## U.S. NUCLEAR REGULATORY COMMISSION REGION I

## NOTICE OF LICENSEE MEETING

- Name of Licensee: Good Samaritan Regional Medical Center
- Docket No.: 03009176
- License No.: 37-15480-01
- Time and Date: 1:00 p.m., Wednesday, February 16, 2005
- Location of Meeting: U.S. Nuclear Regulatory Commission Public Meeting Room 475 Allendale Road King of Prussia, PA 19406
- Purpose of Meeting: An open predecisional enforcement conference will be held to discuss the apparent violations identified during an NRC routine inspection conducted on November 17 and 23, 2004. The apparent violations indicated an inadequate control of the brachytherapy program and include: failure to confirm that each therapy administration was in accordance with the written directive; failure to calibrate instrumentation used to measure dosages in accordance with nationally recognized standards or the manufacturer's instructions; failure to perform an assessment to determine that the total effective dose equivalent to a member of the public from exposure to a released individual was not likely to exceed 5 mSv (0.5 rem); failure to provide the released individual, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable; failure to make surveys to locate and account for all sources that had not been implanted; failure to maintain accountability at all times for all brachytherapy sources in storage or use; failure to provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under §§ 35.75; failure to fully review the radiation protection program content and implementation; failure to make surveys to evaluate the magnitude and extent of radiation levels surrounding brachytherapy implant patients;

failure to supply and require the use of individual monitoring devices by adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 10 CFR 20.1201(a); and failure to ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL."

NRC Attendees: George Pangburn, Director, Division of Nuclear Materials Safety (DNMS) Pamela Henderson, Chief, Medical Branch, DNMS Penny Lanzisera, Sr. Health Physicist, Medical Branch, DNMS Shirley Xu, Health Physicist, Medical Branch, DNMS Daniel J. Holody, Team Leader, Allegation/Enforcement Staff, Office of the Regional Administrator (ORA) John Wray, Enforcement Specialist, ORA Karl Farrar, Regional Counsel, ORA

Licensee Attendees: Peter Bergman, President and CEO Darnell Fuhrer, Vice President, Patient Care Services Stephen Whitmoyer, M.D. Radiation Safety Officer Chris Mehlbaum, Chief Technologist, Nuclear Medicine

Note: **This is a Category 1 Meeting:** The public is invited to observe this meeting and will have one or more opportunities to communicate with the NRC after the business portion, but before the meeting is adjourned. Handicapped persons requiring assistance to attend or participate in the meeting shall make their requests known to Shirley Xu, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406, at 610-337-5006, email: <u>ssx@nrc.gov</u>, no later than two business days prior to the meeting. Attendance by other NRC personnel at this meeting should be made known by February 14, 2005.

Accession Number for ADAMS Meeting Package: ML050310401 ADAMS is accessible from the NRC Web Site at http://www.nrc.gov/reading-rm/adams.html

/RA/

Prepared by:

Shirley Xu Health Physicist

/RA by Francis Costello Acting For/

Approved by:

George Pangburn, Director Division of Nuclear Material Safety Distribution: M. Virgilio, DEDMRS J. Strosnider, Director, NMSS F. Congel, OE R. Tadesse, RI EDO Coordinator (Materials) C. Miller, RI EDO Coordinator (Materials) C. Miller, Director, IMNS T. Essig, IMNS J. Moore, OGC M. Elwood, OGC K. Remsburg, OGC G. Morell, OE D. Holody, RI J. Wray, RI R. Urban, RI R. Bores, RI K. Farrar, RI PAO, RI G. Pangburn, RI F. Costello, RI S. Minnick, RI D. White, RI S. Bogle **PMNS OEMAIL RA** Secretary **DRA Secretary DRP** Secretary **DRS Secretary OEWEB RI** Receptionist

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