www.abclabs.com

abc® Laboratories

7200 E. ABC Lane, Columbia, MO 65202 • Tel: 573/474-8579 Fax: 573/443-9033

April 24, 2007

Nuclear Regulatory Commission
Materials Licensing Branch
US Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

ATTN: Kevin Null

RE: License Amendment Request–License No. 24-13365-01, Amendment 29

Dear Mr. Null:

As per your request, please find enclosed the addendum to the renewal document for our radioactive materials license number 24-13365-01. This document supersedes the original renewal application submitted 21 February 2007. Please find two copies enclosed.

If you have any questions or need further information, please feel free to contact Sheila C. Hecht at 573-443-9070.

Sincerely,

G. Scott Ward

G. Scott Ward
Senior Vice President and Chief Administrative Officer

NRC FORM 313 (10-2005) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008

Estimated burden per response to comply with this mandatory collection request: 4.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☐ B. AMENDMENT TO LICENSE NUMBER
- ☑ C. RENEWAL OF LICENSE NUMBER 24-13365-01

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

Analytical Bio-Chemistry Laboratories, Inc.
7200 E. ABC Lane
Columbia, MO 65202

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Analytical Bio-Chemistry Laboratories, Inc.
7200 E. ABC Lane
Columbia, MO 65202

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Sheila C. Hecht

TELEPHONE NUMBER

(573) 443-9070

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maiximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 3L | AMOUNT ENCLOSED $

13. CERTIFICATION *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
G. Scott Ward, Sr. VP Chief Administrative Officer	G. Scott Ward	04/24/2007

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

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8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

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CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
G. Scott Ward, Sr. VP Chief Administrative Officer		04/24/2007

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TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
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ITEM 5.

RADIOACTIVE MATERIAL

a)	Element:	Any byproduct material with a physical half life equal to or less than 120 days with atomic numbers 1 through 83 inclusive
	Chemical and/or physical form:	Any (excluding sealed sources and volatile forms of iodine-131 and iodine-129)
	Maximum amount that the licensee may possess at any one time under this license:	Not to exceed 5 Curies per nuclide and 100 Curies total except as listed below: phosphorus-33 10 curies sulfur-35 10 curies iodine-125 10 curies
b)	Element:	Carbon-14
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	20 curies
c)	Element:	Nickel-63
	Chemical and/or physical form:	Foil Sources Varian Number: 03-908377-00 Varian Aerograph Number: 02-001972-00
	Maximum amount that the licensee may possess at any one time under this license:	No single foil to exceed 8 millicuries, 80 millicuries total

d)	Element:	Nickel-63
	Chemical and/or physical form:	Foil Sources Hewlett-Packard Model Number: 19235
	Maximum amount that the licensee may possess at any one time under this license:	No single foil to exceed 15 millicuries, 200 millicuries total
e)	Element:	Carbon-14
	Chemical and/or physical form:	Solid and/or liquid waste from laboratory studies
	Maximum amount that the licensee may possess at any one time under this license:	Less than 20 curies
f)	Element:	Cesium-137
	Chemical and/or physical form:	Sealed sources (registered pursuant to Section 32.210 of 10 CFR part 32 or an Agreement State)
	Maximum amount that the licensee may possess at any one time under this license:	No single source to exceed 30 microcuries
g)	Element:	Hydrogen-3
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	1.0 curie
h)	Element:	Europium-154
	Chemical and/or physical form:	Liquid or solid
	Maximum amount that the licensee	

	may possess at any one time under this license:	2 microcuries
i)	Element:	Cesium-137
	Chemical and/or physical form:	Liquid or solid
	Maximum amount that the licensee may possess at any one time under this license:	300 microcuries
j)	Element:	Barium-133
	Chemical and/or physical form:	Liquid or solid
	Maximum amount that the licensee may possess at any one time under this license:	750 microcuries
k)	Element:	Manganese-54
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	200 millicuries
l)	Element:	Lutetium-177
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	500 millicuries
m)	Element:	Technetium-99
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	30 millicuries
n)	Element:	Molybdenum-99
	Chemical and/or physical form:	Any

	Maximum amount that the licensee may possess at any one time under this license:	30 curies
o)	Element:	Technetium-99m
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	30 curies
p)	Element:	Cobalt-60
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	1 microcurie
q)	Element:	Gadolinium-153
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	1 microcurie
r)	Element:	Terbium-160
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	60 microcuries
s)	Element:	Thulium-170
	Chemical and/or physical form:	Any
	Maximum amount that the licensee may possess at any one time under this license:	15 microcuries
t)	Element:	Holmium-166m

Chemical and/or physical form:	Any
Maximum amount that the licensee may possess at any one time under this license:	150 microcuries

ITEM 6.

PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED

a., b. and g.

A. Animal Studies

1. Ecotoxicology

   a. Static and Flow-Through Acute and Chronic Aquatic and Terrestrial Toxicity Tests

   b. Bioaccumulation Studies

   c. Soil Biodegradation Studies

   d. Mesocosm/Microcosm Studies

2. Mammalian Studies – Includes Residue, Metabolism, Toxicity, FDA Animal Health, and Dermal Application

3. Avian Studies – Includes Reside, Metabolism, FDA Animal Health, and Toxicity.

4. Non-Target Insects, Specifically honeybees

B. Metabolism/Environmental Fate/Biodegradation Studies

1. Plant and Animal Metabolism Studies – Includes In-Vitro and Analyses

2. Field E-Fate Studies – Includes dissipation, irrigation, and leaching studies.

3. Laboratory E-Fate Studies - includes metabolism, photolysis, soil leaching, adsorption/Desorption,

hydrolysis, Mobility, Volatility, Solubility, vapor pressure, octanol/water partition coefficient, etc.

4. Laboratory Biodegradation Studies – includes activated sludge and aerobic and anaerobic biodegradation studies

C. Metabolite Characterization – Metabolite characterization work could be performed on all studies mentioned above. This would involve the analysis of samples incorporated with ^{14}C, ^{3}H or ^{35}S.

D. Methods Development – Occasionally microcurie to low millicurie amounts of material are utilized to develop analytical methods which will ultimately be used for residue analysis.

E. Custom Radiolabeled Organic Synthesis – Analytical Bio-Chemistry Laboratories offers their clients the option of having test material synthesized on site for use in their studies being conducted here. Low-to middle-millicurie quantities of "raw" material may be used during the synthesis process. Upon completion of the study, the remaining compound is considered the property of the client and is delivered to them or disposed of as per their request.

F. For possession, use, and processing incident to synthesis of radiochemicals.

G. For storage prior to distribution of synthesized radiochemicals.

H. For packaging and distribution of synthesized radiochemicals to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement State.

c. and d.

Nickel-63 electron capture detector cells will be used (in sealed-source form) in gas chromatographs for sample analysis and for cleaning.

e.

Possession incident to storage of waste.

f.

Cesium-137 sealed sources are utilized for the calibration of the various liquid scintillation counters operated at ABC Laboratories, Inc.

h. through j.

These sources are utilized for the calibration of various liquid scintillation counters operated at ABC Laboratories, Inc.

k. through m.

1. For possession, use, and processing incident to synthesis of radiochemicals

2. For packaging and distribution of synthesized radiochemicals to persons authorized to receive the licensed material pursuant to the terms and conditions of specific licenses issued by the Nuclear Regulatory Commission or Agreement State.

n. and o.

For research and development as defined in 10 CFR 30.4

p. through t.

For research and development as defined in 10 CFR 30.4 including studies in animals.

ITEM 7.

INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

All ABC Laboratories personnel who will be working in areas designated for radioisotope studies are required to read and accept the radiation safety program prior to beginning work at the lab. Their performance in handling radioactive materials is monitored by the following listed people. All personnel who will be handling radioisotopes are required to attend in-house radiation safety seminars, and attend periodic refresher courses.

Executive Management

The Chief Executive Officer (CEO) is responsible for the use of radioactive materials under this license. Oversight of all safety and regulatory compliance programs, including radiation safety and compliance, has been delegated to the Senior Vice President & Chief Administrative Officer who also sits as the Chairman of the Radiation Safety Committee. Another member of the Management Team will also serve on the Radiation safety Committee as the Executive Management Representative.

Responsibilities of the Executive Management

- Radiation safety, security and control of radioactive materials, and compliance with NRC and Department of Transportation (DOT) regulations and operating and emergency procedures;

- Completeness and accuracy of radiation safety records and all information provided to the NRC;

- Knowledge about the contents of the license and application;

- Commitment to provide adequate resources (including space, equipment, personnel, time) to the radiation protection program to ensure that public and workers are protected from radiation hazards and meticulous compliance with regulations is maintained;

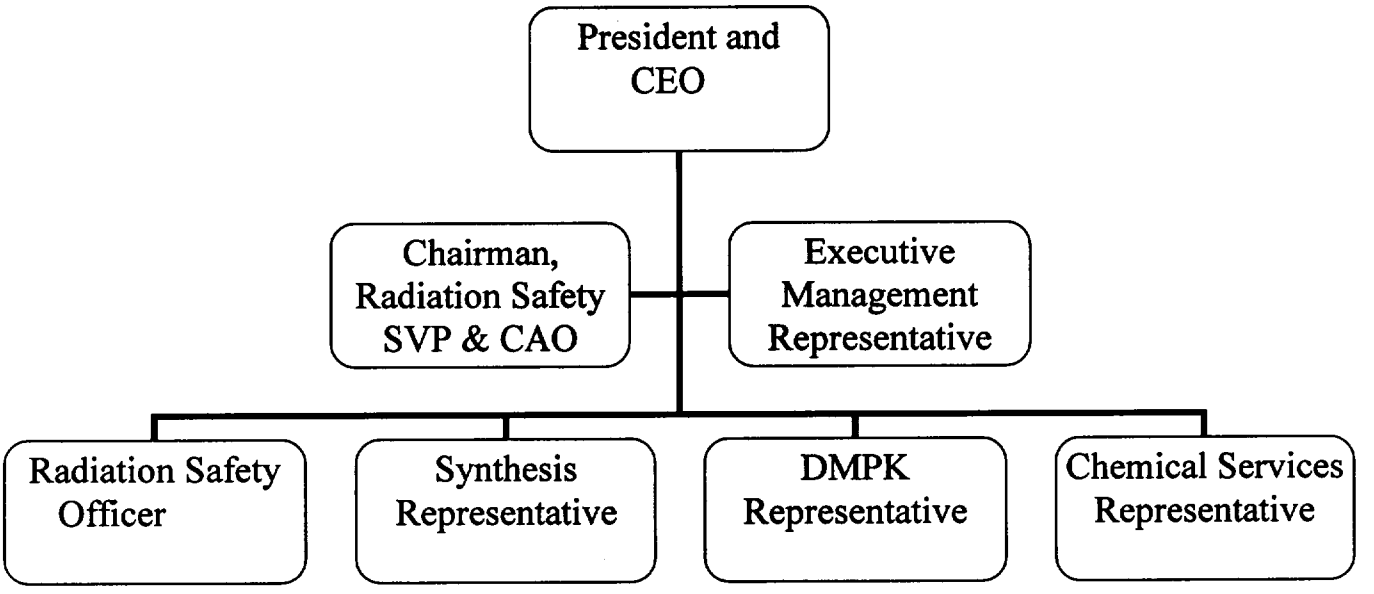
- Selection and assignment of qualified individuals to serve on the Radiation Safety Committee, and to serve as Radiation Safety Officer.

- Prohibition against discrimination of employees engaged in protected activities;

- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7 and 10 CFR 30.10;

- Obtaining NRC's prior written consent before transferring control of the license; and

- Notifying the appropriate NRC Regional Administrator in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.



Radiation Safety Officer: Sheila C. Hecht

Training

Ms. Hecht received approximately 180 hours of training in a radiation specialist training course sponsored by the U. S. Navy at the Naval Undersea Medical Institute in New London, CT. She also received 200 hours of training in the "Medical Officers' Course in Nuclear Medicine and Radioisotope Techniques Course" at the National Naval Medical Center, Bethesda MD. The courses involved training in the detecting isotopes of alpha, beta, gamma, x-ray and neutron emission. Exposure limits, safety operations and various calculations dealing with exposure and activity levels were also covered.

Listed below is a course outline:

1) Atomic and Nuclear Structure
    a) Nuclear Notation
    b) Nuclear Stability
    c) Isotopes

2) Radioactive Decay
    a) Decay Schemes
    b) Half-life
    c) Chart of the Nuclides
    d) Curie and Becquerel

3) Types of Radiation and Interaction
    a) X and Gamma
    b) Alpha and Beta

c) Neutrons
d) Bremsstrahlung

4) Radiation Dosimetry
   a) Absorbed Dose: rad, gray
   b) Exposure Dose: roentgen, C/kg
   c) Dose Equivalent: rem, sievert
   d) Quality Factor

5) Biological Effects of radiation
   a) Acute and Chronic Effects
   b) Radiation and protection Guides
   c) Dose Limits

6) External Radiation
   a) Time
   b) Distance
   c) Shielding

7) Internal Radiation Hazard
   a) Control of Contamination
   b) Waste Disposal

8) Radiation Detection Equipment
   a) Survey Meters
   b) Radiation Scalers
   c) Personnel Dosimeters

9) Regulatory Control
   a) Licensing Procedures
   b) Code of Federal regulations

10) Compliance
   a) Establishing and Posting radiation Areas
   b) Surveying and Wipe Testing Work Areas
   c) Leak testing Sealed Sources
   d) Counting Statistics of Radioactive Materials

Experience

Isotope	Maximum Amount	Where Gained	Duration	Type of Use
^{3}H	200 mCi	NNMC Bethesda	1 year	Research and Development, Instrument

				Calibration
^{14}C	200 mCi	NNMC Bethesda	1 year	Research and Development, Instrument Calibration
^{137}Cs	600 mCi	NNMC Bethesda	1 year	Any manual Brachytherapy Procedure permitted by 10 CFR 35.400
^{125}I	500 mCi	NNMC Bethesda	1 year	Any manual Brachytherapy Procedure permitted by 10 CFR 35.400
^{131}I	2 Ci	NNMC Bethesda	1 year	Any diagnostic study or therapy procedure permitted by 10 CFR 35.300 for which a written directive is required

Ms. Hecht was the Radiation Safety Officer at Naval Hospital Pensacola, Florida for 2 years. Her duties included monitoring of radioactive material packages received, oversight of the usage of radioactive materials in the Nuclear Medicine Clinic, personnel dosimetry and training of hospital personnel in radiation safety procedures.

Responsibilities of the Radiation Safety Officer (RSO)

Responsible for:

- Proper posting, procedural instructions and cautions are displayed in the appropriate areas.
- Ensure security of radioactive material.
- Monitoring and surveys of all areas in which radioactive material is used.
- Reporting and recommendations for corrective actions to management when a radiation hazard exists or when there is a general trend of increased laboratory background.
- Submitting semi-annual evaluation reports to management on the handling of radioactive materials in relation to achieving the minimum practical hazard to ABC employees.
- Training of procedural techniques used by ABC Laboratories personnel.
- Oversight of ordering, receipt, surveys, and delivery of byproduct material.
- Maintain an inventory of all radioisotopes possessed under the license and ensure that licensed material possessed by the licensee is limited to the types and quantities of byproduct material listed on the license.
- Packaging, labeling, surveys, etc., of all shipments of byproduct material leaving ABC Labs.
- Personnel monitoring program, including determining the need for and evaluating bioassays, monitoring personnel exposure records, and developing corrective actions for those exposures approaching maximum permissible limits.
- Radioactive waste disposal program.
- Inventory and leak tests of sealed sources.
- Decontamination.
- Investigating any incidents and responding to any emergencies.
- Maintaining all required records.

- Review and approve all licensing agreements with the NRC.

- Act as liaison with NRC and other regulatory authorities.

The Radiation Safety Officer will be responsible for training personnel involved in working with radioactive materials. Laboratory personnel will be required to attend periodic in-house seminars on radiation safety conducted by the RSO or a designated consultant. The training text may be changed to reflect new NRC regulations or company policies. Ancillary personnel will be trained in the proper safety precautions when in radioactive use areas. This training will involve identifying radioactive waste receptacles (leave for laboratory personnel), general cleaning of laboratory floors, and avoidance of exposure to radioactive materials. Documentation of such training will be in the form of a signature of the attendees on a list which will be maintained by the RSO with the NRC records.

Radiation Safety Technician

1) Schedule and conduct wipe tests as required on:

   a) ECD cells every 6 months
   b) Laboratory work areas every three months

2) Analyze wipe swabs on the Radiation Safety LSC.

3) Date and record results of wipe surveys by category for future reference.

4) Recognize the radiation tolerance levels on wipe tests as specified by the ABC radiation safety guidelines and, if necessary, report the levels to the RSO to implement corrective action.

5) Survey all radioactive parcels received by ABC Laboratories and report contamination to the RSO for reporting under 10 CFR 20.1906. Parcels to be shipped from ABC Laboratories will be monitored for activity and documentation of said shipments and surveys will be maintained.

6) Deliver all radioactive materials received to the appropriate Material Compliance Office.

7) Maintain a file containing documentation of the amount of radioactive materials on site to assure that license limits are not exceeded.

8) Maintain calibration procedures and current certification of calibration for survey meters which are to be used in radioactive material surveys.

9) Assure that radioactive waste shipments are conducted properly, by supervising all such shipments. This will include notification of shipments to be made, verify proper preparation of waste shipped and prepare the proper documentation for the shipment.

10) Maintain a file of NRC licenses for all firms to which ABC sends radioactive material. Review the file to ensure licenses are current when the shipment is made.

ABC Laboratories Radiation Safety Committee

The members of the Radiation Safety Committee will consist of the Chairman of the Radiation safety Committee, Radiation Safety Officer, Executive Management Representative, authorized users from the operating divisions, and/or selected representatives from the divisions.

Responsibilities of the Radiation Safety Committee (RSC)

1) Review and approval of program and procedural changes by the RSC.

2) Monitor the implementation of program and procedural changes.

3) Technical review of study protocols. Approval of handling techniques and application procedures outlined in the protocol, (Any protocol which differs dramatically from those previously used will still be submitted to the NRC for review and approval).

4) Periodically perform audits of licensed operations to determine compliance with license, and taking appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

5) Review of safety procedures used in the laboratory to assure safe practices are being followed.

6) Assist in informing personnel of safety practices and promote safety awareness in the laboratory.

7) Assisting the RSO in maintenance of accountability records, and minimizing levels of radioactive compounds in storage.

8) To observe and report unsafe practices or conditions in the laboratory to the RSO and to assist in correcting the problem by making recommendations to management.

9) To recommend new radiation safety procedures or equipment as needed.

10) To inform the committee of concerns of laboratory personnel in reference to radiation safety issues.

11) Periodically review the radiation safety program to initiate new policies or revise existing ones.

12) Determine and assign limits of activity which each division at ABC Laboratories may possess at any one time.

The Radiation Safety Committee will meet approximately every three months to discuss safety issues. Seventy percent of the members must be present to have a quorum. A quorum is required to approve new study protocols, approve new safety policies and procedures (NOTE: approval of new study protocols may be obtained via email without convening a formal meeting of the RSC). The Chairman, RSO, and Executive Management Representative (or his/her designee) must always be present to constitute a quorum.

The Radiation Safety Committee will decide if lab areas are adequate to assure safe use of radioactive materials. The committee will use 10 CFR 20 as a guide in determining which areas are adequate. The following items will be considered when evaluating areas for radiation use:

1) Are counter tops impervious to solvents, to avoid adsorption of radioactive materials?

2) Will adequate absorbent material be available to allow work areas to be covered?

3) Are the floors constructed so that cracks are filled, to avoid trapping of material?

4) Is there adequate ventilation in the area?

New areas built for radiation use, which have not previously been approved by the NRC, will be presented to the NRC for approval. Approval of these new areas by the NRC is required before radioactive materials can be used.

The committee will be responsible for contacting and working with radiation consultants when required, to aid in the training of personnel or training of general use of radioactive materials.

The committee will have the authority to require a change in any procedure that is not in compliance with the safety procedures of ABC Laboratories. All instances of this will be reported to the group manager.

Authorized User

Licensed material will be used by personnel who have the training and experienced to handle individual isotopes. The competency of the individuals will be assessed by the Radiation Safety Officer and the Radiation Safety Committee. Authorized users of byproduct material with the isotopes for which they are approved will be documented on a list maintained by the RSO. No persons will be allowed to use material if they are not on the list.

Assessment of personnel for use of radioactive materials will use the following criteria:

1. Training received – The Radiation Safety Committee will review the training each individual has received. Length of training, location of training and content of training will be assessed.

2. Experience – The Radiation Safety Committee will review the amount of experience a person has with specific isotopes and the levels of activity that have been used in the past. The committee will authorize persons for use with individual isotopes.

The Authorized Users List will contain the following information:

1. Name of Individual
2. Isotopes for which they are approved.
3. Levels of activity for which they are approved.

There will be three types of users in ABC's radiation protection program. The three types of users and there function are listed below.

1. Class 1 Users – Users that may work unsupervised. Class 1 users are users that may worked unsupervised with radioactive material. Class 1 users have demonstrated the ability and knowledge to work safely without direct supervision.

2. Class 2 Users– Users that must be supervised. Class 2 users are users that have not demonstrated the competence or experience to work without supervision. All new users that will directly work with radioactive material are placed into this category.

3. Ancillary Personnel – Staff members that work in areas controlled for radiological purposes that will not work directly with radioactive material.

ITEM 8.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (INSTRUCTIONS TO WORKERS)

New employees at ABC Laboratories who will be working with radioactive isotopes are required to attend a training seminar conducted by the Radiation Safety Officer, Sheila Hecht. The frequency of training for all personnel will be:

- Before assuming duties with, or in the vicinity of, radioactive materials
- Whenever there is a significant change in duties, regulations, or the terms of the license
- Annually (refresher training)

We will maintain records of training to include, duration, place, instructor, subjects covered and names of attendees.

We will follow the model training program that was established in Appendix J, to NUREG-1556 Volume 7.

Any revision or changes to the training program will be review and approved by the Radiation Safety Committee before implementation.

ITEM 9

FACILITIES AND EQUIPMENT

Licensed materials may be used only at the licensee's facilities located at 7200 E. ABC Lane, Columbia, MO 65202.

ITEM 10.

RADIATION SAFETY PROGRAM

Audit Program

We will follow the model audit program that was established in Appendix L, to NUREG-1556 Volume 7.

The RSC will periodically perform audits to determine compliance with the license, and will take appropriate actions when noncompliance is identified, including analysis of the cause, corrective actions, and actions to prevent recurrence.

Instruments

RADIATION SAFETY INSTRUMENTS USED AT ABC LABORATORIES

List of Radiation Safety Instruments

Type of Instrument	Manufacturer	Model	Number of Instruments	Radiation Detected	Sensitivity Range
Surveying	Ludlum	44-9 Probe 3-Counter	27	Beta/gamma	0-200 mR/hr
Surveying	Ludlum	43-68 Probe 16-Counter	1	Beta/gamma	0-500,000 cpm
Surveying	Ludlum	44-9 Probe 2241-counter	2	Beta/gamma	0-500,000 cpm
Surveying	Beckman	LS-6500	2	Beta	1-1,000,000 cpm
Scintillation Counter	Beckman	LS-60001C	3	Beta	1-1,000,000 cpm
Scintillation Counter	Beckman	LS-6000SC	3	Beta	1-1,000,000 cpm
Scintillation Counter	Beckman	3801	1	Beta	1-1,000,000 cpm

Calibration:

The surveying instruments are calibrated yearly by Ludlum Measurements, Inc, 501 Oak Street, Sweetwater, TX 79556. Calibration certificates are issued by Ludlum Measurements, Inc. and maintained at ABC Laboratories as proof of compliance with the pertinent NRC regulations concerning survey instruments.

The scintillation counters are calibrated monthly by ABC Laboratories' personnel using NBS-certified sources of the appropriate isotope.

Air monitoring for radioactivity will be conducted at least annually using a calibrated portable air particle sampler. Samples will be taken in each laboratory actively using radioactivity. Sampling time per sample will be for a minimum of 4 hours. Documented activities found through LSC analysis (corrected for reagent blank background levels) will be in $\mu Ci/M^3$ averaged for the time of sampling. Activities found will be compared to the exposure levels for the isotopes of interest in Part 20, Appendix B, Table 1.

Material Receipt and Accountability

We will follow the model programs published in Appendix P of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

The Radiation Safety Committee will review any procedural changes submitted to ensure compliance with changes in NRC and DOT regulations.

Occupational Dose

Dosimetry will be provided by an organization holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology.

No personnel monitoring will be required when using carbon-14 or hydrogen-3 in low millicurie amounts.

Urine specimens will be taken from personnel dosing or spraying subplots for field type studies or from metabolism and/or FDA animal health studies where single dose activities per animal are greater than 10 mCi. Bioassays for tritium will be conducted following the guidelines in Regulatory Guide 8.32. This guide will also be used to determine action levels and subsequent calculation of exposure to personnel.

Urine samples assayed for carbon-14 will be evaluated based on section 20.1203 of the Code of Federal Regulations. If the activity in the sample is above the minimum quantifiable limit, a calculation using Appendix B, table 1, column 1 will be performed to assure that over exposure has not occurred.

Safe Use of Radionuclides and Emergency Procedures

We will follow the model programs published in Appendix R of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

The Radiation Safety Committee will continue to review any safety or procedural changes submitted to ensure compliance with changes in NRC and DOT regulations.

Surveys

We will survey our facility and maintain contamination levels and perform bioassays of occupationally exposed workers in accordance with the survey frequencies and contamination levels published in Appendix S of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

We will implement the model leak test program published in Appendix T of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

The Radiation safety Committee will continue to review any safety or procedural changes submitted to ensure compliance with NRC regulations.

ITEM 11.

WASTE MANAGEMENT

Waste Disposal

We will follow the model programs published in Appendix T of NUREG-1556, Volume 11, "Program-Specific Guidance About Licenses of Broad Scope."

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