

7/5/85

MEMORANDUM FOR: File

FROM: C. L. Cain, Radiation Specialist, Region IV

SUBJECT: RESPONSE TO NMSS CRITIQUE OF LICENSING ACTION  
PAUL R. LEON, M.D., 40-07285-02, AMENDMENT NO. 5

Attached is a copy of a critique of a licensing action from Pat Vacca and John Hickey's request for a corrected copy.

The comment is made that the authorization of Dr. Tan for Group III and Iodine-131 therapy is improper because he received his training under a physician (Dr. Leon) listed on a private practice license rather than an institutional license. However, the NMSS presumption that Dr. Leon is listed only on a private practice license is incorrect. This physician is also listed as a user on the license for St. Luke's Hospital, 40-18000-01 and is thereby authorized to provide training to other physicians. In any case, Dr. Tan has been authorized to use Group II materials for some time anyway, and the only additional requirement to add Group III (as indicated in RG 10.8, Appendix A) is that the physician obtain experience eluting generators five times and prepare reagents five times. Additional experience required for the iodine therapy is experience with ten patients. This training was indicated as complete in the statement from Dr. Leon and is so minor in extent that it would have been considered adequate even if Dr. Leon had not been on the St. Luke license.

A second item relates to the inclusion of the phrase "or under the supervision of" in the condition. This phrase will be deleted in a corrected copy to the licensee and will of necessity require an explanation in a transmittal letter since the licensee will otherwise not know the difference. The NMSS interpretation that the absence of this phrase still allows patient injection by a technician when the physician is not physically present is clearly not evident by the wording of the condition. The intent of the NMSS comment is to prevent Drs. Unite and Tan from training other physicians. As was indicated during the NMSS conference call on July 2, 1985, this subtlety is understood by few NRC reviewers much less licensees.

Lastly, the reason Group I was not included is because it was not part of the licensee's original request dated March 28, 1985, which was further affirmed in the telephone conversation with the licensee as documented by Jack Whitten on April 30, 1985. We will include Group I in the corrected copy, however, since Jack and I normally will give a licensee Group I authorization whenever we grant authorization for Groups II and III.

CLC Cain

C. L. Cain

8508300033 850724  
REG 4 LIC 30  
40-07285-02 PDR

License number  
40-07285-02Docket or Reference number  
030-17173

Amendment No. 05

Paul R. Leon, M.D.  
Dakota Midland Professional Building  
1400 N.W. 15th Avenue  
Aberdeen, South Dakota 57401

In accordance with letter dated March 28, 1985, License Number 40-07285-02 is amended as follows:

Condition 12. is amended to read:

12. Licensed material listed in Item 6 above is authorized for use by, ~~or under the supervision of~~, the following individual(s) for the materials and uses indicated:

Paul R. Leon, M.D.

Groups I, II, III, and IV  
Xenon-133

Ismael H. Unite, M.D.

Groups I, II, and III  
Xenon-133  
Iodine-131 as iodide for treatment of  
hyperthyroidism and cardiac dysfunction

Raymundo T. Tan, M.D.

Groups II and III  
Xenon-133  
Iodine-131 as iodide for treatment of  
hyperthyroidism

① Additional auth'n granted  
based on experience obtained under Lic No. 40-07285-02  
which did NOT auth. training of MDs.

② Licensee asked also for  
Groups I; not granted.

Date

MAR 28 1985

not discussed  
in cover letter  
if cover letter  
sent, not in  
Hx files

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Original Signed By

G. L. Cain

By G. L. Cain  
Nuclear Materials Safety Section  
Region IV  
Arlington, Texas 76011

REG-120400 850522  
REG-4 LIC30  
40-07285-02 PDR

Official Record Copy

11 ML40

U. S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Supplementary Sheet

License Number 40-07285-02

Docket or  
Reference No. 30-17173

Amendment No. 01

Paul R. Leon, M.D.  
Dakota Midland Professional  
Building  
1400 N. W. 15th Avenue  
Aberdeen, South Dakota 57401

Category E Priority 4

In accordance with application dated June 15, 1981, License Number 40-07285-02 is amended as follows:

Condition 12. is amended to read:

12. Licensed material listed in Item 6 above is authorized for use by the following individual(s) for the materials and uses indicated:

Ismael H. Unite, M.D.

Groups I, II and III  
Xenon 133  
Iodine 131 as iodide for treatment of  
hyperthyroidism and cardiac dysfunction

Paul R. Leon, M.D.

ALL

Raymundo T. Tan, M.D.

Group II  
Xenon 133

*Correct user condition,  
does NOT auth. training of MDs!*

JAN 28 1982

For the U. S. Nuclear Regulatory Commission  
**PHILIP P. MALOTKO**

Nuclear Licensing Branch

Date \_\_\_\_\_

by \_\_\_\_\_  
Division of Fuel Cycle and  
Material Safety  
Washington, D.C. 20535