

MAY 19 1988

Process Automation Business, Inc.
ATTN: Donald C. Stephens
Radiation Safety Officer
650 Akerman Road
Columbus, OH 43202

SUBJECT: APPLICATION DATED MARCH 18, 1988, FOR RENEWAL OF NRC LICENSE
NO. 34-00255-03

Gentlemen:

Broadscope licenses differ from all other types of materials licenses in that they are primarily based on the administrative procedures and organizational qualifications of the licensee to operate safely under the license rather than on a detailed review by the NRC of the qualifications, equipment, and procedures for each use and user. Therefore, in order to complete our review and issue your renewal request for a broadscope license, we will need information on the following:

1. Intended Use of Radioactive Materials

Your present statements concerning the intended use of licensed material do not provide sufficient information concerning the types of research and development conducted at your company. Although we only need a general description of your activities, you should supply sufficient information to enable us to have a clear understanding of each use. Specifically, you should identify each sealed source used for research and development with an activity greater than 100 millicuries by manufacturer's name, model number, and total activity.

2. Radiation Safety Committee

Paragraph 33.13(c)(1) of 10 CFR Part 33 requires that a radiation safety committee be established. This committee should be composed of such persons as a radiological safety officer, a representative of management, and other persons trained and experienced in the safe use of radioactive materials. One of the main functions of the radiation safety committee is to administer the institution's radioactive material program. The committee should have the authority and responsibility for approval and disapproval of all proposals for radionuclide use prior to purchase of the materials.

The following information concerning the committee should be submitted:

- a. Specify the minimum intervals at which the full committee will meet to conduct its business, e.g., discuss and act upon proposals for the use of radioactive material. Typically a Type A broad scope licensee meets quarterly. Should your committee desire to meet at intervals greater than quarterly, please include a discussion which demonstrates the ability of the committee to adequately monitor and control your radioactive materials.

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- b. If less than the full committee is empowered to act for the committee, the number of members constituting a quorum as well as their names or fields of expertise should be specified. Committee actions should require a simple majority of the entire committee, e.g., at least 3 out of 6 voting members. It appears from your application (Page 4, Item 10.6) that the radiation safety officer can approve the use of sealed sources at temporary sites without committee input. Please clarify.
- c. Since you are requesting radioactive material in sealed form with atomic numbers 1 to 83, you will need to provide us with the procedures and criteria established for making safety evaluations of proposed uses of radioactive material. The procedures and criteria must include consideration of the adequacy of facilities and equipment, and operating, handling, and emergency procedures.
- d. Submit the criteria set by the committee to determine the acceptable training and experience level of the proposed users of radioactive material for the purposes of research and development. The minimum training criteria is set forth in 10 CFR Part 33 Section 33.15. In addition to formal health physics (radiation protection) course work, each applicant must have had actual hands on training and experience with the types and quantities of radioactive materials commensurate with his application.
- e. The committee should perform a review of the entire radiation program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, report from the radiation safety officer, results of NRC inspection, written safety procedures, and the adequacy of the institution's management control system. Please confirm.
- f. Specify the frequency or conditions under which permit holders, or user's applications and qualifications will be periodically reviewed by your committee, e.g., at least annually.
- g. Submit the procedures used for controlling and maintaining inventories, procurement of radioactive material, individual possession limits, total possession limit, transfer of radioactive material within the institution, and transfer of radioactive material to persons outside the institution.
- h. Methods employed for maintaining records of the committee's proceedings and safety evaluations of proposed uses of radioactive material. Submit example copies of forms or the format for maintaining inventories, committee minutes, etc.

3. Radiation Safety Officer

- a. The description of the duties of the Radiation Safety Officer failed to establish his authority to halt any activity which he determines to be contrary to good health physics practices or violates requirements set forth in the license or the regulations. Please describe the authority given your Radiation Safety Officer.
- b. Describe the time availability of your Radiation Safety Officer to perform his duties. Also describe the minimum training requirements for those individuals assisting or designated by the Radiation Safety Officer to perform radiation protection activities.

4. Facilities and Equipment

Submit a detailed diagram of the facilities for each location where radioactive material will be used. Include a description of area(s) assigned for receipt and storage (including waste). Your diagram(s) should show:

- a. Adjacent areas across the walls from use and storage area.
- b. Descriptions of the ventilation system with pertinent airflow rates, for locations where radioactive material may become airborne.
- c. A specified scale or indicated dimensions.
- d. Appropriate labels to identify laboratory or work area and equipment e.g., fume hoods, special sinks, preparation areas, protective clothing change areas, etc.

5. General Laboratory Rules

Submit a copy of your laboratory rules which must be followed by your technicians and other workers while handling sealed sources and devices (i.e., gloves, handling tools, film badges worn, no eating drinking in lab areas). These rules must be posted in all use and storage areas.

6. Training

Item 8 of your application describes the type of training each user of radioactive material will receive. However, the outline for the course given to source handler's was omitted from your submission. It appears to us that the source handler would need a structured course outline to complete as well as the field service personnel. Please submit. Also, describe the type and length of on-the-job training provided to your field service personnel.

7. Instrument Calibration

Your current method for calibrating survey instruments does not meet our criteria. Survey and monitoring instruments, as well as any other instruments and systems used in the radiation program, such as measuring instruments used to assay sealed source leak-test samples and contamination samples (e.g., air samples, surface "wipe" samples), must be calibrated.

An adequate calibration of survey instruments usually cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily or other frequent checks of survey instruments should be supplemented every twelve months with a two-point calibration on each scale of each instrument with the two points separated by at least 50% of the scale. Survey instruments should also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings at ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibrated chart or graph is prepared and attached to the instrument.

If you propose to calibrate your instruments, a detailed description of planned calibration procedures should include, as a minimum:

- a. The manufacturer and model number of source(s) to be used,
- b. The nuclide and quantity of radioactive material contained in the source,
- c. The accuracy of the source(s) and the traceability of the source to a primary standard,
- d. The step-by-step procedures including associated radiation safety procedures, and
- e. The name(s) and pertinent experience of person(s) who will perform the calibrations.

If you intend to contract out the calibration of instruments, the name, address, and license number of the firm should be specified together with the frequency of calibration. You should contact the firm that will perform the calibrations to determine if information concerning calibration procedures has been filed with the Commission. If this information concerning calibration procedures has not been filed, it should be obtained and submitted.

8. Leak Testing

The general procedures section of your Field Radiological Procedures Manual provides a method for performing a "wipe test" of sealed sources as a quick check during field inspection operations on customer gauges. However, procedures for leak testing sealed sources which are capable of detecting the presence of .005 microcurie of radioactive material on the test sample was not presented.

If you intent to analyze your own leak tests, then you will need to supply us with the manufacturer's name and model number of your wipe-sample counting equipment. This equipment should be calibrated before use with standard sources having an accuracy of at least $\pm 5\%$ of the stated value. Standard sources should be traceable to a primary radiation standard such as those maintained by the National Bureau of Standards. You should supply the following information for the calibration of the instrument you will use to perform measurements on leak-test samples:

- a. List the standard sources to be used with each wipe-sample counting instrument by nuclide and quantity of radioactive material contained in each of the sources.
- b. Provide a statement of the accuracy of each standard source (information usually available from the source manufacturer). At a minimum, you should state that the accuracy of the standard will be $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by the National Bureau of Standards.
- c. Provide an example of a calculation for converting leak-test sample counting results to microcuries. If you intend to use a commercial leak test kit and it will be analyzed by an outside firm, then submit the name of that outside firm and the model number of the leak test kit.

9. Ordering Receipt and Opening of Packages Containing Radioactive Material

Describe your procedures for ordering radioactive material, and for receipt of materials during normal working hours. The procedures should be adequate to ensure that possession limits are not exceeded, that radiation levels in unrestricted areas do not exceed those specified in 10 CFR 20.105, and that radioactive materials are secured against unauthorized removal at all times. It is preferable that all radioactive materials be ordered by one person and received in one location so that they may be reliably accounted for and surveyed expeditiously.

Also, describe procedures for safely opening packages containing radioactive materials. These procedures should include instructions to wear gloves, survey the packages before opening, wipe test the final source container, and monitor the packing material for contamination prior to disposal.

10. Customer Service

If you intend to perform leak testing as a service to licensees other than yourself, please so state and submit responses to those items in the enclosed Regulatory Guide for leak testing service applicants (Task FC 412-4) for which you have not already submitted information. Similarly, if you intend to calibrate survey instruments as a service to licensees other than yourself, you will need to supply us with responses to those items in the enclosed Regulatory Guide for instrument calibration service applicants (Task FC 413-4) for which you have not already provided information.

11. Demonstrations

Please identify which materials or items you wish to demonstrate at temporary job sites. Please state the type of licensee (i.e., exempt, general or specific) that you anticipate will be hosting such demonstrations. If these demonstrations are to be conducted at a facility which is specifically licensed, you need to clarify whether these demonstrations will be conducted under the provisions of the host's license (through transfer of the byproduct material from your license to the host's license in accordance with 10 CFR 30.41) or in the physical presence of one of your authorized users and under the provisions of your own license.

12. Distribution to Specific Licensees

- a. Describe how you will verify that each transferee is authorized to receive your gauges (i.e., how you intend to comply with 10 CFR 30.41).
- b. How will you verify the transferee's license is current and not expired.
- c. Please submit color samples of the radiation labels used on the devices to comply with 10 CFR Part 20 requirements.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 17134.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

Sincerely,

J. R. Madera
Materials Licensing Section

Enclosures:

1. Leak Testing Service
Guide (TASK FC 412-4)
2. Instrument Calibration Service
Guide (TASK FC 413-4)

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