ACCEPTANCE REVIEW MEMO (ARM)

Reviewer E Assigned:	Browder	ARM reviewer(s): [ARM-Reviewer] 13 rowder
Type of Action:	New License	Date of Requested Action: 6/27/06
Docket No.: 0	030-37298	Mail Control No 버기 [〇 1 년
Licensee:	HiEnergy Technologies, Inc.	License No.: 04-29234-01

Response	Deliciencies Noted During Acceptance Review
\checkmark	1. RAI as noted in email
	2.
	3.

BB **Reviewer's Initials:**

Date: <u>6/30/06</u>

□Yes ☑No	Request for unrestricted use for Group 2 or higher category should be transferred by memo to FCDB within 10 days of receipt.				
□Yes ⊠No	Decommissioning notification should be completed within 30 days.				
□Yes ^I No	Termination request < 90 days from date of expiration				
⊠Yes □No	Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other) Mct 180 day under 150-20				
OYes ONo	TAR needed to complete action.				
Branch Chief's	and/or HP's Initials: 1983 rouder Date: 6/30/06				

J	UNUI Unicerning a	ceording to mo zo	100-01		
⊡Yes □No Non-Pu	blicly Available, S	ensitive if any item	below is checked		
General guidance:					
RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule Exact location of RAM (whether = or > than Category 3 or not) Design of structure and/or equipment (site specific) Information on nearby facilities Detailed design drawings and/or performance information Emergency planning and/or fire protection systems					
Specific guidance for medical, industrial and academic (above Category 3): RAM quantities and inventory Manufacturer's name and model number of sealed sources & devices Site drawings with exact location of RAM, description of facility RAM security program information (locks, alarms, etc.) Emergency Plan specifics (routes to/from RAM, response to security events) Vulnerability/security assessment/accident-safety analysis/risk assess Mailing lists related to security response					
Branch Chief's and/or	HP's Initials:	196Brounder	Date: 6/30/06		

Pre-Licensing Screening

Applicant Information:

Control No. [Control No.]

Name: HiEnergy Technologies, Inc.	Type of Request: New Licensee - Have a general license under 150.20 Program Code(s): 3620			
Location: CA	License No.: 04-29234-01	Docket No.: 030-37298		

STEP 1–Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 Yes or (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a No "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay. A. The request is from a new applicant. but No ICPUSPP -Undor 15020 Β. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or No significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit. C. The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the lb

Table of Risk Significant Quantities

(Category 2 Colaminies, IAEA Salety Guide No: HS-G-1.9, Categorization of Radioactive Sources, August 2005)						
Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	
Am-241	0.6	16 [.]	Pm-147	Pm-147 400		
Am-241/Be	0.6	16	Pu-238	Pu-238 0.6		
Cf-252	0.2	5.4	Pu-239/Be	0.6	16	
Cm-244	0.5	14	Ra-226 ²	0.4	11	
Co-60	0.3	8.1	Se-75	2	54	
Cs-137	1	27	Sr-90 (Y-90)	· 10	270	
Gd-153	10	270	Tm-170	200	5,400	
lr-192	0.8	22	Yb-169	3	81	

The primary values are TBq. The curie (Ci) values are for informational purposes only.
 The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE-If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	Yes , No, or Not Applicable (NA)
Total Activity–multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	NA
Unity Rulemultiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g.,[(total activity for radionuclide A) \div (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) \div (risk significant quantity for radionuclide B)] \ge 1.0.	NIA

Signature and Date for Step 1:

reviewer

Browder 6/30/06

License Reviewer and Date



June 27, 2006

Ms. Rachel Browder, Health Physicist U.S. Nuclear Regulatory Commission, Region IV/DNMS/NMLB 611 Ryan Plaza Drive, Suite 400 Arlington, TX 76011-8064

Re/ NRC License Application

Dear Ms. Browder,

As per our phone conversation and following instructions from your e-mails today, Please find the attached items in support of HiEnergy Technologies application for an NRC license:

- 1. Signed form NRC 313.
- 2. Signed NRC Form 629, authorization to pay by credit card, in the amount of \$3100.00.
- 3. NUREG 1556 vol. 7, appendix C with supplemental data sheet.
- 4. White paper on SIEGMA Radiation Safety.
- 5. HiEnergy Technologies' Radiation Safety Manual.

Due to the size of the supporting documentation, this application package is also e-mailed to you in a zipped file format. Another copy will be faxed to you this evening.

We very much appreciate your help in expediting this application. Please feel free to contact me if you have any questions or need any additional information.

Best Regards,

Alex Vaucher

Dr. Alexander Vaucher Chief Scientist & Vice President, R&D, HiEnergy Technologies, Inc. 1601 Alton Pkwy., Suite B Irvine, CA 92606 Tel. (949) 757-0855 Fax. (949) 757-1477



NRC FORM 313	U.S.	NUCLEAR REG	ULATORY COMMIS	SION	APPROV	ED BY OMB:	NO. 3150-0	120	E	EXPIRES:	10/31/2005
(4-2004) 10 CFR 30, 32, 33,					Estimated hours. Su	i burden per ibmittal of th	e application	is necessary to	determine	that the a	pplicant is
34, 35, 36, 39, and 40					Send com	ments regard	Juate procedu Jing burden e	stimate to the Re	cords and l	FOIA/Privac	and safety. cy Services
					or by inte	met e-mail	to infocollect	s@nrc.gov, and	d to the De	Sk Officer	, Office of
APPLIC	ATION FO	OR MATER	RIAL LICENSE	=	and Budg	jet, Washing	ton, DC 205	03. If a means	used to in	1056 an in	nformation
					conduct c	or sponsor, a	and a person	is not required	to respon	d to, the in	formation
INSTRUCTIONS: SEND TWO COPI	SEE THE AP	PROPRIATE LIC	CENSE APPLICATION	N GUID TO TH	DE FOR D	DETAILED I	NSTRUCTI ECIFIED BE	ONS FOR CON	PLETING		ATION.
APPLICATION FOR DI	STRIBUTION OF	EXEMPT PRODUCT:	S FILE APPLICATIONS WIT	rH: I	IF YOU ARE	E LOCATED IN	:				
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WASHINGTON, DC	20555-0001				MATERI/ U.S. NUC	ALS LICENSIN CLEAR REGUL	G BRANCH ATORY COMM	ISSION, REGION I	11		
ALL OTHER PERSONS	FILE APPLICAT	IONS AS FOLLOWS	:		2443 WA LISLE, IL	RRENVILLE R 60532-4352	OAD, SUITE 21	0			
IF YOU ARE LOCATED) in:										
ALABAMA, CONNECT	ICUT, DELAWAR	E, DISTRICT OF COL	LUMBIA, FLORIDA, GEORO	31A, J	ALASKA, A	RIZONA, ARK	ANSAS, CALIF	ORNIA, COLORAD	DO, HAWAII,	IDAHO, KAN	ISAS,
KENTUCKY, MAINE, M JERSEY, NEW YORK, ISLAND, SOUTH CARC WEST VIRGINIA, SEND	IARYLAND, MASS NORTH CAROLII DLINA, TENNESS DAPPLICATIONS	SACHUSETTS, MISS NA, PENNSYLVANIA SEE, VERMONT, VIR STO:	IISSIPPI, NEW HAMPSHIRE , PUERTO RICO, RHODE GINIA, VIRGIN ISLANDS, C	e, new 1 Or (LOUISIANA OREGON, F OR WYONII	, Montana, I Pacific Trus Ng, Send Ap	VEBRASKA, NI T TERRITORIE PLICATIONS T	EVADA, NEW MEX 8, SOUTH DAKOT 0:	ico, North A, Texas, U	DAKOTA, O TAH, WASHI	KLAHOMA, Ington,
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KING OF PRUSSIA,	PA 19406-1415				ANLING	1014, 1X 7601	1-4003				
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1. THIS IS AN APPLIC	ATION FOR (Che	ck appropriate item)		ł	2. NAME A	ND MAILING A	DDRESS OF A	PLICANT (Include	ZIP code)	ومساد وتقال	
A NEW LI	CENSE				HiEne	ergy Techn	nologies, In	IC.	-		
B. AMEND	MENT TO LICEN	ISE NUMBER			Irvine	B Alton Pa . CA 9260	arkway 6				
C. RENEW	AL OF LICENSE	NUMBER				-					
3. ADDRESS WHERE	LICENSED MATE	RIAL WILL BE USED	OR POSSESSED		4. NAME O	F PERSON TO	BE CONTACT	ED ABOUT THIS A	PPLICATION		
Southeastern 1234 Market	Pennsylvan Street	ia Transit Auth	ority (SEPTA)		Alexa	nder Vauc	her				
4th Floor	Dueer										
Philadelphia,	PA 19107				TELEPH		c .				
Captin John V	venke				(949)	757-0858	i				
SUBMIT ITEMS 5 THRO	DUGH 11 ON 8-1/	2 X 11" PAPER. THE	TYPE AND SCOPE OF INF	ORMATI	ON TO BE	PROVIDED IS	DESCRIBED IN	THE LICENSE AP	PLICATION	guide.	
 a. Element and mas which will be poss 	ERIAL 5 number; b. chen #8sed at any one	nical and/or physical fr time.	om; and c. maiximum amou	int f	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.						
7. INDIVIDUAL(S) RES TRAINING EXPERIE	PONSIBLE FOR I	RADIATION SAFETY	PROGRAM AND THEIR	8	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.				EAS.		
9. FACILITIES AND EQ	UIPMENT.				10. RADIATION SAFETY PROGRAM.						
11. WASTE MANAGEN	ENT.			-	12. LICENSE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY AMOUNT \$ 3,100.00						
13. CERTIFICATION, UPON THE APPLICAN	Must be complete	d by applicant) THE	APPLICANT UNDERSTAND	OS THAT	ALL STATE	MENTS AND P	REPRESENTAT	IONS MADE IN TH	ISAPPLICAT	ION ARE BIN	DING
THE APPLICANT A CONFORMITY WIT CORRECT TO THE	ND ANY OFFICIA H TITLE 10, COD BEST OF THEIR	L EXECUTING THIS E OF FEDERAL REG	CERTIFICATION ON BEHAI ULATIONS, PARTS 30, 32, BEI IFF	LF OF TH 33, 34, 3	HE APPLICA 5 , 36, 39, A	NT, NAMED IN ND 40, AND TH	NITEM 2, CERT	IFY THAT THIS AF	PLICATION ED HEREIN	IS PREPARE IS TRUE ANI	id ini D
WARNING: 18 U.S. ANY DEPARTMENT	C. SECTION 100	1 ACT OF JUNE 25, 1 F THE UNITED STAT	1948 62 STAT, 749 MAKES ES AS TO ANY MATTER W		MINAL OFFI	ENSE TO MAK		Y FALSE STATEME	ENT OR REP	RESENTATIO	ON TO
CERTIFYING OFFICER - TYPEO/PRINTED NAME AND TITLE SIGNATURE				the	Na			DATE 06/27/20	006		
			FOR	NRC	USE OI	NLY					
TYPE OF FEE	ELOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK	NUMBER	COMMENTS		·····			
APPROVED BY			\$	DATE							
	10			_					4	7101	4

Responses to Form NUREG-1556, Vol 7 Appendix C In support of HiEnergy Technologies Application for an NRC License

- 5. Sealed source uses Deuterium Tritium reaction to produce neutrons. Contains on average 1.5 Ci of Tritium in a solid target.
- 6. Sealed source is an integral part of an explosives detection equipment.
- RSO: Alexander Vaucher, PhD, High Energy Physics, and had been with HiEnergy Technologies since July 2004. Authorized Users: Charles Powell, PhD, Nuclear Physics, has been with HiEnergy since 2004. Jared Sjoberg, Field Engineer, has been representing HiEnergy at SEPTA under reciprocity license for one year.
- 8. Please see attached copy of HiEnergy' Radiation Safety Plan, section 3.3.
- 9. All devices and related equipment is stored in a locked facility provided by SEPTA.
- Radiation Monitoring Devices: a) Neutron Dosimeter, Mfg. Health Physics, Inc. Model #5085 Meridian. b) Gamma Dosimeter, Mfg. Bicron, Inc. Model "Micro-Rem". Physical Inventories will be conducted every 6 month to account for all sealed sources.
- 11. Sealed sources generate no external waste products. All depleted sources are returned to the manufacturer for proper disposal as part of the purchase agreement.

Item No.	Suggested Response	Yes	Description Attached
5.	RADIOACTIVE MATERIAL Unsealed and/or Sealed Sources • For unsealed materials:	*	
	 Provide element name with mass number, chemical and/or physical form, and maximum requested possession limit. For potentially volatile materials (e.g., I-125, I-131, H-3), specify whether the material will be free (volatile) or bound (non-volatile) and the requested possession limit for each form. For sealed materials: 		(م) []
	 Identify each Radionuclide (element name and mass number) that will be used in each source. Provide the manufacturer's (distributor's) name and model number for each sealed source and device requested. Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State. Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State. 	*	
:	Provide an Emergency Plan (if required).		
	Financial Assurance and Record keeping for Decommissioning No response is needed from most applicants. If F/A or a DFP is required, submit the required documents as described in Regulatory Guide 3.66.	N/A	[]
6.	PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED List the specific use or purpose of each radioisotope.	*	N

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Item No.	Suggested Response	Yes	Description Attached
7.	INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE		
	RSO		
	Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.	*	ſ
	AUs		
	Provide the name of each proposed AU, with the types and quantities of licensed material to be used. Also provide information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.	*	¶∕1
8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS (Occupationally		
	Exposed Individuals and Ancillary Personnel)	加於	
	Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.	*	Ń

Item No.	Suggested Response	Yes	Description Attached
9.	FACILITIES AND EQUIPMENT		
	Describe the facilities and equipment to be made available at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage, preparation and measurement of radioactive materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. When applicable to facilities where radioactive materials may become airborne, the diagrams should contain schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.	*	ŗ/s
10.	RADIATION SAFETY PROGRAM		
	The applicant is not required to, and should not, submit its audit program to the NRC for review during the licensing phase.	N⁄A	N/A

Item No.	Suggested Response	Yes	Description Attached
10.	RADIATION SAFETY PROGRAM (Cont'd)		
	Radiation Monitoring Instruments	*	
	Describe the instrumentation that will be used to perform required surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."		Ţ/1
	OR		
	Describe the instrumentation that will be used to perform required surveys and state that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Additionally, we will implement the model survey meter calibration program published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."		[]
	Material Receipt and Accountability		
	Develop and maintain procedures for ensuring material accountability,		
	AND		
	State that: "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license."	*	[]

Item No.	Suggested Response	Yes	Description Attached
10.	RADIATION SAFETY PROGRAM (Cont'd)		
·	Occupational Dose		
	State that: "we have done a prospective evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20," or "we will monitor individuals in accordance with the criteria in the section entitled 'Radiation Safety Program - Occupational Dose' in NUREG - 1556, Vol. 7, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Academic, Research and Development and Other Licenses of Limited Scope," dated December 1999."	*	Ţ⁄1
	Public Dose		
	No response is required from the applicant in a license application.	N/A	N/A
	Safe Use of Radionuclides and Emergency Procedures		
	Develop and maintain procedures for safe use and emergencies. State that such procedures have been developed.	*	ſĮ
	If an emergency response plan is needed, submit it as a separate part of the application.	[]	[]

Item No.	Suggested Response	Yes	Description Attached
10.	RADIATION SAFETY PROGRAM (Cont'd)		
	Survey	*	
	State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions."	ţ / 1	[]

Item No.	Suggested Response	Yes	Description Attached
10.	RADIATION SAFETY PROGRAM (Cont'd)		
	OR		
	State that: "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix Q to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer's (distributor's) and kit supplier's instructions. As an alternative, we will implement the model leak test program published in Appendix R to NUREG - 1556, Vol. 7, "Consolidated Guidance about Materials Licenses: 'Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope,' dated December 1999."	[]	
	No response is needed from applicants during the licensing phase.	N/A	N/A

Item No.	Suggested Response	Yes	Description Attached
10.	RADIATION SAFETY PROGRAM (Cont'd)		
	Minimization of Contamination		
	The applicant does not need to provide a response to this item under the following condition. NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: "Radioactive Material - Unsealed and/or Sealed Sources," "Facilities and Equipment," "Radiation Safety Program - Safe use of Radioisotopes and Emergency Procedures," "Radiation Safety Program - Surveys," and "Radiation Safety Program - Waste Management."	N/A	N/A
11.	WASTEMANAGEMENT	*	
	State that: "We will use the model waste procedures published in Appendix T to NUREG - 1556, Vol. 7, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999,"		<i>V</i>
	OR		
	"We will use the (specify either (1) Decay-In-Storage, (2) Disposal of Liquids Into Sanitary Sewerage) model waste procedures that are published in Appendix T to NUREG - 1556, Vol. 7, 'Program- Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999."	H)	

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<u>WHITE PAPER</u> <u>Radiation Safety of SIEGMATM Detector</u>

Sources of Radiation. X-rays, gamma rays, neutrons, protons, electrons, muons, pions, and heavy ions.

Amounts of Radiation received by human tissue are measured in mRems.

<u>Background Radiation</u>. Each man, woman, and child in the United States receives 300 mRem per year of radiation from all "*natural*" sources: medical x-rays, dental x-rays, gamma rays from the walls, floors, and air and the cosmic ray from outer space (which consists of all), and while flying in airplanes.

<u>Allowed Radiation Doze for General Public</u>. Each man, woman, and child is allowed to safely receive 500 mRem/yr of radiation from all sources above the background radiation level. In contrast, the radiation professionals (scientists, MDs, technicians, etc.) collectively called the "radiation workers," can receive 10 times as much, that is, 5000 mRem from all sources.

There are 3 types of radiation exposure of the personnel:

- 1. Direct radiation;
- 2. Radiation through shielding; and
- 3. Residual radiation.
 - 1a. <u>Direct Radiation</u>. Direct radiation from natural sources. "natural sources": medial and dental x-rays, radiation from walls, air and floor; cosmic rays in airplanes.
 - 1b. Direct radiation from SIEGMA[™] when turned off is zero.
 - 1c. Direct radiation from SIEGMA[™] depends on the distance between the device and the person as shown in the following table.



			How many times/yr you can stand the exposure.	
			L	
		Dose		Radiation
		(mRem)	General Public	Workers
At 3 ft.	10 sec.	0.57	877	8,772
66	1 min.	3.35	149	1,493
۲۴	15 min.	50.25	10	100
At 9 ft.	10 sec.	0.0629	7,949	79,491
"	1 min.	0.37	1351	13,514
£ Ę	15 min.	5.55	90	900
At 15 ft.	10 sec.	0.0228	21,930	219,298
66	1 min.	0.134	3,731	37,313
66	15 min.	2.01	249	2,488
At 23 ft.	10 sec.	0.0096	52,083	520,833
٠٠	1 min.	0.0570	8,772	87,719
66	15 min.	0.8475	590	5,900

<u>Type of Radiation Emitted by SIEGMA™</u>. There are two types of radiation emitted by SIEGMA:

- <u>Primary</u> radiation, which are the neutrons of 14 million electron-volts, also written as MeV.
- <u>Secondary</u> radiation,_caused by the primary radiation when it impacts the "target" i.e. the materials to be examined, and the walls and floors. Secondary radiation is mostly x-rays.

<u>Neutron vs. X-ray Danger to the Body</u>. 1 neutron causes 10 times as much damage as an x-ray photon. On the other hand, 1 neutron provides 132 times more radiation as one photon. Hence, one needs 100 times more photons. As a result, neutrons are 10 times less dangerous.

HiEnergy Technologies, Inc. Irvine, California

RADIATION SAFETY MANUAL

HiEnergy Technologies, Inc. Irvine, CA

DOCUMENT NO: RSM-1

REVISION - 0

JUNE 2, 2006

471014

PREFACE

This Radiation Safety Manual was prepared and approved by the HiEnergy Technologies, Inc. Radiation Safety Officer with the assistance of the Radiation Safety Academy, Inc., Gaithersburg, Maryland. This manual was prepared according to guidance given in NUREG 1556, Vol. 12, Consolidated Guidance about Materials Licenses. Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution, December 2000.

Applicable regulations for the State of California and DOT jurisdiction are incorporated into this manual. This document is to serve as a reference for good radiation safety practices. Users of licensed radioactive material must also have technical knowledge of radiation safety and experience in handling radioactive materials. The best way to achieve this knowledge and experience is through training, on the job experience, and asking questions.

The safety requirements and operating procedures described in this radiation safety manual form the radiation safety program for HiEnergy Technologies, Inc. The Radiation Safety Officer will provide users of licensed radioactive materials with a copy of this manual and training as described herein and required by license condition.

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ABBREVIATIONS USED IN THE MANUAL

ALARA	-	As Low As Reasonably Achievable
ARSO	-	Assistant or Alternate Radiation Safety Officer
AU	-	authorized user
Bq	-	Becquerel
Ci	-	Curie
cm^2	-	square centimeters
cpm	-	counts per minute
dpm	-	disintegrations per minute
GM	-	Geiger-Muller
mCi	-	milliCurie
MeV	-	mega electron-Volt
mrem	-	millirem (0.001 rem)
NRC	-	Nuclear Regulatory Commission
Rad	-	Radiation Absorbed Dose
RSO	-	Radiation Safety Officer
R	-	Roentgen
Sv	-	Sievert
TLD	-	thermoluminescent dosimeter
^{3}H	-	tritium (hydrogen-3)

GLOSSARY OF TERMS

Absorbed dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the RAD and the gray (Gy).

Activity is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

ALARA (acronym for "As Low As is Reasonably Achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical and consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of licensed materials in the public interest.

Background radiation means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by State and Federal agencies.

Controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Dose or radiation dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this document.

Dose equivalent means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and Sievert (Sv).

Dosimetry processor means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

Exposure means being exposed to ionizing radiation or to radioactive material. Exposure is measured as ionization in air in units of Roentgen (R).

External dose means that portion of the dose equivalent received from radiation sources outside the body.

Extremity means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

High radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Lens dose equivalent (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2) .

Licensed material means source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the State of California.

License means a radioactive materials license issued by the State of California.

Limits (dose limits) means the permissible upper bounds of radiation doses.

Member of the public means any individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material, from voluntary participation in medical research programs, or as a member of the public.

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material, or from voluntary participation in medical research programs.

Rad – Radiation Absorbed Dose; unit of dose

Radiation (ionizing radiation) means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing

ionization. Radiation, as used in this part, does not include non-ionizing radiation, such as radioor microwaves, or visible, infrared, or ultraviolet light.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

rem – unit of dose equivalent

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Total Effective Dose Equivalent (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates.

(Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and Sieverts)).

Whole body means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

1 Scope of the Radiation Safety Program

The Radiation Safety Program is provided to protect staff, visitors, the public and the environment from the harmful effects of ionizing radiation and to comply with regulatory requirements of the State of California. The program extends to any and all activities related to or associated with HiEnergy Technologies' Irvine, California office regardless of the location of those activities, including other sites, cities, states, countries, or territories.

2 Audit Program

The content and implementation of this radiation safety program will be reviewed annually (at intervals not to exceed 12 months). Audits will be conducted according to the outline provided in *Appendix J, NUREG 1556, Vol. 12, Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.*

3 Description of the Program and Participants

The radiation safety program is administered by the Radiation Safety Officer (RSO). The program is implemented at the functional level by Authorized Users (AUs), or trained radiation workers under the supervision of an AU. The program has been established to ensure that HiEnergy Technologies acts in compliance with its Radioactive Material License and with all State and Federal regulations pertaining to the safe use and handling of radioactive materials and radiation generating equipment. To facilitate these goals, HiEnergy Technologies, Inc. has established policies and procedures for employees and a training program to ensure that all employees are familiar with these procedures and to provide employees with appropriate information to understand and implement good practices for radiation safety.

3.1 The Radiation Safety Officer (RSO)

An RSO is required by the State of California. The RSO is responsible for implementing the requirements of the radioactive materials license, radiation safety policies, and procedures established by this manual. The RSO also takes action as necessary in emergencies. The RSO is the primary contact with all regulatory agencies. The RSO maintains records as required for compliance purposes.

The qualifications and duties of the RSO are provided below.

(Summarized from Appendix G. NUREG 1556, Vol. 12)

- The RSO has received formal training or education in radiation safety.
- The RSO manages the day-to-day operations of the Radiation Safety Program.
- Assures compliance with the regulations of the State of California and the requirements of the HiEnergy Technologies, Inc. license to procure, use, store, secure, and dispose of radioactive materials.
- Ensures security of radioactive material.
- Posts documents as required by the State of California.
- Ensures that licensed material is transported in accordance with applicable DOT regulations.
- Maintains an inventory of all radioactive sources possessed under the license.
- Develops and implements procedures for: periodic radiological surveys of manufacturing facilities; monitoring of personnel; ordering, receiving, and distribution of radioactive materials; and use of sealed radioactive sources.
- Maintains documentation to demonstrate that doses to individual members of the public do no exceed regulatory limits.
- Distributes personnel monitoring equipment, monitors personnel radiation exposures, notifies individuals and their supervisors of radiation exposures approaching established limits, recommends remedial actions to implement ALARA practices.
- Develops, implements, and assures proper training for all personnel involved in any facet of operations involving radioactive materials.
- Assures that all HiEnergy personnel receive periodic review of important procedures, rules, and methods.
- Maintains records of procurement, area monitoring, personnel monitoring, accidents and incidents, inventories, and any other required documents.
- Oversees the storage of radioactive materials not in current use.
- Approves requests to purchase radioactive materials after assuring that only Authorized Users place orders and that the orders for radioactive materials do not exceed established limits under HiEnergy Technologies, Inc.'s license.
- Responds to all emergencies involving radioactive materials and provides advice and assistance as required by the program.
- Interacts with the State of California on issues related to HiEnergy Technologies Inc's licenses, license amendments, application renewals, and inspections.
- Assures that all facets of the radiation safety program are compliant with the "As Low As Reasonably Achievable" (ALARA) philosophy.
- Immediately terminates any unsafe condition or activity that is found to be a threat to public health and safety or property.
- Holds periodic meetings with, and provides reports to, HiEnergy Technologies, Inc. management.
- Performs periodic audits (at intervals not to exceed 12 months) of the radiation safety program content and implementation.

- Ensures that the results of audits, identification of deficiencies, and recommendations for changes are documented (and maintained for at least 3 years), and communicated to management and other personnel and ensures that prompt actions are taken to correct deficiencies.
- Ensures that all incidents, accidents, and personnel exposures in excess of regulatory limits are investigated and reported to the State of California, if required, within the required time limits.
- Maintains an understanding of, and up-to-date copies of, State and Federal regulations, revised license procedures, and ensures that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments made to the State during the licensing process.

NOTE: The Assistant or Alternate Radiation Safety Officer (ARSO) will assist the Radiation Safety Officer with the duties listed above. In the event the RSO is unable to perform the duties outlined above, for any reason including illness, travel, or vacation, the ARSO will temporarily serve in that role until either the RSO is able to return to service or a new RSO is appointed and authorized by an amendment to the license.

3.2 Classification of Participants

In terms of the Radiation Safety Program, all persons entering the HiEnergy Technologies, Inc. premises may be classified into one of four distinct categories – visitor, non-trained worker, trained worker, and Authorized User (AU). These categories are based upon the level of training and the rights and responsibilities of individuals. Descriptions of these four categories are presented below.

3.2.1 Visitors

A visitor is a guest to the HiEnergy facilities who is not an employee of HiEnergy Technologies, Inc. With respect to issues dealing with radiation safety, visitors may have access to any location within the facility. However, while within restricted areas, visitors must be escorted by an AU or trained radiation worker at all times.

3.2.2 Non-trained Workers

A non-trained worker is an employee of HiEnergy Technologies, Inc or a third party individual working for HiEnergy who has not received basic radiation safety training and has therefore not been approved by the RSO to work with licensed radioactive sources. With respect to issues dealing with radiation safety, non-trained workers may have access to any location within the facility. However, while within restricted areas, non-trained workers must be escorted by a trained worker or AU at all times.

3.2.3 Trained Workers

A trained worker is a guest or an employee of HiEnergy Technologies, Inc or a third party individual working for HiEnergy who may work with radioactive materials under the supervision of the RSO or an AU. To become a trained worker, one must successfully complete a Basic Radiation Safety (BRS) course as approved by the RSO. Annual refresher training in radiation safety is required of all approved trained workers. Refresher training will include a review of one or more of the topics listed below.

An approved BRS course will include the following topics:

- Radiation Safety Awareness (one hour) to include:
 - Exploring views on radiation
 - Understanding sources of radiation around us every day
 - A review of HiEnergy Technologies, Inc. registered devices and potential for radiation exposures
 - Summary and answer questions
- Fundamentals of Radiation Safety (six hours) to include items listed in Appendix H, Radiation Safety Training, NUREG 1556, Vol. 12, Consolidated Guidance about Materials Licenses, Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution.
 - What is radiation, radioactivity, and contamination
 - What are the health effects of radiation, internal vs external exposures
 - A review of radiation detection instruments, surveys, and personnel dosimetry
 - State and Federal regulatory requirements, licensing, inspections
 - Requirements of HiEnergy Technologies, Inc. Radiation Safety Manual, the radioactive materials license issued by California, and the license application.
 - Program audits, record keeping, postings, labeling
 - Need for complete and accurate information and Notice to Employees information
 - Principles of ALARA (time, distance, and shielding)
 - Safe operating and emergency procedures, handling and reporting of incidents
 - Theory and operation of registered devices
 - Hands-on inspection and dose rate measurements of registered devices
 - Summary and answer questions
 - A written examination (75% passing grade required)

The duties of trained workers are listed below.

- Complete an approved BRS course.
- Wear issued radiation dosimeters at all times in restricted areas posted for radioactive materials.
- Practice principles of ALARA using time, distance, and shielding to protect themselves from radiation exposure.
- Be familiar with the location(s) of radioactive sources.
- Report any observed radiation safety infractions, shortcomings, or failures to the RSO in a timely manner.

3.2.4 Authorized User

Authorized Users (AUs) may work with radioactive materials independently and have the authority to supervise trained workers. AUs are individuals who have received training in the safe use and handling of licensed radioactive materials or equipment and who have been named on the license issued by the State of California. AUs are responsible for the safe use of licensed materials and equipment, and compliance with regulatory requirements.

Each AU must be familiar with State of California *Rules and Regulations Pertaining to Radiation Control*, safe radiological procedures, and all related requirements of the HiEnergy Technologies, Inc. radiation safety program. AUs are expected to fully support the ALARA program.

The duties of AUs are listed below.

- Attend the HiEnergy Technologies, Inc. Radiation Safety Training BRS course (described above) prior to beginning work with radioactive materials, unless working under the supervision of a licensed AU. Any exceptions to this must be made by the RSO.
- Read the HiEnergy Technologies, Inc. Radiation Safety Manual and be responsible for its contents as applicable to their duties.
- Receive necessary on-the-job training from the RSO as it relates to the duties of the job.
- Call emergency medical services or the fire department (both at 911) immediately for any fire, explosion, or major accident and tell the dispatcher that the accident involves radioactive materials. Then, notify the RSO immediately.
- Notify the RSO immediately of any known or suspected overexposure of personnel.
- Properly display signage designating radionuclide usage in the manufacturing facilities.
- Instruct trained workers in the proper use of personnel monitoring equipment such as thermoluminescent dosimeters (TLD's) when appropriate, and confirm that they are always worn when required in the posted areas of the HiEnergy Technologies, Inc. facility.

- Keep complete and accurate records of all radioactive sources in his/her possession. Update personal inventory to RSO when requested. Each Authorized User should have an up-to-date record of the quantity of sources on hand in their work areas at any given time.
- Assist the RSO in any surveys that are conducted as part of the HiEnergy Technologies, Inc. Radiation Safety Program.
- Ensure that all problems related to radiation safety are identified and corrected in a timely manner or as soon as identified as the result of an authorized survey.
- Notify the RSO if work with radioactive sources is no longer planned. The AU can permanently discontinue work with radioactive materials, or can be put on Inactive status, which would imply that work may continue in the future.

3.3 Training

All workers who use licensed radioactive sources must receive instruction in radiation safety, the biological effects of radiation, regulatory requirements, and the ALARA philosophy. The type of radiation safety training required for individuals depends on the nature of their involvement with sources of radiation.

Records of all training, including documentation of attendance are required to be maintained by the RSO for review by State of California inspectors.

The BRS course will be made available to all HiEnergy Technologies, Inc. personnel who plan to operate as 'trained' workers or Authorized Users. The training will consist of either conventional classroom training or may take advantage of appropriate computer-based training offerings. At a minimum, the BRS course will include a discussion of all radiological hazards that workers may encounter, including fires or other incidents, and is intended to inform personnel about radiation hazards and appropriate precautions.

Assessment of the successful conveyance of training information will be performed by a written examination and observation of individuals in the performance of licensed duties.

Successful completion of the BRS course leads to the trained worker classification. After this training, a request may also be made by the RSO to add this person to the license as an Authorized User.

In addition to the initial worker BRS training, the RSO will provide annual refresher radiation safety training. The refresher training will cover one or more aspects of the HiEnergy Technologies, Inc. radiation safety program or other appropriate issues as determined by the RSO. The intent is for the refresher training content to vary from year to year.

Qualifications of the Radiation Safety Trainer

Training materials will be prepared by a Certified Health Physicist who is knowledgeable about the licensed materials in use by HiEnergy Technologies, Inc. and who is a specialist in radiation

safety training. For example, training could be prepared and provided by Mr. Raymond Johnson, MS. PE. FHPS, CHP, Director of the Radiation Safety Academy. Mr. Johnson could also train the RSO, ARSO, or other qualified Authorized Users to present the training.

3.4 Radioactive Materials License

A Radioactive Materials License has been issued to HiEnergy Technologies, Inc by the State of California permitting the acquisition, possession, use, and handling of radioactive material. The license defines the types, quantity limits, application, and location of radioactive materials. Any change in the status of these radioactive materials requires prior approval by the RSO and possible modification of the state license.

3.5 "As Low As Reasonably Achievable" (ALARA) Philosophy

The radiation safety program at HiEnergy Technologies, Inc. fully supports the concept that all radiation doses should be ALARA. Our ALARA program depends on the cooperation of all users of radioactive sources. The program includes the use of proper equipment, techniques, and procedures to lower radiation exposure. The RSO will perform an ALARA investigation of any whole-body dose equivalent in excess of 100 millirem (mrem) or shallow dose equivalent in excess of 500 mrem in any one month. Corrective actions stemming from these investigations may require a change in training, policies, procedures, or an increased application of the principles of radiation protection (time, distance, and shielding).

Maintain ALARA exposures by practicing the basic principles of radiation protection.

The licensed activities at HiEnergy Technologies, Inc. are such that exposure to radiation is only possible through exposure to external radiations. External radiation protection is attained through the application of the principles of time, distance, and shielding.

Minimize time of exposure – The less time you remain in a radiation field, the smaller the dose you receive.

Maximize the distance from the source – The dose rate for most radiation sources varies with the inverse square of the distance from the source. Therefore, the further you position yourself from the source of radiation, the smaller the dose you receive. For example, doubling the distance from a radiation source will result in 1/4 the exposure in the same amount of time. Even a small increase in distance can result in a dramatic decrease in dose rate.

Shield the radiation source – Place shielding between yourself and a source of penetrating radiation to decrease your dose. For gamma rays emitted from activation products, lead is used when exposure rates are significant. For neutrons, concrete bricks and masonry are good for radiation protection.

4 **Policies & Regulations**

4.1 Radiation Safety Orientation

Users of radioactive materials and equipment must be knowledgeable of regulations and safety procedures and are required to attend the BRS course. Ancillary personnel whose duties may require them to work in the vicinity of radioactive materials should receive Radiation Awareness Training (described above) to inform them of radiation hazards and receive basic instructions in radiation safety (risks, signs and symbols, emergency contacts, and procedures).

4.2 Regulatory Standards for Radiation Protection

Use of radioactive materials is regulated and licensed by the State of California Department of Health Services (DHS) and by reference, the Nuclear Regulatory Commission (NRC). The license references the California Radiation Control regulations (California Administrative Code, Title 17, Sections 30100-30380 and Title 10 Part 20 of the Code of Federal Regulation) for the control of ionizing radiation. Additional requirements are included in the license issued to HiEnergy Technologies, Inc. governing the possession and use of radioisotopes. Employees are required to abide by these standards and the current license.

4.3 Radiation Exposure Limits

The HiEnergy Technologies, Inc. Radiation Safety Program is designed to reduce all radiation exposures, above background level, to a level "As Low As Reasonably Achievable" (ALARA). The annual limits cited below have been established by the State of California and NRC for adult workers. Actual worker doses should be much lower than the regulatory limits.

Total Effective Dose Equivalent (Whole Body)	5	rem
Individual Organs, Deep Dose Equivalent	50	rem
Eye Dose Equivalent	15	rem
Skin or extremity	50	rem

Additional annual dose limits have been established as follows:

Embryo/fetus	0.5	rem (for the duration of declared pregnancy)
Public, Total Effective Dose	0.1	rem or no more than 0.002 rem in any 1 hour

4.4 Facilities

Radioactive materials may only be used as described in the license and in locations approved by the RSO. Personal protective equipment (PPE) is not required for the working on the SIEGMA

3E3 or 3E3 neutron generators. However, neutron generators must be stored in secured areas and in a manner to minimize the risk of breakage, damage, or theft. All facilities must be posted with appropriate warnings and notices.

HiEnergy Technologies, Inc. has built shielded labyrinth test chambers in the area called "The Lab." Neutron generators will only be operated within the test chambers, with proper interlocks and warning lights in operation. Operators will not enter the test chambers when a neutron generator is in operation, as indicated by the red warning lights at each corner of the test chambers.

When necessary to operate the neutron generators outside of the test chambers, such as for demonstration or at a client's location, a restricted area of about 30 feet will be established around the neutron generator according to procedures described in the Operators Manual for the Siegma 3E3 and 3M3. Restricted areas will be defined by a roped perimeter or by visual observation and verbal warnings to anyone approaching an exclusion area of 30 feet from the neutron generators.

4.5 Signs, Labels, and Notices

Entrances into posted areas containing radioactive materials must be conspicuously posted as noted below and with a California DHS Form RHB 2364 "Notice to Employees" so that they can be easily seen by persons entering or leaving a restricted area. All signs and labels required shall bear the conventional radiation symbol in magenta or purple on a yellow background. Signs and labels are available from the RSO. Posting will also include a "Notice of Availability" to show where the Regulations, Radiation Safety Manual, and Emergency Operating Procedures may be found.

Areas / Facilities:

Unrestricted Area	An area with no limited access. No special signs or postings are needed for these areas.
Restricted Area	An area with access limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.
	These are further explained below.
Radioactive	
Materials Area	An area not meeting one of the below definitions, but containing radioactive materials.

Special Posting Required

"CAUTION - RADIOACTIVE MATERIALS"

Radiation AreaAn area accessible to individuals in which radiation levels could result
in an individual receiving a dose equivalent in excess of 5 mrem (0.05
mSv) in 1 hour at 30 centimeters from the radiation source or from any
surface that the radiation penetrates.

Special Posting Required

"CAUTION – RADIATION AREA"

High Radiation Area An area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 100 mrem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Special Posting Required

"CAUTION – HIGH RADIATION AREA"

Containers:

Storage Container

A temporary or permanent container used for storing radioactive materials

Special Posting Required

"CAUTION-RADIOACTIVE MATERIALS" (Labels must also include isotope, activity and date)

A label is not required on a container when it is continuously attended by the responsible user.

Equipment:

Equipment Containing Sealed Sources

For equipment containing sealed sources such as a tritium foil in a metal hydride.

Special Posting Required

"CAUTION-RADIOACTIVE MATERIALS"

Indiscriminate use of radiation signs and/or labels is prohibited. Such use conveys a false warning, which can breed disrespect for real hazards.

4.6 Inventory

The RSO will keep and maintain an up-to-date inventory of radioactive materials. Workers shall notify the RSO of any and all changes in inventory prior to effecting said change. A physical inventory will be conducted for all licensed radioactive sources every six months. The RSO will maintain records of these inventories for State inspection.

4.7 Personnel Monitoring

External dosimeters from a NVLAP accredited vendor will be provided to all persons who work in the manufacture or testing of SIEGMA 3E3 and 3M3 devices (trained workers and Authorized Users). They will be exchanged on a monthly basis.

4.8 Radiation Instruments and Calibration

Radiation survey meters and detection equipment shall be obtained, maintained, and calibrated annually and after all repairs.

HiEnergy Technologies, Inc. will employ two types of radiation dose rate instruments, a gamma exposure meter and a neutron exposure meter. Currently, for gamma exposure rates, HiEnergy Technologies, Inc. is using the "microRem" model manufactured by Thermo Electron Corporation.¹ This is a plastic scintillator with an energy independent response over a wide energy range. The neutron survey instrument in use is the "Meridian 5085" model manufactured

¹ The "microRem" model x-ray/gamma-ray tissue-equivalent survey monitor was formerly known as the Bicron-St. Gobain microRem (or microSievert) model. The Radiation Measurement division of Bicron-St. Gobain is now a part of Thermo Electron Corporation.

by Far West Technologies.² This is a "rem ball" type instrument. Both of these types of instruments are used:

- 1) to verify the combined gamma and neutron exposure levels at the operator's location remotely from the bomb detectors,
- 2) to determine where to set a restricted area when the bomb detectors are in use at temporary job sites, and
- 3) to determine the presence of neutron activation products after use of the bomb detectors.

One or more of each of these radiation detection instruments will be maintained for use at the Irvine address. One of each type of dose rate instruments will also be sent with the bomb detectors for use at off-site locations. HiEnergy Technologies, Inc. reserves the right to upgrade to other radiation detection instruments.

HiEnergy Technologies, Inc. also has a small single-sample Liquid Scintillation Counter, Hidex Triathler Bioscan Type 425-034. This instrument will be used for acceptance testing of neutron generators as shipped from Thermo MF. Physics. Inc. to determine the presence of any tritium contamination on the outside of the neutron generator housings.

Current Inventory:

Make and Model	Description	# Available	Purpose
Meridian Model 5085	Neutron Survey Mete	r 2	Exposure monitoring
Thermo Electron Corp. MicroRem	Plastic Scintillator	2	Exposure monitoring
Hidex Triathler Bioscan Type 425-034	Liquid Scintillation Counter	1	Acceptance testing

4.9 Leak Tests

The sources on the HiEnergy Technologies, Inc. license are exempt from leak test requirements.

4.10 Exposure Limits and ALARA

Users of materials and equipment are responsible for preventing exposures in excess of limits specified in the State of California Radiation Control regulations. Additionally, use of materials

² More information and an operator's manual for the Meridian 5085 can be found at: http://www.fwt.com/hpi/hpi_5085ds.htm

and equipment shall be designed and used to keep exposures As Low As Reasonably Achievable (ALARA). If an exposure above allowable limits is suspected it must be reported immediately to the RSO.

The RSO will investigate any monthly exposures exceeding 100 mrem. Changes in training, practices, or policies may be made as appropriate for reducing monthly exposures and maintaining ALARA.

4.11 Waste

No radioactive waste will be generated at HiEnergy Technologies, Inc. based on the current licensed activities.

4.12 Accidents, Emergencies, Security

All accidents, emergencies, loss or theft involving radioactive materials and equipment must be reported immediately to the RSO.

4.13 Shipping

All licensed materials shipped from HiEnergy Technologies, Inc. facilities or by HiEnergy personnel require the prior review and approval of the RSO and shall be in accordance with the Department of Transportation and other pertinent regulations.

5 **Regulations**

Copies of all relevant State and Federal regulations will be maintained by the RSO.

6 Radiation Monitoring

6.1 Surveys

The RSO or designee will perform monthly dose rate monitoring consisting of integrated neutron and gamma doses recorded on area dosimeters (TLDs). Area dosimeters will be placed in representative locations in and adjacent to where neutron generator tubes are energized to document acceptable dose rate conditions. These data may be supplemented by collecting realtime dose rate measurements using suitable radiation survey instruments for quantifying neutron and gamma ray dose rates, as appropriate. Area dosimeter survey data will be maintained by the RSO. Any instrument used to collect survey measurements must be calibrated at least annually. Certificates of calibration will be maintained by the RSO.

In addition to routine dose rate surveys, potentially contaminated areas must be surveyed:

- After any spill, leak, fire, or other disturbance in the facility;
- When work with any unsealed radioactive materials is terminated;
- Before maintenance or removal of any equipment that may have come in contact with radioactive material or that contains radioactive material.

Should contamination surveying be necessary, the RSO will arrange for contractor support from a licensed vendor with experience in contamination monitoring and decontamination.

6.2 Dosimetry

Dosimeters -- Personal monitoring devices (dosimeters) are required for workers who handle radioactive material or who may receive 10 percent of the maximum dose of external radiation permissible under California regulations. The RSO will request the dosimetry records of new radiation workers from other institutions where they used radioactive materials for the current year in order to establish compliance with annual dose limits. Records of employee radiation exposure history shall be maintained by the RSO.

Dosimeters will be used for monitoring gamma and neutron exposure. As mentioned above, the RSO will use area radiation dosimeters to monitor levels of radiation in posted areas.

Employees must wear issued dosimeters while working with radioactive materials in posted areas. While not being worn, dosimeters should be stored away from all radiation sources in a "background" area. They are not to be taken home, although they should be taken to client sites where SIEGMA 3E3 devices are operated, installed, or serviced.

NOTE: Individuals issued radiation dosimeters will be provided with copies of their dose history annually; it is recommended that they be reviewed upon receipt.

Any dosimeter contaminated or exposed to excessive heat, moisture, or medical x-rays should be returned to the RSO for replacement. After any accident or if an overexposure is suspected, the dosimeters should be returned immediately to the RSO to be read. Dosimeters should be worn on a shirt, coat pocket, lapel, or in some other position between the waist and the shoulders that will be representative of any radiation exposure.

6.3 Bioassay

Given the terms and conditions of the license, it is not possible that workers will receive intakes of radioactive materials under normal conditions. Therefore, no routine bioassay program will be implemented. Should an incident warrant internal dose monitoring, the RSO will arrange for bioassay sample collection and analysis. Bioassays for tritium are obtained by urine samples.

7 Declared Pregnant Woman

It is recognized that the human embryo and fetus are more sensitive to radiation than are adults. Therefore, the dose limit to the embryo/fetus is set at 0.5 rem for the entire term of a woman who declares pregnancy in writing. An employee who is pregnant or thought to be pregnant has the option of identifying herself as a "Declared Pregnant Female." Declaration of this status invokes certain obligations on the part of the employer as listed below. However, the more rigorous dose limit is applicable only to women who declare pregnancy in writing. All pregnant employees may voluntarily choose to formally notify their supervisor or the RSO so that dose reduction steps can be taken; however, notification is strictly voluntary.

7.1 Declaration

Pregnant employees, if they so desire, should notify their supervisors in writing when they become pregnant or they intend to become pregnant. The notification should include the date of declaration, estimated date of conception, and expected date of birth.

7.2 Supervisor Responsibility

The supervisor, in a confidential manner, shall notify the RSO of all declarations and provide copies of all declarations.

7.3 RSO Responsibility

The RSO will meet with the declared pregnant female employee and, at a minimum, provide a copy of *Nuclear Regulatory Commission Regulatory Guide 8.13 'Instruction Concerning Prenatal Radiation Exposure.'* The RSO will investigate and document the nature of the employee's work and the potential radiation levels in the working area. The RSO will determine if personal monitoring is required and will implement monitoring if necessary. The RSO will determine what steps are necessary to maintain all doses to the embryo/fetus below allowable limits.

7.4 Exposure Limits

The maximum dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, shall not exceed 0.5 rem. An employee who becomes pregnant is strongly encouraged to notify her supervisor and the RSO in writing as soon as possible. The RSO will inform the pregnant woman and her supervisor of individual actions that may need to be taken to ensure compliance with the 0.5 rem limit.

ALARA recommendations on pregnancy and radiation exposure include:

- Notifying supervisor immediately when pregnancy is known or suspected.
- Using appropriate shielding while performing work with certain radionuclides.
- Wearing radiation dosimeter at the waist.

8 **Procuring Radioactive Materials**

No radioactive sources may be ordered without the approval of the RSO or ARSO. Orders for neutron generator tubes must not be placed with the vendor without written approval.

9 Receiving Radioactive Materials

Prior to moving out of the receiving area, all packages containing radioactive materials must be surveyed to determine if the exterior is contaminated and/or if the contents are intact. Package receipt and opening procedures may be implemented by the RSO, AU, or other trained worker. Once opened and surveyed, the package receipt form is signed and dated. After being recorded in the radioactive material logbook, packages will be delivered to the appropriate areas.

The following package opening procedure will be followed:

- 1. Wear gloves to prevent hand contamination
- 2. Visually inspect the package for any sign of damage (e.g. crushed, punctured). If damage is noted, stop and notify the RSO.
- 3. Check DOT White I, Yellow II, or Yellow III label or packing slip for activity of contents, to ensure that the shipment does not exceed the license possession limits.
- 4. Monitor the external surfaces of a labeled package.

- 5. Open the outer package and remove packing slip. Open inner package to verify contents (compare requisition, packing slip and label on the bottle or other container). Check integrity of the final source container (e.g., inspecting for breakage of seals, discoloration of packaging material, etc.). Again check that the shipment does not exceed license possession limits. If anything unexpected is found, stop and notify the RSO.
- 6. Maintain records of receipt and package survey.
- 7. Notify the final carrier and notify the DHS if external radiation levels exceed the limits of 10 CFR 71.47.

If an opened package is found to have compromised contents, the RSO must be notified immediately for guidance. The package should be contained in a restricted area to minimize spread of contamination until it can be safely sealed and removed.

AUs must notify the RSO upon receipt of all licensed sources. Inventory records will be updated as appropriate. Shipping and transfer documents must be forwarded to the RSO where they will be maintained in the radiation safety files.

10 Transportation of Radioactive Materials

Transportation of radioactive materials must be in accordance with all applicable rules and regulations as promulgated by the U.S. Department of Transportation (DOT). Packages of licensed material that are to be offered for transportation can only be prepared by persons who have completed HAZMAT training requirements specified in 49 CFR 172 Subpart H. If the licensed radioactive material will be transported by ground, the shipper must follow the DOT requirements for packaging. If the licensed radioactive material will be shipped by air, you should contact the carrier to determine if the package must be prepared in accordance with International Air Transport Association (IATA) requirements.

The neutron generator used in the SIEGMATM 3E3 is classified as a Class 7 (Radioactive) Material. The neutron generator is categorized as a "radioactive instrument or article". When a neutron generator is being prepared for shipment, it must be placed in a package that meets the DOT's Class 7 package general design requirements (see 49 CFR 173.410). The package must be marked on the outside with the code "UN2911". The name and address of the shipper or recipient must be clearly marked on the outside of the package.

The following requirements apply:

- The dose rate at any point on the surface of the package must not exceed 0.5 mrem/hr,
- The dose rate at any point 10 cm from the unshielded generator must not exceed 10 mrem/hr,

• Removable radioactive contamination on the outside of the package may not exceed 22 dpm/cm² when averaged over at least 300 cm².

If shipped by air under IATA regulations, the following additional information must be marked on the outside of the package:

- the phrase "Radioactive Material, excepted package-Instruments or Articles",
- the name and address of both the shipper and recipient,
- permissible gross weight, if over 50 kg.

Be sure to keep records showing the transfer of radioactive materials to other organizations.

11 Storing Radioactive Materials

Any radioactive material in use must be attended at ALL TIMES, or secured by locking the room when vacated. Radioactive materials may not be left unsecured. Radioactive materials in storage, i.e. not being used, must be secured when the room in which it is stored is unoccupied. The required security may be accomplished by locking the room while unoccupied, or alternatively, by locking the radioactive materials within cabinets or locked boxes. Wherever possible, locked boxes are recommended for storage of radioactive materials. Only the RSO and AUs may have access to radioactive materials. Radioactive materials that are stored or used in areas common to both authorized and unauthorized personnel must be secured at all times from unauthorized personnel. It is strongly recommended that all areas containing radioactive materials be locked when unoccupied during daytime hours and at night.

12 Emergency Procedures

Notify the RSO as soon as possible of all radiation emergencies. The RSO or his/her designee will investigate all accidents, spills, fires, or other incidents in which radiological material is involved. In the event of an accident, the RSO or his/her designee will assist by providing technical advice and by monitoring personnel.

The RSO or his/her designee has the responsibility to plan and to arrange emergency medical care for victims contaminated with radioactive material or overexposed to radiation at the HiEnergy Technologies, Inc. facility. The RSO or his/her designee will ensure that procedures for emergency care, a list of telephone numbers, and contacts are made available to all Authorized Users.

12.1 General Emergency Procedures

All users of radioactive materials should be familiar with these procedures before any emergency arises.

When an accident involving radioactive materials occurs, address the greatest hazard first. Lifesaving measures always take precedence over decontamination or other concerns. Advise personnel working nearby of any hazard or accident as soon as possible and prevent them entering the hazardous area. Notify RSO or his/her designee if an incident occurs.

If the neutron tube were to be broken due to shock or vibration, the tritium gas in the tube (operating tube) and/or the tritium adsorbed on the inner surfaces of the tube would escape into the accelerator head and be contained within the sealed accelerator head. No tritium would be released into the environment. The total amount of tritium released into the accelerator head would be about 1-2 milliCuries. None of the tritium contained in the ion source reservoir or the target will be released into the accelerator head should immediately be sealed into a plastic bag. As a further precaution, the accelerator head could then be sealed into a container fabricated from PVC water pipe. These operations should be done under the supervision of the RSO. Contact the neutron generator tube manufacturer, Thermo MF Physics, for further instructions. The accelerator head should not be opened under any conditions. So long as the sealed accelerator head remains intact, there will be no external release of tritium.

If the neutron tube is broken and the accelerator head is breached, a small amount of tritium gas (~1-2 milliCuries) could be released into the environment. None of the tritium contained in the solid ion source reservoir or the target will be released. The RSO should be contacted immediately. Using the proper precautions, the RSO should first test the exterior surfaces of the accelerator head and surfaces in the immediate area for the presence of tritium. The accelerator head should then be sealed in plastic and placed in a secure container such as PVC pipe. Contact Thermo-MF Physics for further instructions.

If the accelerator head seal is broken, and the accelerator head is subjected to very high temperatures, such as may exist in a fire, some or all of the tritium in the ion source and target could be released as a gas. The released tritium will be dispersed as a gas, or tritiated water vapor, into the environment.

12.2 Specific Emergency Procedures

Fire

- 1. If minor, immediately attempt to put out the fire by approved methods (i.e., fire extinguisher) if other fire hazards are not present.
- 2. Notify all persons present to vacate the area and have one individual immediately call the RSO and the fire department.

- 2. When calling 911, tell the dispatcher that radioactive materials are involved.
- 3. Once the fire is out, isolate the area to prevent the spread of possible contamination.
- 4. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and washing with a mild soap.
- 5. In consultation with the RSO, determine a plan of decontamination for the affected area.
- 6. Do not continue work in the laboratory without RSO or his/her designee approval.

(Again, call 911 without delay for any serious injuries. Give as much information as possible regarding the nature of the accident and the injuries that are present. Do not hang up the phone until you are instructed to do so.)

Explosion

- 1. For any accident involving serious injuries, first call 911. Do not delay. Inform the dispatcher that the accident involves radioactive material.
- 2. Perform any lifesaving and first-aid measure that you can. There may be a significant amount of time before the Hazardous Material (HAZMAT) unit can get to the accident.
- 3. Call the RSO or his/her designee.
- 4. Turn off all fume hoods and ventilation where possible.
- 5. If possible, evacuate the area of the explosion. Restrict contamination to the area by removing your gloves, shoes, and laboratory coats before leaving.
- 6. Wash all contaminated areas of skin thoroughly, without vigorous scrubbing, with cool water and mild soap for five to ten minutes. Do this as soon as possible after the accident.
- 7. Flush any superficial wound thoroughly with cool water and cover with a sterile dressing.
- 8. Remember also to remove all clothing that may have been contaminated. (Take care not to re-contaminate yourself.)
- 9. Do not leave the area until someone (RSO or his/her designee) has determined that you have been successfully decontaminated.

During Device Testing

For emergencies encountered during testing operations of a SIEGMA 3E3 or 3M3 device, implement the following procedure:

- 1. The generator can be deactivated remotely via computer running the generator control software. Disconnecting the serial communication line between the computer and the generator control unit also results in the de-activation of the generator. The generator can also be deactivated by disconnecting the 12 volt power supply.
- 2. In the event of an exposure rate in excess of 2 mR/h at or beyond the restricted area, the generator will be deactivated, and the safety perimeter will be widened. Exposure rate measurements will be acquired at the new perimeter to ensure safe operation of the generator.
- 3. In the event of damage or breakage of the neutron tube, the parts will be placed in a double plastic bag using gloves. Each bag will be sealed and placed in a sealed shipping container. After leak and surface contamination testing, the container must be returned to Thermo MF Physics (the tube manufacturer) for legal destruction. The area surrounding the incident will be surveyed to determine the amount (if any) of contamination resulting from the breakage.

12.3 Personal Contamination

Thorough, gentle washing with soap and water is the best general method. However, it is most important not to harm the integrity of the skin, as that can make the problem worse. Avoid overuse of detergents. In all cases avoid use of organic solvents as they may increase absorption through the skin. Contact the RSO for assistance.

12.4 Contaminated wounds

Skin lacerations should be washed by large volumes of cold water. If bleeding is not too severe, allow bleeding to further cleanse the wound. Notify RSO immediately and administer first aid.

12.5 Ingestion

Accidental ingestion should be treated by drinking any type of diuretic to flush the tritium from the body. Notify RSO immediately.

12.6 Inhalation

Inhalation should be treated by drinking any type of diuretic to help flush the tritium from the body. Notify RSO immediately.

12.7 High Radiation Exposure

In the event of an accident involving exposure to a high dose of radiation sufficient to produce radiation sickness symptoms, notify the RSO immediately. An appropriate medical facility will be utilized for treatment and care of victims exposed to high doses and/or internal contamination.

From:	Rachel Browder
To:	Alex Vaucher
Date:	6/29/2006 9:59:49 AM
Subject:	RE: NRC license application

Dr. Vaucher,

I have several items which require further clarification in order for me to continue with my review. I am actually on vacation the remainder of this week, so if you can contact me on my cell phone at 817-313-4261, I would like to review these deficiencies with you.

1. Please provide the manufacturer's (distributor's) name and model number for each sealed source and device requested. If the device is still under R&D and does not have a SSDR yet, then please so state. Likewise, if the sealed source is still under R&D and does not have a SSDR, then please so state.

2. Please provide the maximum amount of activity which will be possessed at any one time for each respective sealed source.

3. Please clarify whether the requested tritium is in volatile or non-volatile form.

4. Please provide the latest amendment for your CA license. I have Amendment No. 01 and Mr. Charles Powell or Mr. Jared Sjoberg are not listed as AUs.

5. Item 9: please describe the control of the access keys. Does SEPTA have access?

6. Clarifications on your Radiation Safety Manual which needs to be updated:

a. Please ensure that all required references to regulations and license conditions include the NRC regulations, as required.

b. Why did you reference Vol 12 of NUREG-1556 in lieu of Vol 7?

c. Preface, 2nd para, reference NRC.

d. Section 3.1 - reference NRC or federal regulations where applicable.

e. Qualifications of RSO - explain the bullet referencing Manufacturing facilities and distribution of radioactive materials? Do you have a CA license for manufacturing and distribution? Will you continue to perform the work at SEPTA under R&D? Has SEPTA purchased the explosive monitor?

f. Explain the bullet about purchasing radioactive materials and assuring that only AU place orders for materials...?

g. Reference that annual audits are required by 10 CFR 20.1101(c).

h. Training for "Trained Workers" - reference transfer and disposal or shipping OR do they not perform these tasks?

i. Section 3.2.4 (AU) - also specify the AU who have been named on the license issued by the NRC...

j. Section 3.3, second para, records of training should be maintained and made available for inspection by the NRC, as applicable

k. Section 3.4, first para, add second para which references NRC for temporary job sites in exclusive Federal jurisdiction for R&D (?) of A-320.

I. Section 4.2, what is meant by "reference" to the NRC. Is this under reciprocity? Now, the use of

radioactive materials in exclusive Federal jurisdiction would be required by NRC license conditions.

m. Section 4.4, Facilities, Is the SIEGMA the device which uses the A-320 neutron generator? Does the A-320 require such shielding at temporary job sites? (Note: the SSDR for A-320 indicates that the dose rate is 420 mrem/hr at 100 cm) Explain how you minimize the exposure at temporary job sites and discuss warning lights and interlocks. Please make a commitment to maintain exposures ALARA.

n. Section 4.7, Personnel Monitoring, references SIEGMA - does the A-320 required dosimetry?

o. Section 6.2, Dosimetry, reference as required by NRC regulations, as well.

Sincerely, Rachel Browder cell: 817-313-4261

Please note I will be unavailable between 11:00 AM and 2:30 PM CDT today and 5:00 pm and 6:30 PM CDT today.

Rachel Browder, Health Physicist NRC Region IV/DNMS/NMLB (817) 276-6552 rsb3@nrc.gov

From:	"Alex Vaucher" <avaucher@hienergyinc.com></avaucher@hienergyinc.com>
То:	"'Rachel Browder'" <rsb3@nrc.gov></rsb3@nrc.gov>
Date:	6/29/2006 2:57:07 PM
Subject:	RE: NRC license application

Dear Ms. Browder,

Thank you for taking time on your vacation to conduct this review. I apologize for any inconvenience this may have caused. I will be on vacation also tomorrow and Monday, but I will continue to work with you on this. I will have access to my e-mail and some documentation. You may also contact me on my cell Phone: (909)214-5859. I have written the answers to your questions directly below each question. I will also call you on your cell phone during the time window specified below. Again I appreciate your help on this matter.

Best Regards,

Alex Vaucher Office:(949)757-0855 Cell: (909)214-5859

-----Original Message-----From: Rachel Browder [mailto:RSB3@nrc.gov] Sent: Thursday, June 29, 2006 8:00 AM To: avaucher@hienergyinc.com Subject: RE: NRC license application

Dr. Vaucher,

I have several items which require further clarification in order for me to continue with my review. I am actually on vacation the remainder of this week, so if you can contact me on my cell phone at 817-313-4261, I would like to review these deficiencies with you.

1. Please provide the manufacturer's (distributor's) name and model number for each sealed source and device requested. If the device is still under R&D and does not have a SSDR yet, then please so state. Likewise, if the sealed source is still under R&D and does not have a SSDR, then please so state.

*Manufacturer: Thermo Electron Corp.; Model Mp-320; Registered in Colorado, Device Registry No: CO-1021-D-101-S.

2. Please provide the maximum amount of activity which will be possessed at any one time for each respective sealed source.

*Activity differs slightly between generators, on average 1.8 Ci, always less than 2 Ci.

3. Please clarify whether the requested tritium is in volatile or non-volatile form.

*Tritium in the sealed source is in a solid target.

4. Please provide the latest amendment for your CA license. I have

Amendment No. 01 and Mr. Charles Powell or Mr. Jared Sjoberg are not listed as AUs.

*Please find an attached copy, however, Charles Powell and Jared Sjoberg are

in the process of being added to the license. Our license is currently being updated by the state of CA to include SSDR for our devices, as well as manufacturing & distribution. At the discretion of the state, all the changes are being incorporated at once, hence an inevitable delay. The latest information is that all these will be finalized in July.

5. Item 9: please describe the control of the access keys. Does SEPTA have access?

*SEPTA has the keys, and they control access, since this is a law enforcement facility.

6. Clarifications on your Radiation Safety Manual which needs to be updated:

a. Please ensure that all required references to regulations and license conditions include the NRC regulations, as required.

b. Why did you reference Vol 12 of NUREG-1556 in lieu of Vol 7?

c. Preface, 2nd para, reference NRC.

d. Section 3.1 - reference NRC or federal regulations where applicable.

*Our Radiation Safety Manual was prepared with the assistance of Mr. Ray Johnson of the Radiation Safety Academy, Gaithersburg, MD. I will contact him with these questions and reply with answers and an updated version.

e. Qualifications of RSO - explain the bullet referencing Manufacturing facilities and distribution of radioactive materials? Do you have a CA license for manufacturing and distribution? Will you continue to perform the work at SEPTA under R&D? Has SEPTA purchased the explosive monitor?

*We are in the process of applying for a Manufacturing & Distribution License. As of now we don't have it yet. This is why we are operating at SEPTA under NRC (R&D) license. The Radiation Safety Manual sent to you was

part of our Mfg & Dist. Application to the State of CA, and was written with that in mind.

f. Explain the bullet about purchasing radioactive materials and assuring that only AU place orders for materials...?

*This refers to ordering on sealed source neutron generators as specified under our current license with the state of California (copy attached).

g. Reference that annual audits are required by 10 CFR 20.1101(c).

*will update accordingly.

h. Training for "Trained Workers" - reference transfer and disposal or

shipping OR do they not perform these tasks?

*We are not authorized to dispose of depleted sealed sources. Under the purchase agreement, these are shipped back to Thermo Electron Corp. for proper disposal. Our trained workers, however, have the need to package and ship the generators to demo or work sites, for example, SEPTA. The packaging and shipping procedure are conducted strictly according to all applicable rules and regulations.

i. Section 3.2.4 (AU) - also specify the AU who have been named on the license issued by the NRC...

* Will update accordingly.

j. Section 3.3, second para, records of training should be maintained and made available for inspection by the NRC, as applicable

*Training records are kept at our Irvine facility and are available for inspection.

k. Section 3.4, first para, add second para which references NRC for temporary job sites in exclusive Federal jurisdiction for R&D (?) of A-320.

*Will update accordingly.

I. Section 4.2, what is meant by "reference" to the NRC. Is this under reciprocity? Now, the use of radioactive materials in exclusive Federal jurisdiction would be required by NRC license conditions.

*I believe this statement means that the state of CA, in its Regulatory Standard for Radiation Protection "references" the NRC in its said regulation, and that employees handling (low level) isotopes (for calibration purposes) must abide by these rules and regulations.

m. Section 4.4, Facilities, Is the SIEGMA the device which uses the A-320 neutron generator? Does the A-320 require such shielding at temporary job sites? (Note: the SSDR for A-320 indicates that the dose rate is 420 mrem/hr at 100 cm) Explain how you minimize the exposure at temporary job sites and discuss warning lights and interlocks. Please make a commitment to maintain exposures ALARA.

*A side comment, we currently use the model MP-320, which is an improved version of the A-320, please see the attached copy of our current license.

The SIEGMA device requires a minimum distance of 30 feet for radiation safety, please see the "White Paper on Radiation Safety of SIEGMA Detector"

which was sent with the application. The SIEGMA device is bomb detector, and its primary use will be under emergency conditions of a suspicious package possible containing an explosive. Under such circumstance, it is likely that well over 30 feet will be cleared until the inspection is complete. In addition, the device incorporates proper markings and warning

lights which are an integral part of its operation.

n. Section 4.7, Personnel Monitoring, references SIEGMA - does the A-320

required dosimetry?

*Yes it does. Operators of the system must wear a valid radiation badge. The badges are replaced and analyzed once per month. Our supplier is "Global Dosemitry", Irvine, CA.

o. Section 6.2, Dosimetry, reference as required by NRC regulations, as well.

*Will update accordingly.

Sincerely, Rachel Browder cell: 817-313-4261

Please note I will be unavailable between 11:00 AM and 2:30 PM CDT today and 5:00 pm and 6:30 PM CDT today.

Rachel Browder, Health Physicist NRC Region IV/DNMS/NMLB (817) 276-6552 rsb3@nrc.gov

State of California-Health and Human Services Agency

Department of Health Services

Page 1 of 2 pages

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the places(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee	HiEnergy Technologies, Inc.	3. License Number	
		7127-30	Amendment Number : 3
2. Address	1601 Alton Parkway, Suite B	4. Expiration date August 15, 2012	(3)
	Irvine, CA 92606		(1)
Allention:	Alexander Vaucher, Ph.D.	5. Inspection agency Radiologic Heal	th Branch
	Radiation Safety Officer	South	

In partial response to the letter with attachments, dated February 14, 2005, signed by Dr. Bogdan Maglich, Chief Scientist and CEO, and the letter with attachments, dated March 10, 2006, signed by Dr. Alexander Vaucher, Vice President, R & D, License Number 7127-30 is hereby amended as follows:

6. Nuclide	7. Form	8.	Possession Limit
A. Hydrogen-3	A. Sealed sources (Thermo MF Physics Corporation A-3000 Series Neutron Generator Tubes: Model A-3062 and Model A- 3093).	А.	20 sources not to exceed a total of 30 Ci.
B. Hydrogen-3	 B. Sealed sources (D-T accelerator target assemblies, Sodern, Model SODITRON neutron tube) 	В.	10 sources not to exceed 3.4 Ci each.
C. Hydrogen-3	C. Sealed sources (Thermo MF Physics Corporation A-3000 Series Neutron Generator Tubes: Model A-3095)	C.	10 sources not to exceed a total of 70 Ci.

9. Authorized Use

- A. Research and development only. To be used in Thermo MF Physics Corporation Models A-320 and MP-320 neutron generators for neutron activation of materials for gamma spectroscopy. Manufacturing or distribution is not authorized.
- B. Research and development only. To be used as target material contained in the MEN 16G neutron emitting module of a SODERN neutron generator. Manufacturing and distribution is not authorized.
- C. Research and development only. To be used in Thermo MF Physics Corporation Model API-120 neutron generator for neutron activation of materials for gamma spectroscopy. Manufacturing or distribution is not authorized.

LICENSE CONDITIONS

- 10. Radioactive material shall be used only at the following locations:
 - (a) 1601 Alton Parkway, Suite B, Irvine, CA.
 - (b) Temporary job sites of the licensee (see license condition 13).
- 11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.

Department of Health Services Page 2 of 2 pages License Number: 7127-30 Amendment Number: 3

RADIOACTIVE MATERIAL LICENSE

12. Radioactive material may be used by, or under the supervision of and in the physical presence of, the following individuals:

- (a) Bogdan C. Maglich, Ph.D.
- (b) Christian Druey
- (c) Tsuey-Fen Chuang, Ph.D.
- (d) Kevin S. McKinny, Ph.D.

- (e) Mohammed Muniruzzaman, Ph.D.
- (f) Alexander Vaucher, Ph.D.
- (g) Eugene Yamamoto, Ph.D.
- 13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - (a) The new application dated September 9, 2002, with attachments, signed by Bogdan C. Maglich, Ph.D., supplemented by the facsimile letter with attachments, dated February 4, 2003, the letters with attachments dated May 9, 2003 and July 17, 2003, and the letters dated June 10, 2003 and June 26, 2003, all signed by Mu Young Lee, Ph.D.
 - (b) The letters with attachments dated October 22, 2004, November 11, 2004, November 23, 2004, all signed by Bogdan Maglich, Ph.D., supplemented by the letters with attachments dated November 18, 2004, November 24, 2004, and November 29, 2004, all signed by Alexander Vaucher, Ph.D., regarding the addition of the Sodern neutron generator, procedures for use at the temporary job sites.
 - (c) The letter with attachments, dated February 7, 2006, and the letter dated March 15, 2006, both signed by Dr. Alexander Vaucher, Vice President, R & D, regarding operation and dose rates related to the addition of API-120 neutron generator.
- 14. (a) The Radiation Safety Officer in this program shall be Alexander Vaucher, Ph.D.
 - (b) The Alternate Radiation Safety Officer in this program shall be Christian Druey.
- 15. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.
- 16. The licensee shall comply with all requirements of Title 17, California Code of Regulations, Section 30373 when transporting or delivering radioactive materials to a carrier for shipment. These requirements include; (packaging, marking, labeling, loading, storage, placarding, monitoring, and accident reporting). Shipping papers shall be maintained for inspection pursuant to the U.S. Department of Transportation requirements (Title 49, Code of Federal Regulations, Part 172, Sections 172.200 through 172.204).
- 17. Radioactive materials shall be used by occupational workers in such a manner that the dose limits specified in Title 10, Code of Federal Regulations, Part 20, Subpart C, Sections 20.1201 through 20.1208 are not exceeded.
- 18. The licensee shall monitor occupational exposures to radiation and shall supply and require the use of individual monitoring devices by personnel as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (a).

Date: 4/2/06

Issued for the State Department of Health Services

John M. Front John Fassell, CHP By:

John Fassell, CHP Radiologic Health Branch MS 7610, P.O. Box 997414 Sacramento, CA 95899-7414

STATEMENT OF TRAINING AND EXPERIENCE (Use additional sheets as necessary.)

Instructions: Each individual proposing to use radioactive material is required to submit a Statement of Training and Experience (RH 2050 A) **in duplicate** to: California Department of Health Services, Radiologic Health Branch, MS 7610, Licensing Section, P.O. Box 997414, Sacramento, CA 95899-7414. Physicians should request form RH 2000 A when applying for human-use authorizations. Radiographers should request form RH 2050 IR. For more information, go to <u>www.dhs.ca.gov/rhb</u> or phone (916) 327-5106.

1.	Name o Dr. C	of proposed user harles Powell				Position title Senior Research Scientist			
	Employ	er address (number, st	reet)			City	State	ZIP code	
	1601	B Alton Parkway				Irvine	CA	92606	
	Radioa	ctive materials license r	number			Radioactive materials license name			
2.	Traini a. Co	ing ollege or university	Ves	No					
	Nar	me of college or univers	sity			a da a francesco de la construcción			
	Ste	evens Institute of T	echnology			······			
	City Ca	/ astle Point on the F	ludson			State New Jersey			
	Yea	ars completed Degree				Course of study			
		PhD Physics				Experimental Plasma Physic	S		
	b. Ed	ucation specifically	applicable to use	of radioa	active ma	terial			
	Ex	perimental Nuclea	r Physics						
3.	Exper	rience							
	a. Lis	t experience with u	use of radioactive n	naterials	beginnin	ing with most recent:			
	(1)	Dates From: 4/15/04	To: Present	E	Employer HiEnoray	Tochnologios			
		Title(s) and duties			4.11.11.1.1.				
		Senior Scientist	- analyze and pe	erform stu	udies invo	volving neutron generators and gamma ray detection			
		Radioactive materials license number				Date		Date	
		Employer address (number_street)				City	State	ZIP code	
		1601B Alton Parkway				Irvine	CA	92606	
	(2)	Dates From: 1/2001	To: 1/2003	E	Employer DIANA H	i-Tech			
		Title(s) and duties Senior Research	Scientist - researc	ch and pr	oduct de	evelopment using pulsed D-D neutron generators			
		Radioactive materials	license number					Date	
		Employer address (ni 1109 Grand Δια	umber, street)			City North Bergen	State	ZIP code	
	(3)	Dates		F	mplover	North Dergen		0/04/	
	(0)	From: 1/95	To: 12/2000	7	Avogadro	Energy Systems			
		Title(s) and duties Senior Research	Scientist - researc	h and pr	oduct de	velopment using pulsed D-D n	eutron gen	erators	
		Radioactive materials	license number					Date	
		Employer address (nu 101 Daniel Low	umber, street) Ferrace	the transition of the second		City Staten Island	State NY	ZIP code	
	(4)	Dates From: 5/85	To: 12/94	E	Employer Physics [Dept - Stevens institute of Tecl	nology	<u></u>	
		Title(s) and duties Postdoc and Res	search Scientist - r	eseach	-on pulse	ed plasma based radiation sou	irces	<u></u>	
		Radioactive materials	license number		-			Date	
		Employer address (nu	umber, street)			Citv	State	ZIP code	
		Physics Dept - Burchard Building				Castle Point on the Hudson	NJ	07030	

b. Indicate the facilities and operations where training was received and refer to Part 3.a. when answering the following:

 Laboratories using radiochemicals Restricted area laboratories Glove boxes Field operations Environmental applications Other (place describe). Operation of neutron generator 	$ \begin{array}{c} (1) \\ (1) \\ (1) \\ (1) \\ (1) \\ (1) \\ (1) \\ (1) \\ (1) \\ (1) \\ (1) \end{array} $	$(2) \\ (2) $	$ \begin{array}{c} (3) \\ \hline (3) \hline (3) \hline \hline (3)$	
Other (please describe) operation of neutron generator	(1)	(2)	(3)	(4)

c. Radioactive materials previously used. Identify typical radioisotopes in appropriate box and refer to Part 3.a. on page 1:

		QUANTITIES HANDLED						
	(a) Microcuries	(b) Millicuries	(c) Curies	(d) Kilocuries				
(1) Sealed sources	1 at(1),15 at(2)(4							
(2) Unsealed Alpha emitters	15 at (4)							
(3) Unsealed beta-gamma emitters								
(4) Neutron sources			3 at(4)					

d. Describe the procedures similar to those proposed in which you have had experience. Indicate months or years for each and refer to Part 3.a. on page 1.

Operation of D-T Neutron Generator (10E8 strength 14 MeV neutrons) 2 years at (1) Use of Microcurie strength sealed check sources 2 years at (1), 2 years (2), 2 years(3) 8 years, (4)

Use of D-D Neutron Generator 2 years at (2),2 years at (3),8 years at (4)

Use of 3 Curie Americium-Berileum Based Neutron 2 years at (4)

4. Certificate

The information you are asked to provide on this form is requested by the California Department of Health Services, Radiologic Health Branch. This notice is required by Section 1798.17 of the Information Practices Act of 1977 (Code of Civil Procedure, Section 1798–1798.76) and the Federal Privacy Act to be provided whenever an agency requests personal or confidential information from any individual. It is mandatory that you furnish the information requested on this form. Failure to furnish the requested information may result in an inaccurate determination of statements and/or disapproval of your application.

I hereby certify that all information contained in this statement is true and correct.

Signature of proposed user	Date
	5/13/06

STATEMENT OF TRAINING AND EXPERIENCE (Use additional sheets as necessary.)

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1.	Name o Jared	f proposed user Ray Sjoberg	Position title Scientist	Position title Scientist			
	Employ 1601	er address (number, street) Alton Parkway, Suite B		City Irvine	State CA	ZIP code 92606	
	Radioad	tive materials license number		Radioactive materials lic	ense name		
2.	Traini a. Co	ng Ilege or university ☑ Yes	🗌 No				
	Nar Ur	ne of college or university iversity of California Santa Barba					
	City Go	pleta		State CA			
	Yea 4	ears completed Degree BS		Course of study Physics		en e	
	b. Ed	ucation specifically applicable to u	use of radioactiv	ve material			
	Ra	diation Safety Course from Radia	ation Safety Aca	ademy by Ray Johnson			
3.	Exper a. Lis	ience t experience with use of radioacti	ve materials be	ginning with most recent:			
	(1)	Dates From: 10/05 To: Presen	t Empl	^{oyer} nergy Technologies, Inc.	ay Technologies, Inc.		
		Title(s) and duties Scientist - Testing of SEIGMA 3	E3, Sealed sou	Irce neutron generator froi	m Thermo		
		Radioactive materials license number 7127-30	,	Date			
		Employer address (number, street) 1601 Alton Parkway, Suite B		City Irvine	State CA	ZIP code 92606	
	(2)	Dates From: To:	Empl	loyer			
		Title(s) and duties	.				
		Radioactive materials license number			Date		
		Employer address (number, street)		City	State	ZIP code	
	(3)	Dates From: 5/97 To: 4/98	Empl Digi	oyer irad Corp			
		Title(s) and duties Materials R&D Technician					
		Radioactive materials license number			Date		
		Employer address (number, street) 7408 Trade St		City San Diego	State CA	ZIP code 92121-2410	
	(4)	Dates From: To:	Empl	loyer			
		Title(s) and duties					
		Radioactive materials license number			9999	Date	
		Employer address (number, street)		City	State	ZIP code	

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 Laboratories using radiochemicals Restricted area laboratories Glove boxes Field operations Environmental applications 	(1) (1) (1) (1) (1) (1)	(2) (2) (2) (2) (2) (2)	(3) (3) (3) (3) (3) (3) (3)	(4) (4) (4) (4) (4) (4)
Other (please describe)	□ (1) □ (1)	$\square (2)$	$\square (3)$	(4)

c. Radioactive materials previously used. Identify typical radioisotopes in appropriate box and refer to Part 3.a. on page 1:

	QUANTITIES HANDLED						
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(1) Sealed sources							
(2) Unsealed Alpha emitters							
(3) Unsealed beta-gamma emitters							
(4) Neutron sources							

d. Describe the procedures similar to those proposed in which you have had experience. Indicate months or years for each and refer to Part 3.a. on page 1.

3a(1)- Dretation of D-T Neutron Generator for Activation Analysis. System interlocked in convete maze. Used for demonstration of explosive detection system called SIEGMA.

3a(2)- Calibration of Excimer laser and HeNe for photolithography steppers.

3a(3)- Use of check sources for SPEICT Gammay-Ray Medical Imaging.

4. Certificate

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I hereby certify that all information contained in this statement is true and correct.

Signature of proposed user	Date
	5/18/2006

	3. OTHER	2. Correct Fee Paid. Amendment Renewal License	 COMMENTS LICENSE FEE MANAGEMENT Fee Category and Amoun Correct Fee Paid. App Amendment Renewal 				1. APPLICATION ATTACHE Applicant/Licensee: Received Date: Docket No: Control No: License No: Action Type:	A. REGION	LICENSE FEE TRANSMITTAL	BETWEEN: License Fee Management I and Regional Licensing Sect:
Date		Application may be processed for:	Amount:	MENT BRANCH (Check when milestone 03 is entered $/$	Signed College Musehan	A. 00	HIENERGY TECHNOLOGIES, INC 20060627 3037298 471014 New Licensee		T	INFORMATION FROM LTS Branch, ARM Program Code: Status Code: 3 Fee Category: Exp. Date: 0 Fee Comments: Decom Fin Assur Regd: