



United States
Department of
Agriculture

Office of
The Secretary

Office of
Personnel

Washington
D.C. 20250

Mr. Thomas T. Martin
Regional Administrator
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

FEB 25 1996

License Number 19-00915-06
Docket Number 030-04530

Dear Mr. Martin:

This is a request for an expedited review of an amendment to the USDA License Number 19-00915-06 which we submitted to your office in a letter dated September 11, 1995. The request was for approval to use Amersham sources containing cesium-137 in the manufacture of a Husman irradiator. Additional information concerning the request was provided to your office in letters dated October 5, and November 2, 1995.

The Husman irradiator and the Amersham sources are both approved by the NRC for use, however, we have requested that the Amersham sources be approved specifically for use in the Husman irradiator. The Department of Energy and Oak Ridge National Laboratories no longer produce the cesium-137 sources that were originally approved for use in the Husman irradiator. Isomedix, Inc., the manufacturer of the Husman irradiator, and Amersham, the source manufacturer, have determined that the Amersham sources are an acceptable substitute for the sources originally used in the irradiator.

As the enclosed letter dated January 18, 1996, from USDA's Animal and Plant Health Inspection Service indicates, the irradiator being manufactured is urgently needed to implement preventative sterile insect releases at the start of this year's growing season as part of USDA's Medfly eradication program. We would appreciate your help in expediting our request to amend our license. If you have any questions or if we can be of further assistance in this matter, please contact John Jensen, the Department's Radiation Safety Officer, on 301-734-4945.

Sincerely,

James A. Stevens
Director
Safety and Health
Management Division

Enclosure

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MAR - 9 1996



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

4700 River Road, Unit 134
Riverdale, Maryland 20737-1236

Subject:

Husman Irradiator

To:

John Jensen, Director
Radiation Safety Staff

Date: JAN 18 1996

In September of 1995 when APHIS agreed to fund fabrication of an Amersham Cesium source to complete our long-delayed Husman irradiator procurement, we were advised by your office that obtaining a modification of the USDA license to allow use of this Cesium source in the irradiator would probably be a formality. However, in recent conversations with Jack Patterson of your staff, we understand that the Nuclear Regulatory Commission (NRC) will not begin reviewing the Husman Irradiator and new source until the latter part of January 1996. Even if approved by the NRC this process may take a month or longer. Meanwhile, the cesium sources will be ready to ship about February 1, 1996, (see enclosed letter from George Dietz).

Please be advised that we need to move forward with loading the Husman irradiator and getting it up and running as soon as practical. Our existing production facilities become less efficient every day due to the natural decay of their existing ¹³⁷Cesium sources. Our employees are beginning operations at 4:00 a.m. to provide sufficient sterile flies for program needs. Unless a new irradiator and source material for existing units are brought on-line soon, our programs will suffer sterile fly shortages. In addition, our Medfly eradication program is planning to implement preventative sterile insect releases at the start of this year's growing season. This need to generate millions of sterile insects will require that the new irradiator be operational no later than March 1996.

Given the above background information, please petition the NRC to expedite their review of this irradiator and source. If you have any questions regarding this matter, please contact Ron Milberg at Area Code (301) 734-5255.

Jerry L. Fowler
Chief Operations Officer
Domestic and Emergency Operations
Operational Support
Plant Protection and Quarantine

Enclosure



APHIS—Protecting American Agriculture

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MAR - 9 1996

TOTAL P.03

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Docket No. 030-06923

License No. 19-00915-06

Mr. James A. Stevens, Director
Safety and Health Management Division
United States Department of Agriculture
4700 River Road, Unit 91
Riverdale, MD 20737

Dear Mr. Stevens:

This refers to your letter dated February 29, 1996, to Thomas T. Martin, requesting an expedited review of an amendment to the USDA License No. 19-00915-06 which was submitted to the NRC in a letter dated September 11, 1995. We understand your urgency with this matter and have been working with our Headquarters office in expediting this amendment request. The Sealed Source Safety Section completed a review of the amendment request, sent a deficiency letter dated April 10, 1996, (enclosed) to John T. Jensen, and met with Jack Patterson of the USDA on April 29, 1996, to assist the USDA in replying to the deficiency letter. As of May 8, 1996, the NRC has not received USDA's reply.

We understand that the amendment is urgently needed to implement preventative sterile insect releases at the start of this year's growing season and are expediting our review of this action. We are working with the USDA's Radiation Safety staff to ensure that this amendment is completed as soon as possible.

Your continued cooperation with us is appreciated. You may contact Francis Costello at (610) 337-5275 if you have further questions.

Sincerely,

ORIGINAL SIGNED BY:

James H. Byner
For: Charles W. Hehl, Director
Division of Nuclear Materials Safety

License No. 19-00915-06
Docket No. 030-06923

Enclosure:
Deficiency Letter dated April 10, 1996

cc:
State of Maryland

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S. Baggett, NMSS

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

April 10, 1996

John T. Jensen
U.S. Department of Agriculture
4700 River Road, Unit 91
Riverdale, MD 20737

Dear Mr. Jensen:

This letter is in response to your application dated November 2, 1995, requesting safety evaluation of the Model 521 Husman irradiator with Amersham source capsules X.2157 (J.L. Shepherd Model 6810). We are in the process of evaluating your request. However, to continue our evaluation, the following information is necessary:

1. Please provide clear drawings concerning the Model 521 Husman irradiators and the compatibility of the requested sources with the irradiator(s). In particular, provide clearer drawings that indicate the proposed source mounting and containment within the irradiator(s) and specifications and drawings of the previously approved sources and their mounting and containment in the irradiator(s). Please also specify the materials of construction of the proposed spacers.
2. You indicated that the source capsules are supplied by J.L. Shepherd as the Model 6810 source capsules. Registration certificate CA-598-S-119-S for these sources indicates they are to be used under limiting conditions of use as specified in that certificate (temperature range 10-50° C, non-corrosive atmosphere; and limited vibration). Additionally, the certificate indicates sources are only for use in J.L. Shepherd's source holders or devices. Please demonstrate that these source capsules will be used within the limiting conditions of use specified in that document.

Lastly, we will need to issue a registration certificate for the use of the Models 520 and 521 Husman irradiators by the U.S. Department of Agriculture. This certificate will be issued as a "custom" review for your particular use. In order to perform this review, we will need complete construction and use data for these irradiators. Please provide this information by separate cover so that we may perform this review. This action will be processed separately from you current amendment request.

Enclosure

J. Jensen

-3-

Please provide the requested information as soon as possible. If you have any questions, please contact me at (301) 415-7273.

Sincerely,

Original Signed By:

Steven L. Baggett

Steven L. Baggett, Section Chief
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

From: James Joyner
To: TWD2.TWP8(MLB5) *michele Burgess*
Date: 8/13/96 3:06pm
Subject: USDA -Reply

Thanks for the response. I understand that the custom device review is underway, but I need to understand the delay, since it was initially received last fall, and has been the subject of at least two deficiency letters from your group and a meeting with USDA to discuss the issues. Today I received a call from the RSO, John Jensen, seeking information on the status. He indicated you had called him last Friday, but he'd been unable to connect with you so far. Is there anything he or we can do to help out? Their priority, as he described it, is for the new sources to be approved, and then at a later date complete the action for the Source & Device Registry. Is that the course you are following, or is simultaneous review for both underway? Please get back to me either by phone or e-mail and let me know the status. I promised to try to get back to him by close of business tomorrow. Thanks.

CC: DAB, SLB, ADW, FMC, JRM
Doug Broadbush Frank Costello John R. McGrath
S. Baggett A. Duncan White

May 7
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A
resp = 2 questions - 1 answered
1 not → dimensions not add up
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delay = handling other cases/assignments