



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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April 27, 2009

Ms. Penny Lanzisera, Senior Health Physicist  
Medical Branch  
U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

19-00296-21

RE: Docket No. 03037773  
Control No. 142439

Dear Ms. Lanzisera:

Earlier today I sent to you, via email, the response to Bullet 16.g. of your letter dated March 27, 2009, addressed to Michael Gottesman, M.D. This reply has been developed by my staff, in consultation with the cyclotron and cyclotron product development support staff of the various institutes which employ cyclotron produced materials in the NIH Intramural Research Program, both clinical and non-clinical.

Please contact me if you or your staff have questions or need additional information. I may be reached at 301-496-2254 or by email at [zoonr@mail.nih.gov](mailto:zoonr@mail.nih.gov).

Sincerely

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

142439

16. g. For airborne effluents, please provide a detailed description of the design of your effluent monitoring systems or confirm that they will be designed in accordance with ANSI N13.1 (1969) and ANSI N42.18. In addition, please describe any unmonitored effluent releases and provide the basis upon which you have determined that unmonitored releases will not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent concentrations found in column 1 of Table 2 in 10 CFR Part 20, whichever is greater. We understand that your current effluent monitoring system is monitored locally by cyclotron personnel and is currently set to an energy discriminator of 511 keV. We also understand that you are demonstrating compliance with effluent releases by entering production information into the COMPLY code. Please describe this process in greater detail. In addition, in your application, you indicated that you are actively pursuing a continuous monitoring system to replace the SPING-3B (Eberline) system that would provide isotopic analysis of effluents. Please describe this system in detail and provide the schedule for this upgrade.

**In order to demonstrate compliance with applicable effluent release limits, quantities of cyclotron produced radionuclides are evaluated using the EPA's COMPLY computer modeling program. This is done in conjunction with the evaluation performed for all radioactive materials received at the NIH each calendar year. In accomplishing this, DRS has always taken the extremely conservative approach of assuming that 100% of the material received on campus each year has the potential for going up the release stack. Although it certainly could be proven to be a substantially lesser quantity by evaluating material use and disposal records, it would require a significant time and manpower commitment on the part of DRS each year to perform this research and determine "exact" quantities. In short, if compliance can be demonstrated based on 100% of the material received and/or produced, then any lesser quantity used will certainly also be in compliance.**

**The parameters used when running COMPLY:**

- **Screening is performed at Level 4, considering receptor cumulative dose and the dose resulting from radioiodines**
- **Release height of 42 meters**
- **Building height of 42 meters**
- **Source and receptor are not on same building**
- **Building width is 213 meters**

- Building length is 114 meters
- Stack distance to the campus perimeter varies from 137 to 1000 meters
- Wind rose data is averaged over the 10 year period from 1997 through 2006, and is located at Dulles International Airport approximately 35 miles from the NIH
- Average wind speeds range from 3.10 m/s in the ESE sector to 6.35 m/s in the NW sector, and are calm 22% of the time
- Closest receptor notes:
  - o located 137 meters from source in the NNE sector
  - o produces own vegetables at home
  - o obtains meat from farm located 8000 meters from source in the N sector
  - o obtains milk from farm located 8000 meters from source in the N sector

**Typical list of nuclides:**

H-3	SE-75	PB-203
C-11	BR-76	BI-205
N-13	RB-86	RA-224
C-14	Y-86	AT-211
F-18	Y-90	AC-225
NA-22	TC-94M	
P-32	MO-99	
P-33	TC-99M	
S-35	IN-111	
CA-45	I-123	
CR-51	I-125	
MN-54	I-131	
FE-55	XE-133	
CO-57	CS-137	
CO-60	GD-153	
NI-63	SM-153	
CU-64	LU-177	
GA-67	IR-192	
GE-68	TL-201	

The quantities of each nuclide then input into the COMPLY model are derived by taking the aggregate total of each

nuclide possessed as determined from material receipt records and the cyclotron production logs, and then applying the form modifying factors based upon their original physical form (solid, liquid, gas) as provided for in ANSI Standard N13.1.

The Eberline PING 3B (particulate, iodine, noble gas) system currently installed is primarily used as a diagnostic tool for cyclotron staff; the data from this system is not employed to demonstrate compliance with 10CFR20 effluent release limits at this time. The DRS has the capability to generate reports using the PING system data, but cannot view the data in real-time.

The Eberline PING 3B system can be calibrated and maintained to ANSI N13.1-1999 and ANSI N42.18-2004 if it is determined a continuous air monitoring (CAM) system is recommended by ANSI N13.1 Table 2; NIH will assess this utilizing off-line sampling consistent with ANSI N13.1.

NIH reviewed several commercially available CAM systems in 2007- 2008 and determined that the current available systems had similar detection capabilities, and similar limitations as our PING system. For example: we can find no CAM system that differentiates positron emitters allowing identification of PET isotopes. Also, the rationale for purchasing a new CAM system was largely driven by the future cGMP facility and the possibility of a second PET exhaust point. The cGMP construction was delayed indefinitely in December, 2007 halting DRS plans for a new monitoring system. Construction for the cGMP was revitalized in March, 2009; DRS will revisit an updated CAM system to correspond with the cGMP completion. NIH will maintain any new CAM system consistent with ANSI N13.1 and ANSI N42.18 if our preliminary study determines it necessary.