



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352

SEP 21 2005

Richard Joyrich, M.D.
Radiation Safety Officer
Harper University Hospital
3990 John R. Street
Detroit, MI 48201

Dear Dr. Joyrich:

Enclosed is Amendment No. 95 to your NRC Material License No. 21-04127-02 in accordance with your request. Please note that the changes made to your license are printed in **bold** font.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers. If you have any questions concerning this amendment please contact me at either (630) 829-9841 or (800) 522-3025.

This amendment deletes authorization for iridium-192 in the Cordis Checkmate System, as well as the removal of two former Authorized Medical Physicists. Three new authorized Medical Physicists have been added to your license. To prevent excessive re-ordering of the remaining line items on your license I moved Subitem 6.W. to become new Subitem 6.T. at this time. Corresponding Subitems 7, 8, and 9 were deleted and moved also. I also removed all references to the Cordis System in other Conditions and authorizations, so many Conditions have been re-ordered as a result.

At this time I updated Condition No. 19 to permit the decay-in-storage of materials with a half-life less than or equal to 120 days, instead of 65 days. This reflects a new NRC policy change described in Regulatory Issue Summary RIS - 2004-17, which should have been sent to you previously and can be found on our website at <http://www.nrc.gov>.

Your letter dated July 5, 2005, also requested the approval of Margaret M. Syrian, M.S. as an Authorized Medical Physicist (AMP). This request was not approved at this time because the information submitted was insufficient to complete our review. If you wish to pursue this request please submit appropriate information to clearly demonstrate that Ms. Syrian qualifies as an AMP and meets the training and experience requirements in either 10 CFR 35.51 or 35.961 (until October 24, 2005) and 35.59, as appropriate. Please submit this information to my attention and reference control number 314642.

In conducting my review of Ms. Syrian's application, I noted the following:

1. A letter was attached to the July 5, 2005, amendment request, dated May 24, 2005, which stated that Ms. Syrian was an AMP and had been so since May 16, 2000 to the present for uses including non-human use of Am-241, Cu-244, Cs-137, Cf-252 and Ir-192 for instrument calibration and brachytherapy. The July 5, 2005 letter also stated "We have enclosed letters of certification of authorized use from our Radiation Safety Committee, which is approved for this function."

Please note that these assertions are incorrect. Your Radiation Safety Committee (RSC)

is authorized to name Authorized Users in Condition No. 11.B. The RSC may approve certain AMP's in accordance with 10 CFR 35.13(b)(3) and 35.14(a). Ms. Syrian's application does not qualify for this rule.

Further, "Authorized Medical Physicist" is defined in 10 CFR 35.2 as:

"Authorized medical physicist means an individual who--

- (1) Meets the requirements in §§ 35.51(a) and 35.59; or, before October 24, 2005, meets the requirements in §§ 35.961(a), or (b), and 35.59; or
- (2) Is identified as an authorized medical physicist or teletherapy physicist on--
 - (i) A specific medical use license issued by the Commission or Agreement State;
 - (ii) A medical use permit issued by a Commission master material licensee;
 - (iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or
 - (iv) A permit issued by a Commission master material license broad scope medical use permittee."

All AMP use is, by definition, "human use;" there is no "non-human AMP" use. Also, NRC only names an AMP for manual brachytherapy for the decay correction of strontium-90 ophthalmic applicators, in accordance with 10 CFR 35.433. It is not apparent from your license that you are authorized for a strontium-90 ophthalmic applicator. Therefore, Ms. Syrian is not an AMP.

2. I also reviewed two previous applications from Ms. Syrian to be named an AMP, once for this license in 2003 and once for your other NRC license no. 21-04127-06 in 2005.

In my letter to then-RSO Azucena Garzon, M.S. dated February 21, 2003, I transmitted Amendment No. 89, which did not name Ms. Syrian as an AMP. However, this letter contained an error in that the deficiencies I listed for "Margaret Somnay, M.S." should have been listed for "Margaret Syrian." I accidentally juxtaposed Ms. Syrian's first name, correctly, with the last name of Archana Somnay, incorrectly. Ms. Somnay was listed as an AMP on Amendment No. 89. I regret the error and apologize for any inconvenience this may have caused you.

A copy of this letter showing the hand-marked correction is attached.

In addition, I have attached copies of the deficiency telephone conversation records I transmitted to Vijeshwar Sharma, M.S. in reference to Ms. Syrian's application under the 21-04127-06 license. These records are dated June 8, 2005, and July 15, 2005.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The enclosed license document is exempt from public disclosure in accordance with 10 CFR 2.390, because its disclosure to unauthorized individuals could present a security vulnerability.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 21-04127-02
Docket No. 030-02045

Enclosures:

1. Amendment No. 95
2. Copy of letter dtd 2/21/03
3. Copy of fax dtd 6/8/05
4. Copy of fax dtd 7/15/05