

MAY 7 1982

FCML:PG
(10137)
030-19371

BioClinical Group, Inc.
ATTN: Ernest V. Groman, Ph.D.
767B Concord Avenue
Cambridge, MA 02138

Gentlemen:

This refers to your application dated January 20, 1982, for a byproduct material license to authorize the manufacturing and distribution of labeled compounds containing iodine-125. Additional information is needed in support of your application.

For your guidance in providing additional information enclosed is Regulatory Guide 8.21 HEALTH PHYSICS SURVEYS FOR BYPRODUCT MATERIAL AT NRC-LICENSED PROCESSING AND MANUFACTURING PLANTS. Please provide information concerning the following:

1. Calibration of radiation survey instruments - The attachment for Item 11 of your application provides some information concerning calibration of survey meters. In order for you to meet our minimum guidelines radiation survey instruments used to make quantitative measurements should be calibrated at intervals not to exceed 6 months, and these calibrations should be performed at two points on each scale with each point separated by at least 50 percent of the scale. Note that we do not require all survey meters to be calibrated at 6-month intervals - only those used to make quantitative measurements, (e.g., surveys made for record purposes, instruments used to survey shipping containers, etc.).

Please refer to Section 1.12 in the enclosed Guide 8.21 and provide information showing that your calibrations will meet NRC guidelines.

2. Laboratory hoods and filters - Pages 31-33 of your procedures manual describe hoods, filters and filter changing procedures. We need a description of the device installed on your hoods to measure pressure drop across the filters. Also, we need to know the criteria you have established to require filter changes (e.g., a preset pressure drop warning device). Refer to Section 1.14 in Guide 8.21.

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[illegible]

3. As low as is reasonably achievable (ALARA) - Section 20.1(c), 10 CFR Part 20 requires that all persons using licensed material maintain exposures to radiation as low as is reasonably achievable and that all other requirements in Part 20 should also be maintained under this ALARA concept. Please refer to the enclosed Guide 8.10, OPERATING PHILOSOPHY FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AS LOW AS IS REASONABLY ACHIEVABLE. Our review of your application revealed little information concerning the efforts you will make to assure that you will meet the ALARA concept. We will accept your program as meeting the ALARA concept if you will:
- Provide statements that you are committed to a goal of maintaining personnel exposures to within 10 percent and effluent releases to within 1 percent of the limits specified in 10 CFR Part 20, and
 - Provide statements describing the corrective actions you will take in the event any individual's exposure exceeds the 10 percent guidelines and any time effluent releases exceed the 1 percent guidelines. Please note that we have not changed the exposure or effluent release limits but have merely attempted to describe a means of assuring that your personnel and effluent monitoring programs will meet the ALARA concept.

Our review of your application will continue upon receipt of the above information. Please provide two copies of your reply and reference Mail Control No. 10137.

Sincerely,

Paul R. Guinn
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure: As stated

ML18

OFFICE	CRESS	FCML				
SURNAME	261804					
DATE	5/5/82	PGuinn:mdr 5/7/82				

2/10/82

4:05

TELEPHONE OR VERBAL CONVERSATION RECORD

☐ INCOMING CALL

☒ OUTGOING CALL

☐ VISIT

PERSON CALLING

OFFICE/ADDRESS

PHONE NUMBER

EXTENSION

B Jackson

ADM/LFMB

PERSON CALLED

OFFICE/ADDRESS

PHONE NUMBER

EXTENSION

Ernest Groman

Bioclinical Group

417-497-2070

CONVERSATION

SUBJECT

1/20/82 application

SUMMARY

Dr. Groman stated that they will
be applying for licenses to distribute
to general licensees + exempt licensees.
The 1/20/82 application is for
mfg. + distribution to specific
licensees. K (opp's rec'd 2/19/82)

Note to LFMB:

Evaluation fee will be paid under the
3rd application fee.

REFERRED TO:

MLB

ACTION REQUESTED

ML10

"OFFICIAL RECORD COPY"

ACTION TAKEN

☐ ADVISE ME OF
ACTION TAKEN.

INITIALS

DATE

INITIALS

DATE