From:

Glenda Jackson

To:

ARD1.ARP1.JDB, TWP8.SRW

Date: Subject: 8/22/96 2:53pm VA. Denver

Just to keep you posted--

I just spoke with Mr. Peter Vernig at the VA Medical Center, Denver, and told him that the licensing staff had been reviewing the license authorizations and at this point in time it appeared that the fee categories are correct—it is a broadscope license, and therefore the lees were assessed correctly and are due. I also told him that the licensing staff would probably be sending him a letter explaining the change from their May letter, but the full review was not complete yet.

He has faxed us a letter disputing the fee category assignment, referring to and enclosing a copy of the May 23, 1996 letter. He contends he should be 3M ((R&D Other) and 7C (Human use). I told him we would be sending him something in writing confirming the fee categories once the licensing staff finalized their review.

Just to clarify/confirm for your information, any broadscope license issued to a medical institution is subject to fee category 7B, whether or not the broadscope activities involve human use.

CC:

dbd.slk



UNITED STATES

NUCLEAR REGULATORY COMMISSION

REGIONIV

611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-8064

September 11, 1996

Department of Veterans Affairs ATTN: Peter G. Vernig Radiation Safety Officer 1055 Clermont Street Denver, CO 80220

SUBJECT: RESPONSE TO LICENSE AMENDMENT REQUEST TO CHANGE LICENSE TYPE - ADDITIONAL INFORMATION

In an NRC letter dated May 23, 1996, we provided information to the Department of Veterans Affairs (DVA) located in Denver, Colorado, concerning its amendment requests dated September 28, 1993, and June 7, 1994, to change the medical center license from a "Type A Broad Scope" to a "Hybrid Broad Scope" license. As previously stated in our letter dated May 23, 1996, §35.13 was revised to provide authorization to limited specific licensees for approving medial authorized users based upon the certification specifications in paragraph (a) of §§35.190, 35.920, 35.930, 35.940, 35.950, and 35.960. Corresponding NRC notification requirements were also included in §35.14(a) and (b). Authorizations for a limited specific licensee to approve medial authorized users, other than as provided in §35.13(b), and 35.14(a) and (b)(1) requires exemptions to these paragraphs. Such exemptions are reserved for broad scope licensees, pursuant to §35.15. The basis for denying such authorization requests for limited specific programs was therefore established by §35.15.

The May 23, 1996, letter also informed DVA - Denver, Colorado, that during the interim period since receiving these amendment requests, their license was renewed on June 30, 1994. With the renewal of License No. 05-01401-02 and after review of Policy and Guidance Directive FC 92-02, "Guidance on Licensing Medical Facilities with Broad Scope Programs," (which has been superseded by guidance in the enclosed Policy & Guidance Directive (P&GD) FC 85-7, Revision 1: "Standard Review Plan for Applications for Type A Licenses of Broad Scope") the program code for DVA - Denver, Colorado, was changed from 02110 (Medical Institution Broad) to a combination of 02110 and 03610 (Research and Development Type A Broad). The decision on the "hybrid broad scope" issue, specific to DVA Denver, Colorado request was first made available on February 1, 1996, during a Division of Nuclear Materials Safety (DNMS) Division Director conference call with Don Cool, Director of the Division of Industrial and Medical Nuclear Safety. The issue was followed-up with a phone call to Region IV. Generic guidance was subsequently provided in the response to the DVA Northport request signed April 23, 1996 (enclosed).

After an internal review including updated guidance in P&GD FC 85-7, Revision 1, we have determined that assignment of 02110 and 03620 program codes were incorrect and that the program code for DVA - Denver, Colorado, should be a combination of 02120 (Medical Institution Limited) and 03610 (Research and Development Type A Broad). Specifically, Item 6.F. of the current license (License No. 05-01401-02) gives authorization for "any byproduct material with Atomic Nos. 1 through 83, with half-life less than 120 days,

except as specified below" to be used for research and development as defined in Section 30.4 of 10 CFR Part 30. Usually it is agency practice that licenses with authorizations for "any byproduct material with Atomic Nos. 1 through 83" are considered broad scope licenses. In addition, P&GD FC 85-7, Revision 1 outlines the types of authorizations and related scope of combined authorizations that reveal a licensed program of broad scope.

Although the current license gives authorization for the Radiation Safety Committee of DVA - Denver, Colorado, to approve medical and non-medical authorized users in accordance with license application dated August 13, 1991, during the next renewal process in accordance with the revised Part 35, the NRC will have to approve all medical authorized users, other than as authorized for limited specific licensees pursuant to §35.13, against the standards required in Subpart J of 10 CFR Part 35. Also, during the next renewal process DVA - Denver, Colorado, will need to update the existing criteria used to evaluate the training and experience of non-medical authorized users. Applicable guidance for reviewing evaluation criteria used by limited specific licensees to name non-medical authorized users, is provided for in the April 23, 1996, response to the DVA Northport request.

In summary, DVA - Denver, Colorado, is a limited medical institution with Type A broad scope authority for non-human research and development. We apologize for any misunderstanding created by our error.

If you have any questions concerning this letter, please contact Ms. Jacqueline D. Burks of my staff at (817) 860-8132 or me at (817) 860-8191.

Sincerely,

D. Blair Spitzberg, Chief

State Sporte

Nuclear Materials Licensing Branch Division of Nuclear Materials Safety

Enclosure: As stated

License: 05-01401-02 Docket: 030-01234 bcc:
DMB - Original (IE-07)
LJCallan
CCCain
LWCamper, (8 F 5)
SRWoods, (8 F 5)
DBSpitzberg
LLHowell
FAWenslawski
JDBurks
SLMerchant, NMSS/IMAB, (8 F 5)
GCJackson, (9 E 10)
SLKimberley (9 E 10)
NMLB File
MIS System

RIV Nuclear Materials File - 5th Floor

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RIV:NMLB	N	C:NMLB	ADD: DNMS	D:DNMS AN
JDBurks:nh (Burk	DBSpitzberg 75	GCPangburn	RAScaratio
09/6/96		09/4/96	09//96	09/10/96

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