

## Telephone Conversation Log

For  
David Everhart  
March 17, 2005

Person Called	Gegory Hisel	License Number	29-30786-01	Phone Number	518 464-0871
Facility	Pharmalogic	Docket Number	03036157	Mail Control Number	136274

Subject	
Synopsis	<ol style="list-style-type: none"> <li>1. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State; or the application must contain the information identified in 10 CFR 32.210(c).  Please provide this information for the sealed sources requested in your application. Including all sealed sources (therapeutic and diagnostic) which you plan to re-distribute to licensees. In addition, please specify all devices, (Including devices for survey meter calibration) by manufacturer and model number that will be used in conjunction with the sealed sources.</li> <li>2. 10 CFR 32.72(b)(2)(ii) states, in part, that a pharmacist may work as an authorized nuclear pharmacist if the individual meets the requirements specified in 10 CFR 35.55(b), or prior to October 25, 2004, 10 CFR 35.980(b). Please provide the following documentation of training and experience for Vincent De Fedele: <ol style="list-style-type: none"> <li>a. Certification from the State Board of Pharmacy;</li> <li>b. Written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the training and experience requirements in 10 CFR 35.55(b)(1) or 10 CFR 35.980(b)(1), and that the individual has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist. Specifically, confirm the Mr. De Fedele has completed supervised practical experience in a nuclear pharmacy involving all the items listed under 10 CFR 35.55(b)(ii)</li> </ol> </li> <li>3. The possession limits requested in your licensing action require that you submit financial assurance in accordance with the requirements of 10 CFR 30.35. Submit the required financial assurance or modify your licensing request such that financial assurance is not required. You may wish to refer to NUREG-1757, "Consolidated NMSS Decommissioning Guidance", Volume 3 (enclosed) for assistance in formulating your response. Alternatively, you may wish to limit the isotopes in Item 1 of page D.5 to Byproduct Materials with Atomic No. 1 - 83 to include only those isotopes with a half life under 120 days to preclude the need for financial assurance.</li> <li>3. <b>Licensee stated they wish to use materials 1 through 83 with a half life of less than 120 days.</b></li> <li>4. On a detailed version of your facility diagram, please indicate the position of each of the areas described below (a-e) and in addition, identify adjacent areas across the walls from use and storage locations and show that adequate steps have been taken to assure that</li> </ol>

	<p>radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301. Exhibit 8.3 of the enclosed regulatory guide may be helpful in preparing your response and provides an example of a facility diagram that is acceptable to the NRC.</p> <ul style="list-style-type: none"> <li>a. Any neighbors</li> <li>b. Receiving and outgoing package prep areas</li> </ul> <p><b>4. Tenants above and to the right of the drawing, TLD's on the hallway between to moinitor doses. All shipping and receiving in the area to the left of the cyclotron</b></p> <p>5. For each radioactive drug to be distributed, except for products you will redistribute in the manufacturers original shipping container and without manipulation, provide:</p> <ul style="list-style-type: none"> <li>a. The radionuclide and maximum activity for each type of container</li> <li>b. The type and thickness of the "transport radiation shield" provided for each type of container; and</li> <li>c. the maximum radiation level expected at the surface of each transport radiation shield" when the radioactive drug container is filled with the maximum activity.</li> </ul> <p>6. Confirm that you will implement and maintain written procedures for customers return of pharmacy supplied syringes and vials and their contents , to specify that instructions will be provided to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the pharmacy.</p> <p>7. Provide a copy of the registration or license from the state board of pharmacy which designates your facility as a pharmacy.</p> <p>8. Provide the methods for calibrating your dose calibrator for measuring radiopharmaceuticals containing beta emitters.</p>
Action Taken or Required	