Application and Review Checklist for (Acceptance, 1st, or 2nd) Review for SSD 03-23

SUMMARY DATA

Name and Complete Mailing Address of the Applicant:
Montesino, Technologies, Inc.
1900 Superfine Lane
Wilmington, DE 19802-4920

Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:
Peter Schmitt, 302-888-2355, 2350(fax)

The Applicant Is (check one):

	Custom User
	Manufacturer
x	Distributor
	Manufacturer and Distributor

If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:
Electronic Systems, SPA
S.S. 229, Km 12,200
28015 - momo - (no) - Italy

If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:

Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:

Model Number: SINTEL 9000

Principal Use Code (see Appendix E): E

Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):
Thickness Measuring Device (gauge)

For Use by:

	Specific Licensees Only
x	General Licensees Only
	Both Specific and General Licensees
	Persons Exempt from Licensing

Leak-Test Frequency:

x	Periodic Leak-Testing Is Not Required (For Krypton-85 source)
x	6 Months (for Strontium-90)
	Attached is justification for a leak test frequency of greater than 6 months

Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):
10 CFR 31.5

Radionuclides and Maximum Activities (including loading tolerance): Krypton-85 14.8 Gbq (400 mCi) +- 10%
Strontium-90 1.850 Gbq(50mCi) -10%, +25%

CERTIFICATION:

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

Certifying Officer — Typed Name and Title

Signature: **Date:**

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF		COMMENTS
	1st Reviewer	2nd Reviewer	
DESCRIPTION/CONSTRUCTION			
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?	n/a		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	Def.		See RAI's on drawings
Assembly methods (screw, welds, etc.); verify integrity	DT		Screws
Source mounting (size and integrity) and security	DT		Safety lock prevents unauthorized personnel from approaching or removing source holder fixed by screws
Is source ANSI classification sufficient (from ANSI N43.6 and ISO 2919): Radiography - Unprotected ..... 43515 Radiography - In Device ..... 43313 Medical - Radiography ..... 32312 Medical - γ Teletherapy ..... 53524 Medical - Brachytherapy ..... 53211 Medical - Source Applicators ..... 43312 γ Gauges - Unprotected ..... 43333 γ Gauges - In Device ..... 43232 β Gauges, Low Energy γ Gauges, or X-ray fluorescence ..... 33222 Oil Well Logging ..... 56522 Portable Moist/Density ..... 43333 Neutron Applications ..... 43323 Calibration source activity > 30μCi (1 MBq) ..... 22212 γ Irradiators (I) ..... 43323 γ Irradiators (II, III) ..... 43424 γ Irradiators (II, III, IV) ..... 53424 Chromatography ..... 32211 Static Eliminators ..... 22222 Smoke Detectors 32222	DT		AEAT source information contains source classification KR- 43232 SR- 64343
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	DT		Pneumatic piston/mechanical movement safety limit switches. Pressure required for operation
On-Off indicators (description, qty., location)	DT		2 safety limit switches and 2 indicator lights
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	DT		Red light - shutter locked by pneumatic piston solenoid
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	DT		Hermetic seal limits environmental agents / treated materials
Shielding efficiency and integrity	DT		Tungsten added to shutter to lower doses
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	n/a		
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	n/a		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	DT		ANSI N538

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Model:

DESCRIPTION	OK/DEF		COMMENTS
	1st Reviewer	2nd Reviewer	
LABELING			
Copy of label	DT def.		Source label in Italian. Ok?
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	DT		Metal plate with screw attachment
Permanent attachment and location(s) - visible to users?	DT		Outer side of head parallel to head scanning direction
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	DT def		Drawing US 1036 no English text 10CFR 32.51(3)(iii) no ref. to 10CFR 32.51(3)(iii) no dimensions
CONDITIONS OF USE			
Expected working life of the source/device (years, operations)	DT		10 years (both)
Actions to be taken when product reaches end of its working life.	DT		Commitment of manufacturer
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	DT		-10°C +70°C, source in case locked in O-ring, hermetic sealed
How the device will be used	DT		Mounted on scanning frame using company trained operators
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	Def OK p. 27		Did not show calculations, inconsistencies between KR and SR sources
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	Def		details of prototype testing not provided 20,000 cycles
Tests results	Def		See RAI
Years of use (incidents, failures, etc.)	Def		See RAI (8-10 years for similar devices)
Similarities to other sources/devices if they are used as basis.	Def		No details provided to demonstrate similarities
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, etc.)	Def		air ionization chamber, no 30cm measurement for Kr source. Calibration concern for KR (See RAI)
Conditions: including environments, scatter (product in beam), and use of guards and shields	DT		fixed mounting and hermetically sealed unit
Distance from source/surface (per ANSI 538-1979)	Def		no 30 cm measurement for Kr source, profile did not take into account source tolerance
Shutter Open and Closed/Source Shielded	DT		
Verify radiation surveys for γ radiation meet inv^2 law.	DT		
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.	DT		

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QUALITY ASSURANCE			
Materials, subassemblies, services	Def		No QA program provided (see RAI) in US
Assembly methods (screws, welding, etc.)	Def		ISO-9000 certificate not enclosed
Dimensions and tolerances	Def OK		
Activity, radiation levels, leak tests	DT		Source QA from AEAT
QA Manual and comparison of manual to Regulatory Guide 6.9	Def		
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing	DT		Fixed on a screening frame
Inherent shielding, inaccessibility	DT		No access to source/ safety locks. Additional Tungsten shield for closed position doses / pneumatic safety lock
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	DT		Distance between source and detector 12mm for KR and 25mm for Strontium. No access to source
Mounting integrity	DT		
SAFETY INSTRUCTIONS			
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	DT		Instructions discuss training, emergency plan, contamination, etc.
ACCOMPANYING DOCUMENTATION			
Leak tests results and radiation surveys	DT		AEAT test report
Transportation documents	DT		Type A
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	Def		not listed in accompanying documentation requirements
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations			

CHECKLIST

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Model:

<table>
<tr><th colspan="4" rowspan="2">DESCRIPTION</th><th colspan="2">OK/DEF</th><th rowspan="2">COMMENTS</th></tr>
<tr><th>1st Reviewer</th><th>2nd Reviewer</th></tr>
<tr><td colspan="4">SERVICING</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">The following activities may be performed by the persons indicated:</td><td rowspan="11"></td><td rowspan="11"></td><td rowspan="11"></td></tr>
<tr><td>Activity</td><td>by a General Licensee</td><td>Only by a Specific Licensee</td><td>Will be Offered by the Applicant</td></tr>
<tr><td>Installation</td><td></td><td></td><td>x</td></tr>
<tr><td>Relocation</td><td></td><td></td><td></td></tr>
<tr><td>Maintenance</td><td>x</td><td></td><td></td></tr>
<tr><td>Repair</td><td></td><td></td><td>x</td></tr>
<tr><td>Source Exchange</td><td></td><td></td><td>x</td></tr>
<tr><td>Calibration</td><td>x</td><td></td><td></td></tr>
<tr><td>Leak Testing</td><td>x with permission</td><td></td><td></td></tr>
<tr><td>Radiation Survey</td><td></td><td></td><td>x</td></tr>
<tr><td>Training</td><td></td><td></td><td>x</td></tr>
<tr><td colspan="4">FOREIGN VENDORS</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Drop ship</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Who and where is source installed</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Leak test and radiation surveys</td><td></td><td></td><td></td></tr>
<tr><td colspan="4">QA in the U.S.</td><td></td><td></td><td></td></tr>
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1st Reviewer Signature: **Date:**

2nd Reviewer Signature: **Date:**