

McLaughlin
Research



Institute
for
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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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.

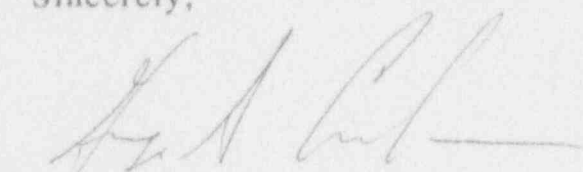
In order to correct Violation A, we will make the necessary changes to our Byproduct Materials License upon renewal. The license is due for renewal by May 31, 1994. We have determined that whole body film badges will be used to monitor exposure to all personnel working in the vicinity of licensed material.

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;



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^{-2}	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