



27 May 2009

**Regional Administrator
U.S. Nuclear Regulatory Commission Region III
Commercial and R&D Branch
Division of Nuclear Materials Safety
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352
630-829-9500**

SUBJECT: NRC RAM License Amendment, License # 2132190-01MD

Dear Sir:

In accordance with changes implemented in 10 CFR Parts 30,32 & 35 (Ref: 72 FR 55864), PharmaLogic would like to amend the Nuclear Regulatory Commission RAM License # 2132190-01MD to include accelerator-produced and naturally occurring radioactive material at the licensee's nuclear pharmacy:

**PharmaLogic MI
1144 Boon Street
Traverse City, MI**

At this time I have provided an information packet listing additional radioactive material and sealed sources, handling and utilization.

1. Requested radioactive material has been listed by radionuclide, form, quantity and purpose of use on enclosed sheet.
2. All requested radiopharmaceuticals will be prepared under the supervision of an authorized nuclear pharmacist or obtained from a supplier authorized pursuant to 10 CFR 32.72.
3. PharmaLogic has included in this amendment request brachytherapy sources for redistribution to authorized users.
 - a. These brachytherapy sources will be distributed upon receipt of a prescription from an authorized user who has a current radioactive materials license listing the prescribed brachytherapy radioactive material, quantity and use on file at the PharmaLogic pharmacy.
 - b. The brachytherapy sources will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent Agreement State requirements.

**PharmaLogic MI
1144 Boon Street ♦ Traverse City ♦ Michigan 49686
231-929-7200 ♦ 231-929-4457 FAX**

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- c. PharmaLogic will distribute the brachytherapy sources in the original, unaltered manufacturer's packaging, labeling and shielding. PharmaLogic will include the manufacturer's package insert, leaflet, brochure or other documentation that provides radiation safety instructions for handling and storing the sources.
4. Transport shielding information has been included for all radiopharmaceuticals distributed under this RAM License.

I wish to thank you for your consideration of this amendment request. Please direct all mailings concerning this amendment to the Traverse City address. I may be reached at the telephone number listed below in the event of questions arising from this request.

Sincerely,



Dana Suttle, RPh
Pharmalogic MI
Radiation Safety Officer
231-929-7200
231-929-4457 FAX

Radioactive Drug Shielding for Distribution

Radioactive Material	Physical Form	Maximum Radioactivity per vial/syringe (mCi)	Manufacturer, Type, Thickness of Transport Shield	Max Radiation Level at Transport Shield Surface (mR/hr)
Chromium-51	solution	2	Note 1	3
Fluorine-18	solution	535	Note 2	50
Gallium-67	solution	10	Note 1	26
Indium-111	solution	3	Note 3	< 1
Iodine-123	solution, capsule	1	Note 1	< 1
Iodine-125	solution	2	Note 1	0.03
Iodine-131	solution, capsule	160	Note 4	50
Iodine-131	solution	0.3	Note 1	6.0
Samarium-153	solution	150	Note 5	50
Strontium-89	solution	4	Note 5	50
Rubidium-81 / Krypton-81m	Special form, gas	25	Note 6	50
Technetium-99m	solution	500	Note 1	0.1
Technetium-99m	solution	50	Note 1	0.05
Thallium-201	solution	6	Note 1	1
Xenon-133	gas	20	Note 6	0.6
Yttrium-90	solution	32	Note 5	50

Note 1: Biodex, 001-281, 0.25" Pb; or equivalent

Note 2: Biodex, 001-785, 0.5" Pb body, 1.2" Pb bottom, 1.44" Pb top

Note 3: Biodex, 001-789, 0.5" Pb; or equivalent

Note 4: Biodex, 001-860 and 001-880, 0.52" Pb body; 1.12" Pb top; 1.0" Pb bottom

Note 5: Biodex, 001-788, 0.09" Pb and 0.36" acrylic; or equivalent

Note 6: Radiopharmaceuticals will be shipped in the original containers and shielding devices as supplied by the commercial manufacturer. Shield has a wall thickness between 0.25" and 0.5" lead.

Radioactive Material and Use				
	Radioisotope	Form or Mfg / Model No.	Maximum Qty	Purpose of Use
1	Byproduct Materials with Atomic Number 1-83	Any, except sealed sources	200 milliCuries per nuclide, 2 Curies total possession, except as noted	10 CFR 32.72 and 10 CFR 30.41
2	Fluorine-18	Any, except sealed sources	1 Curie	10 CFR 32.72 and 10 CFR 30.41
3	Gallium-67	Any, except sealed sources	500 mCi	10 CFR 32.72 and 10 CFR 30.41
4	Indium-111	Any, except sealed sources	300 mCi	10 CFR 32.72 and 10 CFR 30.41
6	Thallium-201	Any, except sealed sources	1 Curie	10 CFR 32.72 and 10 CFR 30.41
7	Any Byproduct Material in a Brachytherapy Source, as listed in 10	Sealed Sources	0.5 Curie	10 CFR 32.74 and 10 CFR

SEALED SOURCES

	Radioisotope	Mfg / Model No.	Maximum Amount	Description	Authorized under	Sealed Sources & Devices Registry #
1	Barium-133	International Isotopes Idaho / Model BM06E & BM06S Series	2 mCi	medical reference source	10 CFR 35.65	NR-1235-S-102-S
2	Barium-133	North American Scientific / Model MED3550	1 mCi	dose calibrator standard	10 CFR 35.65	CA-510-S-114-S
3	Barium-133	North American Scientific / Model MED3400 & 3402	4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
4	Barium-133	Isotope Products Laboratories Model RV-133-250U	1 mCi	dose calibrator standard	10 CFR 35.65	CA-0406-S-148-S
5	Barium-133	Isotope Products Laboratories Model EG-133-MX6-5U	20 uCi	charcoal cartridge standard	10 CFR 35.65	
6	Cesium-137	International Isotopes Idaho / Model BM06E & BM06S Series	2 mCi	medical reference source	10 CFR 35.65	NR-1235-S-102-S
7	Cesium-137	North American Scientific / Model MED3400 & 3402	4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
8	Cesium-137	North American Scientific / Model MED3550	1 mCi	dose calibrator standard	10 CFR 35.65	CA-510-S-114-S
9	Cesium-137	Isotope Products Laboratories Model RV-137-200U & RV-137-250U	1 mCi	dose calibrator standard	10 CFR 35.65	CA-0406-S-148-S
10	Cobalt-57	North American Scientific / MED3550	30 mCi	dose calibrator standard	10 CFR 35.65	CA-510-S-114-S
11	Cobalt-57	International Isotopes Inc / BM03-57L & BM03-57A	48 mCi	calibration point source	10 CFR 35.65	TX-1153-S-104-S
12	Cobalt-57	International Isotopes Idaho / Model BM06E & BM06S Series	30 mCi	medical reference source	10 CFR 35.65	NR-1235-S-102-S
13	Cobalt-57	North American Scientific / MED3503	0.4 mCi	medical reference source	10 CFR 35.65	CA-0510-S-116-S

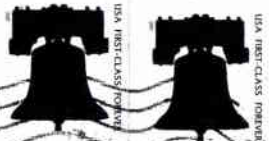
SEALED SOURCES (con't)

	Radioisotope	Mfg / Model No.	Maximum Amount	Description	Authorized under	Sealed Sources & Devices Registry #
14	Cobalt-57	North American Scientific / MED3400 & 3402	4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
15	Cobalt-60	International Isotopes Idaho / Model BM06E & BM06S Series	0.4 mCi	medical reference source	10 CFR 35.65	NR-1235-S-102-S
16	Cobalt-60	North American Scientific / Model MED3550	0.4 mCi	dose calibrator standard	10 CFR 35.65	CA-510-S-114-S
17	Cobalt-60	Isotope Products Laboratories Model RV-060-50U	0.4 mCi	dose calibrator standard	10 CFR 35.65	CA-0406-S-148-S
18	Cobalt-60	North American Scientific / MED3400 & 3402	4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
19	Europium-152	North American Scientific / Model MED3400 & MED3402	0.4 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
20	Europium-152	Isotope Products Laboratories Model GF-152-R2 & GF-152-R3	0.4 mCi	dose calibrator standard	10 CFR 35.65	
21	Iodine-125	Bard Brachytherapy / Model STM 1251	250 mCi	therapeutic sealed source	10 CFR 35.400	IL-1074-S-101-S
22	Iodine-125	IsoAid / Model IAI-125A	20 mCi	therapeutic brachytherapy seed	10 CFR 35.400	FL-1146-S-101-S
23	Iodine-125	North American Scientific / Model MED3631	100 mCi	brachytherapy source	10 CFR 35.400	CA-0510-S-126-S
24	Iodine-125	North American Scientific / Model MED3400 & MED3402	1 mCi	rod source	10 CFR 35.65	CA-0510-S-113-S
25	Palladium-103	Theragenics / Model 200	200 mCi	brachytherapy source	10 CFR 35.400	GA-0645-S-101-S
26	Palladium-103	North American Scientific / Model MED3633	100 mCi	brachytherapy source	10 CFR 35.400	CA-0510-S-126-S

Pharmacologic M
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Traverse City MI
49686



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Re: License Amendment Request