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MS 16
Q-5

July 8, 2005

Docket No. 03005394 License No. 29-11577-01
Control No. 136336

Betsy Ullrich
Senior Health Physicist
United States
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RECEIVED

Dear Ms Ullrich,

In response to issues and concerns raised in your letter of June 21, 2005 with regard to our application for renewal of Nuclear Regulatory License No. 29-11577-01, I have addresses each item as requested.

1. In response to Section 8.10.2 of NUREG-1556, Volume 7, " Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" (NUREG-1556, Volume 7) the radiation detection instruments available for use are:

Type	Radiation Detected	Range	Use
Nuclear Chicago Portable Radiation Survey Meter Model No. 2650 Serial No. 1692	Beta	0.03-7400 mR/Hr	Monitoring, Surveys
Beckman Scintillation Counter Model No. LS1801 Serial No. 7013008	Beta	200-500,000 dpm	Assays, Surveys

136336

NMSS/RGN1 MATERIALS-002

2. In regard to calibration under Section 8.10.2 of NUREG-1556, Volume 7, the Nuclear Chicago Portable Radiation Survey Meter is calibrated annually by Research Products International Corp., Mount Prospect, IL. A copy of the latest calibration report is enclosed for your reference. Calibration of the Beckman Liquid Scintillation Counter is performed annually by the manufacturer under our purchased service agreement.

3. In regard to Section 8.10.6 of NUREG-1556, Volume 7, we have a Radioisotope Lab Safety Manual that clearly states rules pertaining to the safe use, handling and storage of radioactive material. The manual also covers rules for proper protective equipment and monitoring procedures required for the protection of personnel.

4. In regard to Section 8.10.6 of NUREG-1556, Volume 7, the Radioisotope Lab Safety Manual also clearly states rules and procedures that must be followed in the event of an emergency. These rules and contact information for the RSO and a secondary contact are posted inside the laboratory.

5. In regard to Section 8.10.7 of NUREG-1556, Volume 7, the Radioisotope Lab Safety Manual contains rules to ensure we will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG-1556. As stated in the manual, wipe tests and surveys will be conducted at the beginning and end of each work day when the lab is in use. there are prolonged periods of several weeks to several months when the lab is not used. Still surveys will be conducted during periods of inactivity at least every six months.

6. In regard to Section 8.11 of NUREG-1556, Volume 7, all radioactivity will be disposed by Decay in Storage, release into sanitary sewerage or transferred to an authorized recipient according to procedures outlined in Appendix T of NUREG-1556, Volume 7. All disposal rules are clearly stated in the safety manual.

Since most of our responses to the information required in you letter are covered in The Radiation Lab Safety Manual, I am enclosing a copy for your review.

Sincerely,

David Skrincosky

David Skrincosky, Ph.D.
Technical Director

WORTHINGTON BIOCHEMICAL CORPORATION

RADIOISOTOPE LABORATORY SAFETY MANUAL

January 2005
Revised July 2005

SAFETY MANUAL – RADIOISOTOPE LABORATORY

General Safety Rules:

All work with licensed materials is confined to the radioactivity lab.
Do not eat, drink smoke or apply cosmetics in radioactivity lab.
Do not store food, drink or personal effects in radioactivity lab.
Limited access to the laboratory by all persons under 18 years of age and by pregnant women.
All persons handling radioactivity will receive instruction in the safe and proper handling of radioactive materials.
In the event of an emergency, contact the Radiation Safety Officer (RSO) as soon as possible. If contact is not possible, contact Jim Zacka.

RSO: David Skrincosky	Ext. 38
	Home: [redacted]
	Cell: [redacted]
Jim Zacka	Ext. 17
	Cell: [redacted]

Safe Handling of Radioisotopes:

Laboratory coats and protective eyewear are REQUIRED when working in the radioactivity lab and with radioisotopes.
Disposable gloves are required to be worn at all times when working with radioactive materials. "Double gloving is recommended but not required". Extreme care must be exercised to prevent contamination in areas where there is a break in the skin (cut, scratch, abrasion, wound, etc.)
Care should be taken to set up a safe work area. Work which could result in table top contamination should be done over plastic-backed Adsorbent Bench Underpads
NO MOUTH PIPETTING is allowed under any circumstances!
Dosimeter Badges should be worn at all times in the Radioactivity lab.

Receiving, Storage and Transportation of Radioisotopes:

Purchased radioisotopes will be delivered to the Radioactivity Lab in their original shipping packaging by the Receiving Department. Receiving will examine the external shipping packaging looking for damage or wetness.
Survey exterior of shipping packaging with portable Radiation Survey Meter or with wipe test.
Upon removal of the shipping packaging, place the radioisotope (still in its product packaging) on a plastic-backed Adsorbent Bench Underpad. P-32 must be placed behind a 1/4 to 1/2 inch thick plexiglass shield.
Check external product packaging for radioactive contamination. For P-32, monitor the external product packaging with Portable Radiation Survey Meter. For H-3, C-14 and P-32, check for contamination with a wipe test. If contamination is detected, consult the RSO before proceeding.
Remove radioisotope from the product packaging and check exterior of containment vesicle for radioactivity contamination with a wipe test. If contamination is detected, consult the RSO before proceeding.
All radioisotopes and radioactive products and materials contaminated with radioactivity must be clearly labeled and stored only in the Radioactivity Lab.
P-32 must be stored in a lead pig.
Secure all radioactive materials when they are not under the constant surveillance and immediate control of the user.
The Radioactivity Lab should be locked at all times.

Signs and Labels:

All areas in which more than 10 μCi of radioactive materials are used or stored must be posted with a sign stating "**Caution Radioactive Material**". This sign is found on the door to the Radioactivity Lab and on the door to the freezer in the Radioactivity Lab.

Any vesicle containing 1 μCi or more of any radioactive material must be clearly labeled "**Caution Radioactive Material**". All such vesicles must be confined in the Radioactivity Lab.

Emergency Procedures:

1. Objective of Remedial Action: In the event of an accident involving the release of significant quantities of radioactive material, the objectives of all remedial action are to:
    a. Minimize the amount of radioactive material entering the body, by ingestion, inhalation, or through any wounds.
    b. Prevent the spread of contamination from the area of the accident.
    c. Remove radioactive contamination on personnel.
    d. Notify others in area that a spill has occurred and limit entry into the area.
    e. Contact the Radiation Safety officer (RSO).
    f. Start area decontamination procedures under qualified supervision. Inexperienced personnel should not attempt decontamination.

2. Procedures for Dealing with Spills and Contamination: Due to the specific radioisotopes covered by our license, the chemical nature of the compounds containing the radioisotopes and the limited applications of the radioactive compounds used at WBC, any accidents will involve minor quantities of radioactivity release (i.e. in the microcurie level). In other words, due to the nature of our work, contamination will be limited to liquid spills containing low levels of radioactivity. However, protocol must be followed to limit and confine contamination.
    a. Put on gloves to prevent contamination of hands.
    b. Drop absorbent paper or cloth on spill to limit spread of contamination.
    c. Place contamination cleaning materials into plastic bags or other closed containers. Seal and label.
    d. Mark area of spill as "contaminated" as soon as possible, if immediate decontamination is not instituted. A wet spill shall not be allowed to dry and become powdery if significant amounts of radioactivity are involved. This might produce serious air contamination.
    e. Notify the Radiation Safety Officer as soon as possible.
    f. Start approved decontamination procedures as soon as possible.

<u>If the body is suspected of being contaminated</u>

a. Scan with Portable Radiation Survey Meter or other appropriate means to determine contaminated areas of the body. Contact RSO immediately if assistance with scanning is needed.
b. <u>Do not</u> immediately attempt decontamination if cuts, abrasions or open wounds are observed.
c. If cuts, abrasions or open wounds are contaminated, dry clan the area with suction apparatus and swabs. (Wet cleaning might increase absorption.)
d. If the skin is contaminated in the area of cuts, abrasions, and open wounds, use wet swabs in a direction *away from* the cut, abrasion or open wound, taking care not to spread activity over body or into wound.

Emergency Procedures: (cont.)

If the skin appears to be intact, use the following procedure

a. Wet hands and apply mild soap.
b. Work up good later, keep lather wet.
c. Work later into contaminated area by rubbing gently for 3 minutes. Apply water frequently.
d. Rinse thoroughly with lukewarm water (limiting water to contaminated areas).
e. Repeat above procedures twice if necessary.
f. If the radiation level is still above background initiate more powerful decontamination procedures, after consultation with Radiation Safety Officer.

If clothing is suspected of being contaminated

a. Scan suspect areas with Portable Radiation Survey Meter or other appropriate means to determine contaminated areas of clothing. Contact RSO immediately if assistance with scanning is needed.
b. Remove contaminated clothing and place in plastic bags. All Laboratory and Production Personnel are instructed to have an extra set of clothing (including shoes) in their lockers.
c. The bottoms of shoes should be scanned after a spill and/or after clean-up with the Portable Radiation Survey Meter or wipe tests to prevent contamination outside the Radioactivity lab.

3. Corrective and/or Preventative Action. An investigation will be initiated by the RSO and/or the WBC Safety Officer after any and all contamination incidents. The primary purpose of the investigation will be to determine whether any actions can be taken to prevent further incidents in the future or to determine if additional training or equipment are required.

Monitoring and Surveys:

a. Personal: All employees trained for the safe use of radioisotopes and all employees required to enter the Radiation Lab for non-scientific reasons (i.e., maintenance, engineering, housekeeping) will be issued Dosimeter film badges. Badges must be worn at all times when working in the Radioactivity Lab and with Radioisotopes. ***Badges are not transferable***. Badges are collected once a month and are sent to a certified outside vendor for evaluation. A monthly exposure report is issued to WBC for all relevant employees. A copy of this report is posted in the Radiation Lab and the original is kept in Document Control. All effected employees have access to these reports for their review.

b. Facility and equipment. Usage of radioactivity at WBC is sporadic. Usage of radioactivity could be followed by several months of inactivity. However, when the radiation lab and radioactivity is used, the laboratory work area and equipment must be monitored for radioactivity contamination at the beginning and end of each work day. For H-3 and C-14, monitoring is done with wipe tests. P-32 contamination can be checked with wipe tests and/or scanning with the Portable Radiation Survey Meter.

c. In the event that a survey detects radiation above background levels, the RSO must be contacted immediately. Appropriate steps will be taken to remedy the immediate situation and to prevent occurrences in the future.

Disposal of Radioactivity:

a. All waste containers must be clearly identified and stored under appropriate conditions.

b. The type and approximate amount of radioactivity shall be recorded when added to waste containers.

c. All liquid waste shall be placed in clearly labeled appropriate waste containers. Use separate containers for H-3, C-14 and P-32 waste. The P-32 waste container must be stored in a plexiglass box.

d. Similarly, disposable labware, Underpads, gloves and other solid waste shall be place in proper radioactive waste disposal barrels. Use separate barrels for H-3, C-14 and P-32 contaminated solid waste. The P-32 waste barrel must be stored in a plexiglass box.

Disposal of Radioactivity: (cont.)
e. Glassware and laboratory instruments contaminated with radioactivity must be washed at least twice. Washes must be collected and contained radioactivity must be measured and recorded. Liquid washes may be disposed of in the sink provided we do not exceed our yearly sanitary sewerage disposal limit. The amount and type of radioactivity disposed of down the drain at any one time must be measured and recorded, along with the date. Sanitary sewerage disposal must be accompanied by profuse flushing with water. The total quantity of licensed material released into the sanitary sewerage system in a year cannot exceed 185 GBq (5 Ci) of H-3, 37 GBq (1 Ci) of C-14 and 37 GBq (1 Ci) of all other radioisotopes (including P-32) combined. Please note that any radioactive samples disposed into the sanitary sewerage system must be readily soluble in water.
f. Liquid scintillation media (including vials and other items contaminated with liquid scintillation media) containing no more than 1.85 kBq (0.05 μCi) of H-3 or C-14 per gram of scintillation medium can be considered to be non-radioactive and can be disposed in ordinary trash.
g. All P-32 waste shall be disposed by the Decay-In-Storage Method. Waste will be kept for at least 10 half-lives (130 days) in the Radioactivity Lab. Waste can be disposed in ordinary trash at the end of this time if surveys determine radioactivity is equivalent to background levels. Record must be maintained of surveys prior to disposal.
f. Waste containers shall be emptied and disposed of when either they are full or the total amount of isotope in the facility is near our yearly limit. Disposal will be coordinated with a licensed outside vendor qualified to dispose of such material.

Isotopes permitted by License:

Isotope	max. allowable on-hand qty.
Hydrogen 3, Tritium	5 mCi
Carbon 14	2 mCi
Phosphorus 32	1 mCi

Isotope Specific Information:
Tritium, H-3.
Tritium is a very low beta energy emitter and even large quantities of H-3 pose no appreciable hazard to the user. The emergy travels only a fraction of an inch and is so weak it cannot even penetrate the outermost dead layers of skin. Since H-3 beta particles are so weak they will not be detected with Dosimeter badges or Portable Radiation Survey Meter. The only way we can detect H-3 here is by scintillation counting. However, tritium can be a hazard if it is internalized. This can happen through an opening in the skin (an apparent wound or a microscopic lesion) or through the eyes. Still, the danger is not present until tritium is taken up internally by cells. Eventually it can be incorporated into nucleotides and incorporated into DNA. Here the weak beta energy could damage DNA and cause genetic mutations. Keep in mind, tritium can be incorporated into other macromolecules (proteins, carbohydrates and fat) and since it has a half life of 12.28 years, it can linger in the body for decades. Sooner or later in could eventually be incorporated into DNA. Note that more than 95% of the tritium used at WBC is tritiated thymidine, this has a high probability of it being incorporated directly into DNA if internalized.

Carbon 14
C-14 is also a beta emitter but in contrast to tritium, it has a longer pathlength (about 8.6 inches), has more energy and a half life of 5730 years. Still energy from C-14 will not penetrate the outer most layers of dead skin or be detected with Dosimeter badges. It can possibly be detected with the Portable Radiation Survey Meter. However, it is probably better to use scintillation counting here at WBC.

Isotope Specific Information: (cont.)

Phosphorus 32

Of the three isotopes covered by our license, P-32 warrants the most precaution. It is also a beta particle emitter but has significantly more energy than H-3 and C-14 emissions. P-32 beta emissions have 10 and 90 times more energy than C-14 and H-3, respectively, and can penetrate up to 0.8 cm into living skin tissue. The pathlength (maximum range traveled through air) is 18 to 20 feet which is more than 25 and 1300 times further than C-14 and H-3, respectively. In contrast however, P-32 has a relatively short half-life (14.29 days) compared to H-3 and C-14. The Dosimeter badges and the Portable Radiation Survey Meter will certainly detect P-32. Wipe tests and Liquid Scintillation Counting (LSC) can also be used. When working with P-32, precautions should be made to minimize exposure. Plan work thoroughly so work can be done as quickly and safely as possible. Opened containers of P-32 must be shielded behind a 1/4 to 1/2 inch thick plexiglass shield. All work needs to be performed behind plexiglass shielding. Waste containers must be encased in a plexiglass box. Refresher training and a demonstration of safe handling procedures will be provided as needed when work with P-32 is required.

Physical Data and Information:

Isotope	Energy	Pathlength	Half-life	Shielding	Detection
H-3	0.019 MeV	0.167 inch	12.28 yr	no	LSC
C-14	0.156 MeV	8.6 inches	5730 yr	no	LSC
P-32	1.71 MeV	18-20 feet	14.29 days	yes	Dosimeter Survey Meter LSC

MeV = Mega electron volt
LSC = Liquid Scintillation Counting

Research Products International Corp.

CERTIFICATE OF CALIBRATION

DATE: February 25, 2005 **CERTIF. No.: 6268**

PERFORMED FOR :
WORTHINGTON BIOCHEMICAL CORP.
MR JIM ZACKA
730 VASSAR AVENUE
LAKEWOOD, NJ.
08701

P.O.# 021813

MFR.: Warrington

MODEL: 2650 DETECTOR: End Window GM

SERIAL #: 1692 DET. SER. #: None

Range	SDD(cm)	*Level mR/hr.	Reading	% Error	Correction
.1		Background	.02	N/A	NONE
	128(2TVL/HVL)	.060	.060	0.0	REQ'D
.3	128(2TVL/HVL)	.060	.060	0.0	NONE
	280TVL	.250	.250	0.0	REQ'D
1	280TVL	.250	.25	0.0	NONE
	163TVL	.740	.74	0.0	REQ'D
3	163TVL	.74	.74	0.0	NONE
	280	2.50	2.50	0.0	REQ'D
10	280	2.5	2.5	0.0	NONE
	163	7.4	7.5	+1.3	REQ'D
30	163	7.4	7.5	+1.3	NONE
	99	20.0	20.0	0.0	REQ'D
100	99	20.0	23	+15.0	X 0.9
	53	70.0	75	+7.1	X 0.9

All readings less than 1.0 mR/hr. were corrected for background

Ck Source Reading: High Side = 21 mR/h, Low Side = 1.6 mR/h
Scale: 30, 3 - w/Battery Set @ mid-green
Geometry: Contact, into window

By Frank J. Varada
Frank J. Varada

COMMENTS:
No significant change in calibration since last calibration.

*Cs137 100mCi Assay on 12-15-81, NIST Traceable, New England Nuclear Model NER-570A #CS1481

RAM Lic. No. IL-01995-01 | 2650.doc | Next Suggested Calibration Date: Feb. 25, 2006

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