

FILED IN OPEN COURT
DATE 7/22/04
WESTERN DISTRICT OF VIRGINIA
HARRISONBURG DIVISION
DEPUTY CLERK

UNITED STATES OF AMERICA

v.

PERRY MORRISON BEALE

Criminal No. 3:04CR0052

All in violation of:

18 U.S.C. §1341

INFORMATION

The United States Attorney charges:

INTRODUCTION

At all times relevant to the Information:

**THE FOOD AND DRUG ADMINISTRATION'S REGULATION
OF MAMMOGRAPHY**

1. The Food and Drug Administration (FDA), United States Department of Health and Human Services, was an agency of the United States charged with the responsibility of protecting the health and safety of the American public by assuring, among other things, that mammography facilities and equipment were properly certified and adhered to certain quality standards to assure safe, reliable, and accurate mammography on a nationwide level.
2. The Mammography Quality Standards Act of 1992 (MQSA) and implementing regulations, codified at Title 42, United States Code, Section 263b, and Title 21, Code of Federal Regulations, Part 900, established national uniform quality standards for

mammography facilities, equipment, and personnel, including the qualifications for a medical physicist.

3. FDA regulations issued pursuant to the MQSA mandated that, as a part of its overall quality assurance program, each hospital shall have a medical physicist establish, monitor, and perform a survey of the hospital and its mammography equipment to assure that it meets the quality control and equipment standards. Such surveys were to be performed at least annually, and reports of such surveys were to be prepared and transmitted to the facility. Title 21, C.F.R. § 900.12(e)(9)(iv). Ultimately, these surveys would be provided to the FDA-approved accrediting body, which used the information to identify necessary corrective measures for facilities and to determine whether the facilities should maintain accreditation to perform mammography. Title 21, C.F.R., § 900.4(e)(20)(iii).

4. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program must have met, in part, the following initial qualifications: state licensure or approval or certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics surveys; a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics; 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and the experience of conducting surveys of at least one

mammography facility and a total of at least 10 mammography units. Title 21, C.F.R. § 900.12(a)(3)(i).

5. The regulations provided "alternative initial qualifications" for medical physicists who had maintained active status of any state licensure or approval, and had, prior to April 28, 1999, obtained a bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics, had 40 contact hours of documented specialized training in conducting surveys of mammography facilities, and had conducted surveys of at least one mammography facility and a total of at least 20 mammography units. Title 21, C.F.R. § 900.12(a)(3)(ii).

6. The American Board of Radiology (ABR) was a body determined by FDA to have procedures and requirements in place to ensure that medical physicists certified by the body were competent to perform physics surveys under 21 CFR § 900.12 (a)(3)(i) or (ii).

**THE NUCLEAR REGULATORY COMMISSION'S REGULATION OF
RADIOACTIVE DEVICES**

7. The United States Nuclear Regulatory Commission (NRC) was responsible for protecting the public health and safety, the common defense and security, and the environment, by licensing and inspecting nuclear facilities and activities of entities and individuals (licensees) using radioactive materials in areas where NRC maintained jurisdiction. Under Section 274b of the Atomic Energy Act, the NRC may enter into agreements with interested states

(Agreement States) to cede to those states its authority to license and inspect certain users of radioactive materials within state jurisdiction. Virginia and West Virginia did not enter into agreements with the NRC under Section 274b; therefore NRC maintained jurisdiction over certain entities or individuals using radioactive materials within these states. The NRC responsibilities included, among other things, the development and promulgation of regulations governing the possession and use of radioactive materials. The NRC was responsible for identifying and taking action to address noncompliances with its regulations and coordinating with international, Federal, state, and local agencies, as appropriate. The NRC's regulations were published in the Federal Register and codified in Title 10, Chapter I, of the Code of Federal Regulations, Volumes I and II, Parts 1-199.

8. Hospitals throughout the United States, in both Agreement States and states where NRC maintained jurisdiction, had nuclear medicine departments that provided, among other activities, diagnostic services to patients. Some of the diagnostic testing performed by nuclear medicine departments required the use of radioactive material. The NRC, in areas where it maintained jurisdiction, regulated the use of radioactive material and established specific requirements for handling these materials. Specifically, the NRC mandated that licensed hospitals conduct routine testing and inspections of certain equipment used by the nuclear medicine departments.

9. Title 10, C.F.R. § 35.900 established the requirements for a Radiation Safety Officer (RSO). An authorized RSO was an individual who, in part:

a. was certified by a specialty board whose certification process included all of the training and experience requirements of this section and whose certification had been recognized by the Commission or an Agreement State;

or

b. has had classroom and laboratory training as specified in the regulation; and has had one full year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the RSO on a Commission or Agreement State license that authorizes the medical use of byproduct material;

or

c. was an authorized user identified on the licensee's license.

10. Xenon 133 Gas (hereinafter referred to "Xenon gas") was a radioactive gas used for inhalation in pulmonary ventilation studies. Appendix O to NRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," provided model procedures for calculating worker doses from concentration of gases in work areas and for calculating spilled gas clearance times. Xenon gas clearance rate calculations, required by 10 C.F.R. 35.205(c) determined the amount of time that would be needed to clear accidentally spilled radioactive Xenon gas from rooms where it was to be used. The clearance times were important for workers and patients in instances where Xenon gas was spilled and workers and

patients needed to be evacuated. Dose calibrator accuracy tests, required by 10 C.F.R. 35.50(b)(2), compared a known radiation activity to that measured by the calibrator. The dose calibrator tests were important for ensuring that the dose administered was as prescribed.

11. The American Board of Radiology was a specialty board whose certification process incorporated all the training and experience requirements of NRC regulations, and whose certification had been recognized by the NRC in accordance with 10 C.F.R. § 35.900(a).

PERRY MORRISON BEALE

12. The defendant PERRY MORRISON BEALE, who fraudulently held himself out to be a medical physicist and RSO, provided services to Warren Memorial Hospital, Front Royal, Virginia, Page Memorial Hospital, Luray, Virginia, Winchester Women's Specialist, Winchester, Virginia, Culpeper Memorial Hospital, Culpeper, Virginia, and other hospitals and medical facilities in Virginia, Maryland, West Virginia, North Carolina, Pennsylvania, and the District of Columbia.

13. As part of his duties as a medical physicist and Radiation Safety Officer, BEALE purportedly inspected various hospitals, medical facilities, and medical equipment and provided the necessary federal and state certifications confirming that the hospitals, medical facilities and equipment were functioning in a safe and efficacious manner, and in accordance with applicable federal standards.

14. Beale did not qualify as a RSO under NRC's regulations. In addition, Beale did not

qualify as a medical physicist under the qualifications set forth in FDA's MQSA regulations.

15. BEALE conducted certain tests, including Xenon gas clearance rate calculations for nuclear medicine imaging rooms at Warren Memorial Hospital and City Hospital. BEALE submitted numerous Xenon gas clearance rate reports to Warren Memorial Hospital, City Hospital, Martinsburg, West Virginia, and Culpeper Memorial Hospital, stating that he had calculated Xenon gas clearance rates according to the procedures specified in Appendix O to NRC Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs."

16. BEALE submitted purported mammography quality control and test summary reports to Warren Memorial Hospital and to other medical facilities in the Western Judicial District of Virginia and elsewhere. BEALE falsely and fraudulently reported that he had conducted required tests and surveys and that Warren Memorial Hospital was in compliance with federal law.

**THE SCHEME AND ARTIFICE TO DEFRAUD OR TO DEFRAUD OR TO
OBTAIN MONEY BY MEANS OF FALSE OR FRAUDULENT PRETENSES,
REPRESENTATIONS, OR PROMISES**

17. From a date unknown to the United States Attorney, but beginning in or before 1990, and continuing until at least November 15, 2002, the defendant, PERRY MORRISON BEALE, did knowingly devise and intend to devise a scheme and artifice to defraud and to obtain money by means of false and fraudulent pretenses, representations, promises and half-truths

using the United States mails in order to obtain money and funds for providing services as a purported medical physicist under FDA regulations and as a purported health physics consultant that the hospital relied upon to maintain compliance with NRC regulations, from Warren County Memorial Hospital, Front Royal, Virginia, an FDA MQSA certified facility, and from other hospitals and medical facilities, including, but not limited to, the following medical facilities:

FACILITY	APPROXIMATE DATES IN WHICH BEALE WORKED AT FACILITY	APPROXIMATE AMOUNTS BEALE RECEIVED FROM FACILITY
Annapolis OBGYN Associates, P.A. Annapolis, MD	6/1995 - 12/2001	\$4,560.00 (only partial records available for 1998 to 2001)
Culpeper Regional Hospital Culpeper Outpatient Center Culpeper, VA	7/1/1992 - 10/31/2000	\$44,555.65
American Radiology Services, Inc. Annapolis, MD Columbia, MD	10/1995 – 8/1997	Payment records not available.
Shore Health System Diagnostic and Imaging Center Easton, MD	1993 – 1997	\$5,060.00
The George Washington University Ambulatory Care Center Washington, DC	11/2001 - 6/2002	\$1,050.00
Georgetown University Radiology Associates Washington, DC	11/93 – 11/95	\$2,000.00 (only partial records available)

Harbor Hospital Center Baltimore, MD	10/1994 – 11/1996	Payment records not available.
Jefferson Memorial Hospital Ranson, WV	1/1997 – 9/2002	\$18,542.90
Radiation Services Organization Laurel, MD	1995 - 2003	\$29,236.00
Carolina Premier Medical Group Raleigh, NC Chapel Hill, NC	8/1995 – 11/1999	Payment records not available.
Kaiser Permanente Falls Church, VA Woodbridge, VA Washington, DC Charlotte, NC Temple Hills, MD	5/1995 - 6/2003	\$8,400.00 (only partial records available)
The Bull Run Family Practice, P.C. Manassas, VA	11/1997 – 2/2000	\$1,800.00
Diagnostic Imaging Associates, P.C.- Vienna, VA and Mitchellville, MD	5/1995 – 1/1997	Payment records not available.
North Arundel Hospital Glen Burnie, MD	1981-2000	\$28,613.56 (only partial records available for 7/97 - 12/2000)
Northern Virginia Radiology & Nuclear Medicine Falls Church, VA	9/1994 - 8/1996	Payment records not available.
Medi-Cen of Southern Prince George's Oxon Hill, MD	12/1995 – 12/1996	Payment records not available.

Page Memorial Hospital, Inc. Luray, Virginia	9/1995 – 9/2000	\$9,410.00 (only partial records available)
Prince William Hospital Manassas, VA Gainsville, VA	11/1997 - 5/2002	\$42,593.75
Smith Radiology, Inc. New Cumberland, PA Millersburg, PA Etters, PA Halifax, PA Harrisburg, PA Enola, PA	10/1996 – 4/2003	\$22,210.85
The Fauquier Hospital & Warrenton Professional Center Warrenton, VA	1993 - 1997	\$50,910.00
Denton Diagnostic Center Denton, MD (Shore Health System)	1993 - 1997	Included in amount provided by Shore Health System Diagnostic and Imaging Center
Winchester Women's Specialists Winchester, VA	7/1996 - 6/2002	\$2000.00 (only partial records available)
Sterling Radiology Sterling, VA	8/1995	Payment records not available.
Laurel Diagnostic Imaging Drs. Branda & Greyson Laurel, MD	9/1995 – 1/2002	\$12,680.90
The Greater Baltimore Osteoporosis Center Owings Mills, MD	6/1995 – 8/1997	Payment records not available.
Hedin House Imaging Center Washington, DC	11/1996	Payment records not available.
Potomac Valley Hospital Keyser, WV	11/1992 - 4/2003	\$12,277.60 (partial records for 1993, 1995, 1996, 1998, 2000 only)

City Hospital, Inc. Martinsburg, WV	2/1995 - 2002	\$36,734.00
Hampshire Memorial Hospital, Inc. Romney, WV	5/1992 – 12/01	\$4,989.81 (partial records for 1993, 1995, 1996, 2000 only)
BMMH, Inc. Perry Hall Medical Center Baltimore, MD	9/1995	Payment records not available.
The Radiology & MRI Institute, Inc. Lanham, MD	3/1997 - 3/2002	\$3,995.00
Ashok K. Sharma, M.D. Arlington, VA	6/2002	\$1,300.00
Harbor Family Care Baltimore, MD	10/1994 – 10/1995	Payment records not available.
D.C. Chartered Health Center Washington, DC	7/1996 - 6/2003	\$6,825.00 (only partial records available)
Northern Virginia Radiology & Nuclear Medicine Woodbridge, VA Falls Church, VA	9/1994 – 8/1996	\$2,187.50
The George Washington University MFA-Mobile Mammo Van Washington, DC	11/2001	\$1,050.00
Ultrasound Associates / Women's Imaging Center Alexandria, VA	1997 – 6/2002	\$7,350.00
Central Intelligence Agency Office of Medical Services Langley, VA	3/2002	\$1,050.00
John Shavers, M.D. Linthicum, MD	4/02	\$782.68

Shenandoah Valley Mobile X-Ray, Inc. Harrisonburg, VA	1997	Payment records not available.
Michael L. Smith, M.D. Warrenton, VA	1/2000	Payment records not available.
Sterling Dulles Imaging Center Sterling, VA	10/2001	Payment records not available.
The Breast Center Clinton, MD	1/2002	Payment records not available.

18. It was part of the scheme and artifice that BEALE, in an effort to secure and maintain employment for monies, would and did provide to the hospitals and medical facilities false and fraudulent credentials and supporting documentation to establish his qualifications as a medical physicist under FDA regulations and as a RSO under NRC regulations when in fact he was not so qualified. Specifically, BEALE submitted, in part, the following materials to at least some of the above listed hospitals and medical facilities:

- a. a fraudulent certificate purportedly issued by the American Board of Radiology that stated that BEALE was certified in a specialty area sufficient to satisfy FDA and NRC regulations, *i.e.* Radiological Physics.
- b. a fraudulent undergraduate college record transcript from Elon College in North Carolina that falsely represented that BEALE took and successfully completed the required semester hours or equivalent of undergraduate or graduate level physics needed to satisfy the initial or alternative initial qualifications for medical physicists outlined in FDA's MQSA regulations.
- c. a fraudulent resume that stated, among other things, that BEALE had received a

Masters of Science in Radiological Technology, Nuclear Medicine, and Radiological Physics from the University of Virginia in May, 1980.

19. It was part of the scheme and artifice that BEALE falsely and fraudulently provided services as a medical physicist when he then well knew that he was not accredited in accordance with the requirements of applicable federal and state law.

20. It was also part of the scheme and artifice that BEALE represented to the hospitals, medical facilities, and state and federal regulatory authorities that services had been provided and that medical equipment met the requirements of federal and state law when in fact he had not performed the reported services and in some cases had falsified reports. Among other things, Beale specifically:

- a. submitted false Xenon gas clearance rate calculation records, which determined the amount of time that would be needed to clear accidentally spilled radioactive Xenon gas from rooms where it was to be used, to Warren Memorial Hospital and the NRC;
- b. submitted false dose calibrator accuracy evaluations, which compare a known radiation activity to that measured by the calibrator, to Warren Memorial Hospital and the NRC;
- c. submitted false survey meter calibrations, which should be performed before first use, annually, and after repair, to the NRC;
- d. falsely certified to the Commonwealth of Virginia that he inspected and found fully functional the Fluoroscopic Radiographic System at the Warren Memorial Hospital

when in fact the system had been totally disabled by hospital personnel one year prior to BEALE's purported inspection.

21. It was also part of the scheme and artifice that BEALE used the United States mail to send and receive invoices, payments and other documents to further the scheme.

COUNTS ONE THROUGH THIRTY-EIGHT
(MAIL FRAUD)

The United States Attorney charges:

1. The factual allegations of paragraphs 1 through 21 are realleged and incorporated by reference as if fully set forth herein.
2. From in or about July 1999, through on or about November 15, 2002, in the Western Judicial District of Virginia and elsewhere, the defendant, PERRY MORRISON BEALE, for the purpose of executing, and attempting to execute, the scheme and artifice set forth above and to obtain money by means of false and fraudulent pretenses, representations, and promises, did take and cause to be taken and received, from the United States mail, checks from Warren Memorial Hospital, Front Royal, Virginia, which were mailed to BEALE at his residence in Stafford, Virginia and elsewhere, for services BEALE allegedly provided to Warren Memorial Hospital, and which computer payment checks were sent from a facility located in the Western Judicial District of Virginia.
3. The computer payment checks sent by Warren Memorial Hospital (WMH) to BEALE are set out in the chart below, each such instance being a separate count of this Information:

COUNT	DATE	AMOUNT	PAYOR	PAYEE
1	7/28/1999	316.00	WMH	BEALE
2	8/25/1999	316.00	WMH	BEALE
3	10/20/1999	948.00	WMH	BEALE
4	12/08/1999	316.00	WMH	BEALE
5	1/05/2000	632.00	WMH	BEALE
6	1/26/2000	316.00	WMH	BEALE
7	2/23/2000	316.00	WMH	BEALE
8	4/05/2000	316.00	WMH	BEALE
9	5/03/2000	316.00	WMH	BEALE
10	6/07/2000	316.00	WMH	BEALE
11	6/28/2000	316.00	WMH	BEALE
12	8/02/2000	316.00	WMH	BEALE
13	8/30/2000	501.00	WMH	BEALE
14	9/27/2000	316.00	WMH	BEALE
15	10/18/2000	316.00	WMH	BEALE
16	11/29/2000	316.00	WMH	BEALE
17	12/27/2000	316.00	WMH	BEALE
18	1/24/2001	316.00	WMH	BEALE
19	3/07/2001	316.00	WMH	BEALE
20	3/28/2001	316.00	WMH	BEALE
21	5/02/2001	316.00	WMH	BEALE
22	5/23/2001	316.00	WMH	BEALE
23	6/20/2001	316.00	WMH	BEALE
24	7/25/2001	316.00	WMH	BEALE

25	8/22/2001	316.00	WMH	BEALE
26	9/19/2001	316.00	WMH	BEALE
27	10/31/2001	841.00	WMH	BEALE
28	11/20/2001	316.00	WMH	BEALE
29	1/09/2002	316.00	WMH	BEALE
30	1/30/2002	316.00	WMH	BEALE
31	2/27/2002	316.00	WMH	BEALE
32	3/20/2002	316.00	WMH	BEALE
33	4/17/2002	316.00	WMH	BEALE
34	6/05/2002	316.00	WMH	BEALE
35	7/17/2002	316.00	WMH	BEALE
36	7/31/2002	316.00	WMH	BEALE
37	8/21/2002	316.00	WMH	BEALE
38	9/25/2002	316.00	WMH	BEALE

4. All in violation of Title 18, United States Code, Section 1341.

Date: *July 23, 2004*

John L. Brownlee
 JOHN L. BROWNLEE
 UNITED STATES ATTORNEY