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 X Distributor X

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

loose, as an option. In March 2004, the licensee began to phase out the use of the loose source train. At the time of this inspection, the phase-out was ~ 80% complete.

Another outcome from the complaint tracking system was modifications to the design of both the 5 Fr (loose source train) and 3.5 Fr (jacketed source train) catheters to minimize the incidence of kinking, dislodging from the transfer device, and improve the integrity of the catheter tip. These changes have been incorporated in the SS&D certificate when the design affected the existing text of the certificate.

Prior to 2002, the transfer device was assembled by a sub-contractor and shipped to the licensee assembled (except for the source train). In 2002, the licensee began performing this operation itself, utilizing the same materials suppliers, procedures, and QA/QC procedures as had been approved in the SS&D certificate. QA/QC program is valid; structure has not changed since the last device amendment.

No items of non-compliance identified.

12. Action and Date: (X) No Violations / Compliance letter dated: 08/26/2004

( ) Violations / Notice of Violations dated:

( ) Inspection Acknowledgment Form: Clear/Violations

13. Inspector: Eric Jameson Date of Report: 08/26/2004

14. QUALITY ASSURANCE OF SOURCE/DEVICE

Does visual inspection match written description? (source/device on site only).....Yes

Does device contain the proper sources?.....Yes – verified documentation

Is source activity < maximum activity?.....Yes

Certificate of Conformance for received sources.....Yes

Source has valid leak test.....Yes

Shutter mechanism operates as described (device only).....Yes

Labeling/identification as described.....Yes
GL label.....N/A

External radiation levels agree (source/device on site only).....Yes

Transportation documents/user instructions as described.....Yes

Describe QA/QC procedures performed by licensee

verify suppliers meet defined quality criteria; material receipt inspection involving tests of critical properties (i.e., dim, tolerance, resistivity, materials of construction, etc.); functional checks and performance tests to verify system specifications (during installation and final device checks)

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