



August 14, 2003

Mr. David Tiktinsky
Senior Project Manager
Regulatory Guidance Branch
Division of Industrial & Medical Nuclear Safety
Office of Nuclear Material Safety & Safeguards
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Tiktinsky:

In response to your e-mail of June 24 2003 requesting additional information, attached please find the QA procedures and label information requested. I trust that this information will be helpful, and will allow completion of evaluation of the registration application.

As always, please feel free to contact me if you have any questions whatsoever. Thank you.

Sincerely,

Perry Fan
Montesino Technologies, Inc.
perry.fan@montesino.com
Mobile: 201-888-6721

PROCEDURES TO BE FOLLOWED IN THE U.S. BY MONTESINO TECHNOLOGIES, INC.

The gauges will be shipped by Electronic Systems spa directly to the installation location. Electronic Systems will have performed and documented a leak test and a radiation survey. Montesino Technologies shall conduct a visual inspection, conformance inspection, additional leak test, radiation survey and document inventory at the installation site.

1. The visual inspection will ensure that:

- The General License label is correct
- The 'CAUTION - RADIOACTIVE MATERIAL' label is correct

If either label is damaged or unreadable, it will be replaced with a new label.

2. The conformance inspection will ensure that the gauge to be installed conforms to the specification that were reviewed and approved by the NRC. The conformance inspection will include an operational check to ensure that the device operates in its intended manner and to its specifications. This inspection includes verification of:

- Shutter operation
- Emergency functions
- Safety features

3. The leak test shall ensure that a transferred gauge has leak test results below 0.005 μCi . Analysis of leak tests shall be by a licensee authorized by the NRC or an Agreement State to analyze leak tests.

4. The radiation survey will ensure that radiation levels do not deviate significantly from the survey results reported by Electronic Systems. Surveys shall be performed using an energy independent survey meter calibrated by a licensee authorized by the NRC or an Agreement State to calibrate survey meters.

5. The document inventory will ensure that the following documents are correct and complete and are provided to the General Licensee:

- Operator's Manual
- General License for the jurisdiction of the installation
- Leak test results
- Installation survey results

Montesino Technologies shall inspect 100% of product and the Lot Tolerance Percent Deviation shall be 0% for all requirements. Deviations shall be corrected prior to transfer and non-conformance shall be reported to Electronic Systems spa for corrective action to prevent recurrence.

Montesino Technologies is committed to the delivery of products that meet the NRC's quality control requirements. Electronic Systems has a QA/QC program which complies with the requirements of ISO-9001.

Montesino Technologies will perform quarterly audits of the Quality Control Program records from Electronic Systems. Records of these audits shall be retained for inspection at Montesino's Delaware office.

The following labels shall be affixed to the device with rivets. Markings on the label shall be by anodizing, stamping or engraving.

LABEL MOUNTED ON SOURCE HOUSING

CAUTION – RADIOACTIVE MATERIAL

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, containing __nnn__ mCi of __XX-nn__ on mm/dd/yy, are subject to a General License or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority.

DO NOT REMOVE THIS LABEL!

GENERAL LICENSE LABEL

Receipt, possession, use and transfer of this device are subject to a General License or equivalent and regulations of the U.S. NRC or an Agreement State.

Installation, relocation, maintenance and repair of this gauge shall be performed only by Montesino Technologies, Inc. or by another person specifically authorized by the U.S. NRC or an Agreement State. The gauge shall be tested for proper operation of the on/off shutter mechanism and indicator, and the integrity of the sealed sources at intervals not to exceed 6 months.

Immediately suspend operation of the gauge if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive source or the on/off mechanism or indicator, or upon the detection of 0.005 micro curie or more in a leak test. The gauge may not be operated until it has been repaired by Montesino Technologies or other person holding a specific license to repair this gauge that was issued by the NRC or an Agreement State.

The source may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the gauge. Do Not Disassemble. Read the General License that accompanied the gauge for additional requirements. Where the NRC has jurisdiction, Montesino Technologies has provided the General License in 10 CFR 31.5. If the gauge is installed in an Agreement State, Montesino Technologies has provided that state's General License.

Montesino Technologies, Inc.
1900 Superfine Lane
Wilmington, DE 19802
Phone: 302-888-2355

DO NOT REMOVE THIS LABEL!