

## UNITED STATES NUCLEAR REGULATORY COMMISSION REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-4005

April 13, 2006

Advanced Isotopes of Idaho ATTN: Troy Curnutt, RT(N) Radiation Safety Officer 4968 Rainbow Lane Chubbuck, Idaho 83202

SUBJECT: LICENSED AMENDMENT

Please find enclosed Amendment No. 01 to NRC License No. 11-29216-01MD, **authorizing Dr. Nicole Chopski as a nuclear pharmacist**. An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iii). You should review this license carefully and be sure that you understand all conditions. If you have any questions, please contact me at 817-276-6552.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

- 1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
- 2. Notify NRC in writing of any change in mailing address.
- 3. By 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
  - a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area;
  - b. If you decide not to acquire or possess and use authorized material; or
  - c. When no principal activities under the license have been conducted for a period of 24 months.

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- 4. Request and obtain a license amendment before you:
  - a. Change Radiation Safety Officer;
  - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;
  - c. Add or change the areas or address(es) of use identified in the license application or on the license; or
  - d. Change the name or ownership of your organization.

## Advanced Isotopes of Idaho

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In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address: http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf.

The NRC no longer publishes the NRC Rules and Regulations loose leaf supplements due to budget constraints. However, an electronic version of the NRC's regulations is available on the NRC Web site at <u>www.nrc.gov</u>. To view these regulations, highlight "Electronic Reading Room" and choose "Regulations" on the drop down menu. An electronic version of the NUREG-1556 Series publications is also available on the NRC Web site. To view these guidance documents, highlight "Electronic Reading Room," choose "All Document Types" on the drop down menu. Scroll down to "NUREG-Series Publications" and select "Publications Prepared by the NRC Staff." Then, choose "NUREG-1556" from the table and select the appropriate volume(s) for your license type.

On October 25, 2004, the NRC suspended public access to NRC's electronic document system (ADAMS.) The NRC initiated an additional security review of publicly available documents to ensure that potentially sensitive information was removed from the ADAMS database, which is accessible through the NRC's web site. As a result of our security review guidance, it was determined that this document will not be made publicly available through ADAMS. If there are any questions regarding this determination please contact me at the above listed telephone number.

Thank you for your cooperation.

Sincerely,

· /RA/

Rachel S. Browder, Health Physicist Nuclear Materials Licensing Branch

Docket: 030-37048 License: 11-29216-01MD Control: 470948

Enclosure: As stated

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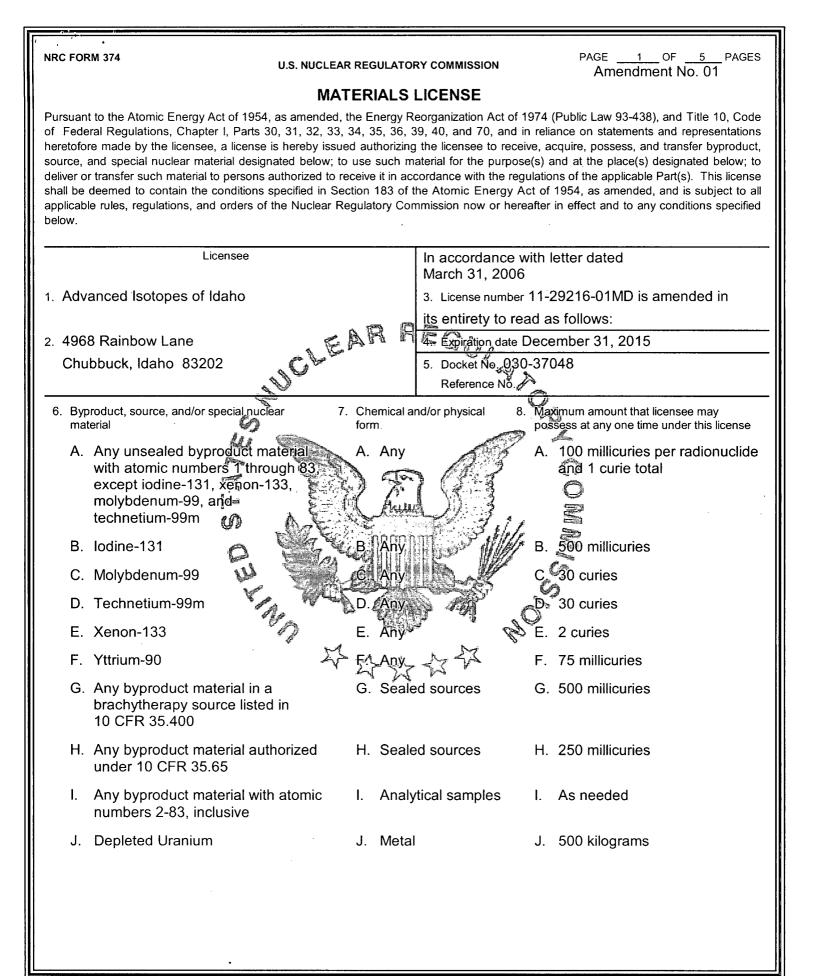
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			License Number 11-29216-01MD									
		MATERIALS LICENSE SUPPLEMENTARY SHEET	Docket or Reference Number 030-37048									
			Amendment No. 01									
9.	Authorized us	e:										
	A. through F. Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of used and unused molybdenum-99/technetium-99m generators to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals including compounding of iodine-131 and redistribution of used and unused molybdenum 99/technetium 99m generators to authorized recipients for non-medical user											
	G. Redistribution of sealed sources initially distributed by a manufacturer licensed pursua to 10 CFR 32,74. Redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons/specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.											
	H. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients for non-medical use											
	I.         Possession incident to the performance of wipe testing of customer's sealed sources.           J.         Shielding for molybdenum 99/technetium 99m generators.											
	CONDITIONS											
10.	10. Licensed material shall be used only at the licensee's facilities located at 4968 Rainbow Lane, Chubbuck, Idaho.											
11.	1. Licensed material shall be used by, or under the supervision of:											
	<ul> <li>A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2).</li> </ul>											
	B. Authorized Nuclear Pharmacists:											
	Catherine Heyneman, PharmD. Nicole Chopski, PharmD.											
12.	The Radiation	n Safety Officer for this license is Troy Curnut	t, RT(N).									

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	1	MATERIALS LICENSE SUPPLEMENTARY SHEET	License Number 11-29216-01MD Docket or Reference Number 030-37048							
			Amendment No. 01							
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13.	A.	Sealed sources and detector cells shall be tested for exceed 6 months or at such other intervals as specifie 10 CFR 32.210.	•							
	В.	Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.								
	C.	In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested								
	D.	Each sealed source fabricated by the licensee shall b leakage, and contamination prior to any use or transfe								
	E.	Sealed sources need not be leak tested if:	AS O							
	ŝ.	<ul> <li>(i) they contain only hydrogen 3; or full</li> <li>(ii) they contain only a radioactive gas, or</li> </ul>								
		(iii) the half-life of the isotope is 30 days or less, or								
		(iv) they contain not more than 100 microcuries of b than 10 microcuries of alpha emitting material; c								
		(v) they are not designed to emit alpha particles, ar when they are removed from storage for use or been tested within the required leak test interval sealed source or detector cell shall be stored for tested for leakage and/or contamination.	transferred to another person, and have not , they shall be tested before use or transfer. No							
	F.	The leak test shall be capable of detecting the present the test sample. If the test reveals the presence of 0. contamination, a report shall be filed with the U.S. Nu 10 CFR 30.50(c)(2), and the source shall be removed repaired, or disposed of in accordance with Commiss days of the date the leak test result is known with the Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington Nuclear Materials Safety. The report shall specify the action taken.	005 microcurie or more of removable clear Regulatory Commission in accordance with immediately from service and decontaminated, ion regulations. The report shall be filed within 5 U.S. Nuclear Regulatory Commission, n, Texas 76011, ATTN: Director, Division of							

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	MATERIALS LICENSE SUPPLEMENTARY SHEET						Docket or Reference Number 030-37048									
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	G.	specifical the licens	Illy licen see is a	sed by th uthorized	e Com I to col	nmissio lect lea	on or ar ak test	n Agreer samples	me s fo	ned by the licen nt State to Perfe or analysis by pe n services.	orm s	such s	ervic	es. I	In ac	
	sou	rce holder	rs by th	e license	э.	<u> </u>	AA	RE(		al shall not be of	•					
15.	The rece	e licensee s eived and	shall co posses	nduct a j sed unde	ohysica er the li	al inver	ntory e	very 6 m	nor	ths to account t	for al	lsour	ces a	and/o	r de	vices
16.	5. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."															
17.	. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:									)						
	Α.	be disting	guishec	from the	backg	round	radiati	on level	wi	sal and determi th an appropriat osed shielding;	te rac					
	B.	Removes container licensee;	rs and t	teratês a hat wil <u>l</u> b	ll radia e maña	tion lat agedia	pels, e: s biom	xcept foi edical-w	r]ra /as	adiation labels of te after they ha	on ma ve be	aterials een re	s tha lease	t are ed fro	with om th	in าe
	С.	of the dis	sposal, d at the	the surve	y instri	ument	used, t	the back	٩	for 3 years. The ound radiation le the name of the	evel,	the ra	idiati	on le	vel	
18.	. Radioactive waste may be picked up from the 1icensee's customers and disposed of in accordance with the procedures, statements, and representations in application dated September 21, 2005 and letter dated December 13, 2005.															
19.	mat		uantities	below th	e mini	mum lii				nall further restri 0 CFR 30.35(d)					lice	nsed

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MATERIALS LICENSE	License Number 11-29216-01MD Docket or Reference Number 030-37048						
SUPPLEMENTART SHEET	Amendment No. 01						
<ul> <li>20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.</li> <li>A. Application dated September 21, 2005</li> <li>B. Electronic mail dated December 13, 2005</li> <li>C. Electronic mail dated December 13, 2005</li> </ul>							
AXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	A COMMAN SOLUTION						
FOR THE U	.S. NUCLEAR REGULATORY COMMISSION						
Nuclear Region	/ <b>RA</b> / S. Browder, Health Physicist r Materials Licensing Branch IV on, Texas 76011						