DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON, DC 20350-2000

IN REPLY REFER TO

5104
Ser N45S1/11U158069
14 February 2011

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406
(Attn: Ms. O. Masnyk-Bailey)

Dear Ms. Masnyk-Bailey:

SUBJECT: NOTIFICATION OF EMBRYO DOSE GREATER THAN 5 mSv

The Naval Radiation Safety Committee received a report that Naval Medical Center Portsmouth (NMCP) administered a byproduct material to a pregnant individual. The resultant dose equivalent to the embryo/fetus was calculated to be greater than 50 mSv (5 Rem). In accordance with 10CFR 35.3047 attached you will find the required notification to the Nuclear Regulatory Commission (NRC).

In summary, the violation of regulation occurred when a patient was administered 98.1 mCi of I-131 for thyroid ablation on 12 January 2011. Prior to the administration of the isotope a pregnancy test was conducted with negative results. On 28 January 2011, the patient presented to the Emergency Department with symptoms consistent with pregnancy. Further analysis verified the patient was approximately 2 weeks pregnant. The patient denies having sexual intercourse after the injection of the isotope therefore it is inferred that the patient was with child during the injection of the radioisotope. The senior medical physicist at NMCP calculated the dose to the embryo to be approximately 21.3 Rem.

For additional information, please contact me at Radiological Controls and Health (N455) Energy & Environment Readiness Division Office of the Chief of Naval Operations (703) 602-5365, facsimile (703) 602-1982, or E-mail at lino.fragoso@navy.mil.

Sincerely,

L.L. Fragoso

L.L. Fragoso
Executive Secretary
Naval Radiation Safety Committee

SUBJECT: NOTIFICATION OF EMBRYO DOSE GREATER THAN 5 mSv

Copy to: Bureau of Medicine and Surgery (M3FP2)
Navy and Marine Corps Health Center

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(i) The licensee's name;

U. S. Navy,
Medical Treatment Facility, Portsmouth, VA

(ii) The name of the prescribing physician;

David B. Turton, MD

(iii) A brief description of the event;

On 12 Jan a Nuclear Medicine patient received a dose of I-131 of 98 milliCuries for a thyroid ablation. She received a pregnancy test just before the dose was administered and the result was negative. Two weeks after the dose she made an ER visit complaining about nausea and vomiting; she was then administered a serum pregnancy test. The result indicated she was roughly two weeks pregnant. On 27 Jan the doctor notified the Navy that the patient became pregnant very close to the therapy time. On 28 Jan a dose calculation estimated the dose to the embryo to be 213 mGy (21.3 rads). On 31 January the Naval Radiation Safety Committee was notified that the patient was possibly pregnant prior to the therapy.

(iv) Why the event occurred;

Pregnancy test performed immediately prior to therapy was negative. Patient was not trying to get pregnant prior, but did have unprotected intercourse in the few days before therapy. She denies intercourse in the week after therapy. Standard precautions were given to the patient during a visit several weeks prior to the therapy and included the following: 1). She could not be treated if she was pregnant, and 2). A pregnancy test would be performed immediately prior to therapy.

(v) The effect, if any, on the embryo/fetus or the nursing child;

At a dose estimate of 213 mGy, there is a slight increased risk of failure to implant, but if the fetus survives, the outcome is expected to be good. This was discussed at length with the patient.

(vi) What actions, if any, have been taken or are planned to prevent
recurrence;

Internal SOP changes are being made to stress the importance of discussing sexual abstinence prior to therapeutic doses. Patients are to be made aware that a pregnancy test may remain negative for up to a week after fertilization.