

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, Idaho, 83401
Licensee/Certificate Holder contact and phone number	Mr. John Miller 208-524-5300
Docket No.	071-0929
Inspection Report No.	071-0929/2008-201
Inspection Dates(s)	August 19-21, 2008
Inspection Location(s)	Idaho Falls, Idaho
Inspectors	Jim Pearson, Team Leader, Senior Safety Inspector Rob Temps, Senior Safety Inspector
Summary of Findings and Actions	<p>This inspection involved the review of International Isotopes Incorporated (I³) Quality Assurance Program Description (QAPD) which had been submitted in 2004 and approved by the Nuclear Regulatory Commission (NRC). The inspection focused on management controls and material transport activities and how these activities were being controlled under the NRC approved QAPD and the regulations of 10 CFR Part 71 by I³ as a user of transportation packagings.</p> <p>Overall, I³ was determined to be implementing its NRC-approved user-only QA program in an adequate manner for 10 CFR Part 71 transportation activities. The team identified an observation in that in several areas, I³ had over-committed to implement controls on activities that they do not perform related to shipment of Type B packagings. I³ committed to review the observation and to modify their QAPD to more closely reflect the actual activities they perform. One violation was identified with regard to the adequacy of internal QA program audits.</p>
Lead Inspector Signature/Date	Jim Pearson <i>Jim Pearson</i> 8/26/08
Inspector Notes Approval Branch Chief Signature/Date	<i>David W. Pataki</i> 8/26/08

INSPECTOR NOTES: IP 86001 WAS USED IN CONJUNCTION WITH APPLICABLE PARTS OF NUREG/CR 6314. INSPECTION RESULTS USING THE NUREG/CR 6314 FORMAT ARE DOCUMENTED BELOW:

INSPECTION BACKGROUND:

On August 19 through August 20, 2008, the U.S. Nuclear Regulatory Commission (NRC) performed an announced team inspection of International Isotopes Incorporated (I³) at their Idaho Falls, Idaho facility. I³ was chosen as the first user of transportation packagings under 10 CFR Part 71 to be inspected using the applicable standard inspection criteria found in inspection procedure 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings." The inspection assessed I³'s compliance with 10 CFR Part 71, and verified that any transportation package(s) which I³ had registered as a user and were in use at the time of the inspection, were verified to be properly used and maintained.

4.1.1 Quality Assurance Policy

The team determined that the I³ procedures and controls in place governing the implementation of their QA program for 10 CFR Part 71 activities were adequate. I³ has a dedicated full-time Quality Manager (QM) position. The QM is responsible for Part 71 activities as well as other company activities. The QM has appropriate organizational independence and reports directly to the President. The team noted that I³ should consider defining the roles of the QM in the QA program procedures as well as the roles of other managers and personnel with regard to Part 71 activities.

4.1.2 Nonconformance Controls

The team determined that I³ has procedures and a basic structure for the handling of nonconformances.

4.1.3 Documentation Controls

The team reviewed the procedures for document control, document preparation, and document distribution used by I³. The QM was interviewed regarding the distribution process for controlled documents to ensure approved and current procedures are available to individuals performing activities affecting quality. Through the interview, review of documents, and verification of hard copy controlled copies throughout the facility, the team verified adequate control of procedures.

4.1.4 Audit Program

The team determined that I³ had been performing Type B packaging audits and has considered that this met the requirements of 10 CFR 71.137, "Audits." While the team considered the packaging audits to be a good practice, they were viewed more as being job surveillances and therefore did not meet the 10 CFR 71.137 requirements. Specifically, 10 CFR 71.137 states, in part, that the licensee shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the QAPD and to determine the effectiveness of the program. Contrary to this requirement, I³ did not have procedures or a program in place to ensure that all aspects of the QAPD were audited for compliance and to determine effectiveness of the program. This is a violation of NRC requirements and was cited on the Form 591 attached with these inspector notes. The team discussed the noncompliance with I³ Management and the QM to ensure they understood what the NRC requires with regard to audits. They acknowledged they understood the basis for the violation and that appropriate corrective actions would be taken to address the issue.

4.3.1 Material Procurement

During this inspection, the team discussed, with both the RSO and the QM, the use of transportation packagings that I³ has been registered for, with the NRC, as a user. In all cases discussed, the team determined that I³ only uses packagings, maintained current from the certificate of compliance (CoC) holder of the transportation packagings. Overall, the team concluded that actual procurement of parts for transportation package maintenance does not occur at I³, as the need for maintenance parts is satisfied by the CoC holder.

4.4.1 Maintenance Controls

The team discussed the maintenance of transportation packagings with both the Radiation Safety Officer (RSO) and the QM. It was determined by the team that I³ does not perform maintenance but rather requires all maintenance actions to be performed by the packaging supplier (CoC Holder) prior to delivery of the packaging to I³ for use.

The team also determined that the only calibrated equipment used at I³ for Part 71 activities was a torque wrench. The team verified that the torque wrench, identified as Serial # 400316286, had current calibration records and was properly labeled with the current calibration due date information.

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/CERTIFICATE HOLDER

International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, Idaho, 83401

REPORT NUMBER(S) 71-0929/2008-201

2. NRC/REGIONAL OFFICE

Division of Spent Fuel Storage and Transportation
U. S. NRC
M/S EBB-3D-02M
Washington, DC
20555-0001

3. LICENSEE/CERTIFICATE NUMBER(S)
71-0929

4. INSPECTION LOCATION
Idaho Falls, Idaho

5. DATE(S) OF INSPECTION
August 19-21, 2008

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 of Certificate of Compliance (CoC). 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:

- 1. Based on the inspection findings, no violation or nonconformances were identified.
- 2. Previous violation(s) or nonconformance(s) closed.
- 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) was/were discussed involving the following requirement(s) and Corrective Action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of nonconformance of NRC requirements and are being cited. This for is a NOTICE OF VIOLATION OR NONCONFORMANCE, which may be subject to posting in accordance with 10 CFR 19.11.

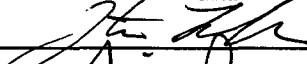
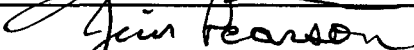
(Violations, Nonconformances, and Corrective Actions)

10 CFR 71.137, "Audits," states, in part, that a licensee shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. Contrary to this requirement, the NRC determined that International Isotopes, Inc., did not have procedures in place to ensure the above auditing requirements were met.

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 I 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; OR

Written Response requested in 30 days Yes No

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE	STEVE LAFLIN		8.20.08
NRC INSPECTOR	Jim Pearson		8/20/08