

OFFICIAL RECORD COPY

The Applied Radiant Energy Corporation
ATTN: James J. Myron, Ph.D.
Vice President of Safety and Regulation
Venture Drive\Forest Commercial Center
P. O. Box 289
Forest, VA 24551

Dear Dr. Myron:

SUBJECT: RESPONSE TO QUESTIONS ABOUT LICENSE CONDITIONS (REFERENCE LICENSE NO. 45-11496-01; 030-007099)

This refers to your letter dated March 20, 1997, containing questions about license conditions in Amendment No. 19 of License No. 45-11496-01.

As discussed in our telephone conversation of April 11, 1997, I have reviewed these conditions and, as appropriate, have revised your license (enclosed).

Clarifying comments about each is outlined below.

Condition No. 10: Since the purpose of this condition is to permit use of the licensed material only within the pool irradiator at the ARECO facilities at 2432 Lakeside Drive, Lynchburg, VA, no change has been made.

If it is your plan to remove and transfer the licensed material from the Lakeside location under the terms and conditions of License No. 45-11496-01, you must first apply for and receive a license amendment to authorize such a transfer.

Condition Nos. 11 and 12: The name G. Middaugh has been deleted as requested.

Condition No. 15: This condition has been revised to delete references to systems that are not a part of your pool irradiator and the words "the irradiator manufacturer or other." As pointed out in your letter, these do not apply to your "custom built" irradiator.

The intent of this condition as stated is to prohibit ARECO from removing sealed sources from the pool irradiator or from taking any other actions that might lessen the safety of the pool irradiator.

The current wording does not prohibit removal of sources from the source plaque or relocation and storage within the pool.

Furthermore, this condition is not intended to limit ARECO's activities that are covered by applicable standard operating, emergency and maintenance procedures.

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 19

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer by product, source, and special nuclear material designated below, to use such material for the purposes and at the place(s) designated below, to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

In accordance with application dated November 14, 1996 (Revised)

1 Applied Radiant Energy Corporation

3 License Number 45-11496-01

is recaved in its entirety to read as follows

2 Venture Drive/Forest Commercial Center
P.O. Box 289
Forest, Virginia 24551

4 Expiration Date February 28, 2007

5 Docket or Reference No. 030-07099

6 Byproduct, Source, and/or Special Nuclear Material

7 Chemical and/or Physical Form

8 Maximum Amount that Licensee May Possess at Any One Time Under This License

A. Cobalt 60

A. Sealed sources (BNL standard source strips or Neutron Products, Inc. sources encapsulated as described in letters dated July 3, 1968, February 5, 1981 and February 6, 1981 and/or Nordion International Model C-188 sources

A. 400,000 Curies (See Item 9.A and Condition No. 19)

B. Cobalt 60

B. Nuclear Chicago Model RR-61

B. 100 millicuries (See Item 9.A and Condition No.19)

9. Authorized Use:

A. For use in the licensee's custom pool irradiator facility for underwater irradiation of materials, except those prohibited by 10 CFR 36.

B. For use in calibration of instruments.

CONDITIONS

10. Licensed material shall be used only in the licensee's pool irradiator facility located at 2432 Lakeside Drive, Lynchburg, Virginia.

11. The Radiation Protection Officer for this license is, James J. Myron, Ph.D. or in his absence, Rodney W. Bell, or Lawrence G. Barrett.

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License Number 45-11496-01

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

Task Order Reference Number 090-07099

CORRECTED COPY

Amendment No. 19

CONDITIONS

Continued

12. **Licensed material shall be used by, or under the supervision of, Lawrence G. Barrett, James J. Myron, Rodney W. Bell or by other licensee employees who have been trained as specified in revised application for renewal dated November 14, 1996.**
13. **Sealed sources containing licensed material shall not be opened by the licensee**
- 14.A. (1) **The source(s) specified in Item 7, shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.**
(2) **Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material**
- B. **Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.**
- C. **The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U. S. Nuclear Regulatory Commission, Region II, Division of Nuclear Materials Safety, Nuclear Material Licensing/Inspection Branch, 101 Marietta Street, Suite 2900, Atlanta, Georgia 30323. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission.**
- D. **Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.**
- E. **In lieu of the standard leak test, the licensee may perform the tests described in letter dated February 21, 1997. If any radioactivity above normal background is detected, the licensee shall determine if the radioactivity is due to a leaking source. Upon verifying a leaking source, the licensee shall immediately secure the irradiator, discontinue regular operations and promptly notify NRC by telephone and FAX. After consultation with the sealed source and irradiator manufacturer and after NRC written approval, the licensee shall cause the leaking source to be removed in accordance with procedures specifically approved by this license. Within five days after verifying positive test results, a written report of the leaking source shall be provided to the U. S. Nuclear Regulatory Commission, RII, Division of Nuclear Materials Safety, Materials Licensing, Inspection Branch, 101 Marietta Street, N.W., Suite 2900, Atlanta, GA 30323.**
15. **The licensee is prohibited from removing, replacing, and/or disposing of sealed sources from the irradiator pool. In addition, the licensee shall not perform repairs and/or alterations on the pool irradiator, its control and safety systems, its shielding or any other mechanism that might affect the containment integrity of the sealed irradiator sources, or the physical security of the pool irradiator. Unless otherwise specified in writing by the Commission, these services shall be performed only by persons specifically licensed by the Commission or an Agreement State to perform these services.**

License Number

45-11496-01

Docket or Reference Number

030-07(P)

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

CORRECTED COPY

Amendment No. 19

CONDITIONS

Continued

16. The licensee shall provide and require the use of written procedures for maintenance and servicing, and routine and emergency operations. These procedures shall conform to the sealed source and pool irradiator written specifications and to pertinent NRC rules, regulations and to the specific requirements of this license.
17. The licensee shall notify NRC, RII, in writing, at least 2 weeks before the anticipated receipt of a shipment of cobalt 60 capsules.
18. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's address specified in Item 2 pursuant to the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
19. The licensee shall maintain financial assurance for decommissioning as specified in 10 CFR 30.35.
20. Except as specifically provide otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A Applications dated:
 - (1) January 21, 1988 [Initial application for renewal-background information applicable to pool construction, facilities and equipment]
 - (2) November 14, 1986 [Revised application for renewal]

License Number 45-11496-01

License Expiration Date 03/07/97

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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Amendment No. 19

CONDITIONS

22.(cont.)

B. Letters dated

- (1) April 11, 1986 [applicable to licensee's training program only]
- (2) July 3, 1968, February 5, 1981, and February 6, 1981 (Description of Neutron products sealed sources, including drawings)
- (3) April 11, 1986 (Engineering contractor's pool construction evaluation report)
- (4) November 14, 1986 (Explanation of revised application)
- (5) January 30, 1997 (Description of operation involving pool water to improve polymerization reaction times)
- (6) February 21, 1997 (clarification of radiation safety and operational safety procedures involved in the licensee's product irradiation process)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

LAURENCE G. WRIGHT

Date APR 04 1997

By *Laurence G. Wright*
 Division of Nuclear Materials Safety
 111 Marietta Street, N.W. Suite 2900
 Atlanta, GA 30323

NAME LICENSEE ACCEPTED



UNITED STATES
 NUCLEAR REGULATORY COMMISSION
 REGION II
 101 MARIETTA STREET, N.W., SUITE 2900
 ATLANTA, GEORGIA 30323 0199

APR 04 1997

OFFICIAL RECORD COPY

INFORMATION FOR NRC MATERIAL LICENSEES

- Please find enclosed:
- Your NRC material license - *Corrected Copy*
 - Amendment to your NRC material license
 - Amendment renewing your NRC material license
 - Amendment terminating your NRC material license
 - Notice for Radiographer Quality Assurance Approval Program

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify this office (ATTN: Ms. Diane Heim at (404) 331-4673) so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day in the month and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR 19, "Notice, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:
 - a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and
 - b. you have notified the U. S. Nuclear Regulatory Commission, Region II, ATTN: Materials Licensing/Inspection Branch, in writing, that activities authorized by the license will be initiated.
 - c. you have submitted and certified implementation of a Quality Management Program (10 CFR 35.32) for radiotherapy, or for administering > 30 uCi of I-125 or I-131.
3. Notify NRC, in writing, within 30 days:
 - a. when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change; or
 - b. when the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly in writing, and request termination of the license:
 - a. when you decide to terminate all activities involving materials authorized under the license; or
 - b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material

5. Request and obtain a license amendment before you
 - a. receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this part.
 - b. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as an authorized user under a license for medical use of byproduct material.
 - c. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as a Radiation Safety Officer, Teletherapy Physicist, or Nuclear Pharmacist, under a license for medical use of byproduct material.
 - d. order byproduct material in excess of the amount, or a different radionuclide or form, other than authorized on the license.
 - e. add or change the areas of use or address (or addresses) of use identified in the license application or on the license, or
 - f. change ownership of your organization.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. Transfer of licensed materials must be consistent with 10 CFR 30.41, 40.51 or 70.42, as applicable. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a Notice of Violation, or imposition of a Civil Penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, (7/95). Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken against those who do not achieve the necessary attention to detail and standard of compliance expected of licensees.

Thank you for your cooperation.

Enclosures:

1. NRC License
2. Category Marked Below for:
 - New licenses: NUREG-1600 (7/95), 19, 20, 30, 40 or 70, as appropriate, 71, 170; NRC Form 3; Agreement State list; and NRC Form 313
 - New radiography licenses: Parts 34, 150.
 - New medical and teletherapy licenses: Part 35
 - Amendments and renewals: NRC Form 313

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