



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

MAR 06 2011

Michael Klug, R.Ph.
Radiation Safety Officer
Triad Isotopes, Inc.
2252 East 14 Mile Road
Warren, MI

Dear Mr. Klug:

Enclosed is Amendment No. 01 to your NRC Material License No. 09-32781-02MD 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.

Please note that, at this time, I only authorized the possession and use of the Draximage Smart-Fill iodine-131 capsule filling device for installation, calibration, training and demonstration purposes. Use of this device for the preparation of capsules for dispensation to humans is not yet permitted on this license.

I also excluded several requests made in the December 3, 2010, letter requesting approval of this device that pertained to internal training in use of the device by staff members who were trained initially by the vendor and who would then train other staff members who were not trained by the vendor.

I excluded the request to "replace Appendix D," as it appeared in the December 3, 2010, letter because it was not clear what was meant or intended, i.e., "Appendix D" to which document?

Several documents bearing different dates are listed in the last condition of your license, called the "tie-down" condition and if your letter is referring to one or more of these documents and an "Appendix D" you may respond by being specific about which document correlates with the "Appendix D" request.

My intention in restricting your authorization for the use of the Smart-Fill device is to learn more about the device and its impact on your radiation safety program before approving full authorization and use to prepare capsules for humans. As discussed in emails exchanged between me and Brigitte Nelson, M.S., Pharm.D., BCNP, Senior director of Quality and Safety for your company, I would like to arrange to visit your facility and observe this device before considering full authorization to use it. Please contact me when you expect to have the device installed so we can schedule a site visit.

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

M. Klug

It is possible I will develop additional questions and concerns regarding the use of the Smart-Fill device but the following questions and concerns will need to be addressed in a written response in order for NRC to consider full authorization for use of the Smart-Fill device for preparation of iodine-131 capsules for humans:

1. Will you be retaining the ability to manually prepare iodine-131 capsules even after installation of the Smart-Fill device and gaining full authorization for its use to prepare capsules for humans? My concern is whether the Smart-Fill device will replace your current compounding and preparation method and what your recourse might be if the device became unusable at some point in the future. Please explain your intentions and describe your plans in this matter.
2. Will use of the Smart-Fill device negate or change your safety procedures, such as the wearing of protective clothing, disposable gloves, extremity dosimetry badges, consumption of food/beverages, application of cosmetics, etc. in areas where the device will be used? Please explain and describe your intentions and plans in this matter.
3. How will you decontaminate the unit if it should become contaminated? Please describe the safety procedures you will employ and who will perform these procedures in the event of a contamination incident involving the Smart-Fill device.
4. Please confirm that the dose calibrator built-in to the device will be calibrated in accordance with the manufacturer's instructions or with nationally recognized standards.
5. Please explain what you will do to calibrate iodine-131 capsules if the dose calibrator should become contaminated or fail to work properly.
6. Please describe whether there is a limit on how much iodine-131 that can be safely prepared in capsule form in the Smart-Fill device and if so, how much activity is the upper limit allowed or recommended.
7. Please describe the volatility of the iodine-131 sodium iodide solution that you will use in the Smart-Fill device, i.e., is the solution buffered to reduce its volatility?
8. Regarding the "in-house training," or "pyramid training (my terminology)," proposed in the December 3, 2010 letter, please:
 - a. describe the topics and subjects covered by the training you plan to provide;
 - b. describe the qualifications of the staff who will conduct the training and their training and experience using the Smart-Fill device;
 - c. confirm that normal operating and emergency procedures will be included in the training;

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d. confirm that "qualified-instructor-supervised hands-on, practical training" in the use of the device will be provided prior to allowing trainees to use the device without direct supervision;

e. confirm that "dry runs" or "cold runs" will be employed to enable trainees to safely master use of the device before using actual radioactive iodine-131;

f. confirm that a written, closed book examination will be administered to trainees to demonstrate their understanding of the use of the device and include how many questions will be asked, what a passing grade will consist of, confirm that incorrect answers will be reviewed with trainees, how much time, minimally, the training is expected to last, and how often will retraining/refresher training in use of the device take place.

Your written response can be addressed to my attention as "additional information to control number 574023" to facilitate proper handling in our office. Your written response should be signed by a senior management representative or by the Radiation Safety Officer.

Please contact me at (630) 829-9841 or (800) 522-3025, ext. 9841 if you wish to speak with me and to arrange the site visit requested above. My fax number is (630) 515-1078.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 Code of Federal Regulations 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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.

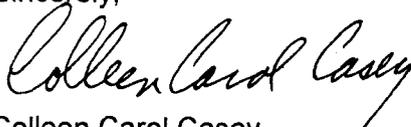
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Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 09-32781-02md
Docket No. 030-38278

Enclosure:

Amendment No. 01

Cc w/encl:

Shannon Julian
Triad Corporation
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Orlando, FL 32801

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