UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

29 FEB 1988

Docket No. 030-30392
Control No. 108324

BACHEM Bioscience Inc.
ATTN: Ronald A. Pepin, Ph.D.
Radiation Safety Officer
3700 Market Street
Philadelphia, PA 19104

Gentlemen:

This is in reference to your application dated January 19, 1988, for an R & D byproduct material license. In order to continue our review, we need the following questions answered:

1. Confirm you will include in your "STANDARD LABORATORY PROCEDURES" instructions that individuals working with radioactive materials will monitor their hands and clothing prior to leaving the work areas.

2. Regarding your radiation detection and counting instruments; specify the name of the manufacturer, model number, type and sensitivity range of these instruments. In addition, name the company who will calibrate them and specify ther NRC or Agreement State license number that authorizes this activity. If the contractor is not licensed to calibrate instruments for outside clients, then submit a copy of their calibration procedures - including the kind of isotope, activity and calibration accuracy of their calibration standard(s) used for calibrating survey and counting instruments.

3. Submit sample calculations demonstrating that you will maintain compliance with the requirements in 10 CFR 20.103(c) (enclosed) for sink disposals of liquid radioactive waste.

4. Confirm that prior to opening incoming packages of radioactive material, users will survey and perform wipe tests on them.

5. Regarding your bioassay program for H-3 and I-125:

   (a) An individual carrying a burden of 1 mCi/l concentration of H-3 in their urine indicates, by our calculations, that air concentration levels for H-3 in restricted areas have exceeded the limit in 10 CFR 20.103. Please review the enclosed guide on tritium bioassays and submit a more conservative action level.

   (b) Your action limit for I-125 by urinalysis, exceeds the acceptable limit by at least a factor of one thousand. Submit your calculations, describing how you will arrive at

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the average air concentration levels of I-125 in air from a urinalysis. In addition, submit a more conservative action limit and justify it by calculations, demonstrating how this new action limit relates to the air concentration limit for I-125 specified in 10 CFR 20.103.

(c) You have specified that urine specimens for bioassay will be obtained within 48 hours of work with these radioisotopes. Please confirm as well, that specimens will not be submitted until after 6 hours have elapsed.

We will continue our review of your application upon receipt of the above information. Please reply in duplicate, referencing Control No. 108324. If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By
John E. Glenn, Ph.D.

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and
Safeguards

Enclosures:
1. 10 CFR 20
2. Regulatory Guide 8.20
3. APPLICATIONS OF BIOASSAY FOR TRITIUM

RI:DRSS
Varela
02/29/88

RI:DRSS
Glenn
02/29/88

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