ACCEPTANCE REVIEW MEMO (ARM)

Response	esponse Deficiencies Noted During Acceptance Review				
Reviewer Assigned:	Roberto Torres	ARM reviewer(s): Cook			
Type of Action:	Amend	Date of Requested Action: 08-23-07			
Docket No.:	030-34474	Mail Control No.: 471492			
Licensee:	Alaska Heart Institute, LLC	Alaska Heart Institute, LLC License No.: 50-29111-01			

 Add - delete IC license condition. Add IC paragraph in cover letter. Split license from cover letter. Add SUNSI marking to license.
[] Ask the licensee if they have any type-amount of EPAct Material.

Reviewer's Initia	als:	Date:		
□Yes □No	Unrestricted release Group 2 or >: Tr	ansfer memo to FCDB within 10 days.		
□Yes □ No	Decommissioning notification should be completed within 30 days.			
□Yes □No	Termination request < 90 days from a	date of expiration		
□Yes □No	Expedite (medical emergency, no RS license, RAM in possession not on lic	-		
□Yes □No	TAR needed to complete action.			
Branch Chief's	and/or Sr. HP's Initials:	Date:		

SUNSI Screening according to RIS 2005-31						
DYes INO Non-Publicly Available, Sensitive if any item below is checked						
General guidance:						
RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule Exact location of RAM (whether = or > than Category 3 or not) Design of structure and/or equipment (site specific)						
Information on nearby facilities Detailed design drawings and/or performance information Emergency planning and/or fire protection systems						
Specific guidance for medical, industrial and academic (above Category 3): RAM guantities and inventory						
Manufacturer's name and model number of sealed sources & devicesSite drawings with exact location of RAM, description of facility						
RAM security program information (locks, alarms, etc.) Emergency Plan specifics (routes to/from RAM, response to security events) Vulnerability/security assessment/accident-safety analysis/risk assess						
Mailing lists related to security response Branch Chief's and/or Sr. HP's Initials: \mathcal{M} Date: 11-9-07						

Pre-Licensing Screening

Applicant Information:

Control No. 471492

Name: Alaska Heart Institute, LLC	Type of Request: Amend Program Code(s): 02201				
Location: AK	License No.: 50-29111-01	Docket No.: 030-34474			

STEP 1-Radioactive Materials and Quantities Requested:

Instructions for Step 1: <u>Complete Step 1 for all applications</u> . If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.		
А.	The request is from a new applicant.	No
В.	NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	No
C.	The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	No

Table of Risk Significant Quantities

(Category			9, Categorization of Rad		st 2005)
Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Cl ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
lr-192	0.8	22	Yb-169	3	81

The primary values are TBq. The curie (Ci) values are for informational purposes only.
 The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE-If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	Yes , No, or Not Applicable (NA)
Total Activity–multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	
Unity Rulemultiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g.,[(total activity for radionuclide A) \div (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) \div (risk significant quantity for radionuclide B)] \ge 1.0.	

Signature and Date for Step 1:

-11-9-07

License Reviewer and Date



Richard A. Anschuetz, MD, FACC James A. Baldauf, MD, FACC Leo B. Bustad, MD, FACC John C. Finley, MD, FACC Seth L. Krauss, MD, FACC, FSCAI William P. Mayer, MD, FACC, FACP Paul A. Peterson, MD. FACC Mark A. Selland, MD, FACC David W. Sonneborn, MD, FACC

Krzysztof W. Balaban, MD Mario Binder, MD Steven J. Compton, MD, FACC Thomas K. Kramer, MD, William A. Kutchera, MD, FACC Mark W. Moronell, MD, FACC George S. Rhyneer, MD, FACC Alan E. Skolnick, MD, FACC

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Margaret Barnet t, ANP Laurel K. Racenet, ANP Robert G. Baeten, II. PA

Janet E. Campana, ANP Susan W. Morrow, ANP Vicki L. Vermillion, ANP Mary Weppler, MSN, NP Sharon A. Masinelli, PA

August 23, 2007

Jacqueline Cook, Health Physicist US Nuclear Regulatory Commission Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, TX 76011-8064

Re: License No.: 50-29111-01

Dear Ms. Cook,

This letter is an amendment request to change our radiation safety officer.

- 1. The current RSO is Alan E. Skolnick, M.D.
- 2. We have appointed Mark A. Selland, M.D. to replace Dr. Skolnick as the RSO. Dr. Selland is currently listed as an authorized user on our license.

Thank you for your consideration.

Sincerely,

Baxter Burton, J.D. CEO

950 E. Bogard Rd. Suite 214 Wasilla, AK 99654 907-561-3211

3. OTHER	B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered //)	3. COMMENTS Signed <u>Caller Murnu</u> hlan Date <u>9-05-07</u>	2. FEE ATTACHED Amount: Check No.:	1. APPLICATION ATTACHED Applicant/Licensee: ALASKA HEART INSTITUTE, LLC Received Date: 20070828 Docket No: 3034474 License No.: 471492 License No.: 50-29111-01 Amendment	LICENSE FEE IRANSMIITAL A. REGION	Fee Lice