Maine Radiation Control Program
Policy 94-01 Metastron (Sr-89 Cl injection)

APRIL 28, 1994
Subject: Metastron (Strontium-89 (Sr-89) Chloride injection)

BACKGROUND

Metastron has been cleared for marketing by the FDA for the palliation of pain in patients with metastatic bone cancer. This radiopharmaceutical is approved for therapeutic use and is manufactured by Amersham in Illinois. Recently requests have come in from Doctors and Hospitals wishing to use it, prompting this interpretation of Maine regulations.

REGULATORY REQUIREMENTS

The State of Maine Rules Relating to Radiation Protection (SMRRRP) regulate therapeutic use of radiopharmaceuticals in Part G.300 and the applicable training requirements in G.930 and G.972.

G.300 allows any authorized licensee to use a radioactive material in a radiopharmaceutical for therapeutic use for which the FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA).

G.930 sets training requirements for the therapeutic use of radiopharmaceuticals including specific supervised clinical experience requirements for Iodine-131 (I-131), Phosphorus-32 (P-32), and Gold-198 (Au-198).

G.972 requires this training to have been received within the last five years or continuing applicable experience.

POSITION STATEMENT

1. Due to the similarities between P-32 and Sr-89 and the "blanket" authorization of G.300 Authorized Users currently authorized for G.300 are authorized to use Sr-89.

2. The training requirements for Sr-89 are as specified in G.930.A and B plus supervised clinical experience under an authorized user for treatment of three (3) individuals with Sr-89 or P-32.

3. If prior training is sufficient but does not meet the requirements of G.972 (within 5 years) then we require a minimum of supervised clinical experience under an authorized user for the treatment of one (1) individual with Sr-89. Additional supervised use will be at the discretion of the supervising physician.

Item 2 and 3 above will require the submission of a preceptor statement.
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