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Laboratories

June 09, 2008

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: Additional Information Requested for License Amendment Request – License No. 24-13365-01, Amendment 33

Gentlemen:

Attached is the additional information requested in regards to the Amendment 33 application for License No. 24-13365-01.

Sheila Hecht

S. C. Hecht
Director, Safety and Environmental Health

Item10: Radiation Safety Program

Surveys:

Bioassay Procedure for Assessing Exposure to Radioactive Material (OESH-813)

Exposure from radioactivity produced by the carbon-14 and hydrogen-3-labeled compounds utilized in studies at ABC Laboratories is expected to be well within regulatory limits due to environmental controls and proper laboratory techniques demonstrated by our laboratory personnel. To verify implementation of controls and monitor exposures that may be received by laboratory personnel working with levels of radioactivity of 100 millicuries and greater, bioassays (urinalyses) will be collected within 24 hours of completion of work and analyzed.

Definitions

Annual Limit on Intake (ALI): The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue.

Derived Air Concentration (DAC): The concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate of 1.2 cubic meters of air per hour), results in an intake of one ALI.

Evaluation and Intake Monitoring Action Levels

Levels of regulatory concern for given incidents are based on fractions of the annual limit of intake for carbon-14 and hydrogen-3 as stated in 10 CFR 20.1001 – 20.2401, Appendix B. These tables list intake (inhalation, adsorption and/or consumption) activities for given isotopes which would give a committed dose equivalent of 50 rem (0.5 seivert) to any individual organ or tissue.

ABC Laboratories will recognize an indicated intake of 0.02 times the ALI as an **Evaluation Level** and 0.10 times the ALI as an **Action Level**. At the evaluation level, the contaminated associate will be required to submit frequent bioassay samples (at least every four hours) so as to properly estimate total intake. If the action level is reached or exceeded, in addition to the more extensive biomonitoring and possible consultation with the corporate physician, the Radiation Safety Committee will meet to review the incident and decide if additional environmental controls are required in the area.

Values (From 10 CFR 20.1001 – 20.1204 and Appendix B)

ALI for Carbon-14 and Hydrogen-3

Compound ^{14}C	2×10^{3} µCi
$^{14}CO_2$	2×10^{5} µCi
Compound and gas 3H	8×10^{4} µCi

DAC for Carbon-14 and Hydrogen-3

Compound ^{14}C	1×10^{-3} µCi/cc
$^{14}CO_2$	9×10^{-5} µCi/cc
Compound and gas 3H	2×10^{-5} µCi/cc

Incidents and Activities requiring Biomonitoring at ABC Laboratories

- Spraying of test plots in greenhouses or open-air designated areas with labeled material.

- Procedures using 100 millicuries of carbon-14 compounds

- Individuals involved in an incident whereby they may have come into direct contact, via skin, inhalation, or consumption of activity levels equal to or greater than 0.02 times the ALI. An example of such an incident is where a chemist in the laboratory has checked out a stock solution with a total activity of 15 mCi. While transferring an aliquot of the material, the chemist accidentally knocks the storage container holding the material over, spilling a portion of the contents on him/herself. As the incident likely involved contact with more than 0.02 times the ALI of ^{14}C-compound (40 µCi), the individual must undergo biomonitoring.

- Individuals who are working in areas where air monitoring has demonstrated that they are exposed to concentrations of non-$^{14}CO_2$ (i.e., compound ^{14}C) radioactivity sufficient to cause an exposure equal to or greater than 0.02 times the ALI. The determination of exposure from $^{14}CO_2$, is covered under the air sampling for the determination of radioactivity section.

Procedure for Submitting Urine Samples for Analysis

Within 24 hours after completion of work involving one of the above listed activities, the laboratory worker(s) will perform the following steps:

- Obtain a urine sample container. Write name or ABC employee identification number, the date, and the time that the urine sample is taken on the urine sample container label.

- Fill the urine container approximately one half full and screw the lid back on tightly.
- Place the filled urine container in the appropriate collection box.

If the urinalysis is being conducted because of a possible incident where an employee has been exposed to a significant amount of activity, the Radiation Safety Officer or, in their absence, the Radiation Safety Technician should be contacted immediately. The incident should be reviewed for severity, based on the nature of the exposure (primary area of contact and the duration of the contact) and the level of activity to which the employee was exposed. If significant intake is viewed as unlikely, an initial sample plus an additional one at 24 hours will be sufficient. If the intake is estimated as being more serious, as may occur from the inhalation of dry material with a high specific activity, a more regimented sampling schedule will be required.

Counting the Urine Samples

- Radiation Safety will collect the urine containers daily and perform the bioassay using a Liquid Scintillation Counter.

- One (1.0) milliliter of a urine sample will be pipeted into a 20-milliliter scintillation vial. Fifteen (15) milliliters of liquid scintillation cocktail (Beckman ReadyGel or equivalent) will be added, the vial capped, and the vial shaken to insure homogeneity. The identity of the sample must be recorded on the cap of the vial.

- The above step will be repeated for each individual urine sample.

- Two reagent controls containing 15 mL of scintillation cocktail solution will also be prepared.

- The samples will be placed in a laboratory refrigerator for at least 90 minutes to decrease sample fluorescing.

- The samples will be counted in a Liquid Scintillation Counter per the instrument's SOP (typically for 5 minutes or to a 2 sigma/95% confidence). The activity (in disintegrations per minute) will be counted.

Analysis and Actionable Exposures

After the samples have counted the Radiation Safety Officer will review the bioassay results. If the indication is that no excretable radiation can be detected, no further samples need to be taken. If significant activity was detected, additional samples will be taken. A second sample will be taken followed by a third sample taken within 4 hours of the second sample, and a fourth sample within 4 hours of the third sample. The samples will be analyzed as soon as

possible the next day. Significant activity will be defined as when the activity in the second sample is 40 dpm (1.8×10^{-5} µCi) greater than the initial sample, corrected for control values.

Following the completion of the urinalyses, the contaminated associate will be requested to submit a written description of the incident. Information included in the incident report are: name, job title, manager, date and time of the incident, description of the incident, description of the contaminating material (including the activity of the material) and efforts made to limit the contamination. The incident report plus the results of the urinalyses will be provided to the Radiation Safety Officer to record the incident. In addition, the employee's manager will be requested to fill out an accident report form, documenting the incident and acknowledging actions which were taken.

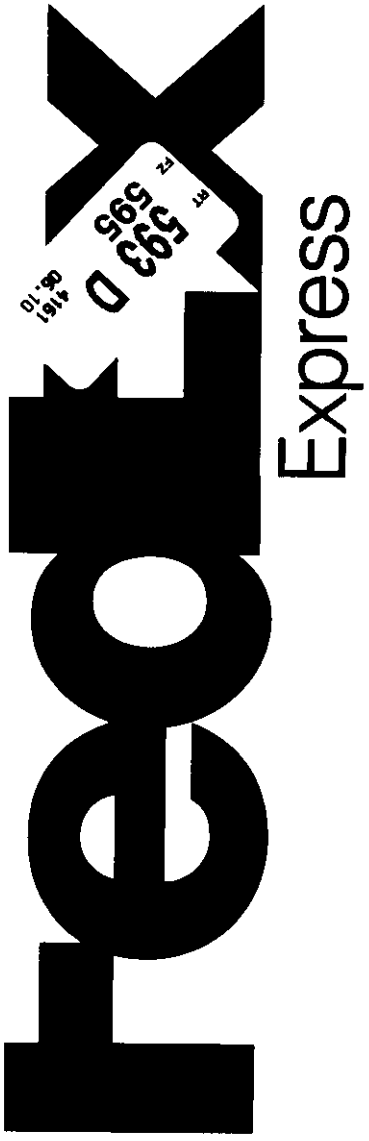
If an employee's total exposure for the year reaches 10% of the ALI, an evaluation of the employee's work activities will be conducted by the Radiation Safety Committee. If the total exposure for the year reaches 50% of the ALI, the employee will be removed from working with radioactive materials and their work activities will again be reviewed by the Radiation Safety Committee for approval to continue working. If total exposure reaches 100%, the employee will be removed from working until the next calendar year.

Calculation of Intake

The following table will be used to determine intake from all forms of H-3 and from compounds labeled with C-14 by multiplying the activity in dpm in one milliliter of urine times the appropriate factor for the radionuclide, time since the incident, and physical unit (ALI or mrem). These calculations are based on an effective biological half-life of 9.4 days for H-3 and 12 days or 40 days for C-14. Typically, biological clearance rate data are fragmentary. In this case, the standard 9.4 days should be applied for H-3 and either 12 days or 40 days should be applied for C-14, depending on the available data. If only one bioassay data point exists, no biological clearance rate can be estimated. The logarithmic mean of the 12 and 40 days values may be applied. If reliable direct measurements of biological half-life are obtained for a specific person or incident, the factors may be modified.

	C-14 (12 day $T_{1/2}$)		H-3 (all)		C-14 (40 day $T_{1/2}$)	
days after intake	mrem per dpm/ml in urine	ALI per dpm/ml in urine	mrem per dpm/ml in urine	ALI per dpm/ml in urine	mrem per dpm/ml in urine	ALI per dpm/ml in urine
0						
1	1.92E-02	3.85E-06	1.52E-02	3.04E-06	6.28E-02	1.26E-05
2	2.04E-02	4.07E-06	1.63E-02	3.27E-06	6.39E-02	1.28E-05
3	2.16E-02	4.32E-06	1.76E-02	3.52E-06	6.50E-02	1.30E-05
4	2.29E-02	4.57E-06	1.89E-02	3.79E-06	6.62E-02	1.32E-05
5	2.42E-02	4.84E-06	2.04E-02	4.08E-06	6.73E-02	1.35E-05
6	2.57E-02	5.13E-06	2.19E-02	4.39E-06	6.85E-02	1.37E-05
7	2.72E-02	5.44E-06	2.36E-02	4.73E-06	6.97E-02	1.39E-05
8	2.88E-02	5.76E-06	2.54E-02	5.09E-06	7.09E-02	1.42E-05
9	3.05E-02	6.10E-06	2.74E-02	5.48E-06	7.22E-02	1.44E-05
10	3.23E-02	6.47E-06	2.95E-02	5.90E-06	7.34E-02	1.47E-05
11	3.43E-02	6.85E-06	3.17E-02	6.35E-06	7.47E-02	1.49E-05
12	3.63E-02	7.26E-06	3.42E-02	6.83E-06	7.60E-02	1.52E-05
13	3.85E-02	7.69E-06	3.68E-02	7.36E-06	7.73E-02	1.55E-05
14	4.07E-02	8.15E-06	3.96E-02	7.92E-06	7.87E-02	1.57E-05
15	4.32E-02	8.63E-06	4.26E-02	8.52E-06	8.01E-02	1.60E-05
16	4.57E-02	9.15E-06	4.59E-02	9.18E-06	8.15E-02	1.63E-05
17	4.84E-02	9.69E-06	4.94E-02	9.88E-06	8.29E-02	1.66E-05
18	5.13E-02	1.03E-05	5.32E-02	1.06E-05	8.43E-02	1.69E-05
19	5.44E-02	1.09E-05	5.72E-02	1.14E-05	8.58E-02	1.72E-05
20	5.76E-02	1.15E-05	6.16E-02	1.23E-05	8.73E-02	1.75E-

						05
21	6.10E-02	1.22E-05	6.63E-02	1.33E-05	8.88E-02	1.78E-05
22	6.47E-02	1.29E-05	7.14E-02	1.43E-05	9.04E-02	1.81E-05
23	6.85E-02	1.37E-05	7.69E-02	1.54E-05	9.20E-02	1.84E-05
24	7.26E-02	1.45E-05	8.28E-02	1.66E-05	9.36E-02	1.87E-05
25	7.69E-02	1.54E-05	8.91E-02	1.78E-05	9.52E-02	1.90E-05
26	8.15E-02	1.63E-05	9.59E-02	1.92E-05	9.69E-02	1.94E-05
27	8.63E-02	1.73E-05	1.03E-01	2.07E-05	9.86E-02	1.97E-05
28	9.15E-02	1.83E-05	1.11E-01	2.22E-05	1.00E-01	2.01E-05
29	9.69E-02	1.94E-05	1.20E-01	2.39E-05	1.02E-01	2.04E-05
30	1.03E-01	2.05E-05	1.29E-01	2.58E-05	1.04E-01	2.08E-05
35	1.22E-01	2.43E-05	1.60E-01	3.20E-05	1.09E-01	2.19E-05
40	1.62E-01	3.25E-05	2.31E-01	4.62E-05	1.19E-01	2.38E-05
45	2.17E-01	4.34E-05	3.34E-01	6.68E-05	1.30E-01	2.60E-05
50	2.89E-01	5.79E-05	4.83E-01	9.66E-05	1.42E-01	2.84E-05
55	3.86E-01	7.73E-05	6.99E-01	1.40E-04	1.55E-01	3.09E-05
60	5.16E-01	1.03E-04	1.01E+00	2.02E-04	1.69E-01	3.37E-05
65	6.88E-01	1.38E-04	1.46E+00	2.92E-04	1.84E-01	3.68E-05
70	9.19E-01	1.84E-04	2.11E+00	4.22E-04	2.01E-01	4.01E-05
75	1.23E+00	2.45E-04	3.05E+00	6.11E-04	2.19E-01	4.37E-05
80	1.64E+00	3.27E-04	4.41E+00	8.83E-04	2.38E-01	4.77E-05
85	2.19E+00	4.37E-04	6.38E+00	1.28E-03	2.60E-01	5.20E-05
90	2.92E+00	5.83E-04	9.23E+00	1.85E-03	2.84E-01	5.67E-05
120	7.12E+00	1.42E-03	2.77E+01	5.54E-03	3.80E-01	7.60E-05



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