

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM

QA INSPECTION FORM FOR SS&Ds

Revised July 31, 1997

1. Name and Address of Licensee:

Novoste Corporation
3890 Steve Reynolds Boulevard
Norcross, Georgia 30093

Latitude: _____ Longitude: _____ How obtained: _____

2. Is licensee: Manufacturer Distributor

3. Licensee Contact: Craig Reed Telephone Number: 770-717-0904

4. Certificate Number: GA-1115-D-101-S
Model: A1000 series: Beta-Cath A1732, A1733, A1730, A1767; Corona A1730

Date of Last Amendment: April 8, 2002

5. Date of Inspection: 08/13,16/2004 Date of Previous Inspection: N/A

6. Type of Inspection: (X) Announced () Unannounced
(X) Routine () Special
(X) Initial () Reinspection

7. Priority: III

8. Next Inspection Date: 03/2007 (X) Normal () Reduced () Extended

9. Scope and Summary of Inspection: This inspection covered the QA/QC procedures and checks identified in the SS&D registry certificate(s). Verification of these items confirms that the source(s)/device(s) are being manufactured/distributed as stated in the registration certificate(s).

10. Participants (Include name and title of persons involved):

Eric Jameson GA Radioactive Materials Program inspector
Craig Reed Director of Radiation Science, RSO
Andrew Green VP – Scientific Affairs
Adam Lowe VP – Operations
Juan deCardenas Director of Instrument Operations

11. Management Interview and Inspection Findings (Discuss general inspection findings, overall status of program, individuals involved):

Overall design of the device has evolved based on licensee response to customer complaints, incidents, and general feedback as outlined in its complaint tracking system. To address concerns regarding visualization of seeds, the potential for lost seeds, and the intermittent failure of the device gate mechanism, the licensee applied for an amendment (amend .02, issued March 2002) to incorporate a new source train configuration, a jacketed source train instead of

NOTE: prior to 2002, the above processes were conducted by a sub-contractor, with the results verified by the licensee. In 2002, the licensee began performing this operation itself.

The licensee also conducts QA/QC on incoming source trains. These include a leak test upon receipt where the entire source train is soaked in liquid for an extended period of time; after removal of the source train, the remaining liquid is dried and analyzed (this is different from a standard wipe test). The source train is then tested for uniformity of dose rate distribution, both axially and radially.

After device has passed all required checks and tests, the source train is installed in the device (refer to section 15 for manufacturer's QA on the source train). The device is cycle tested with a catheter to simulate actual use. If the device does not complete 10 cycles (source train sent out and returned equals one cycle) without incident, it is not allowed to be transferred/distributed to a customer.

15. FOR FOREIGN MANUFACTURED SOURCES AND DEVICES

Receipt Documentation complete?.....	Yes
Certificate of Conformance.....	Yes
Transportation Documentation	Yes
Valid leak test.....	Yes
Receipt Surveys.....	Yes
QA/QC verification by manufacturer.....	Yes
Third party independent QA/QC, copy of report provided to Division.....	Yes – ISO cert

Describe manufacturer's QA/QC procedures

perform material receipt inspections; assemble sources to specification; verify activity per source does not exceed specification; verify uniform dose distribution (axially and radially) along length of source train.

16. FOR DROP SHIPPED SOURCES AND DEVICES (directly to end user).....N/A

Describe QA/QC procedures performed by Field Service Technician