

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

May 31, 2019

Edwin M. Leidholdt, Jr., Ph.D., Director National Health Physics Program (115 HP/NLR) Department of Veterans Affairs Veterans Health Administration 2200 Fort Roots Drive North Little Rock, AR 72114

SUBJECT: NRC INSPECTION REPORT 03034325/2018007 (DNMS) - VA CONNECTICUT

HEALTHCARE SYSTEM, WEST HAVEN, CONNECTICUT

Dear Dr. Leidholdt:

On April 24, 2019, the U.S. Nuclear Regulatory Commission (NRC) completed a routine inspection at the VA Connecticut Healthcare System, West Haven, Connecticut. The inspection was limited to a review of activities authorized under Permit No. 06-00092-05. The inspector conducted an exit meeting with the management and staff at the facility at the completion of the inspection. Additional follow-up related to Part 37 requirements was provided by you to the inspector on May 2, 2019, and a final exit meeting was held with you by telephone on May 3, 2019.

The inspection was an examination of activities conducted under the Permit as they relate to radiation safety and to compliance with the Commission's rules and regulations. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of the inspection, no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

In accordance with Title 10 of the Code of Federal Regulations (CFR) 2.390 of the NRC's "rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or the NRC's Agencywide Documents Access and Management System (ADAMS, accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions concerning this inspection or the enclosed report, please contact Bryan Parker of my staff at 678-828-7050.

Sincerely,

/RA/

Patricia J. Pelke, Chief Materials Licensing Branch Division of Nuclear Materials Safety

Docket No. 030-34325 License No. 03-23853-01VA Permit No. 06-00092-05

Enclosure: IR 03034325/2018007

NRC FORM 591M PART 1 U.S. NUCLEAR REGULATORY COMMISSION						
10 CFR 2.201 SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION						
1. LICENSEE/LOCATION	ON INSPECTED:		2. NRC/REGIONAL OFFICE			
VA Connecticut Healthcare System 950 Campbell Avenue West Haven, CT 06516 REPORT NUMBER(S) 030-34325/2018007			Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352			
3. DOCKET NUMBER(S	3)	4. LICENSE NUMBER	(S)	5. DATE(S) OF INSPEC	TION	
030-34325		03-23853-03VA	L .	April 23-24 and M	May 3, 2019	
Regulatory Commiss procedures and representations of the following services are services and representations of the following services are services as the services are serv	an examination of the activities conductors on (NRC) rules and regulations and the esentative records, interviews with person the inspection findings, no violations with violation(s) closed. Itions(s), specifically described to you by titive, and corrective action was or is being were satisfied. Non-cited violation(s) were discuss	ne conditions of your listonnel, and observation were identified. by the inspector as noteing taken, and the re	icense. The inspection consists ons by the inspector. The inspector on the inspector of the	ed of selective examina ection findings are as for cited because they we	ations of ollows: ere self-identified,	
cited in ac with 10 C	is inspection, certain of your activities, a ccordance with NRC Enforcement Polic FR 19.11. s and Corrective Actions)	is described below are. Y. This form is a NOT	nd/or attached, were in violation TCE OF VIOLATION, which ma	n of NRC requirements ay be subject to posting	and are being j in accordance	
corrective actions is r	State within 30 days, the actions described by the made in accordance with the requireme indice will be achieved). I understand the	ents of 10 CFR 2.201	vill be taken to correct the violaticorrective steps already taken	, corrective steps which	h will be taken.	
TITLE	PRINTED NAME	at no rather whiten	SIGNATURE	- The same of the	DATE	
LICENSEE'S REPRESENTATIVE						
NRC INSPECTOR	Tara L. Weidner (Region I)	lot.	ela Den Tour Wil	ednes	5/31/2019	
BRANCH CHIEF	Patricia J. Pelke	Lin			5/2/2010	

NRC FORM 591M PART 3 (07-2012)	D	ocket File Info		CLEAR REGULATORY COMMISSION			
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION							
1. LICENSEE/LOCATION INSPECTE	ED:		2. NRC/REGIONAL OFFICE				
VA Connecticut Healthcar 950 Campbell Avenue West Haven, CT 06516	re System		Region III U. S. Nuclear Regulato 2443 Warrenville Road Lisle, IL 60532-4352				
REPORT NUMBER(S) 030-34	4325/2018007		Disie, 115 00552- 1552				
3. DOCKET NUMBER(S)		4. LICENSE NUMBER(S)		5. DATE(S) OF INSPECTION			
030-34325		03-23853-03VA		April 23-24 and May 3, 2019			
6. INSPECTION PROCEDURES USE	ED	7. INSPECTION FOCUS	S AREAS				
87134, 87137		All	All				
SUPPLEMENTAL INSPECTION INFORMATION							
1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTAC		4. TELEPHONE NUMBER			
02110, 03610, 03510	2110, 03610, 03510 2 Ed Lei		n.D., Director, NHPP	(707) 562-8374			
Main Office Inspec	tion	Date: N/A					
✓ Field Office Inspection VA West Haven, Connecticut campus							
Temporary Job Sit	e Inspection						
PROGRAM SCOPE							
This was an unannounced, Affairs' (DVA) Master Ma diagnosis and therapy, rese CT campus that is part of t	aterials License (MMI earch, and irradiation	L). The permittee of materials. The	e is a medical broad scopere is one location of use	tment of Veterans e facility authorized for medical authorized at the West Haven,			
Seven nuclear medicine te	chnologists (NMT) re	otate through the l	Nuclear Medicine and PF	ET Denartments A full-time			

Radiation Safety Officer (RSO) oversees radiation safety activities, including training, dosimetry, sealed source inventory and leak tests, surveys, dose specific calculations, and program audits. The RSO is assisted by a full-time Assistant RSO. The Radiation Safety Committee (RSC) meets on a quarterly basis and oversees the radiation safety program.

The Nuclear Medicine Department operates Monday through Friday and performs a wide range of nuclear medicine studies (5 patients per day). Unit dosages from Cardinal Health are assayed prior to administration. In 2018, five iodine-131 (I-131) therapies were performed and in 2019 no I-131 therapies had been done to date. Fifteen administrations of radium-223 Xofigo, provided by Bayer, were performed in 2018 and none to date in 2019. Records of the activity administered, user training, and written test procedures were reviewed and found to be adequate. The inspector reviewed a selection of written directives and determined that therapies were being performed in accordance with the written directives. The PET department operates Monday through Friday (Mon/Weds cardiac studies and Tues/ Thurs imaging) and treats approximately 8 patients per day. PET procedures include whole body scans with fluorine-18 (F-18) provided by PETNET, and/or rubidium-82 cardiac scans from strontium-82/rubidium-82 (Sr-82/Rb-82) generators provided by Bracco. Doses were assayed as required prior to administration.

There are three principal investigators (PI) in two labs performing research activities (C-14 and Tc-99). Use is limited and continues to decline. One new PI was approved by the RSC since the last inspection. The inspector reviewed the training documentation and confirmed the RSC's approval of the PI.

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1. PROGRAM CODE(S) 2. PRIORITY	3. LICENSEE CONTAC		4. TELEPHONE NUMBER				
02110, 03610, 03510 2	Ed Leidholdt, Ph	.D., Director, NHPP	(707) 562-8374				
Main Office Inspection Next Inspection Date: N/A							
Field Office Inspection VA West Ha	ven, Connecticut c	ampus					
Temporary Job Site Inspection							
PROGRAM SCOPE Security and use of a higher activity source complied with the requirements in 10 CFR Part 37. The permittee has implemented the National Heath Physics Program (NHPP) procedures and maintains records consistent with NRC requirements. The inspector performed independent surveys and determined that the results were consistent with the permittee's surveys. A selection of permittee records were reviewed including, program audits, patient specific calculations,							
surveys, written directives, instrument calibrations, leak tests/inventories, etc. All were found to be acceptable.							
Within the scope of the inspection, no violations were identified.							
An exit meeting was held with the facility staff on April 24, 2019 at the end of the onsite inspection. Followup for information related to Part 37 requirements was provided on May 2, 2019 and another exit meeting held with the NHPP Director by telephone on May 3, 2019.							



Letter to Edwin Leidholdt, Jr., from Patricia J. Pelke dated May 31, 2019.

SUBJECT: NRC INSPECTION REPORT 03034325/2018007 (DNMS) – VA CONNECTICUT HEALTHCARE SYSTEM, WEST HAVEN, CONNECTICUT

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NAME	TWeidner:ps		BParker		PJPelke			
DATE	5/23/2019		5/22/2019		5/31/2019			

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