



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

February 15, 1996

Mr. Darrell Basinger
Hauni Richmond, Inc.
2800 Charles City Rd.
Richmond, VA 23231

Dear Mr. Basinger:

This letter is in response to your application dated May 24, 1995, requesting registration of the Model 2314-0-0 DS density measuring head. We are in the process of evaluating your request. However, in order to continue our evaluation, the following information is necessary:

1. The source indicated in your application is the Amersham Buchler Type VZ-1876. Please provide information that verifies that the source is registered with the NRC or an Agreement State. Otherwise, please provide sufficient information to allow registration of the source. A copy of Regulatory Guide 10.11 is enclosed for your reference.
2. On page 10 of your "Technical instruction" manual, it states that "[i]n case of dispute, only the original German text shall be valid." Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your registration certificate. The English translation of any foreign document is used as the basis for the safety review and your commitment to the U.S. Nuclear Regulatory Commission. Therefore, please verify that the information submitted is accurate or provide corrected information as necessary.
3. The cover page to your "Technical instruction" manual indicated that the information was copyrighted. In addition, excerpts from the document may be included in the registration certificate that we will generate for the device. Therefore, please provide us with an exemption to the copyright restriction.
4. Please provide detailed engineering drawings of the device, including all dimensions, tolerances, methods of fabrication, and materials of construction. The drawings should include complete engineering drawings of each component (e.g. the source, source material holder, shielding, source movement, scanner casings, locks, and any other safety features). Describe any safety features (e.g. relief valves, locks, automatic shut-offs), including how they operate, under what conditions they operate, and any conditions where they will not operate.
5. Please provide a description of the source material holder mechanism. Include detailed descriptions (materials, dimensions, etc.) of the electric and pneumatic cylinders and the spring mechanism which will automatically return the source material holder to the reference position in case of power failure. Please indicate what assurances are made to keep dust, dirt, debris, and water out of from around the source material holder mechanism.

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6. Please provide information regarding the tungsten material which is used in the scanner housing design. The information must include it's physical characteristics (e.g. melting point, tensile strength) that illustrate that it will withstand the operating conditions the device will encounter.
7. Please describe the ON-OFF indicator(s). Your application indicates both a green/yellow indicator and a pop-up type indicator. Include the number and location on the device, including their visibility to users. In addition, please be aware that the color red is most commonly used to indicate that a source is out of its shielded position and that you may need to provide additional clarification to the user on the significance of the yellow indicator.
8. Please indicate the materials of construction and method of attachment for the label on the scanner housing. Your application shows that you plan to use units of Becquerels on the labels. Please aware that users in the U.S. may not be familiar with these units. We suggest that you provide the activity in millicuries in the users manual to assist those that are not familiar with SI units.
9. Please explain the significance of the "Measuring head no." and "Source no." on the label.
10. Please be aware the label must state the exact activity at time of assay, and not the maximum activity allowed in the device. Please verify that all devices contain the maximum activity or that the label will reflect the actual activity.
11. Since the device labeling contains the source activity and the date of assay of the source, please verify that this label will be changed if a new source is installed in the device.
12. Your application states the operating temperatures for the device. Please describe any other environmental extremes and operating conditions that the device can expect during use (e.g. humidity, corrosive atmosphere, impact, puncture, vibration, fire).
13. Please indicate the estimated number of cycles the source material holder may experience over it's useful life. Include the number of cycles per day and per year.
14. Please submit details (with results) of tests performed on prototype devices. These tests should verify that the device would withstand the environment described in your response to Question #12. Any engineering analysis and/or extrapolation of data must be explained in detail.
15. Please provide a copy of a manual or set of instructions which details the quality assurance and control program implemented in the U.S. which will ensure that the devices are manufactured to the correct drawings and specifications. Please include procedures that detail inspection and radiation profiles performed on the design when it enters the U.S.

or when received by the customer. It is assumed that all devices will be shipped to the Hauni Richmond facility in Virginia prior to distribution to the customer. If this is not the case, please describe where the devices will arrive in the U.S. and how they will be distributed.

16. Please provide the dose rate on the surface of the scanner housing.
17. Your application included a "Technical instruction" manual. Please indicate whether this is the users manual for the device. Please provide copies of any other information or documents that will be provided to the user.
18. Please provide information on who will be performing the installation and servicing of the device (i.e. calibrations, wipe test, maintenance, measuring tube exchanges, source installation, etc.) and information on the dose the worker will receive when performing such services.
19. NRC policy requires that leak testing be performed at intervals not to exceed six (6) months unless sufficient operational data is available to support a request for a larger interval. If you wish a longer frequency, please provide sufficient information to demonstrate that such longer interval is justified. Your response should address the points listed in Section 32.51(b), 10 CFR Part 32. A copy is enclosed for your reference.

We are looking forward to receiving your response and will continue our review upon receipt. Please provide the requested information as soon as possible. If you have any questions, please contact me at (301) 415-5868 or Mr. John Lubinski at (301) 415-7868.

Sincerely,

~~Original Signature~~

Michele L. Burgess, Mechanical Engineer
Sealed Source Safety Section
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated

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