



# INDIANA INSTITUTE of CARDIOLOGY

*Tomorrow's Cardiovascular Care Today*

**MEDICAL STAFF**

WILLIAM G. ESPAR, MD  
Medical Director  
Co-Director of Coronary  
Interventions

McKINDRA FLETCHER, JR, MD  
Director of Invasive Cardiology  
Co-Director of Coronary  
Interventions

GEORGE J. GRACEVICH, MD  
Director of Clinical Cardiology  
Co-Director of Noninvasive  
Imaging

JOSEPH ROSENBLUM, DO  
Director of Vascular Medicine  
Co-Director of  
Non-Invasive Imaging

**ADMINISTRATION**

MARC A. ESPAR, CPA  
Administrator  
Chief Financial Officer

## Facsimile Cover Sheet

To: Jim Mullauer

Date: 6/18/07

From: Joe Weiss

Fax #: 630-829-9873

Re: \_\_\_\_\_

Pages: 9  
(Including Cover Sheet)

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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(219) 874-1400

1000 Washington Street  
Michigan City, Indiana 46360  
(219) 874-1400  
Fax (219) 874-1398

3723 Franklin Street  
Michigan City, Indiana 46360  
(219) 874-3313  
Fax (219) 878-2330

810 Michael Drive  
Chesterton, Indiana 46304  
(219) 926-4700  
Fax (219) 926-3133



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**- ADMINISTRATION -**

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Chief Financial Officer

June 18, 2007

Mr. James Mullauer  
U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road  
Suite 210  
Lisle, IL 60531-4351

Dear Mr. Mullauer:

Please see the attached documents and the data listed below which is submitted in response to your questions regarding the license application for the Indiana Institute of Cardiology.

A letter of agreement between Digirad Imaging Solutions (DIS) and Indiana Institute of Cardiology (IIC) is attached. We trust that this document satisfactorily addressed the transfer of responsibility from DIS to IIC.

In regard to the appointment of Sue Weiss, Associates in Medical Physics (AMP) as the RSO for IIC the following is submitted in answer to your questions:

- On site availability at IIC to conduct RSO duties will be a minimum of four (4) times per year and on an as needed basis. RSO duties will also be conducted by review of records submitted to the AMP office in Minnesota on a monthly basis. In addition, Dr. Grcevich will be trained for the duties and responsibilities of the RSO so that he may assume the position at the conclusion of one year of practical experience.
- Response time for an emergency involving radioactive material will be immediate via telephone. Response time for the RSO to arrive in person at the facility will be same day, most probably within three (3) hours depending on flight availability. Since this facility uses only Technetium unit dose radiopharmaceuticals, the likelihood of an emergency situation requiring the RSO to be onsite is very low.
- An oral report will be provided to management regarding unsafe practices and incidents during each RSO visit to the facility. A written report will be provided following the visit. Management will be required to provide the RSO with a response in writing to any unsafe condition or incident.
- Radiation safety reports will be provided orally at the time of the RSO visit to the facility and written reports for each visit will be provided following the visit.
- Ms. Weiss holds no other RSO positions currently.

We request approval of Dr. Grcevich as an Authorized User on the license under 10CVR35.290.

We request the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used. Also attached is the data regarding the efficiency of the current detector used for wipe

Mr. James Mullauer  
June 18, 2007  
Page Two

testing analysis. This information was referenced because the facility does not have a well chamber and it is intended to insure that the equipment is sufficient to perform adequate analysis of the wipe samples.

Also attached is a dated page 4 of the preceptor form.

We trust that these responses are adequate responses to your questions regarding the license application for IIC.

Sincerely,



William G. Espar, MD  
President and CEO

WGE:jab

Enclosures

Indiana Institute of Cardiology

13-32652-01, 030-37464, CN 316218, ML 071220222

New license application dated 4/26/07.

Initial Review Status

1. Please provide a letter signed by both managements (DigiRad Imaging Solutions and Indiana Institute of Cardiology (IIC)) that DigiRad releases the facility as is to IIC and IIC accepts full responsibility for the facility, i.e. any radioactive contamination that may be present and all sources of radiation, i.e. check sources, etc.
2. Please provide the following concerning your appointment of RSO for IIC.
  - a. How you will divide your time between your consultation duties and onsite availability at IIC to conduct the duties of RSO.
  - b. Please specify the amount of time it will take you to respond to an emergency involving radioactive materials when you are not present.
  - c. Please describe the mechanisms for reporting to management of unsafe practices and incidents and management role in responding to such circumstances.
  - d. Please state the minimum frequency that you will provide radiation safety reports to management.
  - e. Please list all other RSO positions you currently hold at NRC as well as Agreement States licensee's facilities if any.
4. The checklist in your application references Appendix J in 10 CFR Part 35 for the training and experience of George J. Groevich, M.D. Please make the proper current reference to 10 CFR 35.290.
5. Please confirm that you reserve the right to upgrade survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used. Also, the checklist states that the efficiency test results are attached, however, no results were attached. (Side note, I am not sure why this statement is in the application?)
6. Preceptor form on Page 4 is not dated. Please date provide page 4.

05-31-'07 10:26 FROM-DIGIRAD

610-366-1483

T-028 P02/03 U-520

Paul J. Early, DABSNM, DABR  
Vice President, Radiation Safety Officer  
Digirad Corporation



Please respond to the address indicated with the "X"

REC'D JUN 01 2007

CONY OFFICE:

P.O. Box 340  
Bernus Point, NY 14712  
PH: 716-386-3860  
FX: 716-386-5118  
Cell: 216-496-7824

( ) GA OFFICE:

106 Barkentine Ct.  
St. Simon's Island, GA 31522  
PH: 912-634-9951  
FX: 912-634-9961  
Cell: 216-496-7824

May 30, 2007

VIA FAX (610-337-5393)

U.S. Nuclear Regulatory Commission, Region I  
475 Allendale Road  
King of Prussia PA 19406-1415

Re: Amendment for License No. 31-30666-01

To Whom It May Concern:

Please amend our license to **DELETE** the following **CLINICAL SITE**:

Indiana Institute of Cardiology (IIC)  
1000 Washington St.,  
Michigan City, IN 46360

Digirad Imaging Solutions, Inc. (DIS) is relinquishing the Indiana Institute of Cardiology as a hub location to their own radioactive material license, now being considered by NRC Region I. Indiana Institute of Cardiology will accept responsibility for all radioactive sources and any residual contamination at the site.

Thank you for your immediate attention to this matter.

Sincerely,

Paul J. Early, DABSNM, DABR  
Vice President, Corporate Radiation Safety  
Digirad Corporation

Signature  
William G. Espar / President & CEO  
Name/Administrative Position at IIC

13950 Stowe Drive  
Poway, CA 92064-6803

t 858.726.1800  
f 858.728.1700  
www.digirad.com

05-31-'07 10:26 FROM-DIGIRAD

610-366-1483

T-028 P03/03 U-520

Paul J. Early, DABSNM, DABR  
Vice President, Radiation Safety Officer  
Digirad, Inc.



Please respond to the address indicated with the "X"

(X) NY OFFICE:

P.O. Box 340  
Bemus Point, NY 14712  
PH: 716-386-3860  
FX: 716-386-5118  
Cell: 216-496-7824

( ) GA OFFICE:

106 Barkentine Ct.  
St. Simon's Island, GA 31522  
PH: 912-634-9951  
FX: 912-634-9961  
Cell: 216-496-7824

May 30, 2007

VIA FAX (630-829-9782)

U.S. Nuclear Regulatory Commission, Region III  
801 Warrenville Rd.  
Lisle, IL 60532-4351

Re: License No. 31-30666-01 (NRC Region I)

To Whom It May Concern:

Please coordinate the deletion of the following clinical site from the above identified radioactive material license from NRC Region I with the issuance of a new RML for the same clinical site from NRC Region III:

Indiana Institute of Cardiology (IIC)  
1000 Washington St.,  
Michigan City, IN 46360

Digirad Imaging Solutions, Inc. (DIS) is relinquishing the Indiana Institute of Cardiology as a hub location from their own radioactive material license. Indiana Institute of Cardiology will accept responsibility for all radioactive sources and any residual contamination at the above site.

Thank you for your immediate attention to this matter.

Sincerely,

Paul J. Early, DABSNM, DABR  
Vice President, Corporate Radiation Safety  
Digirad Corporation

Signature  
William G. Espar / President & CEO  
Name/Administrative Position at IIC

13950 Stowe Drive  
Poway, CA 92064-8803

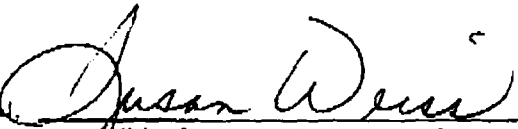
t 858.728.1600  
f 858.728.1700  
www.digirad.com

## Delegation of Authority

To: Radiation Safety Officer

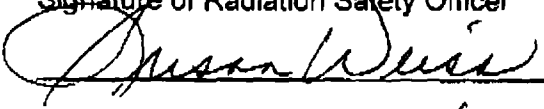
From: Chief Executive Officer

Subject: Delegation of Authority

You, , have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the State of Indiana and/or the NRC at any time.

I accept the above responsibilities,

\_\_\_\_\_  
Signature of Radiation Safety Officer



Date

4/12/07

  
Signature of Management Representative

4/4/07

Date

cc: Appropriate Personnel

2007 06/19 12:00:45  
06/18/2007 13:32 219-874-1398  
05/26/2003 12:39 9176349961

8/9  
IND INST OF CARD  
DIGIRAD IMAGING SOL

PAGE 08

PAGE 02



## EFFICIENCY TEST

Facility: Digirad Imaging Solutions  
Michigan City, IN

Date: 4/23/2003

Instrumentation: Geiger-Mueller  
Manfu: Ludlum  
Model: 14C  
Serial #: 17325

NaI(Tl) Probe  
Manfu: Ludlum  
Model: 44-3  
Serial #: PR198189

### Scaled Source Information:

Nuclide: Co<sup>57</sup>  
Type: Disk  
Cal. Activity: 0.1 uCi

Cal. Date: 4/1/2002

Calc. DPM: 82,520

### Testing Data:

Observed Average Reading: 4,000

Bkg: 400 cpm

Efficiency:  
Observed CPM/Calculated DPM

MDA Calculations:  
(4.65 (Sq. Root(Bkg))/Eff)

Co<sup>57</sup> Eff: 0.048

MDA: 1938

MDA Action Level: 2000 DPM/100 cm<sup>2</sup>

Comments: The sensitivity of the instrument is sufficient to detect 2000 DPM/100 cm<sup>2</sup>  
or 6000 DPM/300 cm<sup>2</sup>.

Performed by: Karen Hatcher, Chief NMT

Reviewed and approved by: Paul J. Early, Corporate RSO

A handwritten signature in black ink, appearing to read "Paul J. Early", written over a horizontal line.



NRC FORM 313A (AUD)  
1-0 2005

U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**PART II - PRECEPTOR ATTESTATION**

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

**First Section**

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that \_\_\_\_\_ has satisfactorily completed the requirements in

Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that \_\_\_\_\_ has satisfactorily completed the 60 hours of training and

Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that \_\_\_\_\_ has satisfactorily completed the requirements in

Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

X I attest that GEORGE J. GROEVICH, M.D. has satisfactorily completed the 700 hours of training

Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**Second Section**

Complete the following for preceptor attestation and signature:

X I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

X 35.190 X 35.290 ☐ 35.390 ☐ 35.390 + generator experience

Name of Preceptor

Signature

Telephone Number

Date

ROBERT L. LITCHFIELD, D.O.

License/Permit Number/Facility Name

(219) 836-9390

4/17/07

RADIOACTIVE MATERIALS LICENSE # 13-32400-01/CARDIOSPECIALISTS GROUP