.

Quadramet is approved by the Food and Drug Administration (FDA) for pain relief in bone cancer patients and is administered intravenously. The petitioner states that the average dosage is 70 mCi and that the main route of elimination is urinary excretion which is usually complete within the first six hours of administration. Less than one percent of the administered dosage remains in the blood five hours after administration. Any remaining activity will be retained in the skeleton for the physical half-life of Sm-153 and results in minimal risk of radiation exposure to health care workers, family members, or other individuals who have contact with the patient. The petitioner believes that the patient can be released under the provisions specified in NUREG 1556, Vol. 9. The petitioner also states that patients can be released immediately if the administered activity of Sm-153 is less than 700 mCi and that no instructions are required if the administered activity is less than 140 mCi.

Bexxar has been approved by the FDA for intravenous treatment of non-Hodgkin's lymphoma. The petitioner indicates that the average dosage administered ranges from 33 to 161 mCi, averaging about 84 mCi, generally less than the dosage used for oral treatment of thyroid cancer with Na I-131. The petitioner states that a patient who receives an oral dosage of 30 mCi of I-131 for hyperthyroidism presents more of a radiation exposure hazard than a patient who is treated with an average dosage of Bexxar, for which the dose to other persons is usually less than the 500 mrem limit. The petitioner believes an oral dosage of I-131 remains in the body much longer than the typical Bexxar dosage. The petitioner also states that the I-131 present in Bexxar is firmly attached to the protein antibody and therefore, represents a much lower contamination hazard than from oral I-131 administration.

Zevalin has also been approved by the FDA for intravenous treatment of non-Hodgkin's lymphoma and is administered according to the patients body weight up to a maximum dosage of 32 mCi. The petitioner states that the Y-90 radionuclide presents a minimal risk to individuals who may come in contact with the patient and that the patient can be released after treatment under the provisions specified in NUREG 1556, Vol. 9.

The petitioner notes that all administrations of Quadramet, Bexxar, and Zevalin require written directives and believes that these drugs are

generally less hazardous than oral dosages of I-131. The petitioner therefore believes that the training and experience requirements should not exceed the 80 hours specified for an endocrinologist who treats thyroid disorders with oral dosages of I-131. (See, 10 CFR 35.392 and 35.394.) The petitioner has concluded that the training and experience requirement for parenteral administrations under 10 CFR 35.396 is unnecessarily burdensome because it requires board certification in radiation oncology.

The petitioner notes that 10 CFR 35.390 requires 200 hours of classroom training and laboratory experience for oral administration of I-131 and all parenteral administrations, §§ 35.392 and 35.394 require 80 hours of training for oral administration of I-131, and § 35.396 requires 80 hours for all parenteral administrations, but only applies to board-certified radiation oncologists. The petitioner also notes that in SECY-05-0020, "Final Rule: Medical Use of Byproduct Material—Recognition of Specialty Boards" (January 19, 2005), the NRC justified the 200-hour classroom training requirement in § 35.390 by stating that these physicians are authorized to prepare radioactive drugs and administer many types of radionuclides that require written directives and that pose a greater risk of exposure to radiation.

The petitioner states that § 35.396 was published in the **Federal Register** on March 30, 2005 (70 FR 16335), as part of the final rule that amended training and experience requirements for administration of radiopharmaceuticals. The petitioner believes that the NRC's rationale for the training and experience requirements in § 35.396 is not known and that an opportunity for public comment period was not provided for this provision before it appeared in the final rule. The petitioner also states that preparation of Quadramet, Bexxar, and Zevalin does not require use of generators and reagent kits. These radiopharmaceuticals are usually prepared at a commercial facility and then supplied to medical facilities as a unit dosage that the petitioner believes is much less than the dosage used for oral administration of I-131 for thyroid cancer treatment. The petitioner has concluded that because the parenteral administration of Quadramet, Bexxar, and Zevalin poses no greater potential risk than oral administration of I-131, use of these drugs should be considered a medical issue, not a radiation safety issue.

The petitioner believes that physicians who seek AU status for the

limited authorization of parenteral administration of Quadramet, Bexxar, and Zevalin should only be subject to an 80-hour training and experience requirement, plus supervised work experience and written attestation, similar to the current requirement for oral I-131 administrations at 10 CFR 35.394. The petitioner states that, moreover, the NRC has not considered codification of new drugs that require written directives as they become available for medical use and that there is an unmet regulatory need to address the ability of physicians to qualify for medical use authorization for certain unsealed byproduct materials that are currently commercially available and for which written directives are required. The petitioner also states that under 10 CFR 35.390(b)(1)(ii)(G)(3) and (4) and § 35.396 (d)(2)(iv), only two generic types of parenteral administrations for which written directives have been considered: Parenteral administration of any beta emitter, or photon-emitting radionuclide with a photon energy of less than 150 keV; and parenteral administrations of any other radionuclide.

The petitioner states that the current training and experience requirements governing all parenteral administrations do not adequately consider the training necessary to attain AU status for Quadramet, Bexxar, and Zevalin. The petitioner recognizes that other more hazardous parenterally-administered drugs may become commercially available that require the increased training specified in §§ 35.390 and 35.396. However, the petitioner believes that radiopharmaceuticals should be subjected to training requirements according to potential radiation risk as is the case for oral administrations of I-131, rather than being lumped into a collective group, which the petitioner characterizes as being the NRC's current practice. The petitioner believes that the current requirements are burdensome and deficient in this regard and that, without regulatory relief, physicians would be discouraged from providing these FDA-approved and commercially available treatments resulting in an adverse impact on their ability to practice medicine. Under the current requirements, the petitioner believes that physicians would be required to become board-certified radiation oncologists under § 35.396 or complete 700 hours of training (including 200 hours of classroom and laboratory training) under § 35.390 to attain AU status to parenterally administer Quadramet, Bexxar, or Zevalin.

The petitioner also states that to be able to conclude that parenteral

administration of Quadramet, Bexxar, and Zevalin requires more than 80 hours of training, the NRC would have to assert that each of these drugs presents more potential radiation hazard than oral administration of I-131. The petitioner believes this is more of a practice of medicine issue than a radiation safety issue. The petitioner also states that the NRC would be intruding into the practice of medicine if it did not conclude that medical oncologists/hematologists who have completed 80 hours of classroom and laboratory training, appropriate work experience, and obtained written attestation could be granted AU status for these drugs. The petitioner also believes that such a prohibition would prevent physicians from administering these radiopharmaceuticals and limit patients' access to treatments for life threatening diseases. The petitioner therefore requests that the NRC recognize as adequate and sufficient the 80-hour classroom and laboratory training requirement for physicians to attain AU status to administer Quadramet, Bexxar, and Zevalin as is required for oral Na I-131 administrations to treat thyroid cancer.

The petitioner states that the additional training required under §§ 35.390 and 35.396 is justified because these physicians prepare radioactive drugs and handle unsealed source material in quantities that can involve increased radiation exposure risks. However, the petitioner notes that physicians who administer parenteral doses of Quadramet, Bexxar, and Zevalin do not need to prepare radioactive drugs.

#### **The Petitioner's Conclusion**

The petitioner has concluded that the current 700-hour training and experience requirement (that includes a minimum of 200 hours of classroom and laboratory training) governing parenteral administrations of radiopharmaceuticals in 10 CFR part 35 with regard to administration of Quadramet, Bexxar, and Zevalin is unnecessarily burdensome. The petitioner therefore requests that the NRC recognize that 80 hours of classroom and laboratory training, supervised work experience, and a written attestation for physicians is adequate and sufficient to attain AU status for parenteral administrations of Quadramet, Bexxar, and Zevalin, all requiring written directives. The petitioner offers the following options for addressing this issue:

(1) A specific requirement should be added to 10 CFR part 35 essentially equivalent to the language in § 35.394 that governs oral administration of I-131

particularly with regard to the alternate pathway. An important language change should be made as specified in § 35.394(c)(2)(vi) to require administering dosages to patients or human research subjects that includes at least three cases involving each of these parenteral administrations.

(2) A separate requirement should be added for Quadramet, Bexxar, and Zevalin similar to the training and experience codification for administration of I-131 to allow the NRC to evaluate each substance individually so all radioactive drugs can be handled appropriately from a radiation safety perspective.

(3) 10 CFR 35.396 should be revised to specify an 80-hour classroom and laboratory training period, appropriate work experience, and a written attestation to apply to the alternate pathway for any physician, not limited to board-certified radiation oncologists. Specifically, the petitioner recommends removing the current § 35.396(c) and redesignating §§ 35.396(d)(1), (d)(2), and (d)(3) as §§ 35.396(c)(1), (c)(2), and (c)(3). However, the petitioner recognizes that the Commission may not agree with this change if other more hazardous parenterally-administered radiopharmaceuticals become available, necessitating the increased training currently specified in this requirement.

Dated at Rockville, Maryland, this 8th day of June, 2006.

For the Nuclear Regulatory Commission.

**Annette L. Vietti-Cook,**

*Secretary of the Commission.*

[FR Doc. E6-9246 Filed 6-13-06; 8:45 am]

BILLING CODE 7590-01-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 23

[Docket No. CE248; Notice No. 23-06-03-SC]

#### **Special Conditions: Thielert Aircraft Engines GmbH, Piper PA 28-161 Cadet, Warrior II and Warrior III Series Airplanes; Diesel Cycle Engine Using Turbine (Jet) Fuel**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed special conditions.

**SUMMARY:** This notice proposes special conditions for the Piper PA 28-161 Cadet, Warrior II and Warrior III series airplanes. These airplanes, as modified by Thielert Aircraft Engines GmbH, will

have a novel or unusual design feature(s) associated with the installation of a diesel cycle engine utilizing turbine (jet) fuel. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for installation of this new technology engine. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**DATES:** Comments must be received on or before July 14, 2006.

**ADDRESSES:** Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Regional Counsel, ACE-7, Attention: Rules Docket, Docket No. CE248, 901 Locust, Room 506, Kansas City, Missouri 64106, or delivered in duplicate to the Regional Counsel at the above address.

Comments must be marked: CE248.

Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

**FOR FURTHER INFORMATION CONTACT:**

Peter L. Rouse, Federal Aviation Administration, Aircraft Certification Service, Small Airplane Directorate, ACE-111, 901 Locust, Kansas City, Missouri, 816-329-4135, fax 816-329-4090.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

Interested persons are invited to participate in the making of these proposed special conditions by submitting such written data, views, or arguments, as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. The proposals described in this notice may be changed in light of the comments received. All comments received will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to CE248." The postcard will be date stamped and returned to the commenter.

## Background

On February 11, 2002, Thielert Aircraft Engines GmbH, of Lichtenstein, Germany applied for a supplemental type certificate to install a diesel cycle engine utilizing turbine (jet) fuel in Piper PA 28-161 Cadet, Warrior II and Warrior III series airplanes. The Piper PA 28-161 Cadet, Warrior II and Warrior III series airplanes, currently approved under Type Certificate No. 2A13, is a four-place, low wing, fixed tricycle landing gear, conventional planform airplane. The Piper PA 28-161 Cadet, Warrior II and Warrior III series airplanes to be modified have gross weights in the range of 2325 to 2440 pounds in the normal category. The affected series of airplanes have been equipped with various gasoline reciprocating engines of 160 horsepower.

Expecting industry to reintroduce diesel engine technology into the small airplane fleet, the FAA issued Policy Statement PS-ACE100-2002-004 on May 15, 2004, which identified areas of technological concern involving introduction of new technology diesel engines into small airplanes. For a more detailed summary of the FAA's development of diesel engine requirements, refer to this policy.

The general areas of concern involved the power characteristics of the diesel engines, the use of turbine fuel in an airplane class that has typically been powered by gasoline fueled engines, the vibration characteristics and failure modes of diesel engines. These concerns were identified after review of the historical record of diesel engine use in aircraft and a review of the 14 CFR part 23 regulations, which identified specific regulatory areas that needed to be evaluated for applicability to diesel engine installations. These concerns are not considered universally applicable to all types of possible diesel engines and diesel engine installations. However, after review of the Thielert installation, the Thielert engine type, and the requirements applied by the Lufthart Bundesamt, and applying the provisions of the diesel policy, the FAA proposed these fuel system and engine related special conditions. Other special conditions issued in a separate notice included special conditions for HIRF and application of § 23.1309 provisions to the Full Authority Digital Engine Control (FADEC).

## Type Certification Basis

Under the provisions of § 21.101, Thielert Aircraft Engines GmbH must show that the Piper PA 28-161 Cadet, Warrior II and Warrior III series