

# NORD<sub>x</sub>

Mr. John D. Kinneman, Chief  
Nuclear Materials Safety Section B  
Division of Radiation Safety and  
Safeguards  
U. S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

September 1, 1989

Gentleman:

In response to the findings and subsequent correspondence of Special Inspection No. 99990001/B9-012, I am submitting several statements and attendant documentation.

Corrective action was taken immediately to reduce our receipt and inventory of iodine-125 to less than 200 microcuries at any one time. Previously we had been on standing orders of materials that would allow longer periods of time between shipments and receipt of these materials. By canceling all standing orders, our daily receipt of iodine-125 was reduced to well below 100 microcuries with only four exceptions when the amount received plus current inventory was still well below the cutoff of 200 microcuries. Our average usage rate is 50-60 microcuries per day. This information is documented in the attached copies of our isotope inventory log.

In addition, we have reduced the level of iodine-125 used to quantitate digoxin by 6.5 microcuries per package of one hundred tests.


Effective the week of September 4, 1989, we will be eliminating the use of radioactive isotope for the measurement of ferritin and T3-uptake. This will reduce our inventory of iodine-125 by approximately 40 microcuries per week.

At present, we are in the process of changing our total T4 procedure to one that doesn't use radioactive labeling. This process will probably take another week or two before completion. The net result will be a reduction of iodine-125 inventory of approximately 50 microcuries per week.

We will continue to reduce our radioactive inventory by changing to procedures using nonradioactive labeling.

Our intent is to fully comply with the rules and regulations of the Nuclear Regulatory Commission.

Sincerely,

  
Gene R. Putz, Ph.D.  
Laboratory Director

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DIAGNOSTIC  
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99490001

ISOTOPE INVENTORY

Nordx

Total  
µCi (F)  
Rec'd

DATE	TECH	COMPANY	ANTIGEN	ISOTOPE	µCi	KITS RECEIVED	LOT #	Total µCi (F) Rec'd
6/11/89	RA	Clin Assay	FT4	I <sup>125</sup>	2 23µCi	4	1084	6/12/89
6-14	esi	Ciba/Corning	HC6	I <sup>125</sup>	≤24µCi	3	12070	(72)
6-16	com	Amersham	LH	I <sup>125</sup>	≤60µCi	1	88A	(6.0) 75
6/19	com	"	FSH	I <sup>125</sup>	≤6µCi	1	89	(46)
6/19	com	BIOEAT	TRIPPHAM	I <sup>125</sup>	≤10µCi	2	9029211	10/16
6/20	ju	Ventur	VAST	I <sup>125</sup>	≤10µCi	1	01639	(10) 8-2-89
6-22	esi	Ventur	Digoxin	I <sup>125</sup>	≤20µCi	2	01679	(20)
6-23	cec	Clin Assay	FT4	I <sup>125</sup>	≤14µCi	2	0083	(17) 6/27/89
6-26	cec	Boston/Dick	Gastin	I <sup>125</sup>	≤3.5µCi	1	255025	(3.5)
6-27	cec	Clin Assay	FT4	I <sup>125</sup>	≤28µCi	4	0089	7/28/89
		Ventur	TR4	I <sup>125</sup>	≤60µCi	6	11669	8-24-89 (58) nr
			VAST	I <sup>125</sup>	≤10µCi	1	01719	8-2-89
6/28	com	Biosed	femtin	I <sup>125</sup>	≤40µCi	1	9029270	
6/28	com	Ciba	HCG	I <sup>125</sup>	≤48µCi	2	14073	(48)
6-28	esi	Ventur	IgE	I <sup>125</sup>	≤10µCi	1	21789	
			Digoxin	I <sup>125</sup>	≤20µCi	2	01679	7-5-89
6/28	com	Farnsworth	FSH	I <sup>125</sup>	≤6µCi	1	89	7/20/89
		DPC	Cortisol	I <sup>125</sup>	≤1µCi	1	07314	8/7/89
		"	Estrodiol	I <sup>125</sup>	≤1µCi	1	075	(31)
	cec	Ventur	Digoxin	I <sup>125</sup>	≤10µCi	1	01779	7-5-89
7/3	14C	Ventur	IgE	I <sup>125</sup>	≤20µCi	1	21789	7/13/89
7/3	14C	Ventur	I3	I <sup>125</sup>	≤30	3	11779	8-2-89
-	14C	"	Dig	I <sup>125</sup>	≤30	3	01799	(30)
7-6	esi	Amersham	LH	I <sup>125</sup>	≤6	1	90	(6) 7/26/89
7-7	esi	Amersham	LH	I <sup>125</sup>	≤6	1	90	7/2
	esi	"	FSH	I <sup>125</sup>	≤6	1	90	7/26/89
	esi	DPC	Estrodiol	I <sup>125</sup>	≤6	1	075	(47)
	esi	"	Cortisol	I <sup>125</sup>	≤9	1	314	7/26/89

ISOTOPE INVENTORY

Don Dr

Total  
µCi  
Rec'd

DATE	TECH	COMPANY	ANTIGEN	ISOTOPE	µCi	KITS RECEIVED	LOT	Total µCi Rec'd
3/7	KIC	Ventrex	TY	I125	≥ 10	1	01799	8-24
	KIC	"	ASTH	I125	≥ 10	1	01819	
3/10	H	Chemistry	Free Ty	I125	≤ 7 µCi	1	0094	(7)
3-11	OR	Ventrex	Digoxin	I125	20 µCi	2	01799	7/14
			I <sub>125</sub>	I125	20 µCi	1	21789	8-24
			VAST	T125	≤ 10 µCi	1	01779	8-24
		Chem	<del>ASTH</del>	T125	10 µCi	2	12180	(118)
		Ventrex	TY	I125	≤ 3	2	11799	8-24
	OR	Amersham	FT4	I125	2 µCi	3	0094	8-24
	KIC	Ventrex	TY	I125	≤ 3	3	11799	8-24
7/14	OR	DPC	standard	I125	≤ 6 µCi	1	075	8/3
		Ventrex	Digoxin	I125	≤ 20 µCi	2	01939	(26)
7-17	OR	Ventrex	Digoxin	I125	410 µCi	1	01929	(110)
		BioRad	Biz/Folate	I125	440 µCi COSY 616 µCi I125	2	91-19281	8-24
			Ferritin	I125	≤ 80 µCi	2	90-29335	
7-18	OR	CORNING	Ty1	I125	415 µCi	3	K0179	(15) 8-24
7-19	OR	Ventrex	TY	I125	430 µCi	3	31959	(30) 8-24
7/20	OR	Ventrex	Digoxin	I125	≤ 20	2	0935	(20)
7-23	OR	Amersham	FSH	I125	≤ 6.0 µCi	1	90	(52)
	OR	Amersham	HCG	I125	≤ 48 µCi	2	12180	
7/24	OR	<del>Ventrex</del>	Urb/2	I125	44 µ COSY 16 µ I125	1	9119282	8-16
		BioRad	Insulin	I125	480	1	9029406	(157)
		Chem	FT4	I125	≤ 2 µCi	1	0095	7-24
7/24	KIC	Ventrex	TY	I125	≤ 30	3	01959	8-24
	KIC	Ventrex	IGP	I125	≤ 10	1	01929	8-24
	KIC	"	Digoxin	I125	≤ 10	1	01939	7/24
7/25	KIC	Ventrex	TY	I125	≤ 30	3	01959	(30) 8-24
	OR	Ventrex	RASD	I125	≤ 10 µCi	1	01999	8-24

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ISOTOPE INVENTORY

North

Total  
uci  
Rec'd

DATE	TECH	COMPANY	ANTIGEN	ISOTOPE	uci	# KITS RECEIVED	LOT #	Total uci Rec'd
7/30		Ventex	T4	I <sup>125</sup>	<20	2	21959	7/28 <sup>60</sup>
		"	T3U	I <sup>125</sup>	<20	2	01879	8-27 mf
7/28		Clin Assay	FT4	I <sup>125</sup>	<10	2	0546	(17)
8-1		Ventex	TT4	I <sup>125</sup>	≤20uci	2	02089	8-27 mf
		Clin Assay	FT4	I <sup>125</sup>	21	3	0099	8/8 <sup>60</sup>
		Ciba King	HCG	I <sup>125</sup>	24	2	12180	(65)
8-2		Ventex	T4	I <sup>125</sup>	≤20	3	12149	8-27 mf
		"	T3U	I <sup>125</sup>	≤10	1	02019	(40)
8-3		Ciba	Digoxin	I <sup>125</sup>	2 uci	3	K01949	(22)
		Ventex	T3U	I <sup>125</sup>	≤10uci	1	02019	8/10 <sup>mf</sup>
8-4		Amerishan	LH	I <sup>125</sup>	≤6uci	1	312591	
		"	FSH	I <sup>125</sup>	≤6uci	1	91	8/16 <sup>64</sup>
		Clin Assay	FT4	I <sup>125</sup>	≤21uc	3	0104	8/17 <sup>60</sup>
		Ciba-King	HCG	I <sup>125</sup>	≤48uci	2	12180	(96)
		DPC	Cortisol	I <sup>125</sup>	≤1 uci	1	320	
		DPC	Estriol	I <sup>125</sup>	≤6	1	077	
8/8		Ventex	Vast	I <sup>125</sup>	≤10	1	02199	(30)
		IGE	IGE	I <sup>125</sup>	≤10	1	22209	8/22 <sup>64</sup>
		T3U	T3 up	I <sup>125</sup>	≤10	1	02199	
8/9		Digoxin	Digoxin	I <sup>125</sup>	≤12	3	K12209	8/15 <sup>64</sup>
		TT4	Digoxin	I <sup>125</sup>	≤20uci	2	02219	(32)
8/10		Bio-Rad	Bio-folate	1057/I <sup>125</sup>	≤40 uci	2	9119416	
		Bio-Rad	Ferritin	I <sup>125</sup>	48 uci	2	9029406	(123-5)
		Beckon-Dick	Gravel	I <sup>125</sup>	≤35 uci	1	255017	
8-11		DPC	Estriol	I <sup>125</sup>	≤6 uci	1	076	
		Ventex	TT4	I <sup>125</sup>	≤30 uci	3	02219	8-24 <sup>54</sup> mf
8-11		"	T3U	I <sup>125</sup>	≤20 uci	2	02199	(56)
8/14		Ameriex	FSH	I <sup>125</sup>	≤6	1	91	(12)
		"	LH	I <sup>125</sup>	≤6	1	91	

ISOTOPE INVENTORY

Norms

DATE	TECH	COMPANY	ANTIGEN	ISOTOPE	uCi	# KITS RECEIVED	LOT	Total uCi Rec'd (#)
8-15-81	lu	CIBA	HCG	I <sup>125</sup>	≤24uCi	1	12286	(36)
		CIBA	diagn y/u	I <sup>125</sup>	≤12	3	K02229	
	oll	Ventrex	TT4	I <sup>125</sup>	≤20uCi	2	02219	MP 8-24-81
			Vant	I <sup>125</sup>	≤10uCi	1	22199	(30)
8-17	eyr	Clin Assays	FT4	I <sup>125</sup>	≤14uCi	2	0112	
	ox	BD	Gestur	I <sup>125</sup>	≤3.5uCi	1	XN1745	(52.5)
8/17	Wh	VENTREX	TOTALIT	I <sup>125</sup>	≤40uCi	4	02219	
8-18	Ue	Amersham	FSH	I <sup>125</sup>	≤3uCi	1	92A	(6)
			LH	I <sup>125</sup>	≤3uCi	1	91	
8-21	ox	BioRad	Biz/Folate	I <sup>125</sup>	≤20uCi	1	9119417	
		Baxter	FT4	I <sup>125</sup>	≤14uCi	2	0112	(64)
		Ventrex	TT4	I <sup>125</sup>	≤30uCi	3	02219	
			Vant	I <sup>125</sup>	≤10uCi	1	02279	
8/22	Ue	CIBA	dig	I <sup>125</sup>	≤4uCi	1	12286	(36)
			dig	I <sup>125</sup>	12uCi	3	K02229	
8-23	Ue	DPC	Estradiol	I <sup>125</sup>	≤6uCi	1	082	
		Baxter	TT25	FT4	≤7uCi	3	0114	(52)
		Ciba-Cam	DIG	I <sup>125</sup>	≤11uCi	4	K02229	
	Ue	Ventrex	TT4	I <sup>125</sup>	≤20uCi	3	02369	X24-81 MP
8-28	Ue	Bio-Rad	Biz/Folate	I <sup>125</sup> COS	≤16uCi ≤4uCi	2	9119952	(70)
8-29	lu	CIBA	HCG	I <sup>125</sup>	≤48uCi	2	4391	(78)
8/30	Ue	Ventrex	TT4	I <sup>125</sup>	≤30uCi	2	12369	
8/30	Ue	Ventrex	T3U	I <sup>125</sup>	≤20	3	02299	(60)
8/30	Ue	Ventrex	IgE	I <sup>125</sup>	≤10	1	02349	
8/31	Wh	VENTREX	T3U	I <sup>125</sup>	≤10	1	12299	(50)
		VENTREX	TOTALIT	I <sup>125</sup>	≤40	4	12369	
9/1	f	DPC	Condit	I <sup>125</sup>	≤9	1	327	(48.5)
		DPC	Estradiol	I <sup>125</sup>	≤18	2	084	



# NORD<sub>X</sub>

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