Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

November 16, 2004

Please find the attached pages detailing recent program test data as supporting material regarding the Application for Variance letter from Valley Forge Composite Technologies (VFCT) docket number 2004V-0155/VAR1. Our company is currently developing "next-generation" Explosives Detection Systems (EDS) technology for Homeland Defense applications and our design necessitates a variance from maximum energy as detailed in CFR Title 21 Section 179.26.

During a recent progress meeting held at the Lawrence Livermore National Laboratories, project scientists presented test data gathered by gamma quanta detection methods using a modified accelerator and detector. Several items such as food stuffs, personal items, and chemical samples were investigated during the tests. As this testing was conducted during the first phase of our system's development, an existing reactor and detector were modified for use to support the "proof of principle" test.

The graphs below detail the findings of preliminary testing using a prototype Accelerator Detection Complex (ADC) and power supply.

Sincerely,

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2004V-0155

SUP 1

Experimental Observation of Photonuclear Effect

The following text and graphs describe the results of experiments conducted at an overseas research facility in conjunction with the ongoing development of VFCT's Explosives Detection System (EDS). The objective of this testing was to observe and quantify decay of short-life isotopes. Isotopes $_{12}N$ and $_{12}B$ are produced in photonuclear reactions as a result of irradiating substances containing nitrogen and carbon. As carbon and nitrogen are common materials in almost all explosive compounds, this irradiation and investigation process is the basis of our detection technology.

Being preliminary in nature, these tests were conducted using a larger and more powerful accelerator than proposed by our system. The ~~accelerator's energy output~~ was modified to produce the 55 MeV required of our system design. A prototype power supply was created specifically for testing.

Thirteen individual items were examined during testing – 8 food and 5 personal items. The following graphs detail the half-life decay over time of the investigated substances.

The goal of the experiment was to obtain information about gamma-produced induced radioactivity in some widespread objects and food stuffs by gamma-doze equivalent to one pulse of gamma-radiation from projected race-track microtron RAM-55.

Mode of irradiation: E(γ max) = 100 MeV. Doze is 1.7×1012 γ(eff).

List of subjects

No	Subjects	size	mass
1.	**Cotton wool**	∅90 mm x 50 mm (length on the beam)	50 g
2.	**Water (bottle of Shweps)**	Plastic bottle ∅80 mm (length on the beam)	1 L
3.	**Vodka**	Glass bottle - 68 mm (length on the beam)	0.7 L
4.	**Tools metallic**	12 mm (length on the beam)	500 g
5.	**Tools plastic**	12 mm (length on the beam)	60 g
6.	**Pickled cucumber**	glass bank ∅78 mm (length on the beam)	350 g
7.	**Belt**	curtailed in a ring copper buckle to the middle 60 x 90 mm x 23 mm (length on the beam)	50 g
8.	**Sugar (cardboard packing)**	115 x 90 mm x 55 mm (length on the beam)	500 g
9.	**Block of cigarettes "JAVA" - 10 piece in paper packing.**	270 x 80 mm x 45 mm (length on the beam). Irradiation in the center of the block	200 g
10.	**Sausages. Plastic packed.**	110 x 90 mm x 35 mm (length on the beam).	400 g
11.	**Bread**	120x120 mm x 75 mm (length on the beam).	300 g
12.	**Chocolate**	160 x 73 mm x 9 mm (length on the beam).	100 g
13.	**Sprats (fish) in oil (metal tin)**	∅100 mm x 35 mm (length on the beam).	240 g

IRRADIATON

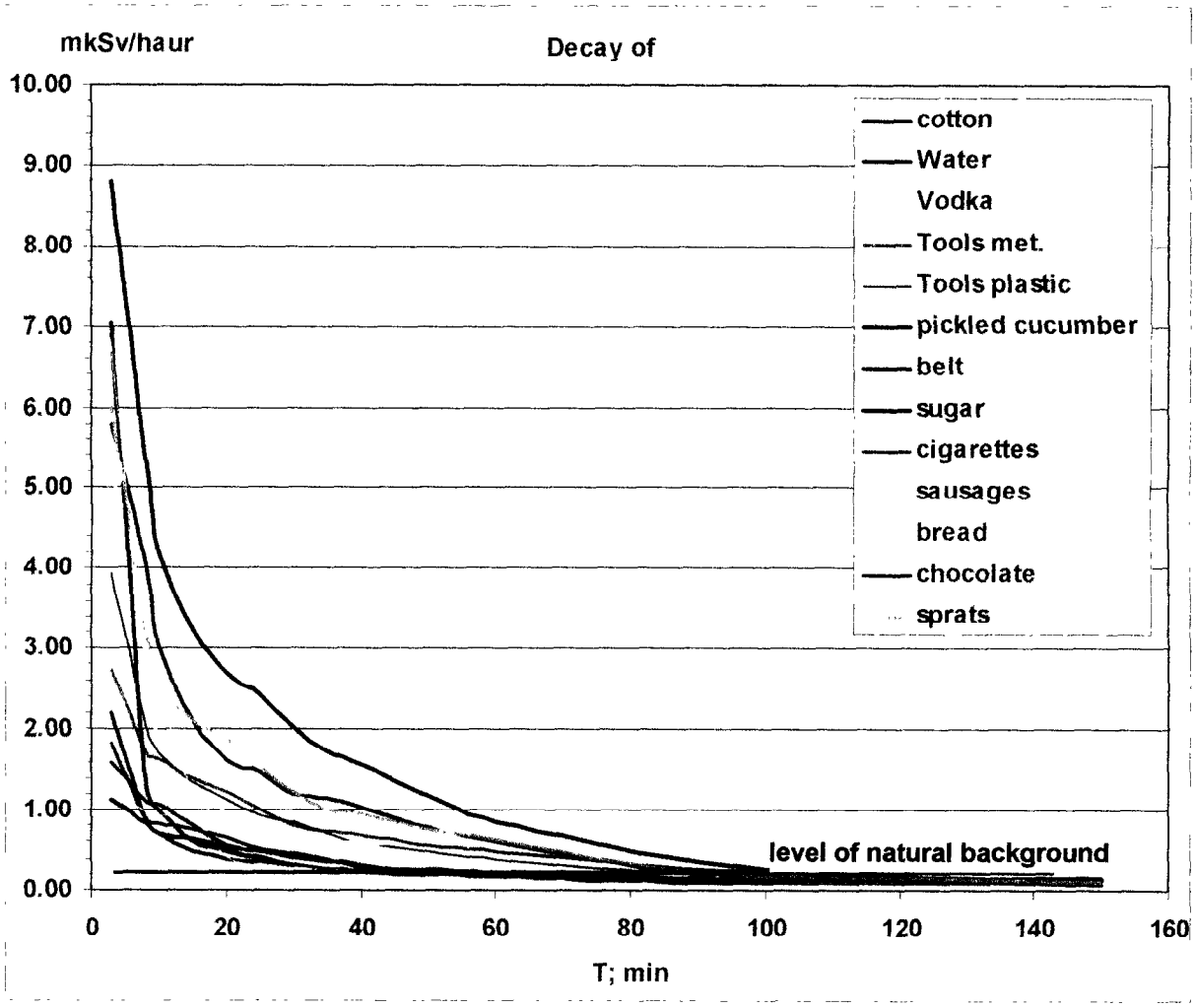
$I_{(flux)} = 8.51 \times 10^{10}$ MeV/sec or, for energy 100 MeV, $I_{(flux)} = 8.51 \times 10^{8}$ $\gamma_{(eff)}$/sec.
$\Delta N(Ik1) = 1.7 \times 10^{10}$ MeV/count or, for energy 100 MeV, $\Delta N(Ik1) = 1.7 \times 10^{8}$ $\gamma_{(eff)}$/count.

Regime of irradiation E(accelerator) = 100 MeV.
Dose by Ik1= **10000 counts** or 1.7×10^{12} $\gamma_{(eff)}$/count.

Table of results (for example #11)

Object	Time of measurement after an irradiation; minutes.		γ-activity, mkR/hour [x100 mkSv/hour]	β-activity, decay/hour	Comments
1	2		3	4	5
Background	9:09 a.m.		6.0	6.0	The moment of time
Background	9:18 a.m.		10.0	2.0	The moment of time
Background	9:27 a.m.		8.0	4.0	The moment of time
Background	9:35 a.m.		10.0	10.0	The moment of time
Background	9:48 a.m.		12.0	2.0	The moment of time
Background	10:00 a.m.		11.0	6.0	The moment of time
Subject - Bread	start - 9:30 a.m. stop - 10:15 a.m.				Time of irradiation by beams of S-25R
	10:18 a.m.	3 min	126	894	Time of measurement after an irradiation
	10:27 a.m.	12 min	86	327	-" -
	10:35 a.m.	20 min	42	175	-" -
	10:50 a.m.	35 min	26	101	-" -
	11:15 a.m.	60 min	21	48	-" -
	11:30 a.m.	75 min	27	27	-" -
	11:45 a.m.	90 min	16	18	-" -
	0:00 p.m.	105 min	14	10	-" -
	0:30 p.m.	135 min	18	2	-" -
	1:00 p.m.	165 min	14	4	-" -

Bread "Ramenskiy" - 300 g, Size: 120x120 mm x 75 mm (length on the beam).


mkSv/haur
Decay of
10.00
9.00
8.00
7.00
6.00
5.00
4.00
3.00
2.00
1.00
0.00
0
20
40
60
80
100
120
140
160
T; min
cotton
Water
Vodka
Tools met.
Tools plastic
pickled cucumber
belt
sugar
cigarettes
sausages
bread
chocolate
sprats
level of natural background