



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

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

APR 12 1994

Docket: 030-30962
License: 25-26973-01

The McLaughlin Research Institute
for Biomedical Sciences, Inc.
ATTN: George A. Carlson, Ph.D.
Scientific Director
1520 23rd Street South
Great Falls, Montana 59405

SUBJECT: RESPONSE TO NRC INSPECTION REPORT 030-30962/94-01

Thank you for your letter of March 29, 1994, in response to our letter and Notice of Violation (Notice) dated March 2, 1994. We have reviewed your reply and find that additional information is required in order to continue our review of the concerns raised in our Notice. The specific information requested is listed below.

Violation A

In your response you stated that you had erroneously committed to using finger rings in your license application dated April 27, 1989, and that as a result of further review you intend to request that this commitment be deleted from your license. You stated that such a request would be made in conjunction with your license renewal due by May 31, 1994.

You must immediately request amendment of your license if you wish to have this commitment considered for elimination from your license. You will remain in noncompliance with the conditions of your license until an amendment deleting the requirement is issued.

In your amendment request you should provide a detailed evaluation addressing each of the conditions in 10 CFR 20.1502 taking into account the types and amounts of isotopes used and the expected doses to the whole body, skin and extremities, eye, and internal doses if any. Provide any assumptions and/or data used in preparing your evaluation.

Violation B

Although we do not require a further response from you in regard to this issue regarding sewer disposal, the data provided in your response indicate that an average of all the monthly releases was calculated. However, you should be aware that 10 CFR 20.2003 requires, in part, that the quantity of licensed material that is released into the sewer in one month, divided by the average monthly volume of water released into the sewer, must not exceed the concentration listed in Table 3 of Appendix B to Part 20. Your evaluation should contain, for each of the isotopes involved, the quantity of material

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released each month to ensure that you do not exceed the annual release limits.

Alternatively, you may demonstrate by calculation that none of the limits imposed by 10 CFR 20.2003 are likely to be exceeded with regards to the quantity of material used by your institution and commit to reevaluate these conditions only when the circumstances of your use of byproduct material changes.

You are requested to provide a further response to Violation A, in writing, within 30 days of the date of this letter so that we can continue our review of this matter. Should you have any questions concerning this letter, please contact the undersigned at (817) 860-8186.

Sincerely,



Charles L. Cain, Chief
Nuclear Materials Inspection Branch

cc:
Montana Radiation Control Program Director

bcc w/copy of licensee's letter dated March 29, 1994:

DMB - Original (IE-07)
LJCallan
SJCcollins
RAScarano, WCFO
MMessier, OC/LFDCB (4503)
WLFisher
CLCain
GLGuerra
NMIB
MIS System
RIV Files (2)

RIV:NMIB	C:NMIB			
GLGuerra*	CLCain			
04/ /94	04/12/94			

*previously concurred

McLaughlin
Research

COPY

Institute
Biomedical Sciences

March 29, 1994

United States Nuclear Regulatory Commission
ATTN.: Document Control Desk
Washington, D.C. 20555

Re: Reply to a Notice of Violation

Docket: 030-30962
License: 25-26973-01

On February 10, 1994, McLaughlin Research Institute received a routine, unannounced inspection visit by Mr. William H. Radcliffe and Mr. Gilbert L. Guerra, Jr. As a result of their visit, McLaughlin was found to have two violations of Severity Level IV, as reported in the Notice of Violation received 3 March, 1994.

Violation A refers to our failure to conduct our program in accordance with statements, representations and procedures contained in the application of License 25-26973-01 as dated April 27, 1989. In our application, we stated that we would establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2. Specifically, Item No. 8 of Appendix I states that "personnel will wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures." In our program, personnel are required to wear whole body monitors rather than finger exposure monitors.

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94-0717

Violation A resulted from our failure to delete Item 8 of Appendix I from our application. The total amounts of isotope and the specific procedures used here preclude the likelihood of exposure exceeding 10% of the annual limit as delineated in 10 CFR 20.1201. For example, using P-32, the maximum annual exposure an individual could conceivably receive in performing procedures without the shielding required in our program would be 50 mrem (shallow-dose equivalent). This would be only 1% of the annual dose limit of 5 rem. In our program, personnel use shielding devices, so the exposure would be much less than 50 mrem.

We feel that wearing finger badges would hamper the ability of personnel to perform procedures using byproduct material in a safe and efficient manner and would increase the likelihood of spills.

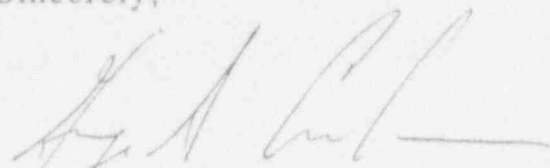
In order to correct Violation A, we will make the necessary changes to our Byproduct Materials License upon renewal. The license is due for renewal by May 31, 1994. We have determined that whole body film badges will be used to monitor exposure to all personnel working in the vicinity of licensed material.

Violation B refers to our failure to evaluate the level of licensed material released into a sanitary sewerage system, to assure compliance with 10 CFR 20.2003(a). This violation occurred because our new facility has not been in operation for a full year. Thus, we felt we could not get an accurate picture of average monthly release of water to the sanitary sewerage system.

Steps have been taken to correct Violation B. The average amount of licensed material released to the sanitary sewerage system from our new facility has been determined for the period from August 1, 1993 to March 31, 1994. It was determined that McLaughlin Research is well within the concentration limits as delineated in 10 CFR 20.2003(a). Release of licensed material into the sanitary sewerage system by our facility will be reassessed on an annual basis to ensure that it does not exceed those concentration limits. A copy of our evaluation is included in this report as ATT. 1.

We hope that you consider the steps we have taken to correct
Violations A and B sufficient to maintain a safe program.

Sincerely;

A handwritten signature in dark ink, appearing to read "G. A. Carlson", with a long horizontal flourish extending to the right.

George A Carlson, Ph.D.
Scientific Director

GAC/skb

ATT. 1.

Evaluation of average monthly release of licensed material to sanitary sewerage

Period evaluated: August 1, 1993 to March 31, 1994.

Isotope	Licensee limits	Releases to Sewers Monthly Average Concentration† (uCi/ml)	Maximum possible release (10% License limits/average monthly water usage*) (uCi/ml)	Actual monthly average conc. of release to sewers (uCi/ml)	Fraction of limit (Table 3)/average release*
H-3	50 mCi	1×10^{-4}	8.6×10^{-6}	-0-	
P-32	60 mCi	9×10^{-5}	1.0×10^{-5}	1.6×10^{-7}	1.8×10^{-3}
S-35	80 mCi	1×10^{-3}	1.4×10^{-5}	5.2×10^{-8}	5.2×10^{-5}
Cr-51	100 mCi	5×10^{-3}	1.7×10^{-5}	-0-	
I-125	10 mCi	2×10^{-5}	1.7×10^{-7}	-0-	
C-14	10 mCi	3×10^{-4}	1.7×10^{-7}	-0-	
P-33	60 mCi	8×10^{-4}	1.0×10^{-5}	-0-	
Sum of Fractions					1.8×10^{-3}

† Values taken from Appendix B, Table 3 of 10 CFR 20.

* Average based on the eight month period from 8/93 through 3/94. Average water released to sanitary sewerage for this period was 5.8×10^8 mls/mo.

Sum of Fractions not to exceed unity.

Total quantity released to sewerage/year not to exceed:

H-3: 5 Ci

C-14: 1 Ci

All other radioactive material combined: 1 Ci

bcc w/copy of licensee's letter dated March 29, 1994:

DMB - Original (IE-07)

LJCallan

SJCollins

RAScarano, WCFO

MMessier, OC/LFDCB (4503)

WLFisher

CLCain

GLGuerra

NMIB

MIS System

RIV Files (2)

RIV:NMIB	C:NMIB			
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