



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555 - 0001

January 27, 2006

EA-05-110

Alfred C. Burris, Senior, M.D.  
1328 Southern Avenue, S.E.  
Washington, D.C. 20032

SUBJECT: CONFIRMATION OF COMMITMENTS FOLLOWING ADR SESSION –  
NOTICE OF VIOLATION AND CONFIRMATORY ORDER  
(NRC Office of Investigations Report Nos. 1-2004-028 and 1-2004-034)

Dear Dr. Burris:

In two separate letters dated September 15, 2005, the NRC provided you with the results of two investigations completed by the NRC Office of Investigations (OI), Region I Field Office, on April 15, 2005, and June 15, 2005. The investigations were conducted to determine: (1) if you, as owner of a private medical practice and as an applicant for an NRC license, deliberately submitted false and/or inaccurate information to the NRC in an application for a license dated February 2, 2004; and (2) if you, as a proposed authorized user, submitted false information to Digirad Imaging Solutions, Inc. (Digirad) to become an Authorized User on Digirad's existing NRC license. As a result of the first investigation (OI Investigation Report No. 1-2004-028), OI concluded that you deliberately provided false, inaccurate and misleading information to the NRC, in support of an application for a license. As a result of the second investigation (OI Investigation Report No. 1-2004-034), OI concluded you deliberately submitted false information to Digirad to become an Authorized User on Digirad's existing NRC license. Factual Summaries of the OI investigations were enclosed with our September 15, 2005, letters.

Our September 15, 2005, letters also informed you that we were considering escalated enforcement action against you for an apparent violation of 10 CFR 30.10, NRC's rule prohibiting deliberate misconduct. This rule, in part, prohibits deliberately submitting false information to the NRC or to a licensee. 10 CFR 30.10(a) provides, in pertinent part, that any employee or contractor (including a supplier or a consultant) of any licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any rule, regulation, or any term, condition, or limitation of any license issued by the Commission. Our letter indicated that in apparent violation of 10 CFR 30.10(a), you deliberately: (1) caused your private medical practice, Alfred Burris, M.D., to submit inaccurate information to the NRC on February 2, 2004, regarding your previous experience and qualifications and thereby caused your medical practice (an NRC license applicant) to violate 10 CFR 30.9; and (2) caused Digirad to submit false information to the NRC in October 2003 regarding your experience and qualifications that was used to name you as an Authorized User on the Digirad license. In doing so, you caused

Digirad (an NRC licensee) to violate 10 CFR 30.9. 10 CFR 30.9 provides, in pertinent part, that information provided to the Commission by an applicant for a license or by a licensee shall be complete and accurate in all material respects.

As a result of these findings, our letter offered you a choice to: (1) attend a Predecisional Enforcement Conference; or (2) request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve any disagreement on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions. ADR is a general term encompassing various techniques for resolving conflict using a neutral third party, and the NRC currently has a pilot program for using ADR. The technique that the NRC decided to employ during the pilot program, which is now in effect, is mediation.

At your request, an ADR mediation session was held between you and the NRC in the NRC offices in Rockville, MD, on December 1, 2005, and a settlement agreement was reached regarding this matter. The elements of the settlement agreement are as follows:

1. You agreed that you were in violation of NRC requirements when, in an application for a new NRC license, dated February 2, 2004, you submitted inaccurate information contrary to 10 CFR 30.9(a). Specifically, your application indicated that you were listed as an authorized user (AU) on the Greater Southeast Community Hospital license, when you were not. In addition, the preceptor statement, prepared by a radiologist and attached to your application, inaccurately described required supervised work experience in handling nuclear materials.
2. While NRC and you agreed the violation was not deliberate, NRC maintained that it was in careless disregard of NRC's regulation.
3. Subsequent to becoming aware of the details of the violation, you took prompt actions to assure that you learned from this violation and provided the NRC with assurance that it would not recur. These actions included: (a) correcting inaccurate information for the record in a letter dated July 26, 2004; (b) providing details of the violation to associates in the process of getting character references; (c) supplementing your work experience in May 2004, when you began working with the nuclear medicine technologists at Greater Southeast Community Hospital; and (d) undertaking efforts to better understand regulatory requirements through self study and review of the consultant's letter of May 4, 2004.
4. During the ADR mediation session, you recognized an opportunity for other potential Authorized Users/Radiation Safety Officers in the industry to learn from your participation in the NRC enforcement process and your experiences regarding the necessity to provide complete and accurate information to the NRC. Therefore, you agreed to take the following future corrective actions: (a) submit an article for consideration to an appropriate medical journal that reaches an audience of cardiologists; (b) offer to speak at a training session at a meeting of the American Society of Nuclear Cardiology, a similar society, or at a Nuclear Cardiology symposium; and (c) write a letter to local cardiologists describing your experiences. In addition, you agreed to meet with a hospital RSO who has a knowledge of imaging and localization studies in order to review NRC requirements.

5. You agreed to complete the additional actions in Item 4 within 12 months of the date of the Order, and send a letter to the NRC informing the NRC that these actions are completed. You agreed to send this letter to the NRC within 30 days of completion of all actions.
6. In light of the actions you took as described in Item 3, those actions you have committed to take as described in Item 4, and your cooperation in providing information during the ADR session, the NRC agreed to issue a Severity Level III Notice of Violation (10 CFR 30.9) to you with no civil penalty. This action will be publicly available in ADAMS, will appear on the NRC "Significant Enforcement Actions - Individuals" website for a period of 1 year, and will be discussed in a press release announcing the ADR agreement between Dr. Burris and the NRC.
7. Any license application received from you will be reviewed without prejudice.
8. You agreed to issuance of a Confirmatory Order confirming this agreement.

After considering the information developed during the investigation and additional information you provided at the ADR session on December 1, 2005, the NRC has concluded that you submitted false and inaccurate information: (1) to the NRC in support of your license application dated February 2, 2004; and (2) to Digirad in October 2003 that was used to name you as an AU on their NRC license. The NRC has also concluded your failure to provide accurate information to the NRC constituted a violation of 10 CFR 30.9(a). The NRC further concluded that the violation was in careless disregard of the requirements of 10 CFR 30.9.

Enclosed with this letter is the Notice of Violation (Notice) and the Confirmatory Order (Order). You are not required to respond to this letter or Notice. However, in accordance with the settlement agreement, you are required to respond to the Order. Your written response to the Order, and your response to the Notice, if you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Regional Administrator, Region I, 475 Allendale Road, King of Prussia, PA 19406, and marked "Open by Addressee Only," within 30 days of the date of this letter.

A copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC will also include this letter on its website for a period of 1 year at [www.nrc.gov](http://www.nrc.gov); select **What We Do**,

Alfred Burris, M.D.

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**Enforcement, Significant Enforcement Actions.** Your response, if you choose to provide one, will also be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

If you have any questions or comments concerning this letter, please contact Ms. Sally Merchant of my staff at 301-415-2747.

Sincerely,

**/RA/**

Michael R. Johnson, Director  
Office of Enforcement

Enclosures: As Stated

cc (w/enclosure):  
Reginald W. Bours, III

Alfred Burris, M.D.

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## ENCLOSURE

### NOTICE OF VIOLATION

Alfred C. Burris, Senior, M.D.

EA-05-110

Based on the results of two investigations completed by the NRC Office of Investigations on April 15, 2005 and June 15, 2005, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.9(a) requires, in part, that information provided to the Commission by an applicant for a license shall be complete and accurate in all material respects.

10 CFR 35.12(b) states in part that an application for a license must be made by filing an original and one copy of NRC Form 313, "Application for Material License," that includes the training and experience qualifications of the Radiation Safety Officer and Authorized User.

Contrary to the above, on February 2, 2004, information provided to the NRC by Dr. Alfred C. Burris, Sr., as an applicant for an NRC license, was not accurate in all material respects. Specifically;

1. Dr. Burris submitted information that indicated he, as the planned Authorized User (AU) and Radiation Safety Officer (RSO) for the new license, was already named as an AU on the existing NRC license for Greater Southeast Community Hospital (GSCH). This statement was inaccurate in that Dr. Burris was not listed as an AU on the NRC license for GSCH at the time of the license application, nor had he ever been listed as an AU on the license for GSCH;
2. Dr. Burris submitted a preceptor statement signed by the Chairperson, Department of Radiology, GSCH, that indicated he had the required experience and training to be named as an AU on the NRC license. This statement was inaccurate because he did not have the required training as described in the preceptor statement.

These statements were material because they could have influenced the NRC as to whether a license should have been issued to Dr. Burris based on his training and experience.

This is a Severity Level III violation (Supplement VII).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved has been already adequately addressed in this letter, and during the ADR mediation session held on December 1, 2005. Therefore, you are not required to respond to this violation. However, if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-05-110" and send it to the U.S. Nuclear Regulatory

Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I within 30 days of the date of the letter transmitting this Notice.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated this 27<sup>th</sup> day of January 2006.

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

In the Matter of  
Alfred C. Burris, Senior, M.D.

EA 05-110

CONFIRMATORY ORDER  
(EFFECTIVE IMMEDIATELY)

I

Alfred C. Burris, Senior, M.D. (Dr. Burris) is a self-employed cardiologist, who is licensed to practice medicine in the State of Maryland and the District of Columbia. Dr. Burris submitted an application for an NRC license dated February 2, 2004, to authorize use of byproduct material for diagnostic nuclear medicine.

II

An investigation was initiated by the NRC Office of Investigations (OI) on May 24, 2004, (OI Case No. 1-2004-028) to determine if Dr. Burris submitted inaccurate and/or misleading information to the NRC in his NRC application to be the sole authorized user (AU) as well as the Radiation Safety Officer (RSO) on a license for use of byproduct material for medical imaging and diagnostic purposes. During the course of this investigation, OI identified that an NRC licensee, a mobile cardiac imaging company, may have provided the same inaccurate information in support of their amendment request to add Dr. Burris and another physician to its NRC materials license as Authorized Users. On August 6, 2004, OI initiated a separate investigation (OI Case No. 1-2004-034) to determine if Dr. Burris submitted false information to an NRC licensee to become an AU on their existing NRC license. Based on the evidence developed during its investigations, OI concluded that Dr. Burris deliberately submitted false and/or inaccurate information (1) to the NRC



as an applicant for an NRC license and (2) to an NRC licensee with the purpose to become an AU on their existing NRC license. The results of the two investigations were completed by OI on April 15, 2005 and June 15, 2005, and were sent to Dr. Burris in two letters dated September 15, 2005.

### III

Subsequent to becoming aware of the details of the apparent violation, Dr. Burris took several prompt actions to assure that these events would not recur. These actions included: (a) correcting inaccurate information for the record in a letter dated July 26, 2004; (b) providing details of the violation to associates in the process of getting character references; (c) supplementing his work experience in May 2004, when he began working with the nuclear medicine technologists at Greater Southeast Community Hospital; and (d) undertaking efforts to better understand regulatory requirements through self study and review of his consultant's letter of May 4, 2004.

In response to the NRC's September 15, 2005 letters, Dr. Burris requested the use of Alternative Dispute Resolution (ADR) to resolve this apparent violation and pending enforcement action. ADR is a process in which a neutral mediator, with no decision-making authority, assists the NRC and the individual to resolve any disagreements on whether a violation occurred, the appropriate enforcement action, and the appropriate corrective actions. An ADR session was held between Dr. Burris and the NRC in Rockville, MD, on December 1, 2005, and was mediated by a professional mediator, arranged through Cornell University's Institute of Conflict Management. During that ADR session, a settlement agreement was reached. The elements of the settlement agreement consisted of the following:

9. Dr. Burris agreed that he was in violation of NRC requirements when, in an application for a new NRC license, dated February 2, 2004, Dr. Burris submitted inaccurate information contrary to 10 CFR 30.9(a). Specifically, his application indicated that Dr. Burris was listed as an authorized user (AU) on the Greater Southeast Community Hospital license, when he was not. In addition, the preceptor statement, prepared by a radiologist and attached to his application, inaccurately described required supervised work experience in handling nuclear materials.
10. While NRC and Dr. Burris agreed the violation was not deliberate, NRC maintained that it was in careless disregard of NRC's regulation.
11. Dr. Burris, subsequent to becoming aware of the details of the violation, took prompt actions to assure that he learned from this violation and provided the NRC with assurance that it would not recur. These actions included: (a) correcting inaccurate information for the record in a letter dated July 26, 2004; (b) providing details of the violation to associates in the process of getting character references; (c) supplementing his work experience in May 2004, when Dr. Burris began working with the nuclear medicine technologists at Greater Southeast Community Hospital; and (d) undertaking efforts to better understand regulatory requirements through self study and review of his consultant's letter of May 4, 2004.
12. During the ADR mediation session, Dr. Burris recognized an opportunity for other potential Authorized Users/Radiation Safety Officers in the industry to learn from his participation in the NRC enforcement process and his experiences regarding the necessity to provide complete and accurate information to the NRC. Therefore, Dr. Burris agreed to take the following future corrective actions: (a) submit an article for consideration to an appropriate

medical journal that reaches an audience of cardiologists; (b) offer to speak at a training session at a meeting of the American Society of Nuclear Cardiology, a similar society, or at a Nuclear Cardiology symposium; and (c) write a letter to local cardiologists describing his experiences. In addition, Dr. Burriss agreed to meet with a hospital RSO who has a knowledge of imaging and localization studies in order to review NRC requirements.

13. Dr. Burriss agreed to complete the additional actions in Item 4 within 12 months of the date of the Order, and send a letter to the NRC informing the NRC that these actions are completed. Dr. Burriss agreed to send this letter to the NRC within 30 days of completion of all actions.
14. In light of the actions Dr. Burriss took as described in Item 3, those actions Dr. Burriss has committed to take as described in Item 4, and his cooperation in providing information during the ADR session, the NRC agreed to issue a Severity Level III Notice of Violation (10 CFR 30.9) to Dr. Burriss with no civil penalty. This action will be publicly available in ADAMS, will appear on the NRC "Significant Enforcement Actions - Individuals" website for a period of 1 year, and will be discussed in a press release announcing the ADR agreement between Dr. Burriss and the NRC.
15. Any license application received from Dr. Burriss will be reviewed without prejudice.
16. Dr. Burriss agreed to issuance of a Confirmatory Order confirming this agreement.

#### IV

In light of the actions Dr. Burris has taken and agreed to take to correct the violation and prevent recurrence, as set forth in Section III above, the NRC has concluded that its concerns regarding the violation can be resolved through the NRC's confirmation of the commitments as outlined in this Confirmatory Order.

I find that Dr. Burris' commitments as set forth in Section III above are acceptable. However, in view of the foregoing, I have determined that these commitments shall be confirmed by this Confirmatory Order. Based on the above, and Dr. Burris' consent, this Confirmatory Order is immediately effective upon issuance.

#### V

Accordingly, pursuant to Sections 103, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR § 2.202 and 10 CFR Part 30 and 35, IT IS HEREBY ORDERED, THAT:

1. Dr. Burris will (a) submit an article for consideration to an appropriate medical journal that reaches an audience of cardiologists; (b) offer to speak at a training session at a meeting of the American Society of Nuclear Cardiology, a similar society, or at a Nuclear Cardiology symposium; and (c) write a letter to local cardiologists describing his experiences. In addition, Dr. Burris agreed to meet with a hospital RSO who has a knowledge of imaging and localization studies in order to review NRC requirements.

2. Dr. Burriss will complete the actions in Section V.1 within 12 months of the date of this Order, and send a letter to the NRC informing the NRC that these actions are completed within 30 days of completion of all actions.

The Director, Office of Enforcement, may relax or rescind, in writing, any of the above conditions upon a showing by Dr. Burriss of good cause.

## VI

Any person adversely affected by this Confirmatory Order, other than Dr. Burriss, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and must include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Rulemaking and Adjudications Staff, Washington, D.C. 20555. Copies of the hearing request shall also be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Materials Litigation and Enforcement, and to the Director of the Division of Regulatory Improvement Programs at the same address. Because of continuing disruptions in delivery of mail to United States Government offices, it is requested that answers and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301-415-1101 or by e-mail to [hearingdocket@nrc.gov](mailto:hearingdocket@nrc.gov) and also to the Office of the General Counsel by means of facsimile transmission to 301-415-3725 or e-mail to [OGCMailCenter@nrc.gov](mailto:OGCMailCenter@nrc.gov). If such a person requests

a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR § 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order shall be sustained. AN ANSWER OR A REQUEST FOR A HEARING SHALL NOT STAY THE EFFECTIVENESS DATE OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

*/RA/*

Michael Johnson, Director  
Office of Enforcement

Dated this 27<sup>th</sup> day of January 2006