

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

July 25, 2001

Docket No. 03031395 Control No. 129882 License No. 37-28453-01

Paul J. Early Corporate Radiation Safety Officer Digirad Imaging Solutions, Inc. 930 N. 4th Street Suite 201 Allentown, PA 18102

## SUBJECT: DIGIRAD IMAGING SOLUTIONS, INC., ISSUANCE OF LICENSE AMENDMENT, CONTROL NO. 129882

Dear Mr. Early:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html.

Thank you for your cooperation.

Sincerely,

## Original signed by Michelle Beardsley

Michelle Beardsley Health Physicist Nuclear Materials Safety Branch 1 Division of Nuclear Materials Safety

Enclosure: Amendment No. 28

## OFFICIAL RECORD COPY

OFFICE	DNMS/RI	Ν	DNMS/RI		DNMS/RI					
NAME	MBeardsley/MRB									
DATE	07/25/2001									

DOCUMENT NAME: C:\Program Files\Adobe\Acrobat 4.0\PDF Output\I37-28453-01.129882.07252001.wpd To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

NRC	FORM 374 U.S. NUCLEAR REGULA	TORY COMMISSION PAGE1_OF _5_PAGES Amendment No. 28								
	MATERIALS LICENSE									
Purs of F here sourd deliv shall appli belov	Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.									
	Licensee	In accordance with the letters dated								
		June 16, July 3 and July 12, 2001,								
1. C	Digirad Imaging Solutions, Inc.	3. License number 37-28453-01 is amended in								
	EAR F	its entirety to read as follows:								
2. 9	30 N. 4th Street	4. Expiration date July 31, 2005								
S	Suite 201	5. Docket No. 030-31395								
A	Allentown, Pennsylvania 18102	Reference No.								
6.	Byproduct, source, and/or special 7. Chemical and/or nuclear material	physical form 8. Maximum amount that licensee may possess at any one time under this license								
A.	Any byproduct material A. Any radiophan identified in 10 CFR 35.100 identified in 10	rmaceutical A. As needed 0 CFR 35.100								
В.	<ul> <li>B. Any radiopharmaceutical identified in 10 CFR 35.200</li> <li>B. Any radiopharmaceutical identified in 10 CFR 35.200</li> <li>E. Any radiopharmaceutical identified in 10 CFR 35.200</li> </ul>									
C.	C. Gadolinium 153 C. Sealed Sources (IPL Model C. 650 millicuries 3409[HEGL-0022])									
9.	Authorized use:									
А. В. С.	<ul> <li>A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.</li> <li>B. Any imaging and localization procedure approved in 10 CFR 35.200.</li> <li>C. For use in a Picker International Model STEP device for patient attenuation correction during S.P.E.C.T. imaging.</li> </ul>									
	CONDI	TIONS								
10.	<ol> <li>A. Licensed material may be stored and possessed, incident to mobile activities, at the licensee's facilities located at 2241 Corsons Lane, Unit D, Plymouth Meeting, Pennsylvania; 5 Laurel Drive, Flanders, New Jersey; 930 N. 4th Street, Suite 201, Allentown, Pennsylvania; and 1811 Executive Drive, Suite 1, Building #18, Indianapolis, Indiana.</li> </ol>									
	B. Licensed material listed in Item 6 may be used at clients' medical care facilities anywhere in the United States where the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.									

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MATE SUPPI	ERIALS LICENSE LEMENTARY SHEET		Docket or Reference Numbe 030-31395	er				
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11. The Radiation Safet	y Officer for this license is Pau	l J. Earl	У					
12. Licensed material lis following individuals	sted in Item 6 above is only aut for the materials and uses ind	horized icated:	for use by, or under t	he sup	pervis	sion (	of, th	ıe
Authorized	<u>Users</u>	Mater	al and Use					
Bindukuma	rc Kansupada, M.D.	35.10 Gadol d	); 35.200 inium 153 for patient a uring S.P.E.C.T. imag	attenu jing	ation	corr	ectic	ึงท
Madhukar F	Pandya, M.D.	35.20 Gadol d	) for cardiovascular cl inium 153 for patient a uring S.P.E.C.T. imag	linical attenu jing	proce ation	edure corre	es ectio	ึงท
Joel S. Raid	chlen, M.D.	35.20 Gadol d	D for cardiovascular cl inium 153 for patient a uring S.P.E.C.T. imag	linical attenu jing	proce ation	edure corr	es ectio	ึงท
M. Khalid M	Ialik, M.D.	35.20 Gadol d	<mark>) for</mark> cardiovascular cl inium 153 for patient a uring S.P.E.C.T. imag	linical attenu jing	proce ation	edure corre	es ectio	ึงท
Albert Saul	, M.D.	35.20 Gadol d	) for cardiovascular cl inium 153 for patient a uring S.P.E.C.T. imag	linical attenu jing	proce ation	edure corre	ectic	ึงท
Habib Bolo	urchi, M.D.	35.20 Gadol	) for cardiovascular cl inium 153 for patient a luring S.P.E.C.T. imag	linical attenu ging	proce ation	edure corre	ectic	ึงท
William Ma	rkson, M.D.	35.20 Gadol	) for cardiovascular cl inium 153 for patient a luring S.P.E.C.T. imag	linical attenu ging	proce ation	edure corre	es ectio	ึงท
Leonard Fe	itell, M.D.	35.20 Gadol d	) for cardiovascular cl inium 153 for patient a uring S.P.E.C.T. imag	linical attenu jing	proce ation	edure corr	es ectio	ึงท
Zulfiqar Ahı	mad, M.D.	35.20 Gadol d	) for cardiovascular cl inium 153 for patient a uring S.P.E.C.T. imag	linical attenu jing	proce ation	edure corr	es ectio	n
Anirudh Kh	anna, M.D.	35.20 Gadol d	) for cardiovascular cl inium 153 for patient a uring S.P.E.C.T. imag	linical attenu jing	proce ation	edure corr	es ectio	n

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	MATERIALS LI SUPPLEMENTAR		MATERIALS LICENSE SUPPLEMENTARY SHEET		Amendment No. 28				
		A	Authorized Users	Material	and Use				
		(	Charles H. Curtiss, D.O.	35.100 a	and 35.200				
		E	Elmer P. Manalo, M.D.	35.200 f	for cardiovascular clinical procedures				
		u	lames Stinebaugh, M.D.	Gadolini duri 35.200 f Gadolini duri	Jolinium 153 for patient attenuation correction during S.P.E.C.T. imaging 200 for cardiovascular clinical procedures Jolinium 153 for patient attenuation correction during S.P.E.C.T. imaging				
13.	In a mat esta	dditio erial t ablishi	n to the possession limits in Item 8, the lice o quantities below the minimum limit speci ng financial assurance for decommissionir	ensee sh fied in 10 ng.	all further restrict the possession of licensed 0 CFR 30.35(d), 40.36(b), and 70.25(d) for				
14.	The 10 (	licen CFR F	see is authorized to transp <mark>ort licen</mark> sed mat Part 71, "Packaging and Tr <mark>ansport</mark> ation of	erial in a Radioact	accordance with the provisions of tive Material."				
15.	A.	Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.							
	B.	Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles sh be tested for leakage and/or contamination at intervals not to exceed three months.							
	C.	In the absence of a certificate from a transferor indicating that a leak test has been made within months prior to the transfer, a sealed source or detector cell received from another person sha be put into use until tested.							
	D.	Each sealed source fabricated by the licensee shall be inspected and tested for construction defects leakage, and contamination prior to any use or transfer as a sealed source.							
	E.	Seal	ed sources and detector cells need not be	leak test	ted if:				
		(i)	they contain only hydrogen-3; or						
		(ii)	they contain only a radioactive gas; or						
		(iii)	the half-life of the isotope is 30 days or le	ss; or					
		(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not than 10 microcuries of alpha emitting material; or							

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		(v)	they are not designed to emit alpha particles, are when they are removed from storage for use or tested within the required leak test interval, they sealed source or detector cell shall be stored for tested for leakage and/or contamination.	e in storage, and are not being used. However, transfer to another person, and have not been shall be tested before use or transfer. No r a period of more than 10 years without being				
	F.	The test : conta dete of in the la Offic cell i	test shall be capable of detecting the presence of sample. If the test reveals the presence of 0.005 amination, a report shall be filed with the U.S. Nuc ctor cell shall be removed immediately from servic accordance with Commission regulations. The re eak test result is known with the appropriate U. S the referenced in Appendix D of 10 CFR Part 20. The nvolved, the test results, and corrective action tak	f 0.005 microcurie of radioactive material on the microcurie or more of removable clear Regulatory Commission and the source or ce and decontaminated, repaired, or disposed eport shall be filed within five days of the date . Nuclear Regulatory Commission, Regional The report shall specify the source or detector ken.				
	G.	The tests Com	licensee is authorized to collect leak test samples for leakage and/or contamination may be perform mission or an Agreement State to perform such s	s for analysis by the licensee. Alternatively, med by persons specifically licensed by the services.				
16.	The dev 35.9	icen ices c 500 ai	see shall conduct a physical inventory every three containing licensed material received and possess nd every six months for all other sealed sources a	e months to account for all sealed sources and sed pursuant to 10 CFR 35.57, 35.400 and and devices.				
17.	<ol> <li>Sealed sources or detector cells containing licensed material shall not be opened or sources remov from source holders by the licensee.</li> </ol>							
18.	Exc acc any prov the mor	ept as ordan enclo vided stater e res	s specifically provided otherwise in this license, th ce with the statements, representations, and pro- osures, listed below, except for minor changes in t in 10 CFR 35.31. The U.S. Nuclear Regulatory C ments, representations, and procedures in the lice trictive than the regulations.	he licensee shall conduct its program in cedures contained in the documents, including the medical use radiation safety procedures as Commission's regulations shall govern unless ensee's application and correspondence are				
	A. B.C. D.E.F.G.H. J.K.	Appl Lette Lette Lette Lette Lette Lette Lette Lette	ication dated February 24, 1995 er dated May 9, 1995 er dated June 6, 1995 er dated July 14, 1995 er dated August 30, 1995 er dated October 27, 1995 er dated July 1, 1996 er dated September 20, 1996 er dated January 6, 1997 er dated February 10, 1997 er dated April 24, 1997					

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L. Letter dat M. Letter dat N. Letter dat O. Letter dat Q. Letter dat R. Letter dat S. Facsimile T. Letter dat U. Letter dat V. Letter dat X. Letter dat X. Letter dat Z. Letter dat AA. Letter dat BB. Facsimile	ted September 19, 1997 ted April 24, 1998 ted September 15, 1998 ted April 7, 1999 ted September 7, 1999 ted April 12, 2000 ted May 18, 2000 e dated May 21, 2000 ted August 11, 2000 ted September 19, 2000 ted September 20, 2000 ted February 19, 2001 ted March 7, 2001 ted March 26, 2001 ted June 16, 2001 e dated July 25, 2001		AULATORY COMMS		
		For the U.	S. Nuclear Regulatory Commissio	n	
Date <u>July 25, 2</u>	2001	By Nu	iginal signed by Michelle Beard chelle Beardsley clear Materials Safety Branch 1	sley	
		Re Kin	gion I ıg of Prussia, Pennsylvania 19406		