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

March 11, 2004

Please find attached the Application for Variance letter from Valley Forge Composite Technologies (VFCT). 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.

A system to detect explosives in closed containers is at the top of the government's list of technologies for homeland defense. The immediate demand for such a system is demonstrated by our company's associations with the Department of Energy, National Nuclear Security Administration, Transportation Security Agency, and Federal Aviation Administration.

VFCT's Explosives Detection System is not an imaging system but rather a photonuclear detection system that identifies contraband at the molecular level. In order to generate the energy needed to completely penetrate cargo containers, a mini-particle accelerator is used. Energy levels of 55 MeV are generated in very brief pulses to interrogate the container in question. This approach allows detection rates of 99.6% for explosives, narcotics, and fissile material.

VFCT has the solution demanded of our country's top agencies. As high-energy explosives detection technology is in its infancy, VFCT realizes it will lead the way in helping shape government regulations covering this new technology. As such, we look forward to working with your agency and others as standards and regulations are developed and implemented.

Sincerely,

Randy Broadright

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Application for Variance

Valley Forge Composite Technologies (VFCT) is currently conducting research and verification of a "next-generation" Explosives Detection System (EDS) for Homeland Security applications. VFCT's EDS is predicted to be able to detect all explosives, narcotics, and fissile material in a closed container with 99.6% accuracy. Our company is conducting this research and development under a grant from the Department of Energy's National Nuclear Security Administration (NNSA). VFCT has joined forces with Lawrence Livermore National Laboratories, named "the Center of Excellence" in EDS technology, for test and verification. The initial EDS models are designed to inspect cargo containers and baggage. Due to the advanced design of this system and the energy required to thoroughly penetrate a modern cargo container, VFCT requests a variance from the maximum power standard of 10MeV as listed in CFR Title 21 Sec 179.26.

Our EDS technology is not an imaging system but rather a photonuclear detection method. The photonuclear detection method inspects a volume for heightened densities of nitrogen and carbon for 1/50 seconds. An X-ray beam with energy up to 55 MeV is directed through a masking substance. If the X-ray beam passes through an explosive substance, nitrogen - 12 and carbon-13 (natural admixture in C-12 is 1.11 %) elements will result in short-life isotopes nitrogen-12 and boron-12 as a result of the photonuclear reaction.

The key to obtaining this photonuclear reaction lies in the energy generated. Due to the large size of the containers being evaluated and the possibility of contraband being shielded, our EDS must generate 55MeV to completely and accurately penetrate the containers width. VFCT's EDS is comprised of a particle accelerator and detector and its associated computer and software components. This initial model of EDS is designed to examine standard cargo containers measuring approximately 8'x10'x 40' or longer. Compliance with current standards would render the system useless for its intended purpose.

Deviation from the current energy standard will allow our EDS to penetrate with enough energy so as to enable the receivers to register any explosives, narcotics, or fissile material in the container being examined.

VFCT will comply with all applicable Federal, State and Local regulations regarding radiation protection and current means need not be altered. The energy pulse at 55MeV is of 20ms in duration and radiation levels of examined objects falls below normal background radiation levels within 30 seconds.

VFCT's EDS has many different applications – airports, seaports, cargo hubs, military force protection, and international border security. Several government agencies desire this advanced technology and VFCT predicts demand to outstrip production for several years. As such, VFCT requests the variance duration to be 5 years.

Pease forward any questions or requests for additional information to:

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