



54943 North Main Street
Mattawan, MI 49071 USA
Tel: +1.269.668.3336
Fax: +1.269.668.4151

March 12, 2018 (revised March 29, 2018)

Via E-Mail & Federal Express – Next Day Air

Patricia Pelke
Materials Licensing Branch Chief
U.S. Nuclear Regulatory Commission – Region III
Nuclear Material Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351

SUBJECT: Notice of Indirect Change of Control for U.S. Nuclear Regulatory Commission
Materials License Number 21-11315-02

Dear Ms. Pelke:

U.S. Nuclear Regulatory Commission (NRC) guidance found in NUREG-1556, Volume 15, Revision 1, “Consolidated Guidance About Materials Licenses, Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses” and in NRC Regulatory Issue Summary 2014-08, Revision 1, “Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Material Licenses” require notice to, and request for approval of, change of control of a licensee, whether direct or indirect.

MPI Research, Inc. and Charles River Laboratories International, Inc. are hereby notifying, and requesting written consent from, the NRC for an indirect change of control for the subject license. The information in this submittal provides details about the impending indirect change of control; provides specific information requested in Appendix E of NUREG-1556; and describes changes in the organization that exercises control over the licensed program as a result of the transaction.

Indirect Change of Control of License 21-11315-02

On or about April 3, 2018, MPI Research, Inc. will become an indirect wholly owned subsidiary of Charles River Laboratories International, Inc. The licensee, MPI Research, Inc., currently is owned through a series of subsidiaries by private equity funds managed by Avista Capital Partners GP, LP. On the closing date, ACP Mountain Holdings, Inc., an indirect parent corporation to MPI Research, Inc., will merge into a subsidiary of Charles River Laboratories International, Inc., with ACP Mountain Holdings, Inc. remaining as the surviving entity and becoming a direct subsidiary of Charles River Laboratories International, Inc. As a result, the licensee will transition from the indirect control of Avista Capital Partners GP, LP, to the indirect control of Charles River Laboratories International, Inc. It is not anticipated at this time that the name of the licensee or the direct control of the subject license will change.

Charles River Laboratories International, Inc. is a known entity. Specifically, Charles River Laboratories International, Inc. entities hold nuclear materials licenses issued by Agreement States, i.e., Nevada (Charles River Laboratories, Inc.; License #11-16-0368, with an expiration date of May 31, 2021), Ohio (Charles River Laboratories Ashland, LLC; License #06320030003, with an expiration date of March 1, 2020) and Pennsylvania (Charles River Laboratories, Inc.; License PA-1261 with an expiration date of March 31, 2025). Copies of these licenses are attached.

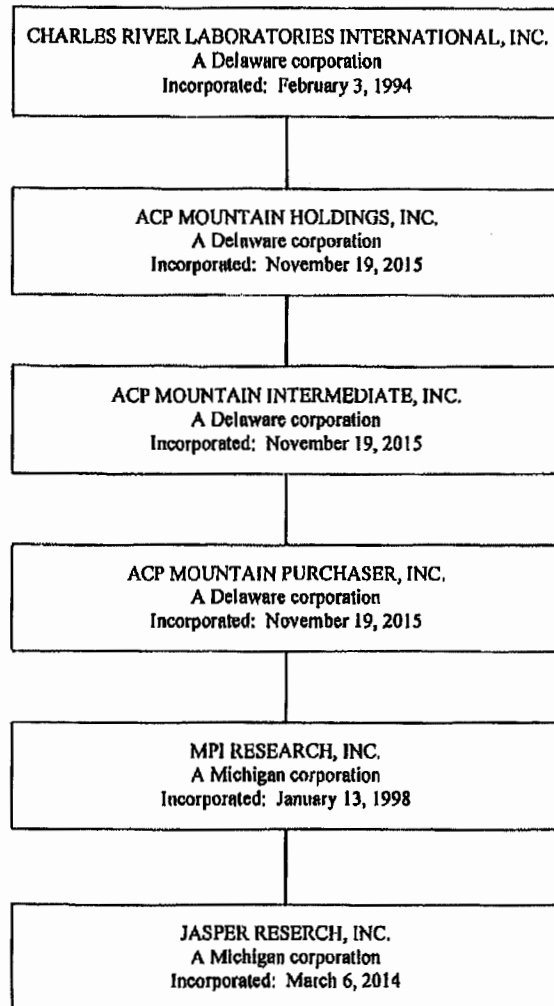
MPI Research, Inc. and Charles River Laboratories International, Inc. understand that, if subsequent organizational changes (involving direct control of the license) or name changes are contemplated, those changes may not become effective until and unless approval is requested and subsequently received from the NRC. Transferor and transferee further understand that certain requested changes may require submission of license amendment requests.

Information Needed by NRC for Transfer of Control (from Appendix E of NUREG-1556)

- 1. Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc. Provide the new licensee name, mailing address, and contact information, including phone numbers. Clearly identify when the amendment request is due to a name change only.*

As described previously, this is an indirect change of control whereby an indirect parent of MPI Research, Inc., ACP Mountain Holdings, Inc., will merge into a subsidiary of Charles River Laboratories International, Inc., with ACP Mountain Holdings, Inc. remaining as the surviving entity and becoming a direct subsidiary of Charles River Laboratories International, Inc. The licensee name, address, contact information and personnel overseeing and implementing the license will not change. A post-transition organization chart for MPI Research and the new parent organization is expected to be as follows:

[POST-TRANSITION ORGANIZATION CHART APPEARS ON THE FOLLOWING PAGE]



2. *Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel and any changes in the training program.*

No changes to personnel, including the Radiation Safety Officer (RSO), or duties of the personnel, are currently planned because of this indirect change of control. No changes will take place to the training program.

3. *Describe any changes in the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program.*

No changes to the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program will result from this indirect change of control.

4. *Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.*

Nothing regarding MPI Research's radiation safety program, including facilities and equipment, will change as a result of this indirect change of control. There are no contaminated areas at the licensed facility that require decontamination prior to transfer. Because current operations will remain unchanged, no decommissioning is planned at this time. All required surveillance items, including calibrations, leak tests, surveys, wipe tests, training, quality control and related records, have been performed, documented, and reviewed.

5. *If current decommissioning funding plans (DFP) will be changed as a result of the transfer, the revised DFP should be submitted. If other financial assurance documents will be changed as a result of the transfer, confirm, that all financial assurance instruments associated with the license will be held in the transferee's name before the license is transferred, and as required by 10 CFR 30.35(f), the licenses must, within 30 days, submit financial instruments reflecting such changes.*

The DFP will remain unchanged and unaffected by the indirect change of control. The license is backed by a fully funded Trust Agreement that will remain in place between MPI Research, Inc. ("Grantor") and Comerica Bank and Trust, National Association ("Trustee"), and that was approved by the NRC on August 12, 2016.

6. *Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.*

All records associated with the subject license will remain with the licensee. As this is an indirect change of control, there will be no transfer of any license-related records associated with the change.

7. *Confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and that the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions.*

Both the transferor and transferee agree to the indirect transfer of control of the licensed material and activities. There are no open inspection items associated with the subject license.

8. *Confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.*

The transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor with respect to the subject license.

9. *The transferee, in the case of fuel cycle facilities, shall provide documentation showing that it is financially qualified to conduct normal operations. The information can be in the form of income statements and balance sheet forecasts.*


The subject license is not a fuel cycle facility license.

Changes in the Organization that Exercises Control over the Licensed Program

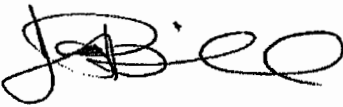
There will be no material changes in the organization that exercises control over the licensed program, other than the oversight and support from Charles River Laboratories International, Inc. contemplated by the transaction. The written program to implement the license will not change. The RSO will not change.

If you have any questions or concerns after reviewing this request, please do not hesitate to contact me at (269) 668-3336, Ext. 2050.

Respectfully submitted,



Richard Granberg, CHP
Radiation Safety Officer
MPI Research, Inc.



Jason Burrill
Director, Corporate Environment Health and Safety
Charles River Laboratories, Inc.

Attachment

cc: Bryan A. Parker, Senior Health Physicist, U. S. NRC - Region III



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Patricia Pelke
Materials Licensing Branch Chief
U.S. Nuclear Regulatory Commission – Region III
Nuclear Material Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351

**SUBJECT: Notice of Indirect Change of Control for U.S. Nuclear Regulatory Commission
Materials License Number 21-11315-04**

Dear Ms. Pelke:

U.S. Nuclear Regulatory Commission (NRC) guidance found in NUREG-1556, Volume 15, Revision 1, “Consolidated Guidance About Materials Licenses, Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses” and in NRC Regulatory Issue Summary 2014-08, Revision 1, “Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Material Licenses” require notice to, and request for approval of, change of control of a licensee, whether direct or indirect.

MPI Research, Inc. and Charles River Laboratories International, Inc. are hereby notifying, and requesting written consent from, the NRC for an indirect change of control for the subject license. The information in this submittal provides details about the impending indirect change of control; provides specific information requested in Appendix E of NUREG-1556; and describes changes in the organization that exercises control over the licensed program as a result of the transaction.

Indirect Change of Control of License 21-11315-04

On or about April 3, 2018, MPI Research, Inc. will become an indirect wholly owned subsidiary of Charles River Laboratories International, Inc. The licensee, MPI Research, Inc., currently is owned through a series of subsidiaries by private equity funds managed by Avista Capital Partners GP, LP. On the closing date, ACP Mountain Holdings, Inc., an indirect parent corporation to MPI Research, Inc., will merge into a subsidiary of Charles River Laboratories International, Inc., with ACP Mountain Holdings, Inc. remaining as the surviving entity and becoming a direct subsidiary of Charles River Laboratories International, Inc. As a result, the licensee will transition from the indirect control of Avista Capital Partners GP, LP, to the indirect control of Charles River Laboratories International, Inc. It is not anticipated at this time that the name of the licensee or the direct control of the subject license will change.

Charles River Laboratories International, Inc. is a known entity. Specifically, Charles River Laboratories International, Inc. entities hold nuclear materials licenses issued by Agreement States, i.e., Nevada (Charles River Laboratories, Inc.; License #11-16-0368, with an expiration date of May 31, 2021), Ohio (Charles River Laboratories Ashland, LLC; License #06320030003, with an expiration date of March 1, 2020) and Pennsylvania (Charles River Laboratories, Inc.; License PA-1261 with an expiration date of March 31, 2025). Copies of these licenses are attached.

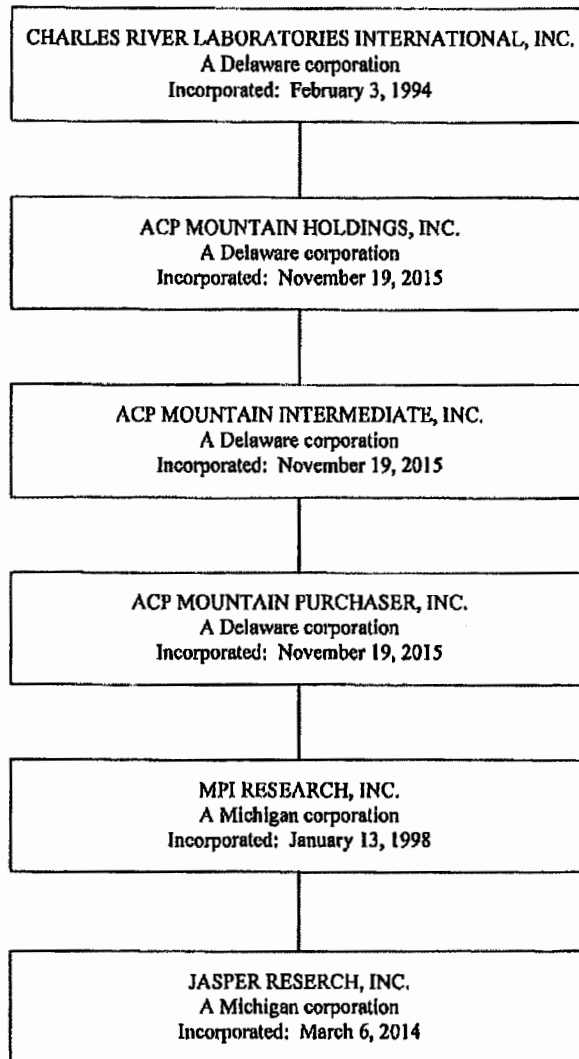
MPI Research, Inc. and Charles River Laboratories International, Inc. understand that, if subsequent organizational changes (involving direct control of the license) or name changes are contemplated, those changes may not become effective until and unless approval is requested and subsequently received from the NRC. Transferor and transferee further understand that certain requested changes may require submission of license amendment requests.

Information Needed by NRC for Transfer of Control (from Appendix E of NUREG-1556)

- 1. Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc. Provide the new licensee name, mailing address, and contact information, including phone numbers. Clearly identify when the amendment request is due to a name change only.*

As described previously, this is an indirect change of control whereby an indirect parent of MPI Research, Inc., ACP Mountain Holdings, Inc., will merge into a subsidiary of Charles River Laboratories International, Inc., with ACP Mountain Holdings, Inc. remaining as the surviving entity and becoming a direct subsidiary of Charles River Laboratories International, Inc. The licensee name, address, contact information and personnel overseeing and implementing the license will not change. A post-transition organization chart for MPI Research and the new parent organization is expected to be as follows:

[POST-TRANSITION ORGANIZATION CHART APPEARS ON THE FOLLOWING PAGE]



2. *Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel and any changes in the training program.*

No changes to personnel, including the Radiation Safety Officer (RSO), or duties of the personnel, are currently planned because of this indirect change of control. No changes will take place to the training program.

3. *Describe any changes in the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program.*

No changes to the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program will result from this indirect change of control.

4. *Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.*

Nothing regarding MPI Research's radiation safety program, including facilities and equipment, will change as a result of this indirect change of control. There are no contaminated areas at the licensed facility that require decontamination prior to transfer. Because current operations will remain unchanged, no decommissioning is planned at this time. All required surveillance items, including calibrations, leak tests, surveys, wipe tests, training, quality control and related records, have been performed, documented, and reviewed.

5. *If current decommissioning funding plans (DFP) will be changed as a result of the transfer, the revised DFP should be submitted. If other financial assurance documents will be changed as a result of the transfer, confirm, that all financial assurance instruments associated with the license will be held in the transferee's name before the license is transferred, and as required by 10 CFR 30.35(f), the licensee must, within 30 days, submit financial instruments reflecting such changes.*

The DFP will remain unchanged and unaffected by the indirect change of control. The license is backed by a fully funded Trust Agreement that will remain in place between MPI Research, Inc. ("Grantor") and Comerica Bank and Trust, National Association ("Trustee"), and that was approved by the NRC on August 12, 2016.

6. *Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.*

All records associated with the subject license will remain with the licensee. As this is an indirect change of control, there will be no transfer of any license-related records associated with the change.

7. *Confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and that the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions.*

Both the transferor and transferee agree to the indirect transfer of control of the licensed material and activities. There are no open inspection items associated with the subject license.

8. *Confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.*

The transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor with respect to the subject license.

9. *The transferee, in the case of fuel cycle facilities, shall provide documentation showing that it is financially qualified to conduct normal operations. The information can be in the form of income statements and balance sheet forecasts.*

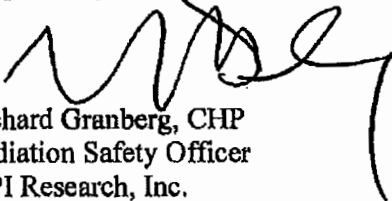
The subject license is not a fuel cycle facility license.

Changes in the Organization that Exercises Control over the Licensed Program

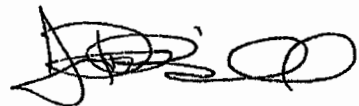
There will be no material changes in the organization that exercises control over the licensed program, other than the oversight and support from Charles River Laboratories International, Inc. contemplated by the transaction. The written program to implement the license will not change. The RSO will not change.

If you have any questions or concerns after reviewing this request, please do not hesitate to contact me at (269) 668-3336, Ext. 2050.

Respectfully submitted,



Richard Granberg, CHP
Radiation Safety Officer
MPI Research, Inc.



Jason Burrill
Director, Corporate Environment Health and Safety
Charles River Laboratories, Inc.

Attachment

cc: Bryan A. Parker, Senior Health Physicist, U. S. NRC - Region III



RADIOACTIVE MATERIALS LICENSE

Pursuant to the Radiation Protection Act, the Act of July 10, 1984 (No. 147, P.L. 888) (35 P.S. §§ 7110.101 - 7110.703) and Title 25, Rules and Regulations, Article V, Radiological Health of the Pennsylvania Department of Environmental Protection, and in reliance on statements and representations heretofore Licensee to receive, acquire, possess, transfer, and use radioactive material listed below for the purposes and at the places designated below. This license shall be deemed subject to all applicable rules, regulations, or orders of the Pennsylvania Department of Environmental Protection now or hereafter in effect and to any conditions specified below.

Licensee	In response to the renewal application dated March 7, 2015 and e-mail communication dated March 24, 2015
1. Charles Rivers Laboratories - Malvern	3. License No. PA -1261 is renewed in its entirety as follows:
2. 358 Technology Drive Malvern, Pennsylvania 19355	4. Expiration Date: March 31, 2025
	5. Client ID: 269506 Program: 3620 Priority: 5

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen 3	A. Any	A. 10 millicuries
B. Carbon 14	B. Any	B. 10 millicuries
C. Phosphorus 32	C. Any	C. 100 millicuries
9. Authorized use:		
A. and B. Calibration of instruments		
C. Research and development as defined in 10 CFR 38.4		

CONDITIONS	
10.	Licensed material may be used or stored only at the licensee's facilities located at 358 Technology Drive, Malvern, Pennsylvania 19355.
11.	A. Licensed material shall be used by, or under the supervision of, Michael J. Hantman, Ph.D., and Douglas B. Brown, Ph.D.
	B. Licensed material in items 6.B. and 6.C., may also be used by, or under the supervision of, Brian P. Ruvolo, B.S.
	C. Licensed material in item 6.C. may also be used by, or under the supervision of, Melissa N. Pryce, M.S.
12.	The Radiation Safety Officer for this license is: Douglas B. Brown, Ph.D.
13.	Licensed material shall not be used in or on human beings.

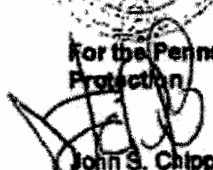
Copy of Original RAM License located in Archive Room. *[Signature]*

16 APR 2015



14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
15. 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:
 - A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
16. The licensee may transport licensed material, or deliver licensed material to a carrier for transport, in accordance with 25 Pa. Code Chapter 230, "Packaging and Transportation of Radioactive Material" and the provisions of 10 CFR Part 71 incorporated by reference.
17. Notwithstanding the requirements set forth in this license, the licensee shall comply with the regulations set forth in Title 25 of the Pennsylvania Code Article V "Radiological Health" and the U.S. Nuclear Regulatory Commission, Title 10 Code of Federal Regulations Parts 19-150 incorporated by reference.
18. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. The Department of Environmental Protection's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated March 7, 2015
 - B. E-mail communication dated March 24, 2015

For the Pennsylvania Department of Environmental
Protection


John S. Chippo
Bureau of Radiation Protection
P. O. Box 8469
Harrisburg, PA 17105-8469

Date: April 6, 2015

**OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIAL**

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

1. Charles River Laboratories Ashland, LLC 2. 1407 George Road Ashland, Ohio 44805	LICENSE NUMBER
	3. 03620030003
	EXPIRATION DATE
	4. March 1, 2020
	FILE NUMBER – ID NUMBER
	5. 501196 - 13458

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Hydrogen-3	A. Any	A. 18.5 GBq (500 mCi)
B. Carbon-14	B. Any	B. 74 GBq (2.0 Ci)
C. Phosphorus-32	C. Any	C. 1.85 GBq (50 mCi)
D. Sulphur-35	D. Any	D. 3.7 GBq (100 mCi)
E. Chromium-51	E. Any	E. 3.7 GBq (100 mCi)
F. Manganese-54	F. Any	F. 370 MBq (10 mCi)
G. Arsenic-73	G. Any	G. 185 MBq (5.0 mCi)
H. Arsenic-74	H. Any	H. 37 MBq (1.0 mCi)
I. Yttrium-90	I. Any	I. 9.25 GBq (250 mCi)
J. Technetium-99m	J. Any	J. 18.5 GBq (500 mCi)
K. Indium-111	K. Any	K. 18.5 GBq (500 mCi)
L. Iodine-125	L. Any non-volatile form	L. 8.51 GBq (230 mCi)
M. Iodine-125	M. Any volatile form	M. 740 MBq (20 mCi)
N. Gadolinium-153	N. Any	N. 370 MBq (10 mCi)
O. Lutetium-177	O. Any	O. 18.5 GBq (500 mCi)
P. Rhenium-188	P. Any	P. 37 GBq (1.0 Ci)
Q. Tungsten-188	Q. Any	Q. 18.5 GBq (500 mCi)
R. Iodine-131	R. Any	R. 1.85 GBq (50 mCi)
S. Copper-64	S. Dissolved in solution	S. 18.5 GBq (500 mCi)
T. Phosphorus-33	T. Any	T. 740 MBq (20 mCi)
U. Actinium-225	U. Any	U. 185 MBq (5 mCi)

9. Authorized Use

A., B., C., D., F., G., H., I., K., L., M., P., R.

Laboratory research as described in license application dated November 20, 2009 and correspondence dated July 17, 2012, August 14, 2012 and August 21, 2014.

E., J., M, N., O., Q., R., B., T., U.

Animal studies.

S.

Chemical research.

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 2 of 2
	License Number: 03620030003
	File Number - ID Number : 501196 - 13458
	Amendment No. 26

CONDITIONS


10. Licensed material may only be used at the licensee's facilities located at: 1407 George Road, Ashland, Ohio 44805.
11. The Radiation Safety Officer for this license is: Justin Godsey.
12. Licensed material shall be used by, or under the supervision of the Radiation Safety Officer.
13. Experimental animals or the products from experimental animals that have been administered licensed materials shall not be used for human consumption.
14. The licensee is authorized to hold radioactive material for decay-in-storage in accordance with OAC 3701:1-38-19(E).
15. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed materials to quantities below the minimum limit specified in OAC 3701:1-40-17 for establishing a decommissioning funding plan.
16. The licensee is authorized to treat biological material by tissue digestion for release into the sanitary sewer provided:
 - A. The residual debris is surveyed for radioactive contamination prior to disposal; and
 - B. Records are maintained demonstrating compliance with sewer effluent discharge limits.
17. 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 Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Renewal application dated January 5, 2015; Amendment 22 renews license 03620030003 in its entirety.
 - B. Correspondence dated February 3, 2015 (Amendment 23).
 - C. Email Correspondence dated June 27, 2016 (Amendment 24).
 - D. Email correspondence dated August 2, 2016 (Amendment 25).
 - E. Email correspondence dated October 27, 2016 (Amendment 26).

For the Ohio Department of Health

DATE: _____

11/28/16

BY: _____



Michael J. Snee
 Bureau of Environmental Health and Radiation Protection
 on behalf of the Director of Health



Nevada Radiation Control Program
Radioactive Material License

16-11-0368-01

LICENSE NUMBER

13

AMENDMENT NUMBER
(AMENDED IN ITS ENTIRETY)

9. AUTHORIZED USE

<p>A & B</p> <p>ITEM</p> <p>For in-situ hybridization of tissue sections.</p> <p>PURPOSE</p>
<p>C - E</p> <p>ITEM</p> <p>For use as calibration, check and reference sources.</p> <p>PURPOSE</p>

Conditions

- 10. Radioactive material shall be stored and used only at the licensee's facilities located at 6995 Longley Lane, Reno, Nevada.
- 11. The Radiation Safety Officer for activities authorized by this license shall be Christina Satterwhite, Ph.D.
- 12. Radioactive material identified in Items 6, 7 and 8 shall be used only by, or under the supervision of the following individuals:

AUTHORIZED USERS	AUTHORIZED USES
Christina Satterwhite Ph. D	P-33, S-35, H-3, C-14, Cs-137
Curtis Chan, B.S	P-33, S-35, H-3, C-14, Cs-137

- 13. The licensee is not authorized to use radioactive material on or in human beings for research.
- 14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
- 15. Experimental animals, or the products of experimental animals, that have been administered licensed materials, shall not be used for human consumption.



Nevada Radiation Control Program
Radioactive Material License

Page 3 of 3

16-11-0368-01

LICENSE NUMBER

13

AMENDMENT NUMBER
(AMENDED IN ITS ENTIRETY)

Conditions, continued

16. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided:
- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
17. 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. Nevada Administrative Code (NAC) 459 shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated April 28, 2016, signed by Christina Satterwhite, Ph.D., RSO; and
 - B. Letter dated July 1, 2016, signed by Karen Beckley, Program Manager; and
 - C. **Letter dated July 6, 2017, signed by Christina Satterwhite, Ph.D., RSO.**



SIGNATURE

August 15, 2017

DATE

Karen K. Beckley, M.P.A., M.S.
Manager, Radioactive Materials Program

IBC Meeting Minutes
3/1/18

Attendance:

COMMITTEE MEMBERSHIP			CONTRIBUTING STAFF			IBC STAFF		
ID	Voting Membership	Attended	ID	Committee Advisors	Attended	ID	Position/Title	Attended
10022-SR	Chairperson/BSO	x	07797-CD	Non-Scientific-IACUC		07457-AT	Administrator	x
10634-JH	Veterinarian		08147-KM	Operations-TMC		07588-ST	Compliance	
08366-KN	Pathologist	x						
09460-TV	Scientific/Study Director							
07740-JJ	Operations-Lab	x						
1122-JS	OCM	x						
1122-BK	OCM	x						
08303-GN	Operations-Security							
08683-RG	Operations-Safety	x						
GUESTS: 11459-RG; 10517-JS								

Meeting start: 2:02 PM
Meeting end: 2:44 PM

1) Hands-on biosafety training discussion

The Director of Corporate Training and Development was invited to attend the meeting to discuss practical implementation of hands-on staff training ideas presented during the 11-7-17 training meeting. Under discussion were items such as eye wash station and spill containment training.

The discussion resulted in the following action items:

- a. A follow-up meeting/tour was scheduled to identify spaces in which to conduct the training scenarios.
- b. 11459-RG, 10022-SR and 08683-RG will create a proposal to present to corporate management in order to gain space and support for the program.

2) Protocol Review

Study #	BSL Level Assigned	AGENT		
2527-005	1	4D-R100.CAG-cohREP1		
<input checked="" type="checkbox"/>	Approved			
<input type="checkbox"/>	Modifications Required			
<input type="checkbox"/>	Rejected	For: 6	Against: 0	Abstained: 0

Study #	BSL Level Assigned	AGENT		
2527-011 Amendment 1	1	4DER000034.01SUP		
<input checked="" type="checkbox"/>	Approved			
<input type="checkbox"/>	Modifications Required			
<input type="checkbox"/>	Rejected	For: 6	Against: 0	Abstained: 0

IBC Meeting Minutes
3/1/18

Study #	BSL Level Assigned	AGENT
591-077	1	AAV1603_CMV-hNrf2-WPRE; AAV1705_2_BEST1-hNRF2-WPRE
<input checked="" type="checkbox"/> Approved <input type="checkbox"/> Modifications Required <input type="checkbox"/> Rejected		
For: 6 Against: 0 Abstained: 0		

Study #	BSL Level Assigned	AGENT
2377-014	2	SPK 3005; SPK 3006; SPK 3017
<input checked="" type="checkbox"/> Approved <input type="checkbox"/> Modifications Required <input type="checkbox"/> Rejected		
For: 6 Against: 0 Abstained: 0		
<p style="color: red;">If requested updates are received, the study may be downgraded to BSL-1. Assigned to designated reviewer (JJ) for updates.</p>		

3) Meeting Minutes

- a. 12/14/17 **Approved**
- b. 1/18/18 **Approved**
- c. 2/15/18 **Approved**

4) Case Study

Lessons learned during preparation for necropsy of the first large animal BSL-2 study were presented.
 PAM of the next necropsy is planned.
 The committee discussed creating or purchasing a cart for transfer of large BSL2 animals.

5) Minority Report: **No minority opinions offered.**

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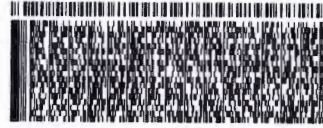
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