July 31, 2018

Bryan Parker, Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road. Suite 210
Lisle, IL 60532-4352

Re: Additional information to control numbers 608854, 609133, 609134 regarding RAM Licenses 13-35179-02 and 13-35179-03

Mr. Parker,

Please find the responses to your email attachment dated July 20, 2018.

Zevacor confirms all license conditions and commitments.

If you have any questions regarding the submitted request, please contact me at the information provided below.

Sincerely,

Matthew Trusner
Corporate Radiation Compliance Officer
Zevacor Molecular
(M) 217-433-7902
mtrusner@zevacor.com

Answer to Questions:

Control Numbers 608854, 609133 & 609134

1. **Please provide a Delegation of Authority for Matthew Trusner as RSO, signed by both management and Mr. Trusner acknowledging his acceptance of the appointment. As discussed, please provide a separate copy for each license being amended.**

   Please see the attached Delegation of Authority for both NRC RAM Licenses 13-35179-02 and 13-35179-03.

2. **Please provide a statement of Mr. Trusner's involvement with cyclotron operations and any formal or informal training in cyclotron operations as it relates to radiation safety.**

   Mr. Trusner's involvement has been from the inception of both NRC RAM licenses. Mr. Trusner was involved in meetings discussing the planning, installation, operation, and safety of the cyclotron. Additionally, Mr. Trusner has written and/or reviewed all radiation safety SOPs concerning cyclotron operations and provides regular radiation safety training to all staff members.

Control Number 608854

1. **Please provide additional evaluation of the shielding of the new hot cells over Vault 1.1 and 2.2**

   Please see the attached shielding evaluation of the new hot cells over Vault 1.1 and 2.2.

2. **Please provide additional description of any physical changes to the ventilation/effluent system(s), as well as any changes in effluent monitoring, from the addition of the new hot cells over Vaults 1.1 and 2.2.**

   The new hot cells over Vaults 1.1 and 2.2 do not require any physical changes to the ventilation/effluent system or effluent monitoring system.

July 31, 2018

You, Matthew J. Trusner, have been appointed Radiation Safety Officer for NRC License 13-35179-02 and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain safety issues. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time.

Martin L. Cohen
Interim CEO
Global Isotopes, LLC dba Zevacor Molecular

2 AUG 2018
Date

I accept the above responsibilities,

Matthew J. Trusner
Radiation Safety Officer
Global Isotopes, LLC dba Zevacor Molecular

2 AUG 2018
Date

July 31, 2018

You, Matthew J. Trusner, have been appointed Radiation Safety Officer for NRC License 13-35179-03 and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain safety issues. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time.

Martin L. Cohen
Interim CEO
Global Isotopes, LLC dba Zevacor Molecular

2 AUG 2018
Date

I accept the above responsibilities,

Matthew J. Trusner
Radiation Safety Officer
Global Isotopes, LLC dba Zevacor Molecular

2 AUG 2018
Date

Sr-82 TARGET PROCESSING LINE SHIELDING CALCULATION

1. Purpose and Scope

This shielding analysis is conducted to define design input parameters based on User Requirements document (REF TBD) for Sr-82 target processing hot cell line. Exposure from target processing operation is estimated. This does not include exposure from all other operations including waste disposal, cyclotron service, target unloading etc. ALARA 10% is used as target exposure rate for this operation.

2. General Assumptions

Target activity is estimated based on a worst realistic case production scenario, as follows:

Processing parameters:

Beam current on one target is assumed to be 250 uA., which is greater than projected target capacity of 200 uA but is still less than max. available from cyclotron 350 uA.

Irradiation time of 12 days followed by 12-24 hour decay in vault and 10 days (from EOB) storage in a cave. Processing one target at a time after 10 days. Actual decay delay will likely be longer to meet USP requirements for Sr-83/Rb-83 impurity. Longer decay time will reduce dose rate.

Geometry and Materials:

Lead density is assumed to be 11.34 g/cm^3, lead glass of two densities is considered, 4.6 and 5.2 g/cm^3 respectively. Point source is placed near hot cell center at 1 meter distance from operator location where dose rates were estimated.

Schedule:

One target processed each week, processing time is 8 hours. Processing takes place 50 weeks each year. It should be noted that many impurities are removed very early in processing, which will result in a lower than estimated here exposure rates during later stages of operation.

3. Target Activity

Production rate and saturation yield of Sr-82 was estimated based on momentary thick target yield of 0.32 mCi/uA*hr. Corresponding saturation yield of 287 mCi/uA was used to estimate Sr-82. This is in line with theoretical sat. yield of 336 mCi/uA, based on published cross sections and stopping by SRIM.

Activity of Ge-68 was estimated based on published cross sections and SRIM stopping.

Activities of all other isotopes were assumed to be in the same proportion to Sr-82 as in INR data below:

Изотоп ($T_{1/2}$, дни)	Активность, мКи		
	10 дней после облучения	3 года после облучения	6 лет после облучения
Sr-82 (25)	1700	$1.7 \cdot 10^{-10}$	$1.7 \cdot 10^{-21}$
Sr-85 (64.78)	640	$6.1 \cdot 10^{-3}$	$5.7 \cdot 10^{-8}$
Rb-83 (86.2)	2100	$3.5 \cdot 10^{-1}$	$6.0 \cdot 10^{-5}$
Rb-84 (32.79)	3200	$3.9 \cdot 10^{-7}$	$4.6 \cdot 10^{-17}$
Rb-86 (18.66)	1700	$6.5 \cdot 10^{-13}$	$2.5 \cdot 10^{-32}$
Sc-46 (83.81)	4	$5.3 \cdot 10^{-4}$	$6.9 \cdot 10^{-8}$
V-48 (15.976)	130	$6.3 \cdot 10^{-19}$	$3.0 \cdot 10^{-39}$
Cr-51 (27.73)	420	$8.0 \cdot 10^{-10}$	$1.5 \cdot 10^{-21}$
Mn-54 (312.3)	0.8	$7.3 \cdot 10^{-2}$	$6.6 \cdot 10^{-3}$
Co-56 (78.9)	47	$3.4 \cdot 10^{-4}$	$2.4 \cdot 10^{-7}$
Co-57 (271.4)	1.3	$8.2 \cdot 10^{-2}$	$5.2 \cdot 10^{-3}$
Co-58 (70.78)	21	$6.3 \cdot 10^{-5}$	$1.3 \cdot 10^{-9}$
Общая активность	10 Кюри	0.5 мКи	0.001 мКи

Resulting target composition at 10 days after EOB was as follows:

	INR target	Our target
Sr-82	1700	**15.1 Ci**
Sr-85	640	**5.7 Ci**
Rb-83	2100	**18.7 Ci**
Rb-84	3200	**28.5 Ci**
Rb-86	1700	**15.1 Ci**
Sc-46	4	**0.04 Ci**
V-48	130	**1.2 Ci**
Cr-51	420	**3.7 Ci**
Mn-54	0.8	**0.01 Ci**
Co-56	47	**0.42 Ci**
Co-57	1.3	**0.01 Ci**
Co-58	21	**0.19 Ci**
Ge-68	-	**2.5 Ci**
Total	**9964**	**91.2 Ci**

4. Microshield calculations

Microshield version 10 was used for this calculation. Detector placed at 1 meter from a point source behind shielding. Gamma emissions of all isotopes were combined. Buildup in lead or lead glass was considered. Resulting exposure rates with buildup were reported.

Details are reported in microshield reports.

Calculations of dose rates and annual exposure based on assumptions described above are summarized below:

Calculation of annual dose

	Case 8	Case 9	Case 10	Case 11	Case 12
Pb, in	**5**	**4**	**6**		
Pb, cm	12.7	10.16	15.24		
Lead glass, in				**14**	**16**
Lead glass density				**5.2**	**4.6**
Lead glass in cm				35.6	40.6
Exp.rate mR/hr from microshield	**5.25**	**19.8**	**1.37**	**1.31**	**1.22**
Times per week	1	1	1	1	1
Weeks in a year	50	50	50	50	50
Operation time, hr per week	8	8	8	8	8
Annual dose, mR	**2100**	**7920**	**548**	**524**	**488**

5. Conclusion

Minimum 6" or 15.25 cm of lead and 14/16" lead glass with density 5.2/4.6 respectively will be required to achieve target 10% ALARA levels of 500 mR/year.

6. Attachments

Microshield case reports 8-12

Excel file with cross sections and yields

MicroShield 10.00
Zevacor Molecular

Date	By	Checked

File Name	Run Date	Run Time	Duration
case 10.msd	December 27, 2015	12:43:30 PM	00:00:00

Project Info

Case Title	Case 10
Description	6" lead 250 uA beam 91.2 Ci target
	1 - Point

Dose Points

A	X	Y	Z
#1	100.0 cm (3 ft 3.4 in)	0.0 cm (0 in)	0.0 cm (0 in)

Shield

Shield N	Dimension	Material	Density
Shield 1	40.0 cm	Air	0.00122
Shield 2	15.2 cm	Lead	11.34
Air Gap		Air	0.00122

Source Input: Grouping Method - Linear Energy
Number of Groups: 25
Lower Energy Cutoff: 0.015
Photons< 0.015: Included
Library: Grove

Nuclide	Ci	Bq
Co-56	4.2000e-001	1.5540e+010
Co-57	1.0000e-002	3.7000e+008
Co-58	1.9000e-001	7.0300e+009
Cr-51	3.7000e+000	1.3690e+011
Ge-68	2.4000e+000	8.8800e+010
Mn-54	1.0000e-002	3.7000e+008
Rb-83	1.8700e+001	6.9190e+011
Rb-84	2.8500e+001	1.0545e+012
Rb-86	1.5100e+001	5.5870e+011
Sc-46	4.0000e-002	1.4800e+009
Sr-82	1.5100e+001	5.5870e+011
Sr-85	5.7000e+000	2.1090e+011
Tl-207	1.0000e-003	3.7000e+007
V-48	1.2000e+000	4.4400e+010

Buildup: The material reference is Shield 2
Integration Parameters

Results

Energy (MeV)	Activity (Photons/sec)	Fluence Rate MeV/cm²/sec No Buildup	Fluence Rate MeV/cm²/sec With Buildup	Exposure Rate mR/hr No Buildup	Exposure Rate mR/hr With Buildup	Absorbed Dose Rate mrad/hr No Buildup	Absorbed Dose Rate mrad/hr With Buildup	Absorbed Dose Rate mGy/hr No Buildup	Absorbed Dose Rate mGy/hr With Buildup
0.0125	1.372e+12	0.000e+00	1.193e-21	0.000e+00	2.100e-85	0.000e+00	1.833e-85	0.000e+00	1.833e-87
0.3201	1.346e+10	6.232e-21	1.236e-20	1.295e-23	2.567e-23	1.130e-23	2.241e-23	1.130e-25	2.241e-25
0.5193	1.476e+12	1.140e-04	3.354e-04	2.263e-07	6.656e-07	1.975e-07	5.811e-07	1.975e-09	5.811e-09
0.592	9.978e+08	4.976e-06	1.548e-05	9.761e-09	3.036e-08	8.521e-09	2.651e-08	8.521e-11	2.651e-10
0.826	2.939e+10	1.395e-01	5.085e-01	2.653e-04	9.669e-04	2.316e-04	8.441e-04	2.316e-06	8.441e-06
0.8878	7.637e+11	1.027e+01	3.839e+01	1.941e-02	7.254e-02	1.694e-02	6.333e-02	1.694e-04	6.333e-04
1.0726	5.609e+10	7.137e+00	2.802e+01	1.307e-02	5.132e-02	1.141e-02	4.480e-02	1.141e-04	4.480e-04
1.236	1.078e+10	5.070e+00	2.030e+01	9.040e-03	3.619e-02	7.892e-03	3.159e-02	7.892e-05	3.159e-04
1.3128	4.398e+10	3.307e+01	1.330e+02	5.804e-02	2.333e-01	5.067e-02	2.037e-01	5.067e-04	2.037e-03
.447	1.902e+08	2.765e-01	1.117e+00	4.709e-04	1.902e-03	4.111e-04	1.660e-03	4.111e-06	1.660e-05
1.6747	3.775e+07	1.197e-01	4.864e-01	1.955e-04	7.944e-04	1.707e-04	6.935e-04	1.707e-06	6.935e-06
1.773	2.512e+09	1.022e+01	4.161e+01	1.641e-02	6.684e-02	1.433e-02	5.835e-02	1.433e-04	5.835e-04
1.898	9.888e+09	5.243e+01	2.142e+02	8.247e-02	3.369e-01	7.199e-02	2.941e-01	7.199e-04	2.941e-03
2.0322	1.738e+09	1.167e+01	4.780e+01	1.797e-02	7.356e-02	1.569e-02	6.422e-02	1.569e-04	6.422e-04
2.2388	1.130e+09	1.019e+01	4.176e+01	1.523e-02	6.241e-02	1.329e-02	5.448e-02	1.329e-04	5.448e-04
2.3095	3.063e+07	3.006e-01	1.231e+00	4.448e-04	1.822e-03	3.884e-04	1.591e-03	3.884e-06	1.591e-05
2.5985	2.625e+09	3.422e+01	1.395e+02	4.874e-02	1.987e-01	4.255e-02	1.734e-01	4.255e-04	1.734e-03
3.0097	1.647e+08	2.830e+00	1.135e+01	3.836e-03	1.539e-02	3.349e-03	1.343e-02	3.349e-05	1.343e-04
3.2386	1.704e+09	3.267e+01	1.295e+02	4.326e-02	1.715e-01	3.777e-02	1.497e-01	3.777e-04	1.497e-03
3.2732	2.874e+08	5.588e+00	2.211e+01	7.376e-03	2.918e-02	6.439e-03	2.547e-02	6.439e-05	2.547e-04
3.4678	1.740e+08	3.632e+00	1.424e+01	4.707e-03	1.846e-02	4.109e-03	1.611e-02	4.109e-05	1.611e-

									04
Total	**3.786e+12**	**2.198e+02**	**8.850e+02**	**3.409e-01**	**1.372e+00**	**2.976e-01**	**1.198e+00**	**2.976e-03**	**1.198e-02**