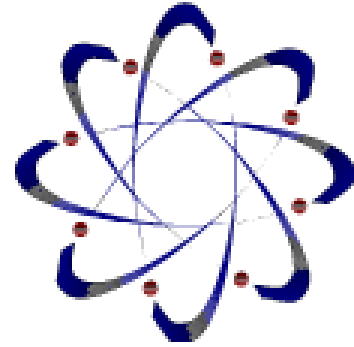


# RADIATION REPORT



Vol. 24, No. 2

BUREAU OF RADIATION CONTROL

WINTER - 2002

## BRC Leads States in Purchase of Equipment Used to Detect Cancer

*By Thomas Cardwell*

The Texas Department of Health (TDH), Bureau of Radiation Control (BRC) is the first state to purchase a dosimeter film digitizer to analyze radiation therapy beam uniformity. The equipment will allow BRC x-ray inspectors to test for x-ray beam symmetry and flatness on cancer therapy accelerators during state inspections. A symmetrical and flat beam assures that the correct radiation dose is delivered to the treatment area with as little damage to healthy tissue as possible and must be within five percent. The symmetry and flatness of the x-ray beam is critical in the treatment of cancer to assure that the cancer is treated properly.

Cancer therapy is an area of medicine where radiation-producing machines deliver the highest radiation dose to a patient in an attempt to destroy cancer cells and control the metastasis of the disease.

To perform the analysis the x-ray inspector will have pre-packaged x-ray film that will be used to align with the accelerator's x-ray field. The inspector will expose the film to a range of

radiation from 30 to 50 rad. The film will be developed at the cancer therapy facility and submitted to the central office. The central office will then place the developed film in the scanner, examine the film, and the software will analyze the optical density of the film. The analysis of the film will determine the uniformity of the dose delivered to the film.

Therapy accelerators are required to have calibrations, surveys and spot checks performed on a predetermined schedule. These tests are required by regulation to be performed by a Licensed Medical Physicist with a specialty in therapeutic radiological physics or medical health physics. The BRC inspects therapy accelerator facilities on either a two or three year inspection interval.

The purchase of the dosimeter film digitizer will allow the BRC to perform many of the same tests that licensed medical physicists perform. This enables the BRC to assure that accelerators are operating as designed and within regulatory limits.



# Texas Radiation Advisory Board Concerns

By Margaret Henderson

The governor-appointed Texas Radiation Advisory Board (TRAB) makes recommendations and furnishes technical advice on all radiation policy and program issues in Texas. During this biennium, TRAB will provide advice and recommendations on two issues in particular. The board has identified these as important to the future of radiation protection in Texas: (1) low-level radioactive waste disposal or isolation, and (2) critical staff and training needs, which includes the possible retirement of Bureau of Radiation Control staff and the training and associated travel funding needed for BRC staff.

TRAB has consistently recommended that Texas needs an appropriate method for disposal or isolation of low-level radioactive waste (LLRW). However, legislation to direct the future of LLRW in Texas did not pass during the 2001 Session. This leaves Texas generators in the position of storing LLRW throughout the state in temporary locations, particularly as options to dispose of waste out of state close. Dale E. Klein, Ph.D., Chair, says he needs only to point to this year's

catastrophic floods in the Houston area to illustrate: "Proper waste disposal or isolation is essential for Texas." Fortunately, no radioactive materials were affected by the flooding. However, the event focuses attention on TRAB's concerns about continuing to store LLRW in facilities not designed and engineered for long term operations.

TRAB also will be making recommendations on a Bureau of Radiation Control "Workforce Plan," required by Senate Bill 585, effective September 1, 2001. The Plan is to address issues TRAB believes have significant implications for the future of radiation control in Texas. Areas of concern include continuity of staffing due to resignations and retirements, and training and associated travel funding.

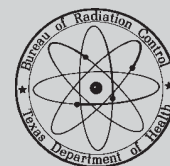
Within the next five years, employees in an estimated 30 - 40 key positions at the BRC will become retirement eligible. This creates a situation where much of the historical knowledge relied upon for today's decision making could be lost in a matter of a few years. The Workforce Plan is to address the need for experienced employees to impart

knowledge to their potential successors, an important element in maintaining an effective radiation control program. TRAB recognizes the importance of continuity during this time of transition.

Staff training and associated travel funding concerns TRAB. Historically, the Nuclear Regulatory Commission (NRC) funded travel, per diem and tuition for the courses required for radioactive material licensing and inspection staff. However, NRC discontinued this funding in 1996. The Texas Legislature has appropriated no funding to continue education of staff and the associated travel. Additionally, there has been a severe restriction in educational training for employees obtaining advance degrees in a field related to their job. Training and education and associated travel funding have been identified by TRAB as crucial to recruit and retain the workforce. TRAB meets quarterly for an open meeting to discuss these and other radiation safety rules, policies and programs. The public is welcome to attend and make comments.



## C O N T E N T S



<b>BRC Leads States</b>	<b>1</b>	<b>Mammography Corner:</b>			
<b>TRAB Concerns</b>	<b>2</b>	<b>Breast Cancer Month</b>	<b>4</b>	<b>FDA Notification</b>	<b>6</b>
<b>Radiography Licensees</b>	<b>3</b>	<b>BRC Exhibit</b>	<b>4</b>	<b>Escalated Enforcement</b>	<b>7</b>
		<b>TX Mammo Conference</b>	<b>5</b>	<b>Letters to the Editor</b>	<b>8</b>

Visit Our Website: [www.tdh.state.tx.us/ech/rad/pages/brc.htm](http://www.tdh.state.tx.us/ech/rad/pages/brc.htm)

# Incident Reporting Requirements for Radiography Licensees

By David Fogle

On April 6, 2001, the U.S. Nuclear Regulatory Commission published Information Notice 2001-03: Incident Reporting Requirements for Radiography Licensees. This notice was prompted by the failure of licensees to notify NRC, within 24 hours, in accordance with requirements in 10 CFR 30.50(b)(2), after the occurrence of an unintentional disconnection of the source assembly from the control cable, and an inability to retract the source assembly to its fully shielded and secured position (source hang-up). The Texas Department of Health (TDH) requires the same notification be made due to the same occurrences in accordance with Title 25 Texas Administrative Code (TAC) §289.202(xx)(7)(B).

Reporting of such problems to TDH is important because it provides the opportunity for the regulatory agency to verify that the material has been properly

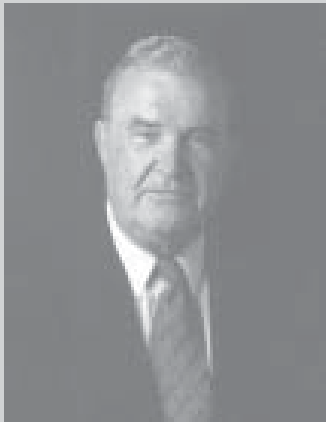
secured and has not been released into the public domain. If notified early, TDH can help ensure that all necessary regulatory actions are completed.

TDH, NRC and Agreement States review information submitted in reports to determine if trends or generic safety issues exist that have the potential to cause a significant safety hazard. If a generic safety issue is identified, those licensees that may be affected will be notified and informed of the proper actions to reduce or eliminate similar incidents in the future and to protect the health and safety of occupational workers and the public. Licensee failure to make the required reports hampers this effort and violates TDH regulations.

Title 25 TAC §289.255(k)(2) describes the types of events that must be reported to TDH in a written report within 30 days of the occurrence. These events include: (1) a source assembly cannot

be returned to the fully-shielded position and properly secured; (2) the source assembly becomes unintentionally disconnected from the drive cable; (3) any component critical to safe operation of the radiographic exposure device fails to properly perform its intended function; (4) an indicator on a radiation machine fails to show that radiation is being produced; (5) an exposure switch on a radiation machine fails to terminate production of radiation when turned to the off position; or (6) a safety interlock fails to terminate x-ray production.

The requirements for the contents of the report are contained in 25 TAC §289.202(yy)(2) and §289.255(k)(3). Two copies of the report must be submitted to TDH, to the address listed in this newsletter or at the website for the TDH, Bureau of Radiation Control at <http://www.tdh.state.tx.us/ech/rad/pages/brc.htm>.



## In Memory: Jack S. Krohmer, Ph.D. (1921-2001)

Jack S. Krohmer, Ph.D., esteemed advisor and friend to the staff of the Bureau of Radiation Control and members of the Texas Radiation Advisory Board, died July 7, 2001, of cancer. Doctor Krohmer served on the TRAB for fourteen years (1986-2000), presiding as elected chair for ten (1990-2000). Three consecutive Governors of

Texas (White, Clements and Richards) appointed him to serve as the state's health physics advisor. Doctor Krohmer donated hundreds of hours of his time over the fourteen-year period, providing expert technical advice and guidance to all state radiation agencies, members of the Texas Legislature and the Governor.

# AMMOGRAPHY CORNER

## October 2001: A Busy Month for TDH Breast Cancer Awareness Month

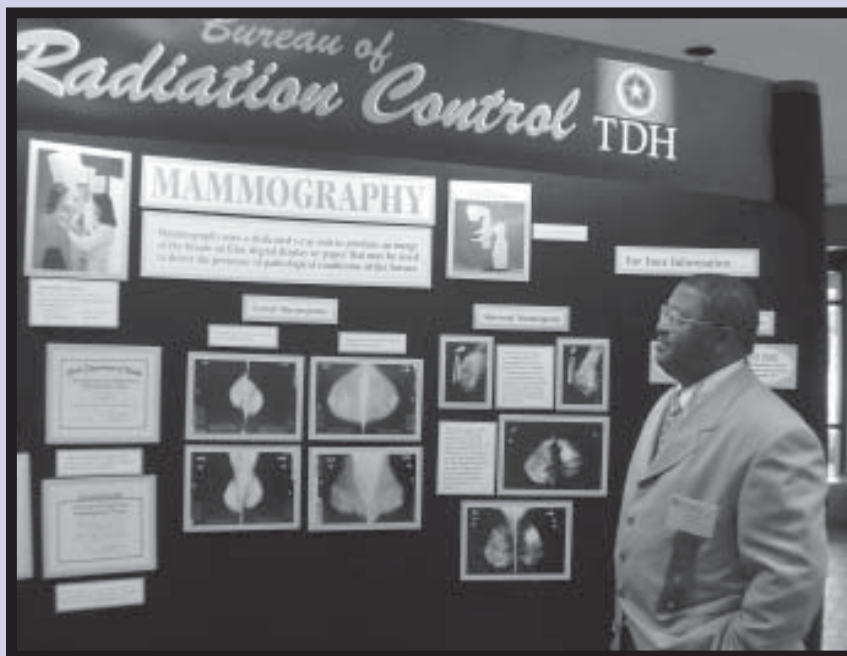
By Kaye Goss-Terry

On October 1, 2001, Governor Rick Perry proclaimed that October was Breast Cancer Awareness Month at the 5<sup>th</sup> Annual Breast Cancer Awareness and Wreath Presentation at the Capitol of Texas in Austin. In attendance were representatives from the Texas Department of Health, the

American Cancer Society, the Texas Cancer Council and the Governor's Commission for Women. The Acting Commissioner of Health, Charles E. Bell, M. D. introduced the First Lady of Texas Anita Perry who welcomed everyone. Ms. Elyse Clark shared with us her breast cancer survivor story.



*State of Texas,  
Governor Rick Perry*



*Texas Department of Health, Bureau of Radiation Control staff member, David Swain reviews the BRC Texas Mammography Program exhibit at the TDH/BRC Mammography Conference held on October 20, 2001, at the J. J. Pickle Research Center in Austin.*

## BRC Exhibit Display

The Bureau of Radiation Control (BRC) displayed the Texas Mammography Program exhibit at various locations in TDH for the entire month of October.

# MAMMOGRAPHY CORNER

## Texas Mammography Conference 2001

By Kaye Goss-Terry

By far the biggest October event for the BRC was the Texas 2001 Mammography Conference held on October 20 in Austin for mammography personnel within Texas. In a partnership with the Breast and Cervical Cancer Control Program, the BRC was able to offer a free all-day mammography conference to over 500 attendees.



*Conference attendees are attentive during a presentation in the main auditorium.*

While attending the conference, attendees were able to earn 8.5 hours of mammography continuing education credits. In addition, 3.5 hours of mammography continuing education credits could be earned by participating in eligible activities.



The attendees were also able to visit 18 exhibitors who were demonstrating the latest in mammography technology.

Exhibitors in attendance included the following: Advanced Health Education Center, AGFA Medical Imaging, Breast Surgical Services,

Diagnostic Imaging Staff, Diagnostic Imaging, Inc, Eastman Kodak, Ethicon Endo-Surgery, Fischer Imaging, GE Medical Systems, i/o Trak, Instrumentarium, Konica, LoRad, R2 Technology, Siemens and Sonosite.



*Donna Cooper, an Ethicon Endo-Surgery exhibitor, shows attendees how to use new technology to retrieve breast tissue samples.*

A review of the course evaluations indicated that everyone enjoyed the conference and is looking forward to the 2003 Mammography Conference.

### Faculty and presentations on the conference agenda included:

- Dorothy Douglas, MQSA Inspector, An MQSA Inspector's Story of Survival
- R. Edward Hendrick, Ph.D., Optimizing Screen-Film Mammography
- Robert J. Pizzutiello, M.S., Stereo-tactic Breast Biopsy Accreditation
- Thomas G. Langer, M.D., State-of-the-Art Mammography
- R. Edward Hendrick, Ph.D., Physics & Q.C. of Digital Mammography
- Thomas G. Langer, M.D., Medical Outcomes Audit
- Priscilla Butler, M.S., Breast Imaging Accreditation Program
- Jerry Cogburn, H.P., MQSA, Mammography Inspector, Sometimes Some Things Just Go Wrong;
- Helen Watkins, B.A., H.P., Complaint Investigations
- Rick Munoz, M.S., H.P., Enforcement Actions



## FDA Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients

While the benefits of computed tomography are well known in diagnosing diseases and trauma and in the guidance of interventional and therapeutic procedures, those benefits are not without risks. This Notification is to emphasize the importance of keeping radiation doses during CT procedures as low as reasonably achievable, especially for pediatric and small adult patients, who may sometimes receive more radiation than needed to obtain diagnostic images. To prevent this we want to stress the importance of adjusting CT scanner parameters appropriately for each individual's weight and size, and for the anatomic region being scanned.

Here are the steps the FDA are recommending. They are not new. Indeed, many facilities are already taking measures to protect children and other small patients from unnecessary exposure during CT procedures.

**Optimize CT settings.** Based on patient weight or diameter and anatomic region of interest, evaluate whether your CT operating condition are optimally balanced between image and radiation exposure. To reduce dose while maintaining diagnostic image quality.

**Reduce tube current.** With all other factors held constant, patient radiation dose is directly proportional to x-ray tube current. For example, a 50 percent reduction in tube current results in a 50 percent decrease in radiation dose.

**Develop and use a chart or table of tube-current settings** based on patient weight or diameter and anatomical region of interest. The diameter of the patient may be a better predictor of the tube current required than body weight because patient diameter beam (i.e., chest, pelvis or abdomen) correlates with the x-ray beam attenuation in the patient. Your facility's physicist and the scanner manufacturer can help in developing this chart or table.

**Increase table increment (axial scanning) or pitch (helical scanning).** If the pitch is increased, the amount of radiation needed to cover the anatomical area of interest is decreased. One study showed that increasing the pitch from 1:1 to 1.5:1 decreases the radiation dose by 33 percent without loss of diagnostic information. Consult your facility's medical physicist, who can advise you on optimal tube-current and pitch settings for diagnostic requirements. You can also contact the manufacturer of the CT scanner for recommendations specific to your model. Note that some newer CT scanners may automatically suggest or implement an increase in the mA if pitch is increased. For these models, increasing the pitch may not result in a lower radiation dose. Contact the CT scanner's manufacturer for recommendations on your model's automatic current adjustment features.

**Reduce the number of multiple scans with contrast material.** Often, CT scans are done before, during, and after injection of IV contrast material. When medically appropriate, multiple exposures may be reduced by eliminating pre-contrast or unenhanced images.

**Eliminate inappropriate referrals for CT.** In some cases, conventional radiography, sonography, or magnetic resonance imaging (MRI) can be just as effective as CT, and with lower radiation exposure. Most conventional x-ray units deliver less ionizing radiation than CT systems, and sonography and MRI systems deliver no x-ray radiation at all. It is important to triage procedures with less or no ionizing radiation.

If you have questions regarding this letter, please contact Marian Kroen, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by fax at (301) 594-2968, or by email at [phann@cdrh.fda.gov](mailto:phann@cdrh.fda.gov). Additionally, a voice mail message may be left at (301) 594-0650, and your call will be returned as soon as possible.

Sincerely yours,  
David W. Feigal, Jr., MD, MPH  
Director, Center for Devices and Radiological Health, Food and Drug Administration

# Escalated Enforcement Finds: Unauthorized Possession, Use of Radioactive Material and Radiation Producing Machines

*By Cathy Mc Guire*

The Escalated Enforcement Program has received several cases involving unauthorized use or possession of radioactive material and radiation producing machines in the past few months. Healing arts screening as defined by §289.227(e)(40) is the testing of asymptomatic human beings using radiation machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts. Regulation also requires that registrants obtain permission from the Texas Department of Health (TDH) before initiation of any healing arts screening program. Without approved selection criteria, some members of the public might receive unnecessary radiation exposure. Two types of healing arts screenings frequently performed are heart and bone densitometry screenings. The following are some examples of the cases the program has recently handled.

In one case, an inspector from San Antonio noticed an ad in the newspaper offering heart screening services to the general public. Upon investigation the inspector found the medical facility had not received prior TDH approval before initiating their screening program. This unauthorized use resulted in the assessment of an administrative penalty of \$5000. A settlement conference was held and an agreement was reached to probate the penalty to

\$1,000 if the registrant agreed to provide heart screenings at no cost to fifteen indigent patients.

A similar case was found during a routine inspection of a facility providing bone densitometry screenings in the Denton area. Screening was being performed without TDH approval. The registrant was issued a Cease and Desist Order, which remained in effect until TDH approved the screening criteria submitted by the registrant.

Another regulation, §289.252(x)(3), requires each licensee to confine the use and possession of the radioactive material licensed to the locations and purposes authorized. In three recent cases, licensees failed to restrict their activities to an authorized site or to the limit of the radioactive materials in their license.

In the Houston area, an investigation was conducted concerning possession of radioactive material not authorized by the license. It was discovered that the Licensee was over the authorized possession limit of Strontium-90. Due to the increased amount of radioactive material in their possession, the Licensee was also in violation of the requirement to provide financial assurance. This resulted in the issuance of an administrative penalty of \$10,000. During a settlement conference, an agreement was reached with the Licensee to pay the full penalty amount.

During an investigation of a complaint in the Austin area, it was

determined that a Licensee was storing a moisture density gauge at an unlicensed location. The owner of the facility denied there was any radioactive material at the location. A TDH investigator surveyed the facility and found the presence of radioactive material. A Notice of Violation was issued and the Licensee was requested to attend an Enforcement Conference.

During the course of the Conference it was determined that two additional violations were present, which included the loss of control and unauthorized use of the gauge. To resolve the problems, the Licensee agreed to submit an amendment request to include the addition of the site and all gauge users to their license, and to submit training records for all users to TDH. It was also requested that copies of training documents be provided to their Radiation Safety Officers. Administrative penalties were not assessed pending receipt of adequate training certification documents for the RSO and satisfactory inspection findings during subsequent visits to the facility.

In another instance in Central Texas, an emergency order was issued to a Licensee as the result of unauthorized use of radioactive material at a location not included on their license. The equipment at the site was impounded until the location was added to the current license. After the license was amended, the emergency order was rescinded.

# LETTERS TO THE EDITOR



## **BRC is often asked: When should one re-establish mammography processor operating parameters, or not?**

BRC inspectors often find the operating parameters for mammography processors have been re-established because a service person could not determine why the processor wasn't operating within limits. Re-establishing operating limits should only be done following specific, significant changes in the mammography system and they are: change in film brand or type, change in chemical brand or type, change in chemical replenishment rate, change in film volume, change in auto-mixer specific gravity settings, replacing the sensitometer or densitometer, a change in processing speed (standard vs. extended) or running out of QC film before a crossover can be performed. Replacement of chemistry, using the same brand and type, as part of routine preventative maintenance, is not an acceptable reason to re-establish operating levels.

At least one film manufacturer advises re-establishing operating limits on an annual basis. But neither TDH nor FDA accepts the practice.

Re-establishment of operating levels is never an acceptable means to correct problems in the processing system. Always troubleshoot and solve the problem with appropriate corrective action. And, when in doubt, always consult your medical physicist prior to establishing new operating levels.

If you have any questions regarding this or any other mammography compliance issues contact Jerry Cogburn at (512) 834-6688 extension 2037.

### **STATE HOLIDAYS**

The BRC will be closed in observance of the following holidays:

February 18, 2002  
President's Day  
and  
May 27, 2002  
Memorial Day

Radiation Report is a newsletter published three times each year in Austin, Texas by the Texas Department of Health, Bureau of Radiation Control for its licensees and registrants. Publication # 22-11249.

Eduardo Sanchez, M.D.  
Commissioner  
Department of Health



Marilyn Kelso  
Publications Advisor

Richard Ratliff, P.E.  
Chief, Bureau of  
Radiation Control

Julie Davis  
Editor

**Bureau of Radiation Control  
Texas Department of Health  
1100 West 49th Street  
Austin, Texas 78756-3189**

**PRSR STD  
U.S. POSTAGE  
PAID  
AUSTIN, TEXAS  
PERMIT NO. 28**