



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

June 7, 1999

Dr. Mohammed Shanbaky, Chief
Materials License and Inspection Branch
Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

License No. 19-00296-17
Docket No. 030-08478

Dear Dr. Shanbaky:

This is a request for an amendment to License 19-00296-17 granted to the NIH. This license covers the self-contained self-shielded Cs-137 irradiators of numerous types located within NIH research facilities.

The current license requires in Condition 17:

"For each J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator installed and used, the licensee shall:

- E. Immediately stop the use of the irradiator and notify the Commission by telephone as described in 10 CFR 20.2202(d) if abnormal levels of radiation or any malfunction of the irradiator is detected."

NIH has, of course, followed this requirement of the license, no matter how insignificant the malfunction. For example, a Mark I irradiator was recently found to be not working perfectly during a routine quarterly check by the area health physicist. As RSO, as soon as I became aware of this, I directed that the irradiator be removed from use by the scientific staff until it could be serviced by J. L. Shepherd. I also notified Region I and the NRC Operations Center. The problem turned out to be low air pressure in the pneumatic system, which was easily adjusted, and a time delay relay that needed replacement. Such "malfunctions" are routine maintenance requirements that will occur during the use of any system such as this. There was never a failure of any of the interlock systems nor the possibility of radiation exposure from the irradiator as a result of these problems.

Furthermore, since the time delay relay only functions during manual operation the relay could not have affected operation when the timing circuit was employed. Use of the timing circuit is the typical way the irradiator is used by our scientists. Yet the license requirement demanded that the irradiator be removed from service due to the malfunction in the manual operating mode.

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SECTION COPY

PKG ML003694424

NM55/RGN-002

I am therefore requesting that the language of Condition 17. E. be modified to allow more flexibility when there is a problem with a J. L. Shepherd Mark I irradiator at the NIH. I suggest the following replacement:

- E. "prohibit the use of the irradiator if a malfunction in the operation of the irradiator compromises interlock or safety systems which could lead to abnormal radiation exposure of personnel. Upon investigation of such a malfunction by the licensee and an authorized service technician of J. L. Shepherd and Associates, the licensee will report the cause of the malfunction to the Commission in accordance with 10 CFR 21.21."

In your review of this request please note that this Mark I irradiator was returned to J. L. Shepherd and Associates in August, 1997 where it was upgraded with the latest design features. Thus it is currently equipped with the newest interlock and safety package as specified in the Registry of Radioactive Sealed Sources and Devices No. CA598D104S.

I think that you will agree that this approach to this requirement is sensible. First, it eliminates superfluous reporting to the NRC Operations Center when only a minor problem or maintenance requirement has occurred. Secondly, it makes more sense to report, if necessary, under Part 21 than Part 20, since what is referenced here is a potential device malfunction.

Thank you for your assistance in this matter. Please contact me at 301-496-2254 or by email to razoon@mail.nih.gov if you or your staff have any questions.

Sincerely,



Robert A. Zoon, M.E., M.S.
Radiation Safety Officer, NIH

cc: Dr. William Bonner, NCI
Mr. Karl Fischer, RSB

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch; ARM
and
Regional Licensing Sections

: Program Code: 03510
: Status Code: 0
: Fee Category: EX 3E
: Exp. Date: 20030731
: Fee Comments: V
: Decom Fin Assur Req'd: N
:

LICENSE FEE TRANSMITTAL

1. REGION *I*

2. APPLICATION ATTACHED

Applicant/Licensee: HEALTH & HUMAN SERVICES, DEPT. OF
Received Date: 19990610
Docket No: 3008478
Control No.: 126934
License No.: 19-00296-17
Action Type: Amendment

3. FEE ATTACHED

Amount: _____
Check No.: _____

4. COMMENTS

Signed *M. A. Perkins*
Date *6/21/99*

5. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /___/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____

This is to acknowledge the receipt of your letter/application dated

6/7/99, and to inform you that the initial processing which includes an administrative review has been performed.

☒ *AMEND. 19-00286-17* There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number **1 2 6 9 3 4**.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

Sincerely,
Licensing Assistance Team Leader