

BIOSURFACE TECHNOLOGY, INC.
One Kendall Square
Building 200
Cambridge, MA 02139
617-494-8484
August 19, 1987

MS = 16
P2

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
631 Park Avenue
King of Prussia, PA 19406

RE: Control No. 107537

Dear Dr. Glenn:

In your letter of August 14, 1987 we received several questions regarding our application for a byproduct material license to use isotopes for R & D studies. The following are our replies:

1. Question/Comment

Are you requesting authorization to have the Radiation Safety Officer (RSO) train other users to work with isotopes in an unsupervised situation? Please clarify.

Reply

Everyone at BioSurface Technology who works with radioisotopes is required to go through the company Radiation Safety Training Program and pass the examination. The initial work with isotopes by an individual in the lab will be under the direct supervision of their (isotope-certified) group leader, group safety coordinator, or other isotope-certified supervisory laboratory personnel.

2. Question/Comment

Specify the maximum anticipated amount of I-125 you expect to handle at any one time. In addition, submit an outline of your specific bioassay program for the use of I-125. Enclosed is Regulatory Guide 8.20, containing the minimum required information we find acceptable. You may adopt this or submit your own program for review.

"OFFICIAL RECORD COPY"

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Reply

All work with I-125 will be carried out in an approved isotope hood. The maximum amounts anticipated to be handled at any one time are 2 mCi in a volatile or dispersible form and 5 mCi in a form bound to a nonvolatile agent. The company bioassay program will be conducted in accordance with NRC Regulatory Guide 8.20. Pages 31 and 32 of our Radiation Safety Guide (Guidelines for I-125 Iodinations) have been updated to reflect this policy. A revised copy of these pages is enclosed. (Attachment 1)

3. Question/Comment

Regarding your ventilation protocol:

- (a) Will you be performing any monitoring for the presence of H-3 and I-125 in the breathing zone of the workers? If so, please specify the frequency and duration of the sampling.
- (b) Is the exhaust exiting from your fume hoods being recirculated back to the labs or other areas in the building?
- (c) Please provide calculations of expected concentration levels of radioisotopes in airborne effluent from the laboratories.
- (d) You should re-measure the airflow rates for the fume hoods at least semi-annually and maintain a record of these results. Please confirm.

Reply

- (a) We do not plan to conduct routine monitoring for I-125 and H-3 in the breathing zone of workers. We plan to conduct breathing zone monitoring whenever the thyroid burden of any individual exceeds 20% of the permissible level.
- (b) All fume hoods, including the isotope hood, exhaust fully and directly to the outside stacks. No exhaust air is recirculated.
- (c) Sampling cartridges will be changed every 15 days initially. If, as expected, no release above background is detected, sampling will be performed monthly. Sample calculation of approximate expected maximum release: ✓ OK

After 15 days (360 hours) with the pump set at 40 liters/minute, 8.64×10^8 cc of air has passed. The cartridge is found to read 1,000 counts/minute at 25% counting efficiency.
 $((1,000 \text{ cpm}) / (0.25 \text{ efficiency})) / (2.22 \times 10^6 \text{ disint. per mCi})$
 $= 1.802 \times 10^3 \text{ mCi}$

$$(1.802 \times 10^3 \text{ mCi}) / (8.64 \times 10^8 \text{ cc air}) = 2.09 \times 10^{-12} \text{ mCi/cc air}$$

With the permissible level at $8 \times 10^{-11} \text{ mCi/cc}$, the above release represents 2.6% of permissible.

I-125

- (d) All airflow rates will be measured semi-annually for maintenance of a safe (100 cfm) face velocity. Records of these measurements will be kept by the company. (Ref. revised copy of Radiation Safety Guide, pgs 31-32, copy enclosed.)

4. Question/Comment

Your sample form sheet, "Radioactive Material Inventory", lists a column labelled "Activity Remaining". Confirm this activity includes the amount that is stored as waste and describe how each isotope is identified on this form.

Reply

Our form sheet, "Radioactive Material Inventory" has been amended (copy enclosed) to indicate the amounts stored as waste as well as the amounts remaining in lab stock. A separate sheet is kept for each isotope on each purchase order. (Attachment 2)

5. Question/Comment

We note your use of a consultant for survey meter calibrations. In addition to maintaining calibration records on your survey meter, confirm that all records made by your consultant(s) for the above as well as for other aspects of your radiation safety program will be kept on file at your facility.

Reply

All NRC records, including all those completed by our radiation safety consultant, will be kept on file with the company at our One Kendall Square facility.

You will have noted that the name of the company has been changed to BioSurface Technology, Inc. This change is reflected in the revised Material Inventory and Guidelines for Iodinations which are enclosed with this letter. As a further indication of changes, we now have a director of regulatory affairs (myself). Please address further communications to me directly.

We trust that you find this information satisfactory. If you have any further comments we will be pleased to discuss them.

Sincerely,

Marguerite Eras

Marguerite Eras
Director, Regulatory Affairs
and Quality Control

ME:bc

Enclosures

**Guidelines for Iodine-125 Iodinations
(and Tritium Experiments of >45 Millicuries)**

Iodine-125 emits 27-31 keV X-rays and a 35 keV gamma. Approximately 2 mm. of lead are required to completely attenuate I-125 in quantities typically used for iodinations. Iodine in the unbound state volatilizes readily and is efficiently taken into the body by inhalation or absorption through the skin. Approximately 30 percent of the activity taken in remains in the thyroid with an effective half life of about 40 days. Thus, the predominant concern on handling unbound iodine should be given to minimizing the contact with body.

1. Always work in a well-ventilated hood. (Hoods are checked for safe [min. 100 fpm] face velocity semi-annually and all records maintained by the company. Check the date of the last safety check and report to the RSO if it is approaching or greater than 6 months.) Preplenum activated charcoal impregnated filters are recommended. A lucite inner hood (mini-hood) with a charcoal filter may be used. BioSurface Technology provides a stainless steel isotope fume hood which is equipped with a continuous air sampler (Eberline RAS-1) installed in the duct system to evaluate release to the environment. The sampling cartridge will be evaluated semi-monthly initially. If data indicates minimal release, cartridges will be changed monthly. Charcoal filters will be installed in the duct if release data indicate that greater than 25% of the permissible level ($> 2 \times 10^{-11}$ $\mu\text{c/cc}$ averaged over the sampling period) is being released. The sampling cartridges will be counted and evaluated by an independent radiation safety consultant. All reports will be forwarded to the RSO.

The cartridges themselves will be counted on a thin-crystal scintillation detector attached to a multichannel analyzer which has been calibrated for I-125.

Any tritium labelling experiments of greater than 45 mc will be sampled by pumping the effluent through a liquid collection system and counting an aliquot in a liquid scintillation counter. This result will also be compared to a materials balance performed by the investigator. All persons handling tritium will, in accordance with regulation, submit urine samples for bioassays within 48 hours.

2. Prepare a detailed written procedure for the iodination and submit it to the RSO for his approval. The procedure should be designed to minimize the opening of any vials through the use of syringe injection of material through septum topped vials. All containers of the radioactive material should be sealed in some manner, e.g., rubber stoppers, plastic cups or parafilm.
3. Conduct a dry (cold) run of the procedure to minimize the chance for error when the activity is used.

4. A baseline bioassay, in accordance with NRC Regulatory Guide 8.20 (ref. 2), is required by the company for all individuals participating in the procedure.
5. Wear a personnel radiation dosimeter.
6. Wear the proper protective clothing, safety glasses and two layers of protective gloves. Iodine diffuses rapidly through vinyl and rubber so replace the outer layer immediately when it becomes contaminated. Keep the inner pair free of contamination.
7. Have a properly operating Geiger Muller survey instrument on and readily available for quick contamination checks. Be careful not to contaminate the instrument itself. The instrument will not detect very low levels of contamination but will be useful for higher levels.
8. Avoid handling the vials directly. Use remote handling devices such as tongs or forceps.
9. To decontaminate equipment or surfaces use a solution of 0.1M NaI, 0.1M NaOH, and 0.1M $\text{Na}_2\text{S}_2\text{O}_3$ in order to efficiently remove the contamination without releasing iodine to the atmosphere.
10. All waste should be sealed in double layers of plastic and disposed of immediately.
11. If exhaust filters are not used, the activity concentration of the exhaust must be monitored to assure compliance with NRC regulations concerning the release of iodine-125 to the environment. See 10CFR20.103.
12. Clean and check all the working surfaces and equipment for contamination immediately after the procedure is finished. Take contamination wipes and count them with your samples. The survey instrument is useful for this work, but should not be used to perform the final check.
13. IT CANNOT BE EMPHASIZED TOO STRONGLY THAT NEAT, CAREFUL WORK HABITS WILL MINIMIZE BOTH CONTAMINATION PROBLEMS AND UNNECESSARY EXPOSURE TO PERSONNEL.

References

1. New England Nuclear Corp. Pamphlet: "Iodine-125 Guide to Safe Handling".
2. U.S. NRC Regulatory Guide 8.20 "Applications of Bioassay for I-125 and I-131".

24 AUG 1987

BioSurface Technology, Inc.

Radiation Safety Guide

BIOSURFACE TECHNOLOGY, Inc.**Radioactive Material Inventory**

Radioactive Material _____ User _____

Date Received _____ P.O. # _____

<u>Date</u>	<u>Activity Used</u>	<u>Activity Remaining in Stock</u>	<u>Activity Stored as Waste</u>	<u>Used by</u>
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
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