

NRC FORM 591M PART 1 (06-2010) 10 CFR 2.201		U.S. NUCLEAR REGULATORY COMMISSION	
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION			
1. LICENSEE/LOCATION INSPECTED: Tried Isotopes, Inc. 2755 Universal Drive, Saginaw, Michigan		2. NRC/REGIONAL OFFICE Region III 2449 Warrenville Road Lisle, Illinois	
REPORT NUMBER(S) 2011-001			
3. DOCKET NUMBER(S) 03038279	4. LICENSEE NUMBER(S) 09-32781-03MD	5. DATE(S) OF INSPECTION 4/29/11	
LICENSEE:			
The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:			
<input type="checkbox"/> 1. Based on the inspection findings, no violations were identified. <input type="checkbox"/> 2. Previous violation(s) closed. <input type="checkbox"/> 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied. _____ Non-cited violation(s) were discussed involving the following requirement(s):			
<input checked="" type="checkbox"/> 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11			
Condition 13 of NRC License No. 09-32781-03MD requires, in part, that the licensee test sealed sources for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210. The applicable certificate of registration number MA-0476-S-894-S for sealed source Model NES-356 states that the leak test frequency is 6 months.			
Contrary to the above, from approximately May 28, 2010, until March 15, 2011, a period greater than 6 months, the licensee failed to test a sealed source Model NES-356 (containing approximately 130 microcuries of cesium-137) for leakage and/or contamination, and the source was used daily.			
As corrective action, the licensee committed to implement a method of reminding its staff to conduct leak tests of all applicable sealed sources when doing the physical inventory of such sources every 6 months no later than May 11, 2011.			
Statement of Corrective Actions			
I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). (I understand that no further written response to NRC will be required, unless specifically requested.)			
Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE	Michael Klag		5/20/11
NRC INSPECTOR	Robert G. Gattone, Jr.		5/16/11
Branch Chief	Tamara E. Bloomer Aaron J. McCord		5/19/11

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Triad Isotopes, Inc. 2795 Universal Drive, Saginaw, Michigan REPORT NUMBER(S) 2011-001		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road Lisle, Illinois	
3. DOCKET NUMBER(S) 03038279	5. LICENSE NUMBER(S) 09-32781-03MD	6. DATE(S) OF INSPECTION 4/29/11	
7. INSPECTION PROCEDURES 87127	8. INSPECTION FOCUS AREAS 02.01-02.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 02500	2. PRIORITY 2	3. LICENSEE CONTACT Mike Klug, RSO	4. TELEPHONE NUMBER 989-392-0274
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Main Office Inspection Next Inspection Date: 4/29/13
 Field Office Inspection _____
 Temporary Job Site Inspection _____

PROGRAM SCOPE

The license's work hours were Monday through Friday from 1:00 am to 2:00 pm. The first run was usually at 4:00 am. The licensee had 3 rotating Authorized Nuclear Pharmacists, 3 Drawing Technicians (DT), and 2 Drivers/Quality Control Technicians (QCT). The licensee did not compound iodine-131 capsules or use I-131 solution. The licensee served approximately 15 clients within a 100 mile radius of its location of use.

PERFORMANCE OBSERVATIONS

The inspector observed: (1) that, based on the RSO's description, the licensee's technique for measuring pure beta emitters with a dose calibrator was as required; (2) the RSO prepare the first run; (3) the RSO use time, distance, shielding, and PPE to reduce his radiation dose; (4) that selected licensee personnel wore dosimetry badges as required; (5) the RSO elute a generator; (6) the RSO test the generator eluate for molybdenum-99 breakthrough; (7) that the RSO knew about the importance of testing each generator eluate for molybdenum-99 breakthrough; (8) that the licensee used heater blocks with sealed containment areas to prevent release of heated radiopharmaceuticals; (9) that selected syringes and vials were labeled as required; (10) a DT conduct removable contamination surveys of unit dosage shields containing licensed material prepared for packaging, and the DT knew how to respond to results in excess of the licensee's action level; (11) a DT use security seals for unit dosages; (12) a QCT conduct paper chromatography quality control testing on radiopharmaceuticals; (13) that the facility was as authorized; (14) that licensed material was secured as required; (15) that unit dosages of xenon-133 received from the manufacturer were not opened by the licensee prior to distribution; (16) that the RSO used a re-capping device to reduce extremity dose; (17) a maximum of 1 mR/hr at selected surfaces in the restricted area after the first run was almost completed, based on the inspector's survey with an NRC survey instrument that was calibrated; (18) that the licensee's facility was equipped with security and fire detection systems; (19) the RSO demonstrate how he would respond to a radioactive spill; (20) members of the licensee's staff conduct personnel surveys of their hands and feet before leaving the restricted area; (21) that the licensee prepared packages of licensed material as required; (22) that the licensee used proper shipping papers; (23) the RSO conduct a physical inventory of all sealed sources; and (24) a QCT demonstrate how daily area surveys were done.

Based on review of monthly dosimeter badge reports, the maximum annual TEDE and extremity doses received between 2008 and 2011 (through 3/31/11) were 65 millirem and 7578 millirem, respectively.