JUN 25 1982

FCML:JBC
(10659)
030-19645

Medical and Scientific Designs, Inc.
ATTN: George Parsons
273 Weymouth Street
Rockland, MA 02370

Gentlemen:

This refers to your application, dated March 3, 1982, for a byproduct material license. After review of your application, we find we will need the following additional information:

It is our understanding, through telephone conversations with Peter Levitch, that you do not intend to manufacture and distribute at this time, but will restrict your activities to research and development of the in-vitro diagnostics. In view of this, we have approached our review of your application from the standpoint that it is a research and development case only. If, in the future, you wish to manufacture and commercially distirbute your product, it will be necessary to amend your license to include such activities.

1. Use of Licensed Material.

   In Item 8.e. of your application, you have listed your use of carbon-14 as simply "research." It is unclear if you will also use carbon-14 in the research and development of in-vitro diagnostics or if you will only use the isotope in other research projects. If the carbon-14 is to be used only in other research projects, and not in the development of in-vitro diagnostics, you should provide us with a general description of your planned experiments.

2. Training and Experience.

   Please provide more specific information concerning Rosemary Polsky-Cynkin's and Anne M. Wood's training and experience in the use and handling of radioactive materials. You should provide an experience chart for each which shows the isotopes used, the maximum activities, the type of use, and the length of time used. Please refer to Items 16. and 17. of Enclosed Regulatory Guide 10.7, "GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR LABORATORY AND INDUSTRIAL USE OF SMALL QUANTITIES OF BYPRODUCT MATERIAL" for more information.

3. Radiation Safety Officer.

   In addition to the responsibilities, for the RSO, you have outlined in Section 2 of your manual, "Required Procedures for Radiation Protection," we recommend that the RSO also be the primary individual responsible for ordering licensed materials.

4. Radiation Detection Instrumentation.

We note that you have made references to liquid scintilation counters in Appendix C of your manual. We need to know the name of the manufacturer and the model number of all instruments which are to be used in containment or contamination control. In this regard, the instruments you have described in your application do not appear adequate for detecting possible removable low energy beta contamination. Please provide appropriate information on the instruments you will use when making these evaluations.

5. Instrument Calibration Procedures.

We note that the calibration procedures you have described in Appendix A of your manual appear only to apply to the Ludlum-177 Alarm Rate Meter/ Gamma Detector. If the Ludlum Model 3 survey meter is to be used for containment or contamination control, and different calibration procedures are to be followed, you should also submit these procedures as a part of your application. Please refer to Items 10. and 11. of Regulatory Guide 10.7 for more information concerning instrument calibration. Also, please note that a calibration chart should be attached to instruments whose accuracy is within plus or minus 10 to 20 percent and that instruments which cannot be calibrated to within plus or minus 20 percent may not be considered acceptable by the NRC for quantitative surveys and may in fact, be in need of repair.

6. Bioassay Program.

We will need additional supporting information concerning your procedures for bioassay of iodine-125 and iodine-131. We have enclosed a copy of Regulatory Guide 8.20, "APPLICATIONS OF BIOASSAY FOR I-125 AND I-131" for your reference. You should submit information to show that your bioassay frequencies, "action levels," remedial actions, and procedures are at least equivalent to those contained in the guide. Please note that bioassays should be considered for all individuals who handle or use at any one time, or within a 3-month period, greater than 10 percent of the limits outlined in Table 1 of the guide.

Also, your application provides no information concerning bioassay procedures and/or requirements for persons working in your facilities who use hydrogen-3. Please refer to the enclosed pamphlet, "GUIDELINES FOR BIOASSAY REQUIREMENTS FOR TRITIUM," and provide information that shows you meet these guidelines. If you have determined that the bioassays for tritium are not necessary for your program, you should provide information to justify your position.

7. Leak Test Procedures.

You should provide more complete information concerning your procedures for leak testing the sealed sources. Please refer to Item 15.c. of Regulatory Guide 10.7 and provide information as described in the guide.

8. Instructions To Personnel.

OK a. We note that Item III.L.(6) of your procedures manual requires the use of gloves by workers when hand contamination is possible. We recommend the use of gloves or remote handling devices by workers whenever radioactive materials are to be used.

OK b. Item III.L.(1) of your manual prohibits smoking, eating, etc. in restricted areas unless authorized by the RSO. We recommend that these activities be prohibited under all circumstances.

OK c. You should also provide information concerning the procedures to be followed by personnel when receiving and opening packages of radioactive materials. Please refer to Item 15.d.(14) of Regulatory Guide 10.7.

9. Radiation Surveys.

OK While you have provided information concerning the frequency for conducting radiation surveys, you should also specify the acceptable levels of both fixed and removable contamination in your restricted and unrestricted areas. We have enclosed Regulatory Guide 8.21, "HEALTH PHYSICS SURVEYS FOR BYPRODUCT MATERIAL AT NRC LICENSED PROCESSING AND MANUFACTURING PLANTS" for your guidance.

OK Also, we recommend that you consider air monitoring in the breathing zone of individuals when performing iodinations. If you do not feel that monitoring would be necessary, you should provide information to justify your position.

OK 10. Effluent Releases.

Your application does not provide us with enough information to enable us to determine that your releases to sanitary sewer systems are unlikely to exceed the limits specified in 10 CFR Part 20. In order to make this determination, we will need to know your daily flow rate of water to the sewer system, the maximum activity of licensed material you will release per day, and your procedures for evaluating or determining the activity.

Also, we are uncertain of your intention in Item A.3. of Appendix II of your manual. Please note that Section 20.303, Paragraph 2 allows you to dispose of 10 times the quantities specified in Appendix C of 10 CFR Part 20 as long as the concentrations do not exceed the Appendix B, Table 1, Column 2 limits when averaged over a 1-month period.

OK 11. We will also need information showing that the concentrations of licensed material in your air/water effluents will be as low as reasonably achievable (ALARA). You should include information concerning the actions you will take to ensure that the effluent concentrations in or released from your facilities are maintained below an established action guideline limit (i.e., 1 percent of the limits specified in 10 CFR Part 20). We will accept

your program as meeting the ALARA concept concerning effluent releases if the information provided by you shows that immediate corrective actions are taken whenever your effluent concentrations exceed the 1 percent action limit.

12. Personnel Exposures.

The ALARA concept is also applicable to personnel exposures. Please provide information to show that you will maintain personnel exposures as low as is reasonably achievable. Refer to enclosed Regulatory Guide 8.10, "OPERATING PHILOSOPHY FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AS LOW AS IS REASONABLY ACHIEVABLE" for more information. Please note that we will accept your program as meeting the ALARA concept if you submit information to us showing that immediate and appropriate corrective actions are taken whenever the radiation exposure to an individual exceeds 10 percent of the limits specified in 10 CFR Part 20.

Our review of your license application will continue upon receipt of the above information. Please reply in duplicate and reference Mail Control No. 10659.

Sincerely,

J. Bruce Carrico
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. Regulatory Guide 10.7
2. Regulatory Guide 8.20
3. Tritium Bioassay Guide
4. Regulatory Guide 8.21
5. Regulatory Guide 8.10

CRESS SS	FCML	FCML
Job B 1	JBCarrico:is	JWNHickey
6/23/82	6/24/82	6/25/82

JBC

NRC FORM 218
(4-76)
NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

DATE 3/22/82

TIME 1:10 ☐ A.M. ☐ P.M.

TELEPHONE OR VERBAL CONVERSATION RECORD

☐ INCOMING CALL ☒ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
D Jackson	LFMB/adm		
PERSON CALLED	**OFFICE/ADDRESS**	**PHONE NUMBER**	**EXTENSION**
Dr. George Parsons	Medical Scientific	617-871-4442	

CONVERSATION

SUBJECT 3/3/82

SUMMARY

They are applying for mfg. only at this time. When they are ready for distribution, they will apply for a 'B' license.

REFERRED TO:	☐ ADVISE ME OF ACTION TAKEN.
ACTION REQUESTED	INITIALS
	DATE
ACTION TAKEN	INITIALS
	DATE

NRC FORM 218 (4-76)