Since the number of cycles of adjuvant chemotherapy was reduced to four (11/13/00, #4), the total sample size was increased to 81 patients to ensure the accrual of 48 patients after the November amendment. This change affects the Schema and Section 13.2. Reference #42 was added.
SUMMARY OF CHANGES

RTOG 99-06

November 13, 2000

The number of cycles of adjuvant chemotherapy was decreased to four (from six). The decision was based on a recent study\(^1\) where one of the findings was that patients had difficulty tolerating a six cycle regimen of gemcitabine and cisplatinum as evidenced by grade 3 and 4 hematological toxicities (neutropenia and thrombocytopenia) and renal toxicities (elevated creatinine and BUN levels and edema).

The following sections have been updated: the Schema, Sections 2.1, 7.3.1, 13.1.1, 13.1.2, 13.2, 13.5.2, and Appendix I (Descriptions of Procedures).

**Other Changes**

**Cover Page** Dr. Kaufman's address was updated.

**Schema** Tumor-related hydronephrosis is not eligible (also affects the Eligibility Checklist [Q2] and Section 3.2.1).

**Section 4.3** Added calculated creatinine clearance (also added to Section 11.1).

**Section 5.1** was updated for patient entry.

**Section 6.5**, line 7 - Changed to "...should be treated off protocol on an individual basis. For a grade 3 acute colitis or any other grade 3 infield radiation related toxicity ... appropriate off-protocol treatment should be administered."

**Section 7.4.2**, line 3 - Changed to "Paclitaxel for injection must be diluted ... and room lighting (Prod Info Taxol, 1997). Use 5% polyolefin ..."

**Section 7.9.3** the first bullet - Changed to "...mannitol 12.5 g i.v.push."

**Section 7.9.4**, first table - AGC corrected to "≥ 1.0"

1. Donald Kaufman, Derek Raghavan, Michael Carducci, Ellis Glenn Levine, Barbara Murphy, Josep Aisner, Timothy Kuzel, Steven Nicol, William Oh, Walter Stadler. *Phase II Trial of Gemcitabine Plus Cisplatin in Patients with Metastatic Urothelial Cancer*. Journal of Clinical Oncology, Vol 18, Issue 9 (May), 2000: 1921-1927 (2000 American Society for Clinical Oncology. Address reprint requests to Donald Kaufman, M.D., Massachusetts General Hospital, 1 Hawthorne Place, Room 107, Boston, MA 02114.)