

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



Please respond to the address indicated with the "X"

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September 20, 2006

Pamela Henderson, Branch Chief, NRC Region One
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

Re: Telephone Conference between NRC staff and Digirad Imaging Solutions on August 21, 2006

Dear Pam,

On behalf of Digirad Imaging Solutions, Inc. ("DIS"), I would like to take the opportunity to respond to some of the concerns and issues voiced by NRC staff during the telephone conference between the parties on August 21, 2006. Please note that this letter is not intended to convey DIS' substantive position on the issues discussed, including on the NRC's contention that certain conduct by DIS may have constituted, or did constitute, various violations. We wish to reserve our position on these matters until we receive a formal notification from the NRC. However, the telephone conference has caused us voluntarily to institute a number of additional safeguards, procedures and corrective actions immediately, and we wish to notify you of these actions and respectfully request that you take them into consideration in connection with your forthcoming notification of us.

Verification of Accuracy of Information Submitted in Connection with Application to add an Authorized User to DIS License

In connection with the NRC's concerns relating to DIS' attempts to verify the accuracy of information submitted to DIS by third parties in connection with DIS' applications to add an Authorized User to its license, DIS has taken the following additional steps:

- (1) Attached hereto as Exhibit A please find a new "Checklist for Verification of AU Credentials" we have created to assist our RSO staff in completing all of the verification steps that DIS has either previously agreed to undertake, or now understands the NRC wishes DIS also to undertake, in connection with seeking to verify the information submitted to it by third parties in connection with DIS' application to add a new Authorized User to its license. We have disseminated this form to all staff tasked with completing such verification attempts, and will from now on require that they complete it, sign it, date it, attach all requisite documentation, and submit it to me for review and sign-off before any application is submitted to the NRC.
- (2) We have counseled and re-trained the individual who did not contact a Continuing Medical Education provider listed in an AU applicant's documentation.

Waste and calibration material retained at DIS licensed facility during time facility status was in dispute

In connection with the NRC's concerns relating to retaining waste and calibration sources at DIS facilities that had been on DIS' license, but concerning which questions had arisen relating to whether DIS' operations there were "fixed" or "mobile," DIS has taken the following steps:

- (1) We have re-trained two of the three clinicians that failed to remove the waste and calibration materials from these premises despite direct orders immediately to collect and remove all such materials (the third has left our employ), and we are in the process of issuing written warnings to them as well.

Blocking and bracing RAM transported in private automobiles.

In connection with the NRC's concerns relating to whether RAM that is occasionally transported in private automobiles is properly blocked and braced, we have taken the following actions:

- (1) We are investigating means of obtaining more effective blocking and bracing materials that can fit uniformly within all types of automobiles and vans, and we will purchase such materials for all our facilities and train our employees in their use.

Thank you for your immediate attention to this matter. Please let us know whether you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Paul J. Early". The signature is written in a cursive, flowing style.

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

CHECK-LIST FOR VERIFICATION OF AU CREDENTIALS

Physician's Name (Print): _____

I. For physicians who are neither CBNC certified or named as an AU on another RML:

- The prospective licensee and AU must show evidence of the requisite number of didactic hours of training by submitting a certificate or letter indicating successful completion of the course.
Letter received on _____ and reviewed by _____
- The prospective licensee and AU must complete Exhibit H.
Exhibit A received on _____ and reviewed by _____
- The preceptor must complete **EITHER**
 - (a) the DIS "Sample Preceptor Letter" (Exhibit G), complete with the "Notice to Physician and Preceptor" at the bottom of the page, and
 - (b) the preceptor must complete the check-off list where the preceptor must initial after each clinical procedure and supervised work experience and RAM Handling procedure, complete with the false information disclaimer at the end of the document
Exhibit G received on _____
and reviewed by _____
Complete preceptor check-off list received on _____
and reviewed by _____
- **OR** the preceptor must complete the NRC Form 313A (10-2005) – see attached
NRC Form 313 A (10-2005) received on _____
and reviewed by _____

To further verify the validity of all physician and preceptor statements, the DIS RSO must:

- Personally contact each preceptor (>1 preceptor is acceptable) and verify that all preceptor statements (accountable to him/her) are valid by identifying each statement made in the preceptor document.

Preceptor _____ contacted on (date) _____
by _____; each preceptor statement
validated and validation confirmed by dating and initialing each
item on _____.

Preceptor _____ contacted on _____
by _____; each preceptor statement
validated and validation confirmed by dating and initialing each
item on _____.

- Contact the didactic training course(s) to verify his/her successful completion of the requisite number of hours.

Didactic training course entitled _____
and consisting of _____ hours verified as having been taken.
Verification completed on _____
by _____
by means of _____.

Didactic training course entitled _____
and consisting of _____ hours verified as having been taken.
Verification completed on _____
by _____
by means of _____.

- Acquire a copy of the preceptor's RML (Agreement or NRC) to prove that the preceptor is eligible to serve in a preceptor capacity (35.200 and/or 35.300 or Agreement State equivalent).

Copy of preceptor's RML license attached _____
Correct type of license verified _____

- Acquire contact numbers for all the above.

List names and telephone numbers/e-mail addresses of all persons
contacted in connection with this verification: _____

II. For physicians who are certified (CBNC, etc.), the DIS RSO must:

- Acquire a copy of the prospective AU's CBNC certificate

Certificate acquired on _____ by _____
Certificate #: _____ Year Certified: _____ and is **attached**.

- Contact the Certification Board (CBNC - www.cbnc.org - look under "Verification of Status" – or phone 240-631-8151) for verification or verify by contacting the Board via their website via the Contact Us form.

Website reviewed on _____

by _____

Results: _____

- **Competency Statement.** Acquire a copy of a written attestation, signed by a preceptor authorized user(s) who meets the requirements in 35.290, 35.390 and 35.290(c)(1)(ii)(G) or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of 35.290 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 35.100 and 35.200.

Competency statement received on _____ by _____

Signed by: _____

Competency statement received on _____ by _____

Signed by: _____

- Acquire a copy of the preceptor's RML (Agreement or NRC) to prove that the preceptor is eligible to serve in a preceptor capacity (35.200 and/or 35.300 or Agreement State equivalent).

Copy of preceptor's RML license attached _____

Correct type of license verified _____

- Acquire contact numbers for all the above.

List names and telephone numbers/e-mail addresses of all persons contacted in connection with this verification: _____

- **If Board Certified** (by whatever Board), verify that the board is one recognized by the NRC (recognition has an effective date, therefore, the status might have changed) via <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

Verification undertaken on _____ by _____

Results: _____

III. For physicians who are named as an AU on another RML, the DIS RSO must:

- **If NRC licensed**, verify that the physician is listed on an NRC license by acquiring a copy of the prospective AU's RML that shows the prospective AU is indeed qualified by being licensed for 35.200 and/or 35.300 clinical procedures.

RML acquired on _____ by _____
and copy attached hereto. Requisite license verified _____

- **If NRC licensed**, contact the NRC website (<http://www.nrc.gov/what-we-do/regulatory/enforcement.html>) to verify that no significant enforcement action has been issued to the physician.

Website reviewed on _____ by _____.

Results: _____

- **If Agreement State licensed**, verify that the physician is listed on an Agreement State license by acquiring a copy of the RML and ensuring that the physician is licensed for that state's equivalent of 35.200 and/or 35.300.

RML acquired on _____ by _____ and
copy attached hereto. Requisite license verified _____

- **If Agreement State licensed**, verify that no escalated enforcement action has been taken against the individual by contacting the applicable Agreement State. The Agreement State contacts can be found at: <http://www.hsrdo.org/nrc/rulemaking.htm>.

Agreement State _____ contacted on _____
by _____.

Results: _____

The foregoing information has been reviewed and verified by DIS' corporate Radiation Safety Officer.

Dated: _____

By: _____