

State of Texas vs FDA as Certifying Agency

2 Years Later

BACKGROUND -

1993 – TEXAS LEGISLATURE

AMENDED CHAPTER 403 OF

THE TEXAS HEALTH AND

SAFETY CODE....

...REQUIRING TEXAS TO APPLY

TO THE FDA TO BECOME AN

ACCREDITATION BODY AND

A

CERTIFYING STATE

TEXAS APPROVED

by the FDA

as an ACCREDITATION BODY

in 1999

TEXAS APPROVED

by the FDA

as a

CERTIFYING STATE

EFFECTIVE

SEPTEMBER 1, 2008

HOW

HAS THIS AFFECTED

FACILITIES

???????

NEW OR RENEWING
FACILITIES

STILL APPLY
FOR
ACCREDITATION

WITH TEXAS
OR
ACR

**STILL RECEIVE
ACCREDITATION
CERTIFICATE FROM
TEXAS ACCREDITATION
PROGRAM or AMERICAN
COLLEGE of RADIOLOGY
ACCREDITATION
PROGRAM**



**STILL APPLY FOR
CERTIFICATION WITH THE
STATE OF TEXAS**



SAME

ANNUAL INSPECTIONS

MQSA & STATE STANDARDS

NOTICEABLE CHANGES

- **TYPES OF CERTIFICATES**
- **FEES/BILLING**
- **FDA HOTLINE**

DIAGNOSTIC MAMMOGRAPHY

**1st page - a Department of
State Health Services (DSHS)
Certified Mammography
Facility certificate with
expiration date replaces the
FDA-issued certificate**

....continued...

DIAGNOSTIC MAMMOGRAPHY

....continued

2nd page – an abbreviated state certificate w/equipment information & no expiration date.

See attachment #1 in handout

....continued...

DIAGNOSTIC MAMMOGRAPHY ...continued...

**1st page - an FDA Certified
Mammography Facility
certificate with expiration
date**

....continued...

-----OR-----

DIAGNOSTIC MAMMOGRAPHY

....continued

**2nd page – a State of Texas
Certification of
Mammography Systems
w/equipment information
& expiration date**

- See attachment #2 in
handout. ...continued...**

DIAGNOSTIC MAMMOGRAPHY

...continued...

The FDA certificate will ultimately be replaced by the DSHS Certified Mammography Facility Certificate as facilities renew or amend their certifications...continued...

DIAGNOSTIC MAMMOGRAPHY

...continued...

Biopsy/Needle Localization

**Units are being removed
from current certifications
and issued a separate
certification...continued...**

....Reasons for separate certifications

- Accreditation is voluntary**
- Units not covered under MQSA standards**
- Fees are different from DX mammography**

CERTIFICATES FOR
BX/NEEDLE LOCALIZATION
UNITS

**Certificates will use same
format as state certificates in
the past**

See attachment #3 in Handout

....Reasons for separate certifications for subsites

Sites with separate FDA #s that have had separate FDA certificates in the past will have to be issued separate DSHS certificates

DIAGNOSTIC MAMMOGRAPHY

...continued...

**Subsites are being
removed from current
certifications and issued a
separate certification**

FEEES – DIAGNOSTIC MAMMOGRAPHY



FEES PRIOR TO 9/1/08

State

\$422/unit

FDA*

\$2150/unit/FDA #

\$ 250/each add. unit

...continued.....

FEES PRIOR TO 9/1/08

...continued...

***\$2150 - inspection fee
billed by the FDA after
each annual inspection**

FEES AFTER 9/1/08

- STATE*

\$1,745 for 1st unit/FDA #

\$ 204 each additional unit

- FDA**

\$ 548 Inspection fee

...continued...

FEES AFTER 9/1/08

...continued...

***STATE FEES NOW INCLUDE
THE MAJORITY OF THE
INSPECTION FEE
PREVIOUSLY BILLED BY FDA**

****FDA WILL BILL \$548 AFTER
THE ANNUAL INSPECTION**

...continued...

FEES AFTER 9/1/08

...continued...

**GOVERNMENTAL ENTITIES
WILL NOT BE EXEMPT FROM
THE PORTION OF THE STATE
FEE FOR INSPECTIONS. MAY
APPLY TO THE FDA FOR
EXEMPTION FROM THE \$548
INSPECTION FEE**

NOTE:

**PRIOR TO 9/1/08,
MQSA INSPECTORS WORKED
UNDER CONTRACT BETWEEN
THE FDA AND THE STATE.**

**INSPECTORS NOW WORK FOR
THE STATE**

FEE COMPARISON 1 UNIT

- Before 9/1/08
- After 9/1/08

State \$ 422

FDA \$1,749

Total \$2,171

State \$1,745

FDA \$ 548

Total \$2,293

FEE COMPARISON 2 UNITS

- **Before 9/1/08**

State \$ 844

FDA \$1,749

2nd 204

Total \$2,797

- **After 9/1/08**

State \$1,745

2nd 204

FDA \$ 548

Total \$2,497

FEES – Bx/Needle Localization Units

Remain at \$422/machine

**Inspection fee from FDA does
not include these units**

FDA HOTLINE.....

**CALLS WILL BE
DIRECTED TO THE
TEXAS MAMMOGRAPHY
PROGRAM**

ASSIGNING FDA #s
FDA assigns numbers
based on Accreditation Body
input & geographic location
per FDA Guidelines

Mobile units – facility may choose to have separate FDA # (Should consider fee ramifications & check on reimbursement)

NOTE:

**Fee of \$1,745 is assessed
for the first unit for each
FDA #**

NAME OF FACILITY ON CERTIFICATES

Every entity doing business in the state of Texas, except sole proprietorships and governmental entities, must register with the Texas Secretary of State's office under their legal name

.....continued.....

NAME OF FACILITY ON CERTIFICATES...continued

**On advice of our attorney
with the Office of General
Counsel, certificates must
be issued in the legal name
of the facility as filed with
the Texas Secretary of
State's office...continued....**

NAME OF FACILITY ON CERTIFICATES...continued

**IF A FACILITY HAS AN
ASSUMED NAME OR A "DOING
BUSINESS AS" (DBA) NAME, IT
MAY BE INCLUDED
FOLLOWING THE LEGAL NAME
...continued...**

NAME OF FACILITY ON CERTIFICATES...continued

**HOWEVER....A CERTIFICATE
MAY NOT BE ISSUED ONLY
UNDER THE ASSUMED
NAME OR DBA NAME**

**NAME OF FACILITY ON
CERTIFICATES...continued**

---ACCEPTABLE---

**METRO HEALTHCARE SYSTEM,
INC (LEGAL NAME)**

DBA: XYZ BREAST CENTER

....continued...

NAME OF FACILITY ON CERTIFICATES...continued

---NOT ACCEPTABLE---

**XYZ BREAST CENTER (DBA
NAME)**

...continued....

NAME OF FACILITY ON CERTIFICATES...continued

**THE NAME SUBMITTED TO THE
ACCREDITATION BODY IS THE
NAME THAT GOES INTO THE
FDA DATABASE...continued..**

**NAME OF FACILITY ON
CERTIFICATES...continued**

**THE NAME IN THE FDA
DATABASE IS THEN
TRANSMITTED TO THE TEXAS
MAMMOGRAPHY
CERTIFICATION
PROGRAM...continued**

NAME OF FACILITY ON CERTIFICATES...continued

**THE ACR HAS A LIMIT ON
NUMBER OF CHARACTERS
ALLOWED IN THE NAME FIELD
IN THEIR DATABASE SO THERE
MAY NOT BE ROOM FOR LEGAL &
DBA NAMES**

.....continued.....

**NAME OF FACILITY ON
CERTIFICATES...continued**

**WHAT SHOULD THE
FACILITY DO??
...CONTINUED...**

NAME OF FACILITY ON CERTIFICATES...continued

- 1. SUBMIT THE LEGAL NAME
TO THE ACCREDITATION
BODY**

...continued

NAME OF FACILITY ON CERTIFICATES...continued

**2. SUBMIT A BUSINESS
INFORMATION FORM WITH
THE LEGAL NAME & DBA
NAME TO THE TEXAS
MAMMOGRAPHY
CERTIFICATION
PROGRAM...continued...**

**NAME OF FACILITY ON
CERTIFICATES...continued**

**THE TEXAS MAMMOGRAPHY
CERTIFICATION PROGRAM
WILL ISSUE A DSHS
CERTIFIED MAMMOGRAPHY
FACILITY CERTIFICATE WITH
BOTH NAMES...continued...**

NAME OF FACILITY ON CERTIFICATES....CONTINUED

**THE LEGAL NAME FOR YOUR
FACILITY THAT WAS FILED
WITH THE SECRETARY OF
STATE'S OFFICE WAS USUALLY
DONE BY THE FACILITIES'
ADMINISTRATION OR LEGAL
REPRESENTATIVE...continued...**

NAME OF FACILITY ON CERTIFICATES.....CONTINUED

**Contact the Texas Secretary
State for information about the
legal name of your facility**

WWW.SOS.STATE.TX.US

1-800-252-1281

REIMBURSEMENT DENIALS

**CLAIMS FOR REIMBURSEMENT
HAVE BEEN DENIED BY
MEDICARE/MEDICAID AND
OTHER THIRD PARTY
PAYERS FOR SEVERAL
REASONS...continued...**

SOME REASONS FOR REIMBURSEMENT DENIALS.....CONTINUED

- 1) DIGITAL OR BIOPSY NOTATION
MISSING ON CERTIFICATE**
- 2) INCORRECT CERTIFICATE
SUBMITTED**
- 3) LEGAL NAME vs DBA NAME**
- 4) OUTDATED POLICIES ON THE
PART OF REIMBURSERS**

**FOR UNRESOLVED
REIMBURSEMENT
DENIALS,**

**Contact JO TURKETTE,
512-834-6688, ext 2247**

.....CONTINUED

TEXAS CERTIFICATION

&

TEXAS ACCREDITATION

**ARE SEPARATE
PROGRAMS**

**EVERY FACILITY MUST
HAVE AN
ACCREDITATION BEFORE
RECEIVING
CERTIFICATION**

**FACILITIES MAY CHOOSE TO
BE ACCREDITED WITH:**

**AMERICAN COLLEGE OF
RADIOLOGY (ACR)**

OR

TEXAS

**CONTACT INFORMATION
ACCREDITATION PROGRAMS**

**TEXAS MAMMOGRAPHY
ACCREDITATION PROGRAM**

**KAYE JIVIDEN, PROGRAM
COORDINATOR**

512-834-6688, ext. 2246

Kaye.Jividen@dshs.state.tx.us

**CONTACT INFORMATION
ACCREDITATION
PROGRAMS...continued**

**ACR ACCREDITATION
PROGRAM**

800-227-6440

www.acr.org

**EVERY FACILITY MUST
HAVE A CERTIFICATION**

**CERTIFICATIONS NOW
COME THROUGH THE
STATE OF TEXAS AND
INCLUDE MQSA AND
STATE CERTIFICATIONS**

CONTACT INFORMATION CERTIFICATION PROGRAM

**TERI HARDI, PROGRAM
COORDINATOR**

**TEXAS MAMMOGRAPHY
CERTIFICATION PROGRAM**

512-834-6688, EXT 2245

512-834-6716 (FAX)

Teri.Hardi@dshs.state.tx.us

**CONTACT INFORMATION
CERTIFICATION
PROGRAM...continued**

CATHY MCGUIRE

**TEXAS MAMMOGRAPHY
CERTIFICATION PROGRAM**

512-834-6688, EXT 2244

512-834-6716 (FAX)

Cathy.McGuire@dshs.state.tx.us

CONTACT INFORMATION

...continued

ACCREDITATION/ CERTIFICATION PROGRAM

JO TURKETTE, MANAGER

512-834-6688, ext. 2247

Jo.Turkette@dshs.state.tx.us

CONTACT INFORMATION...continued...

RADIATION CONTROL

WWW.DSHS.STATE.TX.US/RADIATION

MENU BOX ON RIGHT:

APPLICATIONS/FORMS

RULES/REGULATIONS

NEW MAILING ADDRESS

- **Texas Department of State Health Services, Radiation Safety Licensing Branch (RSLB),
Mail Code 2835, P O Box 149347, Austin, Texas, 78714-9347**

----IF SENDING FEES---

For new certifications, mail application and fees to Mail Code 2003, P O Box 149347, Austin Texas, 78714-9347

**ADDITIONAL
INFORMATION
NATIONAL CANCER
INSTITUTE
FACILITIES THAT OFFER
FREE OR LOW COST
MAMMOGRAMS
800-422-6237**

**ADDITIONAL
INFORMATION...continued...**

FDA WEB SITE

www.fda.gov

**Select "M" from A to Z menu
for MAMMOGRAPHY**