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St. Lawrence Hospital
Sisters of Mercy
ATTN: Mr. Kim Peters
Vice President
Professional Services
1210 West Saginaw Street
Lansing, Michigan 48914

License No. 21-15462-01

Gentlemen:

This refers to the investigation conducted by Messrs. C. H. Weil and W. J. Adam of this office on August 15, 1980, concerning activities at St. Lawrence Hospital, authorized by NRC Byproduct Material License No. 21-15462-01.

A copy of the NRC Investigation Report (Report No. 030-09151/80-01) was sent to you from this office on October 29, 1980. The report stated Region III had retained a medical consultant to review the St. Lawrence Hospital's evaluation of a patient's organ and whole body exposure. The report also stated the medical consultant's review will be made an appendix to the investigation report.

The enclosed report, dated December 9, 1980, from the NRC medical consultant is provided for your information and should be attached to the NRC Investigation Report No. 030-09151/80-01.

Sincerely,

J. F. Streeter, Acting Director
Enforcement and Investigation

Enclosure: Ltr dtd 12/9/80,
from NRC medical consultant

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This report summarizes my role as medical consultant to Region III of the Nuclear Regulatory Commission in the case of patient A, a 40 year old white female who was referred for a thyroid study at the St. Lawrence Hospital at 1210 West Saginaw Street, Lansing Michigan 48914 on August 14, 1980. The patient was described as being euthyroid. The study was apparently ordered because of suspicion of the presence of a palpable nodule. At 9:30 AM the patient received a dose variously reported as 8.5 - 9.8 millicuries of iodine-131 as sodium iodide instead of 8.5 microcuries. This error in administration apparently arose because the nuclear medicine technician was unaware of the labeling on the capsule containers and of the actual readout on the dose calibrator. Also according to one physician, the supplier sent 10 millicurie capsules rather than 10 microcurie capsules as ordered.

This error was apparently discovered by the technician within about one hour but was not communicated to the physician in charge until about 2:30 PM on August 14. At that time 10 drops of Lugol's solution were prescribed immediately and subsequently this drug was continued at 5 drops, three times a day. Tapazol, 20 milligrams daily, was prescribed and began as of 5:30 PM on August 15.

The patient was kept on the above outlined therapy for approximately 12 days. I had spoken with her physicians on several occasions suggesting not only the serial counts over the thyroid and remainder of the body but in addition analyses of urine for ^{131}I, blood counts, and chromosome analyses of peripheral lymphocytes. Except for thyroid counts none of this information has been furnished to me. There is no summary of the clinical course of this patient in regard to the specific details of therapy and no progress notes as to the presence or absence of tenderness over the thyroid gland within the first three weeks after the intake of the dose of radioiodine.

Dosimetry: The measurements were carried out with moderate difficulty. It was not possible to interpret the data prior to a conference between Dr. Malchman in Lansing and Stephen Thomas, Ph.D., physicist, of our Department of Radiology at the University of Cincinnati.

Measurements made with the uptake probe at St. Lawrence Hospital were unsatisfactory. The data obtained with the pinhole collimator on the gamma camera with and without the plug did provide satisfactory information for dose estimation to the patient. Table 1 (attached) summarizes the measurements over the thyroid gland in microcuries versus time. These data were then utilized in a computer program MED-16, MIRD S, A Computer Program to Determine Cumulated Activity and Radiation Absorbed Dose, Biomedical Computing Technology Center (BTIC), Oak Ridge National Laboratory.

The calculations from this program are presented in Table 2 (attached) and compared with spot calculations done in our Laboratory at the University of Cincinnati Medical Center.

In regard to the radiation associated effects of a dose of 5514-6896 rad to the thyroid gland it is estimated that within 5 years the patient has a probability of about 15% (range 8-26%) of developing clinical, radiation associated hypothyroidism (Maxon HR et al Ionizing Irradiation and the Induction of Clinically Significant Disease in the Human Thyroid Gland, American Journal of Medicine 63: 967-978, December 1977). The likelihood of the development of a radiation associated thyroid nodule is about 6500 x 0.11 x 10^{-6} = 7.15 x 10^{-4} (range 3 to 11) chances per year for this patient. For thyroid cancer the probability is 6500 x 0.5 x 10^{-6} = 3.25 x 10^{-4} (range 2.1 to 4.6) per year (Maxon HR et al Am J of Med 63: 967-978, 1977)*. For radiation induced leukemia if one assumes that the bone marrow dose is about the same as the whole body dose, the risk using the 20-50 per 10^6 per rad - 2.9 x 35 x 10^{-6} = 102 x 10^{-4} for a lifetime risk. This estimate is conservative since using the calculation of about 7 rad to the bone marrow in a group of 19,000 hypothyroid patients treated with ^{131}I there had been no significant excess of leukemia when compared to a group of 14,000 hyperthyroid patients treated surgically (Saenger EL, Thoma GE, Tompkins EA, et al, Incidence of Leukemia Following Treatment of Hyperthyroidism: A Cooperative Study, JAMA 205: 147-154, 1968). There was no excess of thyroid cancer in the ^{131}I treated group as compared to the surgical group (Dobyns BM, Sheline GE, Workman JB, et al Malignant and benign neoplasms of the thyroid in patients treated for hyperthyroidism: a report of the cooperative thyrotoxicosis therapy follow-up study, J Clin Endocrinol Metab 38: 976, 1974). Although the accidentally exposed patient was not strictly comparable since she did not have hyperthyroidism, the risk estimates used here are sufficiently applicable to conclude that the likelihood of developing thyroid cancer or leukemia is slight.

Without knowing whether there was any evidence of thyroid abnormality prior to the misadministration, it is not possible to speculate on the subsequent development of more overt non-radiation associated thyroid disease which might be clinically indistinguishable from radiation associated thyroid disorders.

*These risks are based on an approximate average dose to the thyroid of about 6500 rem.

TABLE I

SUMMARY OF PATIENT COUNTING DATA
THYROID 131-I ACTIVITY

DATE	TIME	(In Microcuries)		TOTAL ELAPSED TIME SINCE INITIAL INTAKE (Days)
8-14-80	5:30 pm	Camera (plug in)	1264.8	1
8-15-80	5:30 pm	Camera (plug in)	987.9	2
8-16-80	5:30 pm	Camera (plug in)	920.4	3
8-17-80	11:00 am	Camera (plug in)	800.4	3.73
8-18-80	5:30 pm	Camera (plug in)	695.4	5
8-19-80	5:30 pm	Camera (plug in)	578.4	6
8-20-80	5:30 pm	Camera (plug in)	521.8	7
8-22-80	5:30 pm	Camera (plug in)	449.0	9
8-25-80	5:30 pm	Camera (plug in)	264.00	12
9-02-80	5:30 pm	Camera (plug in)	117.0	20

TABLE 2

Dose Calculations Based on an Oral Dose of 8.5 mCi ^{131}I

Organ	BTIC Computer Calculation rad		UC Spot Calculation rad	
	Plug in	Plug out	Plug in	Plug out
Thyroid	5661	6698	5514-5656	6896
Kidney	.036	.042		
Total Body	2.44	2.89		2.9

E.L. Saenger, M.D.
December 9, 1980