

Carestream Molecular Imaging

Betsy Ullrich, Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 194046-1415

29 March 2010

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RE: License No. 06-21254-01
Docket No. 030-20106
Control No. 144491

Dear Ms. Ullrich,

In response to the questions posed in your 23March'10 email - I hope the answers provided are complete.

1. We will be restricting our isotopic usage to prepared/unit doses where possible (i.e., where unit can be rationalized for a mouse/mice). To the extent that this constitutes bulk dissemination, a Dose Drawing Station will be operational. The total amount of isotope requested is a worst-case scenario of multiple-animal experiments managed over sequential hours/days. Initially, all dosing will be confined to purchased, prepared injectibles, but we are planning for limited probe preparation upon the completion of appropriate training: a professional chemist (Dr. Tao Ji) is planning the limited activity of ^{99}Tc coupling to her DOTA-modified nanoparticles.

2. The facility is still in preparation, and quotations/purchases are active. Aside from our current Victoreen 451 ion chamber, we will purchase a Capintec CRC-25R Dose Calibrator, a Capintec 511 Dose Drawing Station, Berthold LB 25 Gamma Spectrometer, a PET Sharps Container/Shield, a 511 Transport Container, a Nuclear Medicine Mobile Barrier and a Hand/Foot Monitor (VWR). Numerous Lead Bricks (Chevron, V-interlocking, L's and regulars) and lead sheet will be used for active "pit" shielding, bench/drawer/floor shielding as well as customized animal and waste containment (including refrigeration). This facility is being developed with the advice of Dr. Bala Krishnan (Preclinical Image Consultants, LLC), to reasonably replicate the facility he developed/operated at Bristol-Meyers, Princeton, NJ.

3a. Any dosed animal will be used for imaging purposes only. Upon dosage, anaesthetized animals will be imaged and subsequently housed within the Rad-restricted area as recovering or sacrificed animals in waste. Any dosed animal and waste/bedding will be decayed in storage (with appropriate shielding and isotope segregation) prior to removal from the Rad-restricted area. The special case of live-animal recovery/storage will be limited to ^{18}F and ^{99}Tc dosing, where reasonable (secured, short-term) animal housing can be provided within the Rad-restricted area. Similar short-term housing may accommodate the special case of multiple imaging experiments over a few days for appropriate isotopes (e.g., ^{111}In), but the animals will be sacrificed and will be decayed with bedding in waste. No "radioactive" animals will be removed from the Rad-restricted area.

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3b. Animal carcasses (usually in an inverted latex glove) will be refrigerated or frozen in appropriated shielding, and decayed in storage. Contaminated bedding will be decayed in storage in an appropriately segregated/shielded dry waste.

3c. See 3a. All animals are secured/caged in this facility, and no radioactive animal will be returned to our central animal facility - assuring the guidance of Vol.7, Appendix H.

3d. A selected few of our IACUC SOPs related to animal handling could be forwarded to you, but I am not sure you are asking for me to provide them to you. They are certainly provided to our animal handlers and to all that must participate. They are currently in revision to reflect our newer facility, and new SOPs are being revised for animal handling specific to the Rad-restricted area. Preliminary final editions are due in about two weeks, but revisions specific to the Rad-restricted area cannot be readied prior to facility completion. Specific coursework is being prepared for new users, some of which already have ample training and experience, but all of which (new and experienced) will undergo the organized training and cross training for animal handling. The inclusive user group training is essential, since it must be focused on the specific facility, including ergonomics and instrument training. All user group personnel will be badged, some will be ringed.

4. As stated in the amendment, I was projecting 1 μCi ^{137}Cs check sources would be purchased from Berthold. Experience suggests that securing check sources in exempt quantities is sometimes not supported by a vendor unless the isotope is listed on your license. Thus, I request that both ^{137}Cs and ^{51}Cr be listed in the amendment, that these isotopes will be in the form of sealed sources, and that they will be sourced from Isotope Product Laboratories - they will be their Type D Gamma Standards, Catalogue number GF-137-D and GF-051D, and they will be secured in quantities of $<10 \mu\text{Ci}$ each.

5a,b,c To initiate the facility and test the instrumentation, the first badged user group will be confined to the RSO (D. Vizard), Asst. RSO (J. Pizzonia), and Consultant (Dr. Bala Krishnan, 10+ years of experience using all related isotopes and facility development at Bristol-Meyers, retired).

Upon activation of the Rad-restricted area/instrumentation and upon completion of appropriate further training, R. Papineni and M. Leevy will be implementing the animal protocols, under the supervision of the RSO and Consultant. All project planning and dose preparation will be supervised by the RSO. Further training of a supervised user group (M.C. Muenker and others without significant isotope experience) will commence upon facility activation and completion of all SOPs. Additional names and associated training and experience will subject to further amendment of this application.

R. Papineni has 10 years experience handling both ^{125}I and ^{22}Na , at Baylor College of Medicine. He has extensive animal handling experience.

M. Leevy has had 1 year of experience handling ^{18}F at the Notre Dame micro-PET facility, some 12 mouse injections, and has extensive animal handling experience.

M.C. Muenker has had 2 years experience handling ^{22}Na at Albert Einstein College of Medicine, and has gained animal handling experience over the last 2 years.

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6. Introductory training of ancillary personnel will be formally provided, and informal meetings are in process. Critical personnel have engaged in recent training and visitation to comparable facilities. Ancillary personnel shall include all personnel attached to the company to at least familiarize them with verbiage/signage and safety considerations. More specific instructing and SOPs will be devised for and given to the subset of personnel that may enter the restricted access laboratory that houses the Rad-restricted area.

7a. Your information is correct. The scintillation counter was so old (approximately 30 years) that no support from vendors could be elicited. The secured source was carefully examined/wiped/surveyed, and was found to be unlabeled, except for a detached label suggesting Am241 and Rd226. The stripped scintillation counter was eventually discarded, and Chase Environmental Group was contracted to characterize and eventually dispose of the source. They appropriately characterized the source (Ra226 only, low activity), but even they could not verify the heritage of the source. They appropriately managed the disposal with documentation.

7b. I confirm that very low amounts of 3H and 14C (<10 μ C quantities) were used in the laboratory area prior to 1996, all areas were properly wiped, and surveyed by LSC, but those records have long since been discarded. No solid waste from 3H and 14C was ever generated during that period of time (all very low-level, sanitary sewer).

One solid waste barrel designated as 3H was a legacy barrel from a prior facility (25 Science Park), which I decommissioned in the early 1990's. The 3H legacy barrel was nominally labeled as containing 0.1 mCi, since that was my estimate of suspect accounting error upon cleaning out the 25 Science Park facility (which I inherited). As stated in my notes, the contents of the legacy barrel were thoroughly examined, and surveyed to assure that no other isotope (suspect 14C) was significantly present. A sample of suspect lab debris was placed in a LSC vial/fluid and later counted by myself in another laboratory I was visiting; background counts were observed, but never entered into record since the procedure and counter could not be easily verified. Having convinced myself that the legacy barrel contained no significant radioactive waste, and having no confidence that verifiable 3H waste was ever placed in the barrel, I disposed of the contents. Further, in the legacy barrel, I did find a single vial labeled 10 μ Ci of 3H (protein marker) received in 1997 (verified in an old receiving record). The vial was never opened, apparently never used. No liquid contents were apparent. The label was defaced and vial discarded in trash.

7c. Last usage of radioactive materials (32P) in the 4 Science Park laboratory (Room 120, radiation hood) was completed in June 2006. The area was surveyed (background), and all final 32P waste was compiled in the Room 118 32P waste barrel. Prior use of all other isotopes had been long since completed, as mentioned above in 7b. By Oct 2006, all laboratory usage areas had been verified as retired from usage, and all decay-in-storage (Room 118) was completed. Such was documented in the facility status statement (11) in my Oct 27, 2006 "timely notice" statement to the NRC. Any hand-written notes of documentation prior to Oct06 have been discarded.

No unsealed radioisotopes were used in, nor did any enter into the 4 Science Park facility after June 2006.

Final inspection and last access of the 4 Science Park laboratory premises was on Oct 27, 2009, when I removed all records, notices, posters and signage.

In summary, final status surveys for 3H and 14C usage were completed in 1996. Final status 35S and 32P usage was completed in June 2006. Notice of status was documented to the NRC in

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October 2006. Final waste was discarded in October 2009, at which time sealed sources were removed and final inspection was performed.

7d. At no time during the usage of the 4 Science Park facility was unsealed solid 14C waste ever generated, designated or disposed of (see 7b). A legacy barrel of unverified 3H waste was disposed of (as discussed with Farrah Gaskins, and restated in 7b). Any future use of any long-life isotopes under this license and in control of myself (RSO) will be properly administered as secured waste, and properly shipped for disposal - no such use is anticipated. Only materials of <120 day half-life will be decayed in storage, secured and properly segregated.

7e. The 4 Science Park building is a 3-floor brick structure, each floor comprising about 10K sq.ft., whose address is 4 Science Park East, New Haven, CT 06535. An extension of the building comprises 2-floors (1st floor about 12K sq.ft., and a second about 7K sq.ft.) whose address is 4 Science Park West. Our company occupied the second floor of the 3-floor building and both floors of the 2-floor extension, with an entry into the extension and an address of 4 Science Park West. Laboratory areas were confined to the (1st) ground floor of the extension, and isotope usage was confined to a single laboratory (Room 120, southwest corner room), approximately 700 sq.ft., where primary usage was confined to a single bench, hood and sink in the southeast corner of the room. Secured radioactive waste storage was confined to an adjacent hall closet (Rm 118) of about 21 sq.ft.

Upon assuming control of and decommissioning the 25 Science Park facility, I was able to implement a more controlled and modest usage of isotopes in the 4 Science Park facility, limiting the usage of 3H and 14C to 10's of μCi , confining the waste to sanitary sewer only, and within a few years (after 1996), no 3H or 14C was used. From first usage in the 4 Science Park facility (1993), millicurie amounts of 35S and 32P were used and decayed in storage (rationizing my amendment to decay 35S in storage). Approximately 10x250 μCi quantities of 35S and 15x250 μCi quantities of 32P were used in the facility from 1993-2006, distributed irregularly over that period of time. Usage was confined to in-vitro labeling for detection/imaging purposes, as per the license statements.

The 4 Science Park building was renovated in about 1992. The original building was the Winchester Arms Company fire station, and previously used for ammunition storage. The entire "Science Park" in New Haven CT is urban industrial, whose history derives from the 19th century Winchester/Whitney Arms manufacturing site and Olins Chemical Company. My current understanding is that Yale University has assumed nominal control of the entire Science Park, but the Science Park Development Corporation may still maintain the status of landlord.

Sincerely,

Douglas Vizard, RSO

Attest,

John Dellisanti, General Manager
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