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P8

October 28, 1998

Judith A. Joustra
Senior Health Physicist
Nuclear Materials Safety Branch 3
Division of Nuclear Materials Safety
U.S. Nuclear regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Docket #: 030-34773
Control #: 125802

Dear Ms. Joustra:

We are in receipt of your letter dated October 5, 1998 in which you requested additional information in support of our license application. The information that you requested is as follows:

1. Please note that Safety Light Corporation does not have a specific model number for small pieces of their tritium-containing foils. As far as we know, Safety Light Corporation manufactures large sheets of tritiated foil. When we specify the **total** activity of H-3 that we desire **to purchase**, Safety Light Corporation cuts the foil to the requested activity.

2. Rad Monitor Model GM2 will be calibrated on an annual basis and prior to the first use after repair. Rad Monitor Model GM2 will be calibrated by manufacturer, Research Products International Corporation (Mount Prospect, IL), which has a valid license for the calibration of radiation survey meters. A change of batteries will not be a cause for re-calibration. The range of this instrument for survey of radioactivity is from 0.5 to 2,000 count/sec.

3. With reference to your letter of August 11, 1998, item #2.d. requests us to "Provide the maximum amount (activity) per isotope to be used for each procedure performed on the bench in the hot lab outside the hood." The answer in our letter of September 8, 1998 should refer to item #1.d. in our response that states that "Tritiated compounds in quantities below 20 mCi will be purified and analyzed on the bench in the hot lab outside the fume hood. The bench is located under a wide-mouth exhaust."

   With reference to your letter of August 11, 1998, item #2.e. requests us to "Describe surveys to be performed in the hood area immediately after labeling." describe the surveys to be performed in the hood area immediately after labeling. The answer in our letter of September 8, 1998 should refer to item #1.e. in our response that states that "After each

tritiation procedure in the fume hood area, a radiation survey will be performed using wipe tests and tritium air monitor (Fempto Tech, Canada, or similar equipment)."

With reference to your letter of August 11, 1998, item #2.f. requests us to "Describe surveys to be performed in the laboratory every day labeling is performed." The answer in our letter of September 8, 1998 should refer to item #1.f. in our response that states that states that "Working areas of hot lab outside the fume hood will be tested for removable contamination after every day of tritiation. In addition, all areas of the laboratory will be tested for removable contamination on a bi-weekly basis."

Please note that after each labeling procedure with radionuclides other that H-3, a radiation survey will be performed using Rad Monitor (Research Products International Corp. (Mount Prospect, IL) Model GM2 Serial # 01365 and a wipe test will be performed and counted in a liquid scintillation counter by Beckman, Packard, or Wallac with standards that are traceable to NIST

4. With reference to our criteria for determining the need to issue potassium iodate or iodide, please note the following:

   a) Whenever the results of routine wipe testing show that there is I-125 contamination in excess of 22,000 dpm per 100 sq. cm. in areas where I-125 was used, a special thyroid bioassay will be performed.

   b) Personnel involved with handling I-125 since the time of the last acceptable wipe test, will have a bioassay for I-125 performed within 24-hours of discovering the contamination. This bioassay will take place either in our laboratory using a thyroid uptake system (i.e.: Captus-600 or equivalent) or at a local hospital having thyroid uptake capabilities.

   c) If the results of this bioassay indicate that the worker has a thyroid burden of 0.5 ALI, we will seek medical advice and, if indicated by our medical consultant, potassium iodate or iodide will be administered to the worker. Since the ALI for I-125 is 60 microcuries, 0.5 ALI equals 30 microcuries.

   d) To determine the dose to the worker who has been administered potassium iodate or iodide, we will:

      - record the time from the suspected contamination to the time when potassium blocking agents were administered.
      - a thyroid bioassay will be performed daily, at 24-hour intervals, over the course of five (5) successive days or until the thyroid burden is below 0.1 ALI (e.g.: 6 microcuries).
      - the effective half life of I-125 in the blocked thyroid gland will be calculated.
      - the dose from the time of contamination to the time of administration of the thyroid blocking agent will be calculated by the formula:

        $Dt = (A) * (CF) * (1-\exp(-\lambda t))$

        where; Dt = dose from contamination to blocking
        A = thyroid activity from bioassay
        CF = thyroid dose factor (0.780 rad/uCi) per NRC NUREG/CR-6345

t = number of days from contamination to bioassay

- the dose following time of administration of the thyroid blocking agent will then be calculated.
- the committed dose to the worker's thyroid will then be calculated as the sum of the dose prior to blocking and the dose after blocking.

5. Our equipment is as follows:
   - Low level survey meter: Rad Monitor (Research Products International Corp., Mount Prospect, IL), Model GM-2, SN: 01365
   - Tritium air monitor (Fempto Tech, Canada) – or equivalent.
   - Liquid scintillation counter by Beckman, Packard, or Wallac – or equivalent.
   - Captus-600 (Capintec, Ramsey, NJ) – or equivalent.

6. A copy of the audit form used by our consultants is attached and contains such topics as described in your letter of August 14, 1998, Item #14.c.

7. With reference to our facility diagram, the air supply rate is ~600 cfm. A revised diagram showing both the positions of the supply air ducks and the rates both air supply and exhaust rates is attached.

8. It was our understanding that the original license application submitted was for a manufacturing and distribution license. To assist in clarifying our position, please note the following:
   - We do not plan to manufacture or distribute tritiated foils.
   - We will purchase tritiated foils from Safety Light Corporation.
   - We utilize these tritiated foils as a safe source to obtain small quantities gaseous H-3. This H-3 is used in our manufacturing process to tritiate natural and synthetic compounds.
   - We plan to provide a custom tritiation service in which we manufacture unique custom tritiated synthetic and natural compounds in response to specific requests from academic or industrial groups. Our products are unique and made for a specific customer. It is possible that some products will have more than one customer.
   - Our customers intend to use these products for research purposes only.
   - Each product is unique and, depending upon the order, the activity may vary from 50 microcuries to 100 millicuries.
   - The H-3 will be incorporated in synthetic or natural compounds, as chemically linked to carbon.
   - Our product has no set useful life. The useful life of the compounds will be determined by the end user (i.e.: researcher).
   - Tritiated compounds will be provided to properly licensed organizations only. A copy of the recipient's Radiation License will be obtained prior to shipment of the tritiated compound.

9. We intend to use ≤100 mCi of tritium borohydride that are not explosive. The protocol for handling tritium borohydride is described in our letter of September 8, 1998, as "**Use of Tritium Borohydride**".

10. Dr. Sidorov will act as the facility's Radiation Safety Officer.

If any additional information is required, please do not hesitate to contact me.

With best regards,

J. Backer

Joseph M. Backer Ph.D.,
CEO SibTech, Inc.

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Consultants in Medical Physics

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Audit of Radiation Safety and Regulatory Compliance

Client: _____

Date: _____

I. Any license changes without a proper amendment and/or 30-day notification:

1) unauthorized use of RAM for unlicensed procedure ? ....
2) unauthorized users ? .....
3) unauthorized radiation safety officer ? .....
4) unauthorized amount or chemical form of RAM ? .....
5) unauthorized changes in area of use ? .....
6) NRC License - # __-_____-__ -> expires: _____

II. GENERAL ADMINISTRATIVE REQUIREMENTS

1) written radiation protection program present ? .....
2) Are radiation workers familiar with the program ? .....
3) Duties of the RSO:
   a) written policies and procedures established ? .....
   b) investigational action levels established ? .....
4) Is a bioassay program present ? .....
5) Are bioassay result present for all workers who handle radioactive materials covered by the program ? .....
6) Has any worker had a bioassay result in excess of 0.5 ALI ? .....

IV. SURVEY AND WIPE TESTING:

1) Are survey meters calibrated annually ? .....
2) Are dedicated checks sources present on each meter ? ..
3) Check source surveyed each day of meter use ? .....
4) Are proper survey meters present ? .....
5) Are daily GM-meter surveys of areas of use preformed ?.
6) Are routine wipe tests performed ? .....
7) Are decontamination action levels established ? .....
8) Are all records complete and adequate ? .....
9) Do package monitoring limits comply with RG10.8F ? ....
10) Has the auditor performed an independent radiation survey and wipe test ? .....
11) Are outgoing package monitoring records present ? .....
12) Are outgoing package records in order ? .....

13) Are license records present for all customers to whom packages containing RAM was sent ? .....

V. POSTING REQUIREMENTS:

1) NRC rules and regulations posted ? .....
2) License application, conditions and license present ? .
3) NRC Form #3 properly posted ? .....
4) Radiation warning signs properly posted ? .....

VI. GENERAL RULES FOR THE SAFE USE OF RAM:

1) Are lab coats and gloves worn when handling RAM ? .....
2) Was eating, drinking, smoking, food storage, or the application of cosmetics noted in the lab ? .....
3) Are film badges used and worn properly ? .....
4) Do personnel monitor themselves daily for contamination ?.

Results:

Recommendations:

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Michael L. Caprio, Jr., M.S., CHP, DABR
Certified Health Physicist, Diagnostic Radiological
and Medical Nuclear Physicist

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