

**Digirad Imaging Solutions, Inc.
NRC Pre-decisional Enforcement
Conference**

January 17, 2008



Pillsbury
Winthrop
Shaw
Pittman_{LLP}

Mark Casner
Mike Keenan
Paul Early
Traci Hollingshead
Dan Leddy
Daryl Shapiro

Presentation Agenda

- ▶ Introduction: Mark Casner, President/CEO, Digirad Corporation
- ▶ Overview of Presentation: Mike Keenan, President, Digirad Imaging Solutions
- ▶ Discussion of Apparent Violations: Paul Early, Vice President Emeritus – Radiation Safety, Digirad Corporation
- ▶ Discussion of Immediate Corrective Actions: Paul Early
- ▶ Discussion of Long Term Corrective Actions: Traci Hollingshead, Vice President, Corporate Radiation Safety, Digirad Corporation
- ▶ Application of NRC Enforcement Policy: Daryl Shapiro
- ▶ Concluding Remarks: Marc Casner, Mike Keenan



INTRODUCTION

Mark Casner
President/CEO
Digirad Corporation



OVERVIEW OF PRESENTATION

Mike Keenan

President

Digirad Imaging Solutions



Overview of Presentation

- ▶ We appreciate the significance of the issues we are here to discuss
 - The presence of our senior management team today is but one indication of our commitment to radiation safety and regulatory compliance
- ▶ Today we will discuss the specifics of each apparent violation
 - In some cases, we will agree with the NRC's findings
 - In other cases, we will disagree with your findings
 - In either case, our position should not be interpreted as anything short of a robust commitment to radiation safety and regulatory compliance
- ▶ We believe that our corrective actions, both immediate and longer term, have been and will continue to be effective in preventing today's issues from recurring



Overview of Presentation

- ▶ With respect to requests to add authorized users to our license, we believe our current validation and verification process will prevent future license submissions containing less than complete and accurate information
 - Our process goes beyond the commitments contained in the Confirmatory Order
 - Our process also goes well beyond what our peer licensees do
- ▶ With respect to the addition of base sites to our license, it is unfortunate that much of the confusion over the license and resulting impact on our business and patient care could not be avoided. Hopefully, both the NRC and Digirad learned from this experience and similar future scenarios can be avoided
- ▶ We are anxious to discuss with you the many and significant enhancements made to our Radiation Safety and Regulatory Compliance Program. As Digirad grows, so must our oversight and control over licensed activity. We understand this and are committed to maintaining a strong and effective Radiation Safety and Compliance Program



Overview of Presentation

- ▶ Thank you for the opportunity to be here today and address your concerns. We don't expect to be back
- ▶ Paul will begin our presentation with a discussion of the Apparent Violations



DISCUSSION OF APPARENT VIOLATIONS

Paul Early

Vice President Emeritus – Radiation Safety

Digirad Corporation



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Discussion of Apparent Violation #1

▶ Apparent Violation #1:

- 10 CFR 30.9 “Completeness and Accuracy of Information”
- “Digirad Imaging Solutions provided materially inaccurate information to the NRC in a preceptor statement which was part of a license amendment request dated April 19, 2006”

▶ Position on Apparent Violation:

- Digirad agrees that this violation occurred

▶ Reason for Violation:

- Like the NRC, Digirad relies upon doctors and other professionals to provide complete and accurate information
- Also, like the NRC, Digirad confirms or audits information provided to it by proposed Authorized Users and their preceptors
- In this case, despite Digirad confirming preceptor information, the information was false
- The violation on the part of Digirad is neither intentional or in careless disregard of NRC requirements



Discussion of Apparent Violation #1

▶ Facts:

- In response to a previous violation regarding a proposed authorized user providing inaccurate information to Digirad which was included in a license amendment application, Digirad agreed to the following measures to ensure that future submittals would be complete and accurate in all material respects:
 - Digirad now attaches to physician and preceptor statements a notice equivalent to the following:
 - ▶ **“Notice to Physician and Preceptor: 10 CFR Sections 30.9(a) and 30.10(a) require that all information provided to the Nuclear Regulatory Commission by a licensee or its agents shall be complete and accurate in all material respects. The submission of false information constitutes a serious violation of applicable regulations and may cause you or us to be fined, to lose licensing privileges, or to suffer other significant penalties.”**



Discussion of Apparent Violation #1

- Digirad now requires any physician that is added to its license to sign and date a document containing a statement equivalent to the following:
 - ▶ **“In connection with my application to be named as an Authorized User on Digirad Imaging Solution’s (DIS) radioactive materials license. I am aware that the submission of information that is not complete and accurate in all material respects is a violation of 10 CFR Sections 30.9(a) and 30.10(a). I hereby represent and warrant that, to the best of my knowledge, the information I have submitted to DIS in connection with my application to be named as an Authorized User is complete and accurate in all material respects.”**
- For all future applicants, on a yearly basis Digirad audits the training and experience credentials of the first 10 AU applicants and 25% of any applications received after the first 10 by endeavoring to locate and call preceptors as well as Continuing Medical Education providers to verify the information given by AU applicants



Discussion of Apparent Violation #1

Verification of Dr. Greco's Proposed Authorized User Information prior to license submittal:

- Didactic training documents were received:
 - ▶ Training program (Health & Radiological Seminars) was well known and acceptable to the NRC
- T&E documents signed by Dr. Fisher and received **prior to** NRC application submission.
 - ▶ All information validated with preceptor.
 - Preceptor was a therapy radiologist. This did not provide a "red flag" since there are many NRC licenses who have "All" under the "Material and Use" column, thus encompassing all diagnostic and all therapeutic uses of Nuclear Medicine
 - ▶ Confirmation letter from Dr. Wall re: 17 years of experience
 - ▶ Confirmation letter from Dr. McLaughlin re: 12 years of experience
 - ▶ AU Attestation Statement. AU applicant verified the information by signing the Attestation Statement



Discussion of Apparent Violation #1

- Preceptor Check-Off List – check off of all procedures performed under the supervision of the AU & preceptor attestation statement
 - ▶ Contacted preceptor to verify information
 - ▶ NRC does not require a copy of the preceptor RML for verification
- Obtained and reviewed 17 pages of patient studies – over 750 in one year.
- T&E documents received **after** NRC application submission
 - ▶ Confirmation letter from radiopharmacy re: eluting generator/preparing kits
 - ▶ Confirmation letter from Dr. Rossi (an AU) re: review of records
 - ▶ **Physician in this case has passed the CBNC** in the 90 percentile and is, by virtue of that fact alone, eligible for licensure as an AU
- Unfortunately, despite implementing the requirements of the Confirmatory Order and taking action beyond the Confirmatory Order, Digirad relied on information from the preceptor which was false



Discussion of Apparent Violation #2

▶ Apparent Violation #2:

- 10 CFR 30.9 “Completeness and Accuracy of Information”
- “Numerous amendment applications submitted to the NRC between November 2001 and April 2006, requesting certain additional base site locations, were materially incomplete”

▶ Position on Apparent Violation:

- Digirad disagrees that any regulation violation occurred
- Digirad met the requirement of 10CFR20.1801(“Security of Stored Material”) and 10CFR30.80(b)

▶ Basis for Position:

- In February 2005, Digirad Corporate RSO raised to the NRC an issue that Digirad had just resolved with the State of New Jersey pertaining to how fixed and mobile facilities were licensed. NJ resolved by issuing a separate RML for the fixed site – a simple solution
- Corporate RSO raised this issue to NRC in case NRC desired similar licensing action



Discussion of Apparent Violation #2

- Between February, 2005 and April, 2006, many telephone calls and e-mails were exchanged between the Corporate RSO and NRC Region I license reviewers and other NRC personnel regarding this issue. There seemed to be much confusion in what seemed to be a simple matter for NJ. Ultimately:
 - **NRC, Region I did not hold the same definition of “fixed” and “mobile” as State of NJ**
 - **Region I’s focus was whether the site was a base site (either owned by Digirad or supported by a lease agreement) or a client site (neither owned by Digirad nor supported by a lease agreement)**
 - **Region I directed that RAM could not be delivered to sites not owned or leased by Digirad unless given directly to Digirad personnel. This direction was later reversed by OGC/NMSS interpretation**
 - **The overriding concern by Digirad was to be able to receive RAM in the absence of Digirad personnel**



Discussion of Apparent Violation #2

- At all times, sites that were neither owned by Digirad nor supported by lease agreements were covered by Memoranda Of Understanding (MOU) between Digirad and the owner of the facility
 - **These MOUs recognized that material licensed by the NRC would be used and stored at the facility in accordance with NRC regulations.**
 - **Further, the MOUs confirmed Digirad's access to the licensed material and ability to secure radioactive material from unauthorized removal**
 - **Licensed material at these facilities was secured in a hot lab with access restricted to Digirad personnel and the radiopharmacy**



Discussion of Apparent Violation #2

- Digirad prepared a revision of the existing MOU to satisfy the NRC's concern over the control of licensed material. This resolution was rejected by the NRC on April 7, 2006, and the NRC directed that Digirad file an exemption request. On July 6, 2006, the NRC reversed its position on this issue
- As an alternative means of resolving this issue, Digirad proposed that it receive licensed material at its vans at client sites. The NRC rejected this approach on April 12, 2006, directing that "delivery of byproduct material to the DIS van is not currently authorized." On May 22, 2006, the NRC reversed its position and recognized that "licensed material may be delivered to the licensee's mobile van located at temporary job sites."



Discussion of Apparent Violation #2

- On April 4, 2006, at **4:30pm**, NRC Region I told the Digirad Corporate RSO over the phone that:
 - ***Effective immediately***, no RAM could be delivered to any sites without a lease agreement thus changing affected base sites into client sites
 - Digirad could receive RAM either directly at the radiopharmacy and transport them to the clinical site or receive RAM at its vans at the clinical site by DIS personnel
 - another reversal of the 10/17/05 and 12/1/05 email directives from the NRC which said that we could receive RAM at the clinical site if Digirad personnel were present to receive them
 - A verbal request for a time extension was denied, despite MOUs in place at each affected facility that ensure the security of stored material



Tangible Impact to Digirad as a result of NRC's Directives

▶ Patient Care:

- Many patients had to be cancelled because the RAM was not delivered/received on time due to weather, van problems, etc. This was a potential risk to patients with heart problems

▶ Lost customers:

- Michigan City, IN \$330,000 /yr.
- Philadelphia, PA \$670,000/yr
- Egg Harbor, NJ \$960,000/yr
- Ridley Park, PA (retained)

▶ Overtime to personnel:

- Deliver doses/pick up RAM waste 32 x /wk at 4 sites:
- 48 hrs OT/wk @ \$50/hr x 16 weeks = \$38,400
- Travel expense; wear and tear on vans ~\$5,000

▶ Other cost issues:

- Excessive management time to work out logistics and communicating the issue with customers and employees to reduce the anxiety level
- Excessive time spent managing the issue created employee retention problems – and then hiring/training new personnel
- A Tc99m shortage during this time had no impact on the NRC decision.
- Potential risk to our organization due to disruption of service.



Discussion of Apparent Violation #3

▶ Apparent Violation #3:

- 10 CFR 20.1801 “Security of Stored Material”
- “Failure to secure from unauthorized removal or access licensed material stored in an uncontrolled area at various client sites”

▶ Position on Apparent Violation:

- Digirad disagrees with portions of the apparent violation
- Some of the material identified by the NRC as not being secured is exempt material, not regulated by the NRC



Discussion of Apparent Violation #3

▶ Basis for Position:

- On April 4, 2006, the NRC directed that Digirad could not receive radioactive material at sites where it did not possess a lease agreement. This direction caused significant disruption of Digirad's business and patient care
 - This disruption was compounded by the NRC's refusal to grant an exemption or delay in compliance despite all substantive provisions of the required lease agreement being in effect
 - This disruption was also exacerbated due to the fact that all NARM (e.g., Co57 flood) and exempt quantities were able to be secured in the hot lab during this time
 - This disruption was also compounded by the NRC's position that Digirad could not receive RAM in its van located at a client site during the time period when the NRC-required lease agreements were being finalized
 - ▶ The NRC's position was inconsistent with NUREG-1556 – Program-Specific Guidance about Medical Use Licensees
 - ▶ Ultimately, after several months of internal deliberations, the NRC reversed its position and recognized that Digirad could receive RAM in its vans at client sites



Discussion of Apparent Violation #3

- On April 4 and 13, 2006, Digirad, through the Corporate RSO, implemented the NRC direction by issuing immediately effective instructions to the affected facilities. These instructions directed that:
 - **EFFECTIVE IMMEDIATELY**, the only way of transporting RAM to affected sites where Digirad did not possess a lease agreement was by Digirad personnel picking up RAM at the radiopharmacy and transporting them back to these affected sites in accordance with DOT regulations
 - Sites affected by this decree were:
 - ▶ **Ridley Park, PA**
 - ▶ **Egg Harbor, NJ**
 - ▶ **Philadelphia, PA**
 - ▶ **Michigan City, IN**
 - ▶ **Munster, IN** – (never used as a base site)
 - ▶ **Aliquippa, PA** – (never used as a base site)



Discussion of Apparent Violation #3

- April 14, 2006: Digirad confirmed implementation of directives
- After July 21, 2006 meeting with NRC inspectors, the Regional RSO re-confirmed that the affected sites were implementing the RSO's direction regarding the storing of licensed material
- As a results of this action, the Regional RSO discovered that, in some cases, NMTs were leaving RAM waste secured in the hot lab at sites that do not yet have NRC-required lease agreements
- Regional RSO reported this information to the RSO and reinstructed NMTs immediately.
- Same day (7/21/06) Clinical Operations Manager talked to NMTs and confirmed that, until further notice, licensed material would no longer be stored in the hot lab



Discussion of Apparent Violation #3

▶ **CONCLUSION:**

- In some cases, Digirad employees did not ensure that licensed material in the form of waste and a sealed source was removed from affected sites on a daily basis. This material, however, was always secured in the hot lab at each site
- Each of the affected sites are now permitted to receive and store licensed material



DISCUSSION OF IMMEDIATE CORRECTIVE ACTIONS

Paul Early



Discussion of Immediate Corrective Actions

▶ Enhanced Practice to Verify Credentials for Authorized User and Preceptor Information:

- Verify credentials of **ALL** AU applicants prior to license submission, not just audit the first 10 AU applicants and 25% of any applications received after the first 10. **This exceeds the ADR commitments**
- Endeavor to locate and call preceptors as well as Continuing Medical Education providers to verify the information given by AU applicants.
- Created a “*Memorandum Of Understanding (MOU) By An AU To Be Named On a DIS RML*” to be signed by all AU applicants. By signing this form, the AU applicant commits to complying with the DIS Radiation Safety Procedure Manual, and providing guidance and supervision for the receipt, use and/or transfer of RAM and to provide instruction in RAM use. **This exceeds ADR commitments**
- A “Preceptor Check Off List” must be completed by all preceptors. The preceptor is required to initial every procedure that he personally supervised. A “Preceptor Attestation Statement” is included in check off list to reiterate that all information provided on the form must be accurate and that false information constitutes a serious violation subject to significant penalties. **This exceeds ADR commitments.**
- Preceptors are contacted to validate their information. **This exceeds ADR commitments**



Discussion of Immediate Corrective Actions

▶ Enhanced Practice to Verify Credentials for Authorized User and Preceptor Information (cont.):

- A “*Preceptor Attestation Statement*” must be signed by the preceptor to verify that the preceptored physician satisfies NRC regulations for licensure, that the preceptor holds a valid RML indicating that he can serve as the preceptor and includes the “Preceptor Attestation Statement”
 - Ensure valid preceptor RML by obtaining a copy. **This exceeds ADR commitment**
- An “*AU Attestation Statement*” must be signed by the AU to verify that the material submitted by the AU is valid and that information provided by the AU must be accurate and that false information constitutes a serious violation subject to significant penalties
- The “*Check-List For Verification Of AU Credentials*” must be completed by Digirad RSOs to validate AU credentials in 3 categories: (1) for physicians who are neither CBNC certified or named as an AU on a previous RML, (2) for physicians who are CBNC (or other) certified, and (3) for physicians who have been previously named as an AU on another RML. Each category addresses the issues raised in the previous ADR resolution. **This exceeds ADR commitments**



Discussion of Immediate Corrective Actions

▶ **Enhanced Practice for Ensuring Control of RAM at Base Sites**

- All supervisors of NMTs receive specific guidance on changes in NRC regulations. They are required to train all NMTs on these changes
- All NMTs that did not follow the directions of the Corporate RSO have been disciplined. They are made aware that any future such inattention to these kinds of details is cause for termination
- We hold employees accountable for complying with radiation safety procedures by reinforcing requirements and consistently applying our progressive disciplinary policy. As an example, we recently terminated an NMT for failing to comply with corporate procedures
- All present and future lease agreements carry the language of “exclusive control” of the hot lab.
 - This provision will be emphasized at the time of the signing of the lease agreement
 - This control issue will also be reinforced in the annual education of the staff, both Digirad and clinical site staff



DISCUSSION OF LONG TERM CORRECTION ACTIONS

Traci Hollingshead
Vice President
Corporate Radiation Safety
Digirad Imaging Solutions



Discussion of Enhanced Radiation Safety and Compliance Program

- ▶ Digirad Enhanced It's Radiation Safety and Compliance Program over the past 18 months:
 - Developed 3 Regions in the U.S.: NE, SE and W.
 - Developed a Radiation Safety "Emeritus" position to provide oversight for the entire radiation safety and compliance program.
 - Expanded the RSO staff from 3 to 5 Radiation Safety Professionals:
 - V.P. Emeritus – Radiation Safety
 - V.P., Corporate Radiation Safety
 - 3 Regional RSOs (1 position to be filled)
 - Developed a "Hub Operations Supervisor" position for each hub to monitor operations from each hub to provide another layer of supervision, to include radiation safety policies and procedures
 - Expanded the Area Operation Manager (AOM) program to include two to three AOMs in each Region. AOMs provide an additional layer of supervision, to include radiation safety policies and procedures
 - Expanded the third party oversight program



Discussion of Corporate Radiation Safety Program

- ▶ DIS Enhanced Radiation Safety and Compliance Program (continued)
 - Hold bi-weekly Radiation Safety teleconferences, even though a Radiation Safety Committee is not required of the kind of program that is DIS. Attendees are: physicians, management, operations, and NMTs
 - Hold bi-weekly meeting of the RSO team
 - Expanded the “surprise” audit program which performs unannounced audits of the clinical teams in their clinical sites – not a regulatory requirement. The goal is to audit each clinical team at least once per year
 - Expanded the Radiation Safety and ALARA Review from annual (as required by regulation) to semi-annual reviews as requested by the Digirad’s Executive Team



Discussion of Corporate Radiation Safety Program

▶ DIS Enhanced Radiation Safety and Compliance Program (continued)

- Developed a “Preceptor Check Off List”. The preceptor is required to initial every procedure that he/she personally supervised. A “Preceptor Attestation Statement” is included in check off list to reiterate that all information provided on the form must be accurate and that false information constitutes a serious violation subject to significant penalties
- Developed a “Check List For Verification of AU Credentials” to challenges all the appropriate facets of AU credentials for 3 categories: (1) for physicians who are neither CBNC (or other) certified or named as an AU on a previous RML, (2) for physicians who are CBNC certified, and (3) for physicians who have been previously named as an AU on another RML. Each category addresses the issues raised in the previous ADR resolution
- Check List is used for ALL AU applications



Application of NRC Enforcement Policy

- ▶ Apparent Violation #1:
 - Not willful on the party of Digirad
 - Neither intentional or in careless disregard
 - Digirad exceeded the requirements in the Confirmatory Order
 - No actual safety significance
 - Properly cited as Level 4 violation
 - Not caused by “inadequate actions on the part of licensee officials”
 - Caused by inaccurate statement provided by non-employee
 - If cited as level 3 violation, it should be considered 1st non-willful in past 2 years and credit for corrective action is warranted
 - Therefore, no civil penalty should be assessed



CONCLUDING REMARKS

Marc Casner
Michael Keenan

