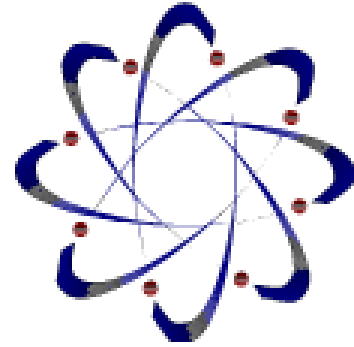


RADIATION REPORT



Vol. 26, No. 2

BUREAU OF RADIATION CONTROL

WINTER - 2003/2004

Legislation Impacts BRC Licensees and Registrants

By Marilyn Kelso

Four bills recently passed the 78th Regular Legislative Session — House Bills (HB) 253, 1678, and 2292, and Senate Bill (SB) 1152 – that will impact the Texas Department of Health, Bureau of Radiation Control's (BRC) Licensees and Registrants.

HB 253 allows BRC to consider compliance history when granting, denying, renewing, revoking, suspending or restricting certificates of registration and licenses. In the past, consideration of compliance history was not factored in.

HB 1678 changes the name of the Radiation and Perpetual Care Fund to the Radiation and Perpetual Care Account and allows administrative penalties, as well as the additional five percent fee for radioactive materials licenses, to go into the account. The funds from the additional five percent charge and administrative penalties are to be used to prevent or mitigate adverse effects of abandonment of radioactive materials, default on lawful obligation, insolvency, or other inability of

licensees to meet requirements of the rules.

HB 2292 establishes a two-year term for certificates of registration and licenses, results in two-year fees and mandates 100 percent cost recovery for the registration and licensing programs.

The BRC already meets 100 percent cost recovery for our registration and licensing programs. The bill mandates that fee payments be made for two years at one time and initiates a two-year license or certificate of registration term, which will be a change for the majority of licensees and registrants with BRC. HB 2292 also mandates expiration of licenses or certificates of registration when fees are not paid on time.

SB 1152 deals with participation on the "TexasOnline" web site, the state's official web site that includes services such as license renewals and fee payments via the web. Although license renewals and fee payments are not yet established for the BRC, you may view the web site at <http://www.state.tx.us>.

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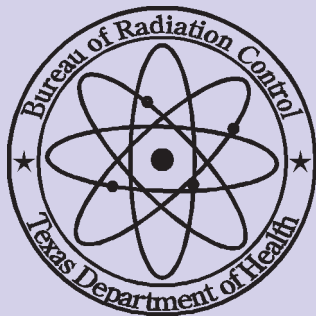
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Visit our website:
[http://
www.tdh.state.tx.us
/radiation](http://www.tdh.state.tx.us/radiation)

BRC NOTICE: **Procedures for Open Records Requests**

The Texas Department of Health (TDH), Bureau of Radiation Control (BRC) is committed to upholding the Public Information Act (PIA) and ensuring public access to its records. The term “Public Information” is defined in [Government Code Section 552.002](#).

Public information means information that is collected, assembled, or maintained under a law or ordinance or in connection with the transaction of official business: (1) by a governmental body; or (2) for a governmental body and the governmental body owns the information or has a right of access to it.

Under Texas law, each person is entitled to complete information about the affairs of government; the official acts of public officials and employees at all times, unless otherwise expressly provided by law.

In order to submit an open records request with the BRC, all requests must be in written form (i.e. letter, email, facsimile, etc.) and must include your name, address and a daytime phone number.

All open records requests must be addressed to the attention of Chrissie Toungate, “Custodian of Records.”

Also, in your request you must submit in detail what you need, the permit number (if you know it), and an address or fax number as to where to send the material. BRC will call to clarify your requests if needed, and a fee may be charged for copies.

QUESTIONS ?



If you have any
questions regarding:

**Confidentiality
and/or
Open Records**

Contact:
ChrissieToungate
via email
[Chrissie.Toungate
@tdh.state.tx.us](mailto:Chrissie.Toungate@tdh.state.tx.us)
or by phone at
(512) 834-6688
ext. 2202

Legislation Impacts BRC Licensees and Registrants

Continued from page 1

Licensees and Registrants had the opportunity in September to offer suggestions or simply get clarification concerning upcoming rule changes by attending two stakeholders' meetings conducted by the Texas Department of Health, Bureau of Radiation Control (BRC),

Division of Licensing, Registration and Standards.

The stakeholders' meetings were offered to allow all licensees and registrants the opportunity to have input into upcoming rule changes. Stakeholder input is an important aspect of rule writing, whether it is through

stakeholder meetings, comments to draft rules via mail or email, or phone calls to the BRC staff. Although the BRC has not resolved some of the issues, the input from the attendees at the meetings have helped BRC staff in finalizing the rules. Future issues of the Radiation Report will address these rules in more detail.

For more information on legislation impacting licensees and registrants refer to:

http://www.capitol.state.tx.us/tlo/reports/daily/78R/eff0901_summary.htm

Look for:



HB 253



HB 1678



HB 2292



SB 1152

BRC Welcomes New Mammography Employee

By Jo Turkette

Cathy McGuire is the newest member of the Mammography Certification Program. Cathy has been with the Texas Department of Health (TDH), Bureau of Radiation Control (BRC) since 1996. Prior to her current position as Environmental Specialist III with

the Licensing, Registration and Standards Division, Cathy worked in the Compliance and Inspection Division as the Escalated Enforcement Coordinator for five years. You can contact Cathy at (512) 834-6688 ext. 2244 or by e-mail: Cathy.McGuire@tdh.state.tx.us.



Photograph by: Julie Davis

Cathy McGuire settles into her new position as Environmental Specialist III in the BRC Mammography Program.

Latest Accreditation News

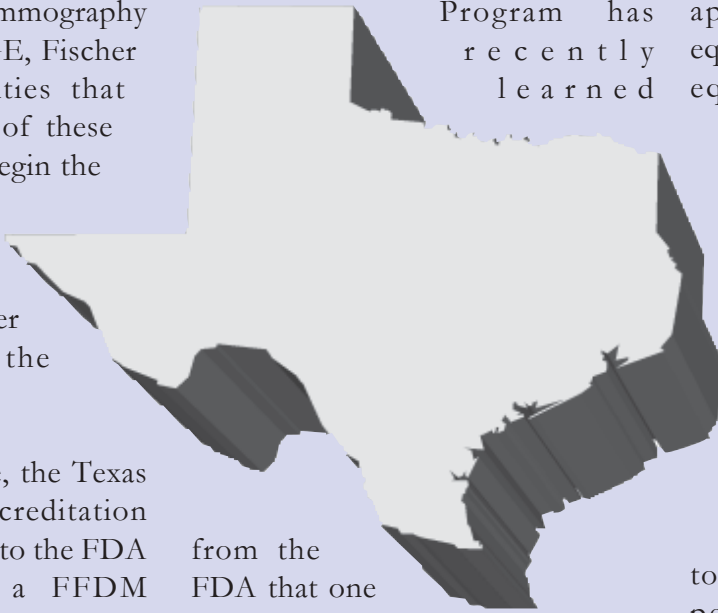
By Kaye Goss-Terry

The U.S. Food and Drug Administration (FDA) has approved the American College of Radiology (ACR) to accredit full-field digital mammography (FFDM) units for GE, Fischer and LoRad. Facilities that currently have any of these FFDM units must begin the accreditation process within nine months of notification by either the FDA or the accreditation body.

In the meantime, the Texas Mammography Accreditation Program is applying to the FDA for approval as a FFDM accreditation body for GE, Fischer and LoRad. The Texas Mammography Accreditation Program is anticipating our approval as a FFDM accreditation body for all three FFDM manufacturers by the end of the calendar year.

If you have a FFDM unit at your facility, please verify with your manufacturer that you have the current copy of the required quality control manual for your

FFDM unit. Also, verify that the FDA has approved the manual for use. The Texas Mammography Accreditation Program has recently learned



from the FDA that one manufacturer has several versions in circulation and only one has been approved for use. At the time of your state/MQSA inspection have your manufacturer's FFDM quality control manual readily available for the inspector. She or he will verify what quality control tests are required for your FFDM unit by referring to your quality control manual.

In other news, the FDA has instructed the accreditation bodies

to require facilities that are adding or replacing mammography unit(s) to obtain the accreditation body's approval for use of that equipment **prior** to using the equipment on patients or developing any images. This requirement is for both film-screen and full-field digital. You will want to contact your accreditation body prior to installing the equipment to verify the accreditation body's process for approving the equipment prior to use.

In Texas, you are required to have a medical physicist perform an equipment evaluation and any pertinent tests to document that the equipment meets the current mammography regulations. Once the evaluation is completed, a copy of the medical physicist documentation and the required accreditation body documentation must be forwarded to the accreditation body for evaluation and approval.

Continued on page 5

AMMOGRAPHY CORNER

Overall Final Assessment of Findings Categories

Vs.

BI-RADS® Category Codes

By Jerry Cogburn

Overall final assessment of findings categories consist of specific sets of words and/or phrases that are included in each mammography medical report to standardize diagnosis indication. Both rules of the U.S. Food and Drug Administration (FDA) under the Mammography Quality Standard Act and Texas Department of Health mammography rules require inclusion of one of the categories in each mammography medical report.

The actual overall final assessment categories are: “Incomplete: Need additional imaging evaluation,” “Negative,” “Benign,” “Probably Benign,” “Suspicious,”

“Highly suggestive of malignancy;” since these categories were established for standardization, only slight variations are allowed. Acceptable variations can be found on the FDA mammography website at: <http://www.fda.gov/cdrh/mammography/index.html>.

Breast Imaging Reporting and Data System, BI-RADS®, is a program developed by the American College of Radiology for the same purpose as overall final assessment of findings categories. However, BI-RADS® uses a set of code numbers, instead of words, to indicate the assessment categories. BI-

RADS® is also used to monitor medical outcomes.

An overall final assessment of findings category is always required on the medical report. Including a BI-RADS® category code may be required by the facility’s accrediting body, but as far as the regulatory agencies are concerned, it is the facility’s choice to do so. It’s perfectly all right to have both overall final assessment of findings category and BI-RADS® category codes on the report, but if there is only one, it must be an overall final assessment category.

Latest Accreditation News

Continued from page 4

Finally, facilities that have chosen to utilize the Texas Mammography Accreditation Program are generally completing the initial accreditation or renewal of accreditation within four months. The cost for accreditation with Texas is \$850 for the first unit and \$460 for all other mammography units listed on the Certification of Mammography

Systems, no matter the site location. Remember, the accreditation body notification is in addition to the state mammography certification requirements for adding or replacing equipment to your facility. You are still required to notify the Texas Mammography Certification Program by submitting the appropriate application and documentation.

For information regarding accreditation issues

Contact:

Texas Mammography Accreditation Program

(512) 834-6688 ext 2246

and/or

American College of Radiology

Toll-free (800) 227-6440

Texas Monitors Environmental Radioactivity By Means Of ERAMS

The Environmental Radiation Ambient Monitoring System (ERAMS) is a national network of monitoring stations that regularly collect air, precipitation, drinking water, and milk samples for analysis of radioactivity. Staff members from the Texas Department of Health's Bureau of

Radiation Environmental Laboratory (NAREL) publish this data in a quarterly report entitled, "Environmental Radiation Data." Previously, this was a paper-only publication, but its now being published online as well: <http://www.epa.gov/narel/erams/erdonline.html>.

Island nuclear reactor accident in the U.S.; in 1986 following the Chernobyl nuclear reactor accident in the Soviet Union; in 1999 following the Tokaimura nuclear fuel processing facility accident in Japan; in 2000 following the Los Alamos and Hanford wildfires in the U.S.; and in 2001 following the terrorist attacks in the U.S. EPA depends on volunteer



BRC staff member Ruben Cortez uses the ERAMS system to record flow rate and sample times on a weekly basis.

Radiation Control office in Austin have participated in the program for over 20 years.

The ERAMS network has been used to track environmental releases resulting from nuclear emergencies and to provide baseline data during routine conditions. Data generated from ERAMS provides the information base for making decisions necessary to ensure the protection of public health. ERAMS also documents the status and trends of environmental radioactivity. The National Air and

ERAMS data provides a means to estimate levels of radioactivity in the environment, including background radiation, as well as fallout from atomic weapons testing, nuclear accidents, and other intrusions of radioactive materials. ERAMS also provides the historical data needed to estimate long-term trends in environmental radiation levels.



Precipitation samples are taken as available.

ERAMS normally operates in a "routine" mode, sampling radiation in all media on a regularly defined schedule. In the event of a threat of a significant radiation release, ERAMS operates in an "emergency" (or alert) mode, accelerating the frequency of sampling and generating many more data records for a given period of time compared to the ERAMS routine mode. This was done in 1979 following the Three Mile



Approximately 100 air filter samples are taken by BRC staff members each year.

operators (generally State employees) to collect the ambient radiation samples and send them to the National Air and Radiation Environmental Laboratory (NAREL) for analysis.

For more information on ERAMS contact Ruben Cortez via email at Ruben.Cortez@tdh.state.tx.us and/or by phone at (512) 834-6688 ext. 2004, or visit the EPA's website at <http://www.epa.gov/narel/erams/>.

Photographs by: Mike Davis

BRC Appoints New Division Director

The Bureau of Radiation Control (BRC) has recently appointed a new Division Director to the Compliance and Inspection Program. Ms. Alice Hamilton Rogers was appointed on November 1, 2003. Ms. Rogers, a licensed engineer, holds a Bachelor of Science in Chemical Engineering from the University of Texas at Austin.

She first joined the BRC in 2001, as manager of the Escalated Enforcement Program. Ms. Rogers has worked extensively in the area of waste management, including permitting and enforcement. Prior to joining the BRC, she worked at the Texas Commission for Environmental Quality (TCEQ) and its predecessor agencies for 18 years. During her tenure at TCEQ, she managed the Underground Injection Control, Uranium and Radioactive Waste Section for eight years, which included managing

the processing of the application for the low-level radioactive waste disposal site outside of Sierra Blanca, Texas.

Ms. Rogers' appointment to her new position follows that of former Compliance and Inspection Division Director Arthur C. "Art" Tate, who had held the position since 1994. Mr. Tate retired from state government effective August 31, 2003.



Photograph by: Julie Davis

Alice Hamilton Rogers takes an active role as BRC's newest Compliance and Inspection Division Director.

STATE HOLIDAYS

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

- December 24 -26, 2003, Christmas
- January 1, 2004, New Year's
- January 19, 2004, Martin Luther King, Jr. Day
- February 16, 2004, President's Day

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