RTOG 95-17, “A Phase I/II Trial To Evaluate Brachytherapy As The Sole Method Of Radiation Therapy For Stage I And II Breast Carcinoma.”

Study Chair: Robert R. Kuske, M.D., (504) 842-3440, FAX # (504) 842-2037, rkuske@ochsner.org

RTOG 95-17 has been updated as follows:

Sections 11.3.1, 11.4.1, 11.4.2, 12.2 and 13.1.3 have been updated to reflect that the RTOG Quality Assurance Department at RTOG headquarters is currently receiving all photographs listed in these sections of the protocol.

Section 12.1 – Updated RTOG mailing address to 1818 Market Street, Suite 1600, Philadelphia, PA 19103.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as “Update Date”, not as a revision.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/
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RTOG 95-17 has been updated as follows:

Section 6.10 — This section has been updated to reflect that the RTOG Quality Assurance Department at RTOG headquarters is currently receiving all photographs listed in this section.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as “Update Date”, not as a revision.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/
The following changes are in effect:

**Cover Page** – E-mail addresses were added to the cover page.

**Section 3.1.6** – Added “. . . or a negative sentinel node”

(also affects the Schema, the Eligibility Checklist [Q 8], and Section 8.2).

**Section 6.2.1** – Added to the first sentence

“. . . or omnipaque contrast”

**Section 6.3** – Added after the first sentence

“A minimum of two planes is required, more planes may be added if justified by the volume.”

**Section 8.1.11** – Corrected to

“. . . superficial and deep positions”

**Section 8.1.13** – Added after the first sentence, “See Section 6.3.”

**Section 12.1** – A copy of the preoperative mammogram report (I2) is due at RTOG 2 weeks from start of treatment. If done, a postoperative/post brachytherapy report will also be collected. See Section 3.1.5. For cases already on study, the requests will be added to each patient-specific calendar to track receipt. Please submit the reports as soon as possible.
SUMMARY OF CHANGES

RTOG 95-17, Breast Brachytherapy

September 8, 1998

The following changes have been made:

**Eligibility Checklist (p.2)** - Added (questions were renumbered)

a) What is the surgeon’s name and

b) Will any component of the patient’s care be at a VA or military facility?

**Section 5.2** - Third line from the bottom, dropped “stereotactic”

**Section 6.2** - Definition of target volume was clarified.

**Section 6.3** - Procedure to design the implant geometry was reworded.

**Section 6.5** - Sources may be loaded as soon as pathological confirmation is available. All criteria in Section 5.2 and 6.1.4.3 must be met, however, to maintain eligibility.

**Section 6.11.2 (DHI)** - The first sentence was expanded.

**Section 6.12** - The last three sentences were added to define the prescribed dose.

**Section 8.1.11** - Reworded after sentence 1 for clip size.