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RADIATION REPORT

REVISED

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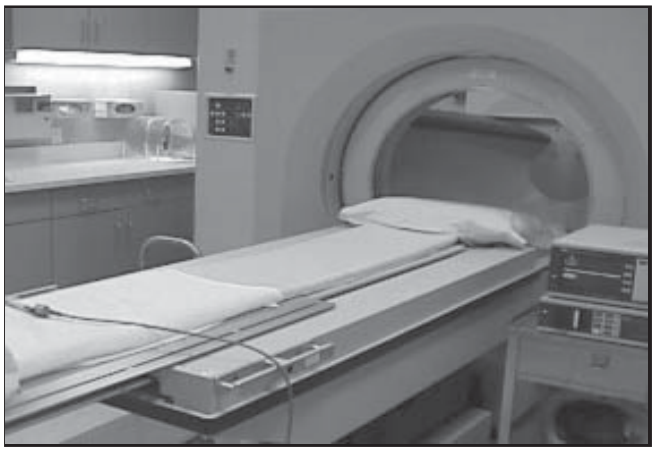
Texas Radiation Advisory Board's Advisory on Whole Body CT Screening

The Texas Radiation Advisory Board (TRAB), in conjunction with the Bureau of Radiation Control (BRC), would like to caution the public about the practice of Whole Body CT (computed tomography) Screening Examinations. Under current regulations X-ray examinations must be ordered by a licensed physician unless approval for healing arts screening has been obtained from the Texas Department of Health's Bureau of Radiation Control. The only self-referred screening examinations currently approved are for mammography, bone densitometry for osteoporosis and x-ray exams for coronary heart disease.

Current policy dictates that the facilities must receive approval from the Bureau of Radiation Control, based on scientific data, prior to being approved to conduct screening examinations. The Food and Drug Association (FDA), the American College of Radiology (ACR), the Society of Thoracic Imaging, and others do not support the use of whole body CT screening of the general public. Whole body CT, however, may be appropriate in certain patients with a specific medical history.

Problems cited with CT Screening include the lack of any specific scientific evidence that CT screening improves medical care for the public or prolongs life. There are also concerns raised over the possibility that unnecessary additional procedures will be required, resulting in an increased monetary cost to the patient as well as a possible increase in morbidity and mortality from these unnecessary follow-up examinations or surgeries. In addition, there is some concern about the relatively high amount of radiation received by patients undergoing the CT screening examinations.



Photograph by Julie Davis

This Ultra-Fast CT Scanner creates detailed three-dimensional images of the human body.

Therefore, until the safety and medical efficacy of the examination is proven, the Texas Radiation Advisory Board and Bureau of Radiation Control will continue to require specific physician orders for this procedure. The TRAB and BRC further wish to encourage the public to discuss with their family physician whether this test may be appropriate for them based on their individual medical history.

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Visit Our Website:

http:/www.tdh.state.tx.us /ech/rad/pages/brc.htm

Intensity Modulated Radiotherapy Tomotherapy (IMRT)

Providing A New X-Ray Method to Treat Cancer

By Julie Davis

One of the latest forms of x-ray treatment for cancer is Intensity Modulated Radiotherapy Tomotherapy or IMRT. It is a new way to deliver radiation treatment for cancer and may be one of the most important advances in radiation therapy.

When radiation is used to treat cancer, an ionizing radiation beam is used in a focused and precise location on the body of the patient being treated. The beam's intensity is used to strike and damage cancerous cells. That is why radiotherapy treatments are divided into many treatments or fractions over several weeks. Eventually, with enough contact the cancerous cells will die.

The goal of Intensity Modulated Radiotherapy Tomotheraphy is to modulate the size, shape, and strength of the radiation x-ray beam in order to focus enough dose on the tumor to kill the cancer cells, while sparing as much surrounding healthy tissue as possible.

Before beginning tomotheraphy treatment, a doctor uses 3-D images (for example, from CT or MRI) and special software to establish precise contours for each region of interest. Regions may include a tumor and/ or any regions at risk, such as sensitive organs or other structures. The doctor will decide how much radiation the tumor should receive, as well as acceptable levels for surrounding structures. Then the tomotherapy system will calculate the appropriate pattern, position and intensity of the radiation beam to be delivered, to match the doctor's prescription as closely as possible.

The tomotheraphy system combines IMRT with helical (or spiral) delivery pattern to verifiably deliver the radiation treatment. Photo radiation is produced by a linear accelerator (or linac), which travels in multiple circles all the way around the gantry ring. The linac moves in unison with a device called a multi-leaf collimator or MLC. The computer-controlled MLC has two sets of interlaced leaves that move in and out very quickly to constantly modulate the radiation beam as it leaves the accelerator. Meanwhile, the couch also moves, guiding the patient slowly through the center of the ring, so each time the linac comes around, it's directing the beam at a slightly different plane.

Tomotheraphy—through the sophisticated delivery system offered through IMRT—integrates treatment planning, delivery and verification in one system, enhancing one of the most effective cancer treatments available today—radiation.

TDH's New Commissioner

Provides A New Perspective On Public Health

By Julie Davis

Dr. Eduardo J. Sanchez, Commissioner of Health welcomes the challenges of his new position.

The Texas Department of Health (TDH) commissioner has the tough job of improving the general public's understanding of public health issues, safety and concerns. In September 2001, Dr. Eduardo J. Sanchez was appointed to become the new Texas Commissioner of Health and he boldly steps up to the challenge.

Dr. Sanchez's interests in high school mathematics and science guided him down a long path of education to seek a career that would eventually lead him to public health. In 1977, after graduation from Carroll High School in Corpus Christi, he received a scholarship from Boston University (BU) where he double-majored in biomedical engineering and chemistry. After BU, he was offered a fellowship, and attended Duke University where he earned a master's degree in biomedical engineering. After Duke, he took a year off to teach high school mathematics in the Dominican Republic. "The Dominican Republic is where my parents are from, and I saw it as an excellent opportunity for me to go," said Sanchez. After teaching, he returned to the United States where he attended medical school, worked as a family practitioner, and received his master's degree in Public Health. He said, "I am a public health physician, but I'm not boarded, as a certified preventive medicine physician, which means completing a residency, and taking an exam."

Dr. Sanchez believes his greatest strength is the experience he brings to TDH from a local public health perspective and a perspective of a practicing physician. He served four years as the Local Health Authority for the Austin/Travis County Health and Human Services Department from 1994 through 1998. At the end of his tenure he worked with a host of others to create the Texas Association of Local Health Officials (TALHO). He said, "I think it is important to bring the public health perspective to the table because many of our endeavors involve the medical community in some form or fashion."

Dr. Sanchez has a desire to include perspectives other than his own in decision and policy making at TDH. He hopes to include outside entities in some of our external decision and policy-making, as well as have open processes that will allow others outside of TDH to observe proceedings that lead to decisions on TDH policy. He added," I hope we can make other outside entities feel that they are participating in policy-making, and not to feel as though they are being dictated to." An example of this inclusion in the decision and policy-making process is the organization of the Bio-Terrorism work group. Dr. Sanchez said, "The Bio-Terrorism working group was originally an internal group. Now, the group is working with many individuals providing local, state and federal government representation through the Governor's Task Force on Homeland Security."

Dr. Sanchez believes that TDH's regulatory programs play a very important role in environmental and consumer health. He said, "It's a role that people understand more than some of our other programs." His objective is to protect the health of the people living in Texas, visiting Texas, and consuming products from Texas. "One way we do that is through our many regulatory programs," said Dr. Sanchez. The BRC is one of five TDH regulatory programs within the Consumer Health Protection Associateship, which also includes: the Bureau of Emergency Management, the Bureau of Environmental Health, the Bureau of Food and Drug Safety, and the Bureau of Licensing and Compliance.

When asked what radiation concerns he had, how he felt about BRC policies, and the Texas Radiation Advisory Board's (TRAB) advisory on whole body CT screening Sanchez said, "My thought is that having Regulatory Programs around medical or industrial technologies is quite appropriate." He believes that when

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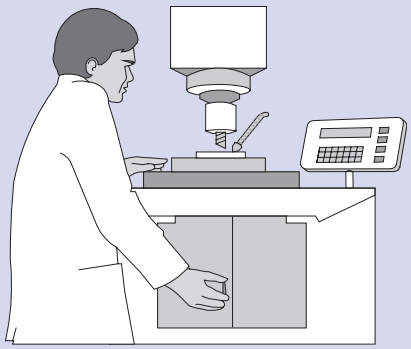
MAMMOGRAPHY CORNER

Changes in Rules Revised by FDA

By Cathy Fontaine

Title 25 Texas Administrative Code (TAC) Chapter 289 Section 230, "Certification of Mammography Systems and Accreditation of Mammography Facilities" has been revised. Several of the changes are the result of revisions in the U.S. Food and Drug Administration rules that implement the Mammography Quality Standards Act. These changes are effective October 28, 2002, and include: a) Compression - mammography machines shall have an initial power-driven compression activated by hands-free controls and containing fine adjustment compression controls. b) Compression device performance - the maximum compression force for the initial power drive shall be between 25 and 45 pounds. c) Automatic exposure control - the machine shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density. d) Focal spot condition - shall be evaluated only by determining the system resolution. e) Radiation output - the machine should be capable of producing a minimum output of 800 milliroentgen per second.

The remainder of the changes went into effect on February 7, 2002, and include: a) New definitions; b) Requirements for backup processors - to establish operating parameters, the backup processor has to meet the requirements of the primary processor for a minimum of five days; c) Clarified requirements for physicist's annual



surveys; d) Revised requirements for stereotactic biopsy - 1. Technologist's qualifications - current certification as a medical radiologic technologist. 2. Continuing education and experience for technologists - six continuing education units and performance of 24 mammographic biopsy examinations during a 24 month period. 3. A qualified mammographer performing biopsies who meets the continuing education and experience requirements of §289.230(f) will have satisfied the continuing education and experience requirements for invasive interventions for localizations or biopsy; e) Accreditation - 1.Clarified requirements for physicist's annual surveys. 2. Revised and new fees for accreditation. 3. Added language on suspension of an accreditation. 4. Deleted requirement to post address where complaints may be filed and f) Clarified requirements for re-qualification for physicians, technologists, and physicists.

The rule has been mailed to all mammography registrants and is also available on the Bureau of Radiation Control's web site, www.tdh.state.tx.us/ech/rad/pages/brc.htm. Please contact Cathy Fontaine at:(512) 834-6688, ext. 2232; by e-mail: Cathy.Fontaine @tdh.state.tx.us,or telefax at (512)834-6716 for any questions regarding the revised mammography regulations.

Crossover, Crossover and More Crossovers!

By Jerry Cogburn

Just when you think this procedure is perfectly understood somebody comes up with another angle. What is crossover? In film manufacturing it is almost impossible to make x-ray film emulsion that maintains the same characteristics from one batch or lot to the other. Crossover is the name given to a process intended to eliminate the effect of film emulsion differences on the daily processor performance evaluations. Although, the crossover process is not required by rule, it is the only practical, and acceptable means to compensate for differences in control emulsion.

On a recent inspection, it was noted that each crossover was being

Continued on page 5

MAMMOGRAPHY CORNER

Optical Imaging Approved for Use in Clinical Trials

By Julie Davis

Mammography centers across the country may soon provide a new cancer-detecting tool to patients in the form of optical imaging. This new technology, called Computed Tomography Laser Mammography (CTLM), will offer an alternative testing method to breast biopsy.

The Food and Drug Administration (FDA) has approved CTLM for use in clinical trials, and a Texas facility will participate. Once accepted for pre-market approval, the CTML technique will assist facilities in determining whether a patient has a cancerous or benign lesion in the breast. Currently, a positive finding in a mammogram leads to a biopsy, but only one in eight suspicious looking lesions actually are cancerous.

Conventional mammography techniques use x-rays as an energy source, and require breast compression during the examination. This new testing system uses state-of-the-art laser technology and proprietary algorithms to create three-dimensional and cross-sectional images of the breast without the use of ionizing radiation or breast compression. The CTLM technology highlights both breast lesions and the blood supply of tumors. It is an adjunctive test, not a screening test. CTLM does not fall under MQSA rules at this time.

Crossover, Crossover and More Crossovers!

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done over a ten-day period, using only the daily QC films by a diligent and responsibile QC Technologist. The QC Technologist was using the average of the sensitrometric measurements, from the daily processor performance evaluations, conducted with the last five sheets of old QC film and the first five days with the new QC film. It is a fact that film processors operate differently every day, for a variety of reasons. Changes in processor operation can be tracked throughout the workday as well.

The main objective of the crossover process is to change the aim points in compensation for the differences in film emulsion, and film emulsion only. At this facility, the objective was defeated, by spreading the process over a ten-day period, which included all the daily processor variations. All ten crossover films must be processed, over the shortest possible time period, if the effects of daily processor variations are to be reduced to a negligible level. In effect, this facility was re-establishing processor operating parameters at every control film emulsion change, but this is not on the list of acceptable reasons for reestablishing operating parameters.

For a comprehensive explanation of the crossover process, please consult the 1999 American College of Radiology Mammography Quality Control Manual. For additional information regarding this, or any other mammography compliance issues contact Jerry Cogburn at (512) 834-6688, extension 2037.

Thefts of Portable Gauges

By David Fogle

During January 1996 through October 2000, the U.S. Nuclear Regulatory Commission and Agreement State licensees reported a total of 156 thefts of portable gauges. Fifty-one of the thefts occurred in Texas and Florida. Most of the thefts occurred when gauges were stored in vehicles parked in areas vulnerable to theft. Only 40 percent of the gauges reported stolen were reported as having been recovered. Two of the 156 thefts involved attempts to sell the stolen gauges. In both of these cases, the gauges were returned to the owner. In another two events, the gauges were found in a scrap metal shipment when a radiation monitor alarmed. In one event, only the source rod was found. In the other case, the gauge was found intact.

Thefts involving portable gauges appear to be occurring most frequently when gauges are stored in vehicles parked in a non-work area. In 83 percent of the thefts from vehicles, the vehicles were parked at locations other than the licensees' facilities or job sites. Of these cases, 37 percent were most frequently stolen from vehicles parked at private residences.

The NRC's analysis of five years of theft data for portable gauges indicates that a large number of gauges are stolen from trucks, even when the gauges are secured with chains. Frequently, the gauges were locked in an open truck bed, visible to passersby. Security measures, other than using locks as a deterrent, should be considered for portable gauges containing radioactive material. To help reduce the number of thefts, licensees may want to consider taking further precautions, such as: (1) requiring gauges to be locked in covered vehicle compartments, (2) not parking vehicles in areas vulnerable to theft, and (3) including a discussion of this article in periodic or special gauge user training, to increase awareness of this problem.

The requirements for control and security of licensed material are given in Title 25 Texas Administrative Code (TAC) §289.202(y). Control and security requirements may also be found on the Radioactive Material License (RAML) and within U.S. Department of Transportation (DOT) regulations.

Unless otherwise specified by license condition or incident to transportation(e.g., nonresidential overnight lodging when return to the permanent storage facility is either not possible, unsafe or logistically impractical), licensees are not authorized to store portable gauges at locations other than the permanent storage facility or on the truck at job sites.

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BRC wants to help defeat the high cost of doing business by offering you the opportunity to join a community of our licensees and registrants who want the ***Radiation Report*** sent to them via email.

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We are in the process of compiling a list and would like to hear from you. If you want us to email future copies of the ***Radiation Report*** simply fill out the form below by writing, taping or pasting your mailing label (on page 12). Then, tear out this page, and either fax it to us at (512) 834-6708 or fold it, tape it, and mail it back to us.

OH YEAH, YOU CAN EMAIL US WITH THIS INFORMATION TOO!

Email: julie.davis@tdh.state.tx.us.

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Regulation, Procedures and Legal Actions

By James Ogden

Title 25 Texas Administrative Code (TAC), Chapter 289 Section 301 establishes requirements for the registration of persons who receive, possess, acquire, transfer or use Class IIIb and Class IV lasers in the healing arts, veterinary medicine, industry, academic, research and development institutions, and of persons who are in the business of providing laser services.

Confusion has arisen over regulations of the various state agencies involved in the regulation of medical devices, control of non-ionizing radiation, and the professional aspects of practitioners and licensed professionals assisting these professionals. The confusion begins with the classification of lasers as both medical devices and laser devices. The U.S. Food and Drug Administration (FDA) regulates both classes.

Laser devices are regulated under their performance standard, Code of Federal Regulations (CFR), Title 21, Part 1040, Section 1040.10 (Performance Standards for Light–Emitting Products). This standard categorizes lasers by classes: Classes I, II, IIIa, IIIb, IV; the higher the class, the greater the risk and degree of regulation. The BRC rules for lasers address the registration and radiation safety requirements as they are classified under the FDA performance standards. The performance standards divide laser devices into classes based on the output power of the laser whether it is an ultraviolet, visible, or infrared laser and the potential exposure duration.

Class I lasers are eye safe under any circumstance and are not considered to be hazardous. Examples of this class include laser printers and compact disc (CD) players. Class II lasers emit visible laser light with an output of less than one milliwatt of power, yet are capable of creating eye damage by chronic viewing of the laser beam. However, based on the human eye blink reflex, which occurs in approximately 0.25 seconds of exposure to the Class II beam, adequate protection is provided. It is possible to overcome the blink response, and stare into the beam of Class II lasers long enough to cause eye damage. Examples of this class include continuous wave (CW) Helium-Neon lasers and some low powered laser pointers. A sub-classification of laser Class IIa has been determined by the Food and Drug Administration (FDA) for lasers less than one milliwatt that produce a visible beam, yet is not intended for viewing. This class of laser causes injury when viewed for longer than 1000 seconds. As with Class II lasers there are neither recommended control measures nor medical surveillance requirements for this subclassification. An example of this subclass would be a barcode reader commonly seen in department and grocery stores.

Class III lasers are subdivided into two distinct subclasses based on power output and optical hazard of the laser. Class IIIa lasers emit visible laser light with an output of one to five milliwatts as measured through a seven millimeter aperture, and are considered to be, depending upon the irradiance, either an acute intrabeam viewing hazard or a chronic viewing hazard. An acute viewing hazard is if viewed directly with optical instruments. These lasers require a warning label that cautions the user not to stare into the beam, and to avoid pointing the beam toward the eyes of other individuals. Examples of this class include: high-powered continuous wave (CW) Helium-Neon lasers and solid state (diode) laser pointers.

Class IIIb lasers are capable of emitting either visible or invisible laser radiation with power levels of five milliwatts to 500 milliwatts for continuous wave (CW) lasers or less than 10 Joules/cm^2 for a 0.25 second pulsed laser. These lasers are considered to be an acute hazard to the skin and eyes from direct radiation exposure. Specific control measures limiting access to areas of operation by key controlled access is required, and medical surveillance is recommended for users. Recommended medical surveillance would include a thorough ophthalmologic or dermatologic examination prior to exposure. The recommendation is a primary concern for medical-legal reasons. An example of this class is an intermediate powered medical laser operating in either visible or invisible wavelengths.

Class IV lasers are capable of emitting either or both visible and invisible laser radiation with power levels greater than 500 milliwatts for continuous wave (CW) laser, and greater than 10 Joules/cm^2 for a 0.25

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TDH Commissioner's Perspectives on Public Health

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radiation is used appropriately it is a very valuable technology in our current society, but when it is used inappropriately or used without proper monitoring it can put people in harm's way." Dr. Sanchez supports the TRAB's advisory cautioning the public about Whole Body CT Screening exams and said, " I respect the fact that the Advisory Board is made up of people of expertise. It gives them responsibility and bearing on an advisory of this sort."

Dr. Sanchez has concerns about radiation being used as a bio-terrorist weapon. That is why he is pleased to know that BRC is taking an active role in preparing for bio-terrorism activities through emergency response planning and drilling exercises. "We all want to be sure that we have plans in place; that we have exercised those plans to be sure that those things we will do when a situation arises that requires action will be done according to plan," he said. Dr. Sanchez believes that unless we practice them now, we may not carry those plans out according to their original design in the event of an emergency.

Routinely, the BRC conducts coordinated response with other state, local and federal governments to emergencies involving radioactive material, and for determining implementation measures to protect life, property and the environment. Sanchez stated that BRC plays an important role in providing a perspective from an entity that has been planning and doing drills for some time to communities that may not have had a lot of experience with drilling. He said, "The BRC can bring some of that perspective, and some prior experience to the TDH table." He followed by saying, "I think it is a good thing for the state, and certainly to our bio-terrorism group, to have BRC representation."

Laser Regulation, Procedures and Legal Actions

Continued from page 9

second pulsed laser. These high power lasers are considered to be an acute hazard to the skin and eyes from the direct beam or from scattered or reflected laser radiation. They present direct hazards to the eyes and skin, as well as the possibility of fire hazards. Specific control measures limiting access to areas of operation of these lasers and key-controlled access is required. The Texas Department of Health requires registration of Class IIIb lasers under Texas Administrative Code (TAC) 25 §289.301, Texas Regulations for Control of Laser Radiation Hazards. Examples of this class include high-powered industrial lasers used for precision cutting, shaping, and drilling of many materials, and high-powered medical lasers operating in the visible or invisible spectrum, or both.

The agencies involved in the regulation of lasers and their professional operation within the state of Texas include: the Texas Department of Health's (TDH), Bureau of Radiation Control (BRC), Bureau of Food and Drug Safety (Drug and Medical Device Division); the Texas State Board of Medical Examiners; the Texas State Board of Dental Examiners, the Texas State Board of Podiatric Examiners; the Texas State Board of Veterinary Examiners, the Texas State Board of Chiropractic Examiners, and the Texas State Board of Nurse Examiners. Each of the State Boards has been tasked with professional regulation of their segment of a particular profession.

Agencies have recently been involved in several legal cases where patients have been burned or died as a result of laser use or the use of IPL devices, which many patients have believed to be laser devices. Coordination between the agencies has pointed to discrepancies in rules applied by the various agencies with respect to both laser and IPL devices. The Texas State Board of Medical Examiners is currently in the process of rulemaking to address use and supervision of use, of both lasers and IPL devices. The BRC was granted the authority to regulate IPL devices effective September 1, 2001. Rulemaking for additions to the current laser rules is planned.

The Texas State Board of Medical Examiners (TSBME) is drafting rules addressing medical supervision for the use of medical lasers. For more information on TSBME rulemaking, contact Pat Wood at (512) 305-7016. What can you do if you have an unregistered laser? Contact the BRC's Registration Branch to request a laser registration packet for laser use, laser services (demonstration and sales, alignment, calibration, and/or repair, or being a provider of lasers on a periodic basis), or for laser light show use. If you have questions concerning laser registration you may contact Debbie Borden or Latischa Merritt at (512) 834-6688 extensions 2245 and 2248 respectively. Questions concerning annual survey, compliance and inspection, or reporting requirements may be made to Tommy Cardwell at (512) 834-6688 extension 2036.

Coping with Disaster on the Texas Coast

The Texas Regulations for Control of Radiation (TRCR), Title 25 Texas Administrative Code (TAC), §289 provides a comprehensive road map for the transportation, possession, storage, use and disposal of radioactive materials, and for the use of radiation-producing devices. Under normal conditions, the regulations provide guidance for almost every aspect of Licensees' and Registrants' actions, but what do you do when Mother Nature changes the rules?

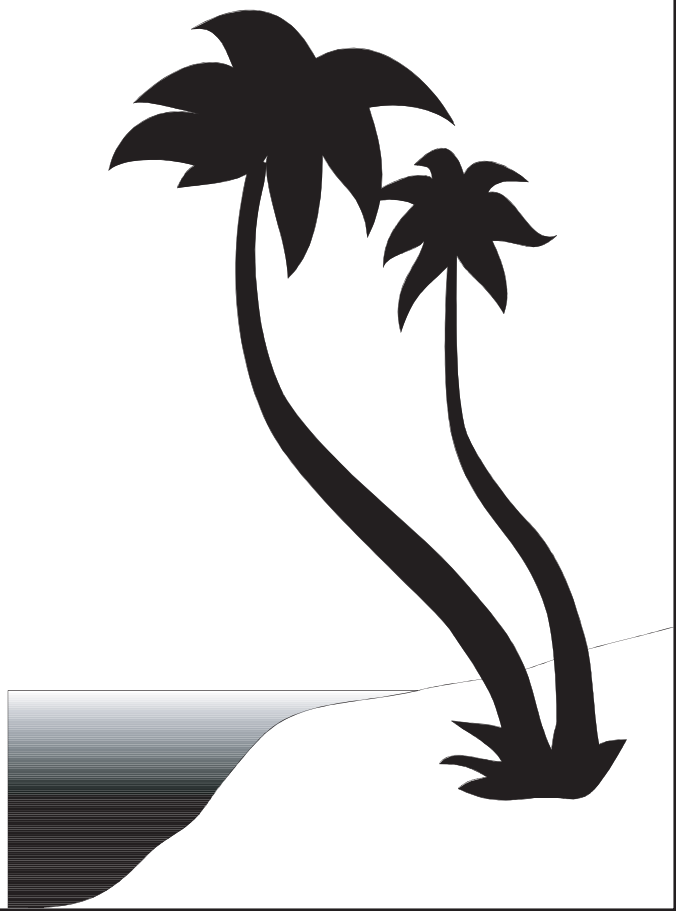
Since hurricane season begins on June 1st and continues through November 30th each year, hurricane vulnerability along the Texas coast is a fact of life. We can work to prevent or to mitigate the affects, but sooner or later some part of the coast is going to be hit.

If a hurricane or other major disaster wrecks your building, your down-hole storage is under water, your RSO has evacuated to another state, or some other disaster effect makes it impossible for you to function in strict compliance with your license or registration, what do you do?

It is crucial to notify local officials and the BRC when your facility that contains radioactive material is flooded. If you are in the impacted area and you can't communicate with local officials or the BRC, we offer some suggestions. Remember these are interim measures only. Required reporting must be resumed, and formal authorization of changes must be requested as soon as communications are reestablished. Do what you need to protect life and property.

At the same time:

- Use appropriate dosimetry and applicable shielding and/or protective clothing and services if available.
- ***Do not*** use any devices or instruments that may have been damaged or that may be out of calibration due to other causes.
- ***Do not*** perform any tasks that you are not trained to perform.
- Even if you are properly trained, perform unlicensed activities only as necessary to prevent injury or to avoid undue delay in provision of urgently needed assistance.
- Document your actions. Keep a written record of adjustments including what actions have been modified, why modification was necessary, and the specific changes to authorized activities that have been made.



BRC Chief Receives 30-Year Service Award

Richard Ratliff, Chief of the Bureau of Radiation Control, received his 30-year state service award and lapel pin on June 10, 2002. The ceremony led by Eduardo J. Sanchez, M.D., Commissioner of Health, recognized Mr. Ratliff for his continued dedication and commitment to serving TDH and the people of Texas.

Mr. Ratliff joined TDH in 1972 as an Environmental Health Specialist II. He has had hands-on involvement with all aspects of Radiation Control including directing programs responsible for inspections of all radioactive materials' licenses and x-ray registrations in Texas, investigations of all radiological incidents, and emergency response planning. His progress over the past 30 years has advanced him to his present position as Chief. Mr. Ratliff is a registered Professional Engineer and a licensed Medical Physicist.

Photograph by Julie Davis

Left to right: Richard Ratliff, BRC Chief and Eduardo J. Sanchez., Commissioner of Health.

STATE HOLIDAYS

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

Labor Day - September 2, 2002

Veteran's Day - November 11, 2002

Thanksgiving Day & Day After - November 28 & 29, 2002

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