

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  
Bernus Point, NY 14712  
PH: 716-386-3860  
FX: 716-386-4376  
Cell: 216-496-7824

**( ) GA OFFICE:**

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

April 2, 2005

**VIA FAX (610-337-5393)**

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

03035802

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

To Whom It May Concern:

Please amend our license to **ADD** the following **Authorized User**:

**Jack Newman, M.D. – for 35.200 Nuclear Cardiology imaging.**

(Refer to attached NC RAM License #060-1014-3.)

Thank you for your immediate attention to this matter.

Sincerely,

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



**RADIOACTIVE MATERIALS BRANCH  
RADIATION PROTECTION SECTION  
N. C. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES**

**RADIOACTIVE MATERIALS LICENSE**

Pursuant to North Carolina Regulations for Protection Against Radiation and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer, and import radioactive materials listed below; and use such radioactive material for the purpose(s) and at the place(s) designated below. This License is subject to all applicable rules and regulations of the North Carolina Department of Environment and Natural Resources now and hereafter in effect and to any conditions specified below.

1. Licensee Name: Digirad Imaging Solutions, Inc.		3. License No: 060-1014-3		License Type 0280
2a. Mailing Address: PO Box 340 Bemus Point, NY 14712		4. Expiration Date: August 31, 2006		
b. Physical Address: 3210 Motorsports Lane, Suite 4 Charlotte NC 28269		<input type="checkbox"/> New License	<input checked="" type="checkbox"/> Routine	<input type="checkbox"/> Corrected Copy
c. Radiation Safety Officer: Costa Andreou, MD		<input type="checkbox"/> Renewal	<input type="checkbox"/> Administrative	<input type="checkbox"/> Termination
		5.a. Amendment No.: 30		
		b. Issuance Date: March 2, 2005		

6. Radioactive Material (element and mass no.)	7. Chemical and/or Physical Form	8. Maximum Amount of Radioactivity and/or Quantity of Radioactive Material which Licensee May Possess at Any One Time.
A. Any radioactive material listed in Groups I - III in DRP Publication 97-01	A. Any radiopharmaceutical listed in Groups I - III in DRP Publication 97-01, except in the form of gases, gases in solution, aerosols, or generators	A. As necessary for uses authorized in 9.A., Groups I - III.
B. Any radioactive material authorized under 15A NCAC 11 .0321(c)(5).	B. Any form as specified in 15A NCAC 11 .0321(c)(5)(A) - (D).	B. No single source to exceed the limits specified in 15A NCAC 11 .0321(c)(5)(A) - (D).
C. Cobalt 57	C. Sealed Source	C. No single source to exceed 15 millicuries.

9. Authorized Use (To be used for):

A. To be used in accordance with a written directive from an authorized user authorized by this license.

B & C. To be used for instrument quality assurance/quality control.

**CONDITIONS**

10. A. Radioactive material may only be used at the following client addresses:
- |                                                                                                |                                                                                     |
|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| i. Bethany Medical Center<br>3604 Peters Court<br>High Point, NC 27262                         | ii. Statesville Cardiovascular Clinic PA<br>738 Bryant St.<br>Statesville, NC 28625 |
| iii. Piedmont Healthcare Internal Medicine<br>138 Sherlock Drive<br>Statesville, NC 28625-1916 | iv. Thomasville Medical Associates<br>309 Pinewood Road<br>Thomasville, NC 27360    |
| v. First Care<br>2938 The Plaza<br>Charlotte, NC 28205                                         | vi. First Care<br>404 South Southerland Ave.<br>Monroe, NC 28112-5060               |



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**CONDITIONS (continued):**

- |                                                                                 |                                                                                 |
|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| vii. Cary Cardiology<br>300 Keisler Dr.<br>Cary, NC 27511                       | viii. William S. Roberts, MD, PA<br>2300 B Randolph Road<br>Charlotte, NC 28207 |
| ix. Piedmont Healthcare, PA<br>208 Old Mocksville Road<br>Statesville, NC 28625 | x. Farrington Family Practice<br>401 Mocksville Ave.<br>Salisbury, NC 28144     |
| xi. South Point Family Practice<br>1220 Spruce St.<br>Belmont, NC 28012         |                                                                                 |

10. B. Radioactive may be used by the following individuals:

- |                                                                                |                                                             |
|--------------------------------------------------------------------------------|-------------------------------------------------------------|
| i. Jack Newman, MD                                                             | ii. Rocco Tritico, MD, and Jack Newman, MD                  |
| iii. Rocco Tritico, MD, Jack Newman, MD, Dale Haggman, DO                      | iv. Jack Newman, MD                                         |
| v. Kevin Sharkey, MD, Jerome Williams, MD, Jack Newman, MD                     | vi. Kevin Sharkey, MD, Jerome Williams, MD, Jack Newman, MD |
| vii. Costa Andreou, MD, Jack Newman, MD                                        | viii. Jack Newman, MD                                       |
| ix. Jack Newman, MD, Rocco Tritico, MD, Dale Haggman, DO                       | x. Jack Newman, MD                                          |
| xi. Costa Andreou, MD, Jack Newman, MD, Kevin Sharkey, MD, Jerome Williams, MD |                                                             |

C. The licensee shall not order radioactive material to be delivered directly from the manufacturer or distributor to the client's address of use.

D. Notwithstanding Condition B. above, the licensee may receive radioactive materials from the manufacturer or distributor directly aboard the mobile coach.

11. The licensee shall comply with the provisions of 15A NCAC 11 .1600 "Standards for Protection Against Radiation," and 15A NCAC 11 .1000 "Notices, Instructions, Reports and Inspections." (The North Carolina Regulations for Protection Against Radiation are contained in 15A NCAC 11.)

12. A. Radioactive materials shall not be used on humans without obtaining prior written approval, in accordance with 15A NCAC 11 .0356, from an authorized user listed in Condition 10.B. above.

B. The Radiation Safety Officer for the activities authorized by this license shall be Costa Andreou, MD.

13. A. The licensee shall obtain a letter signed by the management of each client listed in Condition No. 10.A. at which services are rendered that authorizes the licensee to use radioactive material at the client's address of use. The letter is to be retained for two (2) years after the last provision of service.

B. Notwithstanding the requirements of Condition No. 13.A. above, the licensee pursuant to 15A NCAC 11 .0351(a) shall not provide mobile nuclear medicine services to any facility without prior written approval from this agency.

14. A. The licensee shall maintain all records required by this license and applicable sections of 15A NCAC 11 at the address stated in Item 2.b. above. Such records shall be made available, at all reasonable times, for inspection by the agency.



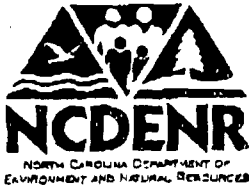
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**RADIOACTIVE MATERIALS LICENSE**

**CONDITIONS (continued):**

14. B. Notwithstanding Condition No. 14.A. above, the licensee shall maintain, at a minimum, the following records on the mobile coach:
1. copies of the license, application, and North Carolina Regulations for Protection Against Radiation;
  2. copy of current policies and procedures manual;
  3. copy of current trip instrumentation QA/QC tests;
  4. copy of current trip sealed source inventory;
  5. copy of survey meter calibration records;
  6. documentation of all contamination and other surveys required by condition of this license;
  7. copy of current trip receipt records for radioactive material.
15. The licensee may transport licensed material or deliver licensed material to a carrier for transport, in accordance with the provisions of Section 71.5, Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material For Transport."
16. Before leaving a client address of use, the licensee shall remove all unused radioactive material and all paraphernalia which were utilized to administer the radiopharmaceutical dose to any patient(s). All areas of use must be surveyed before leaving a client address of use to ensure radiopharmaceuticals and associated radioactive waste have been removed. These records should be retained for two (2) years.
17. The licensee is authorized to conduct a decay-in-storage program at the physical address listed in Item 2.b. above in accordance with 15A NCAC 11 .0362.
18. The licensee must check survey instruments, dose calibrators and all other transported equipment for proper function before medical use at each client address of use.
19. A. The licensee shall establish written procedures for performing the following tests on dose calibrator(s) used to determine the quantity and quality of radiopharmaceuticals:
1. Geometric variation to be performed prior to use at each use location and/or daily;
  2. Accuracy to be performed upon installation prior to use at each use location and/or daily;
  3. Linearity to be performed upon installation and/or daily thereafter;
    - a. The dose calibrator shall be tested for linearity from the highest dosage administered to a patient down to the lowest dosage administered.
    - b. The licensee may use a commercially available attenuator set for performing linearity tests of his dose calibrator provided that the current manufacturer instructions are followed.
  4. Constancy to be performed prior to use at each use location and daily thereafter if at that location more than one (1) day.
- B. Records of the results of the tests outlined in Condition 19.A. above shall be maintained for a minimum of three (3) years following the completion of the test for inspection by the agency.
- C. The licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (0.37 MBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
20. A. The licensee shall establish written procedures for performing the following tests on the gamma camera(s):
1. Uniformity tests to be performed prior to use at each location and daily thereafter if at that location for more than one (1) day.



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**CONDITIONS (continued):**

20. A. 2. Resolution tests to be performed in accordance with manufacturer's specifications.
- B. Records of the results of the tests outlined in Condition No. 20.A., above, shall be maintained for inspection by the agency for a minimum of two (2) years following the performance of the tests.
21. The licensee must secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use.
22. A. The licensee shall conduct a physical inventory to account for all sealed sources before departing the client's address of use.
- B. Notwithstanding the daily physical inventory described in Condition No. 22.A., above, the licensee shall conduct and document a physical inventory every three (3) months to account for all sealed sources received and possessed under this license which are used for the calibration/reference of the dose calibrator and patient imaging equipment. Sealed sources in storage may be inventoried as a group provided that there is no evidence that the storage container has been opened. Records of the inventories shall be maintained for inspection by the agency and shall include the quantities and kinds of radioactive material, location of sources, individual performing the inventory and the date of the inventory.
23. Radiopharmaceuticals and reagent kits shall be procured from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and pyrogenicity.
24. Radioactive materials shall not be used on humans until its assay has been established.
25. A. Each sealed source containing radioactive material, other than Hydrogen 3, with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage at intervals not to exceed three (3) years and prior to any use or transfer to another person unless they have been leak tested within six (6) months prior to the date of use or transfer.
- B. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma-emitting material or 10 microcuries or less of alpha-emitting material.
- C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency.
- D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Agency regulations. A report shall be filed within five (5) days of the test with the Radioactive Materials Branch, Radiation Protection Section, Department of Environment and Natural Resources, 1645 Mail Service Center, Raleigh, N.C. 27699-1645 describing the equipment involved, the test results, and the corrective action taken.
- E. Tests for leakage and/or contamination shall be performed by persons specifically authorized by the Agency to perform such services.
26. In addition to the possession limits in Item 8 above, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 15A NCAC 11 .0353 for establishing decommissioning financial assurance.
27. The licensee shall perform surveys of all areas where radioactive materials and/or radiopharmaceuticals are used, prepared, administered, and/or stored in accordance with 15A NCAC 11 .0360.



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**CONDITIONS (continued):**

18. The licensee shall ensure that no individual "member of the public" [Reference: 15A NCAC 11 .0104(64)] receives a radiation dose in excess of the limits specified in 15A NCAC 11 .1611(a) while conducting licensed operations.
19. The licensee shall institute the provisions of 15A NCAC 11 .1610 when an occupationally exposed woman voluntarily informs her supervisor, in writing, of her pregnancy and the estimated date of conception.
30. The licensee shall annually review its Radiation Protection Program for content and implementation [Ref. 15A NCAC 11 .1603(c)]. Documentation of the Radiation Protection program reviews shall be retained for inspection by the agency [Ref. 15A NCAC 11 .1636].
31. Unless otherwise specified in the North Carolina Regulations for Protection Against Radiation [15A NCAC 11] or a specific condition on this Radioactive Materials License, all records shall be maintained for a minimum of five (5) years by the licensee for agency review.
32. All persons that drive or operate the mobile coach shall be trained in accordance with 15A NCAC 11 .1003.
33. The licensee shall comply with the applicable provisions of 15A NCAC 11 Section .0300 and .1600 regarding decommissioning of the mobile coach and license termination.
34. Neither this license nor any subsequent amendments shall be deemed to constitute compliance with the requirements for health planning review contained in the Certificate of Need Statute, G.S. 131-175 *et seq.*, and regulations promulgated pursuant to that statute. Inquiries concerning the Certificate of Need Statute should be addressed to the Certificate of Need Section of the Division of Facility Services at (919) 733-6360.
35. This license may be subject to amendment, revision, modification, suspension, or revocation in accordance with the provisions of 15A NCAC 11 .0344.
36. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6., 7., and 8. of this license in accordance with statements, representations and procedures and attachments listed below. The North Carolina Regulations for Protection Against Radiation shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
  - A. Application with attachments dated July 24, 2001, signed by signed by Paul J. Early, Corporate R.S.O.; letters with attachments dated April 13, 2001, July 13, 2001 and July 20, 2001, signed by Paul J. Early, Corporate R.S.O. and letter dated July 19, 2001, signed by Stephen A. McAdams, M.D., FCCP, CEO, Mid Carolina Cardiology.
  - B. Administrative Amendment based on corrections needed following license delivery on August 9, 2001.
  - C. Application for Amendment with attachments dated August 28, 2001, signed by Paul J. Early, Corporate R.S.O.
  - D. Application for Amendment with attachments dated October 18, 2001, signed by Paul J. Early, Corporate R.S.O.
  - E. Application for Amendment with attachments dated March 27, 2002, signed by Paul J. Early, Corporate R.S.O.
  - F. Application for Amendment with attachments dated May 6, 2002, signed by Paul J. Early, Corporate R.S.O.
  - G. Applications for License Amendment with attachments dated June 4 and June 24, 2002, both signed by Paul J. Early, Corporate RSO, and telephone conversation held between this office and Paul J. Early, Corporate RSO on June 26, 2002.
  - H. Application for Amendment with attachments dated September 10, 2002, signed by Paul J. Early, Corporate R.S.O.
  - I. Application for Amendment with attachments dated October 25, 2002 and facsimile dated November 04, 2002, both signed by Paul Early, Corporate RSO.
  - J. Application for Amendment with attachments dated January 30, 2003 and February 3, 2003, both signed by Paul Early, Corporate RSO.



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**RADIOACTIVE MATERIALS LICENSE**

**CONDITIONS (continued):**

36. K. Application for Amendment dated March 11, 2003, signed by Paul J. Early, RSO.
- L. Application for Amendment with attachments dated June 11, 2003, signed by Paul J. Early, Corporate RSO.
- M. Application for Amendment with attachments dated August 6, 2003, signed by Paul J. Early, Corporate RSO.
- N. Application for Amendment with attachments dated June 20, 2003, signed by Paul J. Early, Corporate RSO.
- O. Application for Amendment dated August 21, 2003, signed by Paul J. Early, Corporate RSO.
- P. Application for Amendment dated September 9, 2003, signed by Paul J. Early, Corporate RSO.
- Q. Application for Amendment with attachments dated October 16, 2003, signed by Paul J. Early, Corporate RSO.
- R. Application for Amendment with attachments dated October 24, 2003, signed by Paul J. Early, Corporate RSO.
- S. Application for Amendment with attachments dated November 24, 2003, signed by Paul J. Early, Corporate RSO.
- T. Application for Amendment with attachments dated December 08, 2003, signed by Paul J. Early, Corporate RSO.
- U. Application for Amendment with attachments dated December 17, 2003 and Application for Amendment dated December 30, 2003, both signed by Paul J. Early, Corporate R.S.O.
- V. Administrative Amendment.
- W. Letter dated April 1, 2004, signed by Paul J. Early, DABSNM, DABMP, VP, RSO.
- X. Application for Amendment with attachments dated May 11, 2004 signed by Paul J. Early, Corporate RSO.
- Y. Application for Amendment with attachments dated April 15, 2004 signed by Paul J. Early, Corporate RSO.
- Z. Application for Amendment with attachments dated July 8, 2004 signed by Paul J. Early, Corporate RSO.
- AA. Application for Amendment dated September 28, 2004, signed by Paul J. Early, Corporate RSO.
- BB. Applications for Amendment dated September 14, 2004 and September 22, 2004, and facsimile dated September 20, 2004, all signed by Paul J. Early, Corporate RSO.
- CC. Applications for Amendment dated October 8, 2004 and October 17, 2004, both signed by Paul J. Early, Corporate RSO.
- DD. Application for Amendment with attachments dated January 4, 2005, signed by Paul J. Early, Corporate RSO.
- EE. Applications for Amendment with attachments both dated February 7, 2005, both signed by Paul J. Early, Corporate RSO.

**For: Beverly O. Hall  
Chief, Radiation Protection Section**