NOV 24 1975

Harrell Incorporated
ATTN: Mr. H. E. Harris
16 Fitch Street
East Norwalk, Connecticut 06855

Gentlemen:

This refers to your application for a license to distribute Nucleonics Development Corporation devices. In support of your application, you should provide the information requested in Section 32.51 of the enclosed 10 CFR Part 32. You should note that such information is required if you possess the devices prior to distribution or if you modify the devices (such as by substituting your name for Nucleonics Development Corporation.

If you only will possess the devices pursuant to the installation of the devices and if you will make no modifications to the device, an installation license is all that will be necessary.

Upon receipt of the above information, review of your application will continue. In your reply, please reference Control No. 58018.

Sincerely,

Douglas M. Collins
Materials Branch
Division of Fuel Cycle and
Material Safety

Enclosure:
Part 32

OFFICE ▶	MEB M					
SURNAME ▶	DMCollins:bjb					
DATE ▶	11/24/75					

FCRL:NB
(88470)

NOV 23 1977

Mr. H. E. Harris
Harrel, Incorporated
16 Fitch Street
East Norwalk, Connecticut 06855

Dear Mr. Harris:

This letter is to confirm our telephone conversation on November 23, 1977, concerning your application to distribute thickness gauges to general licensees.

Your application indicated that the labels, installation, servicing, leak testing, and operating and safety instructions are the same as previously submitted to us. In reviewing the previously submitted information, it is not clear precisely which operations will be performed by Harrel and which operations you intend that general licensees be permitted to perform. We would appreciate clarification.

Section 32.51(a)(3) of 10 CFR Part 32 specifically identifies the kind of information which needs to be included in labels on devices which will be distributed to general licensees. Your label does not provide sufficient information as specified in Section 32.51(a)(3)(i) since there is no specific information relating to installation, operation, and servicing of the device except in general terms. Your labels should be revised to contain the above information. Copies of the new labels together with the specific operating manuals and safety instructions and precautions should be provided to us.

The label indicates that maintenance, tests, or other service involving the radioactive material shall be performed by persons holding a specific license to provide these services. Since there is no one other than Harrel, to our knowledge, in a position to offer services, the label information or other information provided to general licensees should provide specific guidance to general licensees. We would appreciate receiving from you a specific description of the services which you offer and how your service program will be carried out. The information which you provide should include training of personnel, whether the services will be provided at customers' locations, and specific procedures and radiation safety precautions for carrying out operations.

OFFICE ➤						
SURNAME ➤						
DATE ➤						

Section 32.51(a) indicates that if you desire the general licensee to perform the specific operations, it is necessary that specific written instructions for performing the operations be provided to the general licensee. It is not clear whether you intend for general licensees to install devices and leak test sources. If you wish general licensees to perform these operations, you should submit copies of the instructions which will be given to general licensees. If general licensees will install gauges, it is necessary that they have an appropriate survey meter so that the installation survey may be made and that the general licensees know how to use the meter. Similarly, if general licensees will take the leak test sample, the instructions should indicate how and where the sample should be sent.

We shall proceed promptly with review of your application upon receipt of the above information.

Sincerely,

Nathan Bassin
Radioisotopes Licensing Branch
Division of Fuel Cycle and
Material Safety

OFFICE ▶	FCRL					
SURNAME ▶	NBassin:bjp					
DATE ▶	11/23/77					

HARREL, incorporated
16 Fitch Street
East Norwalk, Conn. 06855
Phone: 203 866-2573

4655

December 9, 1977

Mr. Nathan Bassin
Radioisotopes Licensing Branch
Division of Fuel Cycle & Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Bassin:

This letter is to enclose the further information requested in your letter of November 23d and our subsequent telephone conversation.

1. We have revised the label. The new label will be similar in general layout to the enclosed sample but will have the revised wording shown on the attached sheet.

2. It is our intent that the samples for wipe tests shall be taken by the user. It would, of course, be prohibitively expensive for the user if a specific licensee had to visit every 6 months. It can be done very safely. You confirmed our interpretation of Section 32.51 that having the user do it is permissible.

    a. The label now states that a wipe test is necessary & refers to the manual.

    b. The manual describes Harrel wipe test service.

    c. We will provide with every gauge a folder similar to the attached. The date on the front will be when the first wipe test is due. Complete instructions are inside as to how to take the wipe test smear and where to send it.

    d. When the wipe test smear is received by us, we will evaluate it and return the report to the user. At that time we will send him a new wipe test kit with the next wipe test due date on front.

e. I am enclosing a copy of the leak test procedure we are using. This was suggested by Eberline Instrument Company, who furnished the equipment. We are using the sample holder & DNS-5 suggested to improve repeatability.

3. It is our intent that installation of these devices will be by Harrel, or by a company specifically licensed to install this equipment. We do not limit it to Harrel, because one of our prospective customers has indicated he will seek a specific license to install our gauge. We assume there is no objection to this, since he will have to convince you or an agreement state of his ability to do so.

   In any case, a radiation survey will be taken upon installation. I am enclosing a copy of the installation instructions our people follow.

4. I am also resubmitting an outline of the training program we have been following here.

5. I am enclosing a revised copy of our instruction manual.

We believe that this answers the questions you have raised. If there are any further questions, we would appreciate it if you would phone us at (203) 866-2573. Our program has been at dead halt since July, and we are naturally very anxious to get it under way.

We will certainly appreciate any assistance you can give us in this matter.

Very best regards,

H.E. Harris

HEH:zf
enc

SUMMARY OF TRAINING COURSE TO BE GIVEN PERSONNEL WHO WILL HANDLE INSTRUMENTS USING RADIOACTIVE SOURCES.

Before any person at Harrel is allowed to handle nuclear material, they will be given thorough instructions in the safe handling of nuclear materials. This instruction will include:

1. Types of radiation.
2. Radiation characteristic of Americium 241 and construction of the capsule in which it is received.
3. Potential dangers from capsule leakage.
4. How to conduct and evaluate smear tests.
5. How to conduct radiation tests.
6. Safe radiation and exposure levels.
7. Testing of received packages for leakage.
8. Testing of completed instrument for leakage and for radiation.
9. Storage of nuclear materials.
10. Testing of work areas for leakage.
11. Precautions to be taken in installing nuclear thickness gauges.
12. Radiation surveys of completed installation.
13. Training of user personnel.

HARREL, incorporated

16 FITCH STREET
EAST NORWALK, CONN. 06855
PHONE: 866-2573

0070

January 5, 1978

Mr. Nathan Bassin
Nuclear Regulatory Commission
7915 Eastern Ave.
Silver Spring, Maryland

Dear Mr. Bassin: Via Federal Express

In accordance with our telephone conversation on Friday, we are enclosing the following additional data:

1. Revised text for the label of the instrument, showing the requirements for inspection of the shutter every six months.

2. Additional paragraph in the instruction manual to give the user instructions as to how shutter inspection is to be carried out. Note that if the shutter inspection is carried out using a mirror as described, the inspector should receive no measurable dose of radiation.

3. Instructions for evaluating leak test samples, giving specific steps to be followed with this particular Eberline instrument. Replace generalized instructions previously submitted.

4. Revision of Caution page of instruction manual to eliminate implication that user can do installation himself.

5. Summary of training course to be given to Harrel personnel who will be doing field installation and check-out of gauges.

6. Revised page of instruction manual covering procedure in case of damage to source.

7. Please delete the two pages of the manual headed "Licensing Requirements" which list the licensing officials in Agreement States. Also delete reference to this listing on a previous page.

As you know this application is now over six months old, and we are most anxious to get you all the information you need to process it. If any further data is needed, or if there are any questions, we would greatly appreciate it if you would telephone us at (203)866-2573. Thank you very much.

Very truly yours,

H. E. Harris

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A-21

1. It is strongly recommended that one person in the plant be designated to be responsible for the proper operation of the unit. This person should inspect the gauge periodically to make sure it is properly used, and should be charged with making sure that warning signs are always displayed and that all personnel observe proper safety precautions.

2. Make sure that the shutter is closed whenever the unit is not in use.

3. Never look at the open probe face. If inspection is necessary, use a mirror.

4. Under no circumstances should anyone ever open the probe head, attempt to change it in any way, or touch it with a sharp or pointed instrument.

5. Do not allow uninformed personnel to handle the unit.

6. Make sure that the gauge is always used so that no one can come within two feed of the front of the probe when the shutter is open. This, of course, will normally be taken care of by the initial mounting. However, the individual designated as safety officer should ensure that no one violates safety rules.

7. In case of question, contact the Radiation Safety Officer at Harrel, Incorporated.

IN CASE OF DAMAGE TO THE PROBE

The source material in this probe is a hard-fired ceramic wafer. It is contained within a welded stainless steel capsul, which is in turn mounted inside a shield and then in a one-piece probe head termination. It is therefore highly unlikely that any damage will occur to the source. However, safety is always prudent, and in case of actual or suspected damage to the probe head, the following procedures should be followed:

1. Close off the area, so personnel can not get near.

2. Call Harrel, Incorporated for service.

3. Anyone who has toucned anything in the nearby area should wash their hands thoroughly.

SUMMARY OF TRAINING COURSE WHICH WILL BE GIVEN PERSONNEL WHO WILL INSTALL NUCLEAR THICKNESS GAUGE

Before any personnel at Harrel will be allowed to install nuclear gauges, he will be given thorough instructions in the safe handling and usage of nuclear materials. This instruction will include:

1. Types of radiation and effect of each on humans.
2. Radiation characteristics of Americium - 241 and construction of the capsule in which it is received.
3. Potential dangers from capsule leakage.
4. Safe radiation and exposure levels
5. Precautions to be taken in handling nuclear thickness gauges.
6. Factors to be considered in mounting nuclear thickness gauges so they accomplish their purpose with safety.
7. Characteristics of the radiation survey meter. Practice in its use.
8. How to conduct a radiation survey of a gauge installation.
9. How to conduct a wipe test.
10. Placement of warning signs.
11. Training of user personnel.

Trainee will be asked to describe how he would go through gauge installation from the time he arrives until he leaves.