NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 18

MATERIALS LICENSE

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 byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) 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.

301701

Licensee	
1. Lunar Corporation	In accordance with letters dated July 31, 1996 and October 25, 1996
2. 313 West Beltline Highway Madison, WI 53713	3. License Number 48-20411-01 is amended in its entirety to read as follows:
	4. Expiration Date March 31, 2005
	5. Docket or Reference No. 030-18359

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. Gadolinium-153	A. Sealed sources (Lunar Radiation Corp. Model GD Series)	A. 20 curies total, no single source to exceed 1.5 curies
B. Iodine-125	B. Sealed sources (AECL Models C-324 or C-235, Amersham Corp. Model No. IMC.P2 or Cintichem, Inc. Model No. 6525 in source holders)	B. 4 curies total, no single source to exceed 300 millicuries
C. Americium-241	C. Sealed sources (Amersham Corp. Model AMC.25 contained in Lunar source holders)	C. 1 curie total, no single source to exceed 150 millicuries for Model AMC.P1, No single source to exceed 60 millicuries for Model AMC.25
D. Any byproduct material with Atomic Nos. 1 through 83, inclusive	D. Sealed sources	D. No single source to exceed 250 microcuries, 20 millicuries total
E. Hydrogen-3	E. Any	E. 1000 millicuries
F. Carbon-14	F. Any	F. 100 millicuries

9. Authorized Use:

A., B., C., and D. For use and possession incident to instrument calibration and testing, and for efficiency determination on Lunar Corporation Devices.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
48-20411-01

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E. and F. For use and possession incident to research and development as described in application dated May 20, 1994, and letter dated September 12, 1991.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 313 West Beltline Highway, Madison, Wisconsin. Licensed materials listed in Items 7.A., 7.B. and 7.C. may also be used at facilities of customers who possess a specific license from the NRC authorizing possession of the licensed material.

11. A. Licensed material shall be used by, or under the supervision of, James A. Hanson Ph.D., Joyce C. Knutson, Ph.D., Charles Valliere or Leon LeVan, Ph.D.

B. Licensed material may also be used for service operations as described in letter dated February 17, 1995 by or under the supervision of Thomas Bergman, Mark Bringolf, David Brown, Kenneth Brown, Gary Erickson, Simone K. Horneye, Ken Kamau, John Leja, Victor Miranda, David Nelson, Deborah Ogden, Roger Pellman, Patrick Ploc, Richard Pors, Mark Ritchie, Jeff Salbego, Barbara Schneider (nee Jacky), Robert Schulz, Donald Settergren, David Sloan, Paul Thompson, Joel Trempe, Peter Van Scoik, and Todd Weston.

C. The Radiation Safety Officer for this license is Robert Schultz.

12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Sealed sources need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

E. The leak 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, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Safety Branch, 801 Warrenville Road, Lisle, Illinois 60532-4351. The report shall specify the source involved, the test results, and corrective action taken.

F. 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.

13. Sealed sources containing licensed material shall not be opened.

14. Licensed material shall not be used in or on human beings.

15. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of the sealed sources and the date of the inventory.

16. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

17. This license does not authorized commercial distribution.

18. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

19. The licensee shall maintain records of information important to safe and effective decommissioning at Lunar Corporation, 313 West Beltline Highway, Madison, Wisconsin per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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20. Except as specifically provided 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 U.S. 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 August 25, 1988 (with attachments) and May 20, 1994 (with attachments); and

B. Letters dated September 12, 1991 (with attachments), and February 15, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date November 25, 1996

By
Materials Licensing Branch, Region III

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03214
STATUS CODE: 0
FEE CATEGORY: 3M
EXP. DATE: 20050331
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

SS

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   APPLICANT/LICENSEE: LUNAR CORPORATION
   RECEIVED DATE: 960808
   DOCKET NO: 3018359
   CONTROL NO.: 301701
   LICENSE NO.: 48-20411-01
   ACTION TYPE: AMENDMENT

2. FEE ATTACHED
   AMOUNT: 610
   CHECK NO.: 072547

3. COMMENTS

SIGNED Maria Pearson
DATE 8/9/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /(-1)

1. FEE CATEGORY AND AMOUNT: 3M #610

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
   AMENDMENT ✓
   RENEWAL
   LICENSE

3. OTHER

SIGNED SC
DATE 8/14/96

USPS AUG 12 PM 3:59

RECEIVED
AUG 19 1996
REGION 1

Log Aug 7 III
Remitter
Check No. 72547
Amount 610
Fee Category 3M
Type of Fee Amd
Date Check Rec'd 8/12/96
Date Completed 8/14/96
By: SC

AUG 19 1996

LUNAR

313 W. BELTLINE HIGHWAY MADISON, WI 53713 (608) 274-2663

July 31, 1996

Mr. Kevin Null
United States Nuclear Regulatory Commission
Region III
801 Warrenville Rd.
Lisle, IL 60532-4351

Dear Kevin:

The following is an amendment to Lunar Corporation's license, **#48-20411-01**. There are two items that need to be amended:

1. Delete Kevin Wagner as the Radiation Safety Officer and add Tim Placek as the new Radiation Safety Officer. Mr. Placek's training and experience materials are attached. He has had an 8 h radiation safety course that is specific to Lunar needs, a 2.5 d radiation safety course, and five months of supervised experience. Engelhardt & Associates, Inc. Personnel are on site at least once per month so there is continued performance review.

2. Delete H-3 and C-14 from the license, Joyce Knutson, Leon LeVan and Charles Valliere may also be deleted from the license. While Bone Care and Continental Assays continues to exist, their need for radioactive materials beyond general licensed kits, is terminated. Please see attached final survey for this operation.

If you have questions regarding this amendment, please contact Sue Engelhardt or Dee Kaiser at Engelhardt & Associates, Inc., at 1-608-274-4227. We have enclosed a check for $610.00 to cover the cost of the amendment.

Sincerely,

James Hanson, Ph.D.
Vice President, Marketing

TIMOTHY R. PLACEK

206 S. High Point Rd.
Madison, WI 53717-1657
(608) 827-0342

SUMMARY OF QUALIFICATIONS

- Accomplished Quality Assurance / Regulatory Compliance Manager with expertise in ISO 9001 and CE certification, TQM, FDA GMP, UL and Mil-Q-9858 quality systems.
- Proven process/product development experience implementing statistical process control (SPC) and Taguchi Experimental Design techniques.
- Team player with good communications skills to form successful relationships with clients and peers.
- Innovative, with ability to recognize problems and implement effective solutions while reducing costs and improving quality.
- Proven supervisory skills through team building and motivation for optimum performance.

PROFESSIONAL EXPERIENCE

QUALITY ASSURANCE

- Developed a Quality and Regulatory Department in a start-up manufacturing site.
- Implemented comprehensive supplier rating and dock-to-stock certification procedures for a medical devices manufacturer reducing inspection costs by 25%.
- Developed and implemented a total quality cost monitoring and reporting system.
- Initiated ISO 9001 certification for a medical devices manufacturing company.
- Created inspection and test procedures for electronic and mechanical devices.

REGULATORY COMPLIANCE

- Served as FDA contact person for on-site GMP audits.
- Performed GMP and ISO 9000 training.
- Served as Policy Coordinator for the ISO 9001 Level I Quality Policies.
- Acted as key member of ISO 9001 certification teams and lead auditor.
- Performed supplier quality system audits.
- Implemented complaint management system, FMEA, software assurance, process validation, corrective action, and supplier assurance procedures.

PRODUCT / PROCESS DEVELOPMENT

- Reduced scrap costs by 30%, material rejections by over 50%, and finished device rejections by over 30% for a durable medical devices manufacturer.
- Coordinated periodic maintenance testing of precision passive electronic components in a Mil-Q-9858 regulated manufacturing facility.
- Performed design of experiments, process capability studies, and SPC activities.

TIMOTHY R. PLACEK

MANAGEMENT AND LEADERSHIP

- Managed Quality Engineering, QC Inspection & Control, Reliability, Documentation Control and Regulatory Compliance activities for ISO 9001 and GMP regulated, classes II & III medical devices manufacturing environment.
- Directed Quality and Regulatory activities for 3 GMP regulated, classes I & II durable medical devices manufacturing facilities (domestic and international).
- Managed Quality Engineering, Inspection, Reliability, UL and compliance activities in defense, utilities and commercial equipment manufacturing environments.
- Supervised engineers, technicians, supervisors, and inspectors; handling personnel matters including interviewing, hiring, performance reviews and terminations.
- Participated in strategic business, product and quality planning.

PROFESSIONAL EXPERIENCE

Manager of Quality Assurance & Documentation Control, *Lunar Corporation* Madison, Wisconsin	1996-
Manager of Quality Assurance & Configuration Control, *Orthofix Inc.,* Richardson, Texas	1994-1995
Director of Quality Assurance & Regulatory Affairs, *Everest & Jennings Inc.,* St. Louis, Missouri	1992-1994
Manager of Quality Engineering, *Emerson Electric Co., DCSI Division,* St. Louis, Missouri	1989-1992
Quality Planning Supervisor, *Vishay Intertechnology, Dale Electronics Inc.,* Yankton, South Dakota & Columbus, Nebraska	1986-1989

EDUCATION

A.S.E.E., Electronics Engineering, Computer Design, SDSU, Brookings, SD	1986
B.A., Speech Pathology / Audiology, USD, Vermillion, SD	1975

PROFESSIONAL EDUCATION

Certified Quality Manager Training, Quality Education Services, Dallas TX	1995
ISO 9000 Lead Auditor Training, AAIM Management Assoc., St. Louis MO	1994
ISO 9000 Implementation / Certification, Emerson Electric, St. Louis, MO	1992
Management Principles, Statistics, Lindenwood College, St. Louis, MO	1990
Advanced SPC, Taguchi Experimental Design, Dale Electronics, Columbus, NE	1987
Advanced Radiation Safety Training, Engelhardt & Associates, Madison, WI	1996

PROFESSIONAL MEMBERSHIPS

American Society of Quality Control	1990
Regulatory Affairs Professional Society	1992

Certificate of Completion

Tim Placek

8-hr. Radiation Safety Training
for Lunar Corporation

January 31, 1996

Susan J. Engelhardt
President

Engelhardt & Associates, Inc.

Certificate of Completion

awarded to

Timothy Placek

for participation in a radiation safety training course

Given by Engelhardt & Associates, Inc.
April 1-3, 1996
Ft. Lauderdale, FL

Susan Engelhardt
Susan J. Engelhardt, M.S.

Dee Kaiser
Dee Ann Kaiser, M.S.

Ralph Grunewald
Ralph Grunewald, Ph.D.

Judith Grunewald
Judith Grunewald, R.N., M.S.

T. PLACEK

RADIATION SAFETY EXAMINATION

1. Match the following

a. Geiger counter
b. Film badge
c. Leak test
d. Curie
e. Liquid scintillation counter
f. Betas
g. Gammas
h. Half-life
i. Alpha

___b___ Personnel dosimeter
___c___ Contamination survey on a source
___a___ Exposure rate meter
___g___ Energy, photon, same as x-ray
___e___ Used to count low energy betas
___h___ Time needed for 1/2 of the atoms to undergo decay
___d___ Unit of activity (3.7×10^{10} dps)
___f___ Same as an electron
___i___ Equivalent to the nucleus of a helium atom

2. True/False

a. (T) F Long-term (chronic) exposure to radiation is more hazardous to health than exposure to the same amount of radiation in a short period of time.

b. (T) F Time, distance and shielding are appropriate methods of minimizing exposure to radiation.

c. (T) F Leak tests of sources usually are required every six months.

d. (T) F Rem stands for Roentgen equivalent man

e. T (F) A cell that is damaged by radiation cannot repair itself under any circumstances.

f. (T) F If there is a potential for a person to receive 10% of the annual allowed dose, the individual must wear a radiation badge.

g. T (F) Badges can be routinely used to determine internal deposition of radionuclides.

h. (T) F According to the inverse square law, as you double the distance from a source you decrease the exposure by a factor of 4.

SELECT THE <u>ONE</u> CORRECT ANSWER FOR EACH OF THE FOLLOWING QUESTIONS.

3. The maximum allowed whole body exposure per year for a radiation worker is:

a. 0.5 rem
b. 10 rem
(d.) 5 rem
d. 50 rem

4. The time required to receive 100 mR from a 500 mR/hr source is:

   a. .2 sec
   b. 20 sec
   c. 1.2 min
   d. 12 min

5. Which of the following are not part of the acute radiation syndrome?

   a. Hematopoetic syndromes
   b. Central nervous system syndrome
   c. Delayed syndrome
   d. Gastrointestinal syndrome

6. If the distance from a point source is tripled, the intensity will be:

   a. tripled
   b. doubled
   c. halved
   d. one ninth
   e. one twelfth

7. If a person remains in a radiation area where the exposure rate is 120 mrem/hr for 10 minutes, the dose will be:

   a. 0.2 mrem
   b. 2 mrem
   c. 20 mrem
   d. 200 mrem

8. Half-value layer (HVL) is related to which of the following principles of radiation protection?

   a. time
   b. distance
   c. shielding
   d. monitoring
   e. geometric principle

9. Which of the following is not true about radioactive waste?

   a. You may sewer small quantities if its soluble in water.
   b. You may decay in storage materials with a half-life of 90 days or less.
   c. You may give it to a chemical waste broker.
   d. You may ship it to a licensed radwaste broker.

10. Which one of the following would be the most appropriate shielding to use for gamma emitters?

    a. glass
    b. plastic
    c. lead
    d. cardboard

11. Which one of the following would be the most appropriate shielding to use for beta (beta radiation only) emitters?

    a. glass
    b. plastic
    c. lead
    d. tungsten

12. Which of the following is NOT a method of gamma ray interaction with matter?

    a. Bremsstrahlung
    b. Compton effect
    c. Photoelectric effect
    d. Pair production

SELECT <u>ONE OR MORE</u> CORRECT ANSWERS FOR EACH OF THE FOLLOWING QUESTIONS.

13. Which of the following are considered to be delayed effects of radiation?

    a. Carcinogeneses
    b. Life span shortening
    c. Stunted growth
    d. Cataracts
    e. All of the above

14. Free radicals are:

    a. Electrically neutral
    b. Have an odd number of electrons
    c. Are usually responsible for the indirect effect of radiation
    d. All of the above

15. Which of the following are examples of Radiation Safety Officer duties?

    a. Licensing
    b. Audits/inspections
    c. Control of radioactive material
    d. Waste disposal
    e. Keep management informed on status of the radiation safety program.

16. If responding to a radiation accident:

a. assure the victim has been stabilized prior to treating for contamination
b. notify administration and wait for further instructions
c. remove the victim from the radiation area
d. decontaminate the victim and then provide care so you will not become contaminated

17. When treating a suspected radiation accident victim always:

a. obtain a history of the accident
b. complete a radiation survey prior to treatment if not seriously injured to determine type and severity of the radiation dose
c. since there may be no external or visual damage never send the person home without medical or RSO approval
d. wear protective clothing

18. Which of the following are gas-filled detectors?

a. Geiger-Mueller counter
b. proportional counter
c. thermoluminescent dosimeter
d. ionization chambers
e. film badge

19. Which of the following are operating or functional characteristics of the Geiger-Mueller type of survey instrument?

a. it is good for measuring background levels of radiation
b. it requires little or no amplification
c. it is relatively inexpensive
d. it provides an excellent measure of particle energy

20. Which of the following radiation accidents will not require any additional radiation protection precautions for emergency responders?

a. contamination
b. incorporation
c. irradiation
d. contaminated wounds

PROVIDE WRITTEN ANSWERS TO THE FOLLOWING.

21. One mCi (millicurie) equals:
3.7×10^{10} dps (disintegrations per second)
2.22×10^{9} dpm (disintegrations per minute)
~~3.7x10^10~~ 3.7×10^{10} Bq (Becquerel)

22. List four methods used for radiation protection. Of these, which method is used to prevent potential internal exposure?

DISTANCE
SHIELDING
TIME
CONTAMINATION CONTROL

23. Explain the ALARA concept:

A PROGRAM TO ASSURE EXPOSURE RATES TO BE AS LOW AS REASONABLY ACHIEVABLE

24. What is the difference between being contaminated and irradiated?

~~Physical~~ (internal or external) EXPOSURE TO ~~[illegible]~~ PHYSICAL SOURCE IS CONTAMINATION. IRRADIATION IS EXPOSURE TO RADIATED ENERGY ONLY.

25. Describe the process for doing a leak test:

A COTTON SWAB WIPE of HOUSING. Survey. Document.

NOV 26 1996

Kenneth D. Buroker
Director, Regulatory Affairs
Lunar Corporation
313 West Beltline Highway
Madison, WI 53713

Dear Mr. Buroker:

Enclosed is Amendment No. 18 to your NRC Material License No. 48-20411-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Please be advised that we have not deleted H-3, C-14 and any associated authorized users from your license. If you would like to pursue this request at a later date, please provide the following information to Control No. 301701 with no additional fee:

1. Information regarding major radiological spills of any licensed isotopes such as th location of the spill(s) and pertinent radiological information about the spill(s). (Major spills for the purpose of this document means a spill that resulted in off-site contamination or any other spill where more than minimal decontamination effort is required, e.g., spills requiring assistance in cleanup and monitoring from persons other than the user.)

2. The results of the licensee's final surveys as required by 10 CFR Parts 30.36(j)(2). This includes submitting data in the following units: gamma radiation in units of mSv/hr (μR/hr) @ one meter from surfaces, radioactivity in units of MBq/100cm^2 (dpm/100cm^2) (removable and fixed) for surfaces MBq/ml (mCi/ml) for water, and Bq/g (pCi/g) for soils and concrete.

3. The survey instrumentation used for the final survey along with the certification that each instrument has been properly calibrated and tested and the minimum detectable activity (MDA) for each instrument. This information is needed for instruments used for measuring exposure rates and for those used for analysis of wipes, soil and water samples, etc.

301701

4. Maps and/or drawings which clearly indicate the locations where wipes and fixed measurements were taken. If contaminated drain lines (or other buried or inaccessible pipes) are an issue, blueprints or drawings should be included that show the locations of the drain lines, including where they originate and end.

5. If other than minimal contamination efforts are necessary, both the before and after decontamination survey data should be provided as part of the final survey report, including the locations of these areas.

6. The release criteria used as a basis for demonstrating the site can be released for unrestricted use.

7. If the licensee intends to leave certain portions of the site contaminated in excess of the release guidelines, a risk assessment of the potential dose consequences.

8. The disposition of radioactive waste resulting from any remediation efforts. Under normal circumstances the NRC will not conduct a closeout or confirmatory inspection until all waste (and other licensed materials/sources) have been removed from the site. If these materials have not been removed prior to the licensee's submittal of the final survey data, then these areas will have to be surveyed following removal of the waste and the data submitted and reviewed before an onsite inspection and/or license termination.

9. The names and qualifications of the individuals conducting the final radiological surveys.

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 Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer 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).

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. 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. 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 Policy and Procedures for NRC Enforcement Actions. 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 when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Branch

License No.: 48-20411-01
Docket No.: 030-18359

Enclosures:
1. Amendment No. 18
2. 10 CFR Parts 30, 40 or 70 (as applicable)
3. "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source or Special Nuclear Material"

DOCUMENT NAME: M:\03018359.CL6
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII									
NAME	GWATSON:jaw									
DATE	11/29/96									

OFFICIAL RECORD COPY

LUNAR

313 W. BELTLINE HIGHWAY MADISON, WI 53713 608-274-2663
FAX: 608-274-0853

FACSIMILE

DATE: October 31, 1996

TO: Ms. Gidget Watson
Nuclear Regulatory Commission
(630) 515-1259

FROM: Ken Buroker
Lunar Corporation

RE: **License No. 48-20411-01**
Lunar Corporation

Page 1 of 3

Ms Watson:

Attached is additional information per your request via Sue Engelhardt.

I would appreciate it if you would call me after reading the attached. After I receive a control number from you, I'll mail the hard copy of the letter to you.

Thank you for your assistance in this matter.

Regards,

Kenneth D. Buroker
Director, Regulatory Affairs

cc: Sue Engelhardt
Engelhardt & Associates

LUNAR

313 W. BELTLINE HIGHWAY MADISON, WI 53713 (608) 274-2663

October 31, 1996

Ms. Gidget Watson
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, IL 60532-4351

RE: NRC License No. 48-20411-01
Lunar Corporation

Dear Ms. Watson:

Per your request, I am providing the following additional information concerning our NRC License ammendment that is currently in your possession.

The following are those readionuclide sources that Mr. Robert Schulz has had experience with (Robert Schulz training and experience):

- Gadolinium-153 1 curie +
- Iodine-125 1 curie +
- Americium-241 1 curie +

Also, attached is a memo from Leon LeVan confirming the use level of radionuclides in the Bone Care International group.

Thank you very much for your assistance. Please contact me if I can be of further assistance.

Sincerely,

Kenneth D. Buroker
Director, Regulatory Affairs

Ph: (800) 365-8627, ext 6460
(608) 288-6460 (direct line)
cc: Sue Engelhardt, Engelhardt & Associates

LUNAR

313 W. BELTLINE HIGHWAY MADISON, WI 53713 (608) 274-2663

October 31, 1996

Ms. Gidget Watson
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, IL 60532-4351

RE: NRC License No. 48-20411-01 Lunar Corporation
Information from Bone Care International

Dear Ms. Watson:

I am writing to clarify the use of radioisotopes by Bone Care International, Inc. (BCI), which was a subsidiary of Lunar Corporation until May 8, 1996. Amendment No. 13 to Lunar's NRC license was prepared in part to authorize the use of hydrogen-3 and carbon-14 by BCI in its pharmaceutical research and development activities. Possession limits of 1000 millicuries for hydrogen-3 and 100 millicuries for carbon-14 were requested, based on the anticipated use of radioisotopes at the time Amendment No. 13 was prepared (September, 1991). During 1992, BCI received several shipments of hydrogen-3 labeled compounds, the largest of which was 25 millicuries. These materials were purified in the BCI laboratory and then shipped to other companies within weeks of their receipt at BCI. Subsequent radiation surveys (wipe tests) indicated that there was no contamination of the laboratory, nor has there been since. Therefore, decommissioning is not an issue.

Because of changes in the nature of BCI's activities, the use of radiolabeled materials by BCI since 1992 has been limited to tracer quantities of hydrogen-3 and, since 1995, iodine-125. These radioisotopes are used solely for in vitro laboratory testing (clinical assays) conducted by BCI's subsidiary company, Continental Assays Corporation. Their use is covered by Continental Assays' General License (registration number 8922). At this time, BCI has no intention of resuming use of radioisotopes other than to conduct clinical assays using pre-packaged kit materials obtained from commercial suppliers. Therefore, the provisions of the General License meet our projected needs for radioisotope use, and we are requesting that the use of hydrogen-3 and carbon-14 be deleted from Lunar's NRC license.

Please call me at (608) 288-6432 or contact me at the address listed above if you have questions.

Sincerely,

Leon W. LeVan

Leon W. LeVan, Ph.D.
Director, Assay Development
Continental Assays Corporation (Subsidiary of Bone Care International)

CONVERSATION RECORD

TIME | DATE 10/29/96

O VISIT O CONFERENCE X TELEPHONE

O INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT | ORGANIZATION (OFFICE, DEPT.ETC.) | TELEPHONE NO.
Sue Englehardt, Consultant | Lunar Corp. | 608/274-4227

SUBJECT
License No. 48-20411-01

SUMMARY
I requested the following information in regards to the amendment request to name Robert Schultz as the RSO:

The specific isotopes/amounts that Mr. Schultz had experience with.

Ms. Englehardt stated that she would forwarded the information ASAP.

11/25/96, Sue Englehardt:

I informed Ms. Englehardt that I would authorize Mr. Schultz as the RSO. I also informed Ms. Englehardt that I did not approve the request to delete H-3 and C-14 or any of the users and that I would include the deficiencies in the coverletter.

Ms. Englehardt stated that she would relay this information to Kenneth Buroker, Dir. Regulatory Affairs.

ACTION REQUIRED

Robert Watson | SIGNATURE | 11/25/96
NAME OF PERSON DOCUMENTING CONVERSATION | DATE

ACTION TAKEN

SIGNATURE | TITLE | DATE

LUNAR

313 W. BELTLINE HIGHWAY MADISON, WI 53713 (608) 274-2663

October 25, 1996

Ms. Gidget Watson
U. S. Nuclear Regulatory Commission
801 Warrenville Road
Lisle, IL 60532-4351

RE: NRC License No. 48-20411-01
Lunar Corporation

Dear Ms. Watson:

We currently have a license amendment pending in your office, and I understand that it has been assigned to you for licensing action review.

On that amendment, the person who's name we substituted for Radiation Safety Officer (RSO) has left the employ of Lunar Corporation. I would appreciate very much if you could replace that name with that of Mr. Robert Schulz as RSO.

Mr. Schulz is a long standing employee of Lunar and has extensive education and experience in the design and manufacture of bone densitometry equipment manufactured here at our facility. He is also familiar with NRC rules, and had actually served as an RSO for previous company. A summary of Mr. Schulz's credentials is attached.

Thank you very much for your assistance. Please contact me if I can be of further assistance.

Sincerely,

Kenneth D. Buroker
Director, Regulatory Affairs

Ph: (800) 365-8627, ext 6460
(608) 288-6460 (direct line)

cc: Sue Engelhardt, Engelhardt & Associates

LUNAR

313 W. BELTLINE HIGHWAY MADISON, WI 53713 (608) 274-2663

ROBERT SCHULTZ

EDUCATION AND EXPERIENCE SUMMARY

Education

B.A. Physics, University of Wisconsin-Madison, 1972
Graduate Study in Electrical Engineering, University of Wisconsin-Madison, 1978-1980

Current Position-Responsibilities/Experience

Manufacturing Engineering Manager(May, 1996 - Present)-LUNAR Corporation.

A. Manufacturing engineering support of the entire line of LUNAR bone densitometers, including I-125, Gd-153 and x-ray based systems.

B. Hired by LUNAR in May 1986 as Assistant Production Manager, supervising electrical assembly, quality assurance, calibration of test equipment and GMP program.

C. Promoted to Materials Manager in January 1987, supervising all manufacturing of LUNAR devices, inventory control, shipping, troubleshooting of in-house devices and calibration of test equipment.

D. Service Manager for seven years.

E. Has received device specific training on the service, radiation safety and regulatory requirements of LUNAR densitometers.

Additional Training/Experience

A. Completed 8 hour NRC approved Radiation Safety course

B. Additional experience as Materials Manager at Bahr Technologies, Production Manager at Berg Company and Technical Supervisor at Wehr Steel Company.

C. Radiation Safety Officer at Wehr Steel Company.

D. Personal computer experience with a large variety of applications and device specific software.