Make a divider labeled REGISTRATION CERTIFICATE. You may make a copy and display the original on the wall or you can put the original in the notebook.
Department of State Health Services
CERTIFICATE OF DENTAL X-RAY REGISTRATION

Pursuant to the Texas Radiation Control Act, Title 25 Texas Administrative Code (TAC) §289 (as amended), and in reliance on statements and representations made by the registrant, this Certificate of Registration is issued authorizing the registrant to receive, possess, transfer or acquire radiation machines and to use such machines for the purpose(s) and at the place(s) designated below. This registration is subject to all applicable rules, regulations and orders of Texas Department of State Health Services in effect and to the conditions specified below.

Name and Mailing address of registrant:

**DENTISTRY PA**
ATTN RSO
515 SOUTH WAY STE 102
XXX TX 75051

**CONDITIONS**

1. The authorized use location(s) is:
   Site Location
   000 515 WAY STE 102, TX 75051

2. The individual designated to perform the functions of radiation safety officer for this registration is , D.D.S.

3. The registrant **shall notify** the agency, in writing, of any change in the information shown on the application for registration or this Certificate of Registration in accordance with 25 TAC §289.232.

4. The registrant shall comply with the provisions of 25 TAC §289.232.

5. This certificate will remain in effect until a written request for termination is submitted by the registrant or restrictive action is taken by the agency.

Issuance of this Certification of Registration does not alleviate you from compliance with any outstanding notices of violation or payment of any fees due.

11 MAY 2011
Date Issued

Radiation Safety Licensing Branch
# Authorized Use Categories

**Date:** 11 May 2011

**Facility Name:** Carrier Dentistry, P.A.

**Registration No.:** R30898

<table>
<thead>
<tr>
<th>Use Category</th>
<th>Maximum Number of Units</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>886-Dental</td>
<td>04</td>
<td>000</td>
</tr>
</tbody>
</table>

- This is the maximum number of x-rays you have on file.
Make a divider labeled LICENSE AND CREDENTIALS. Copies are all you need because you will have the originals on the wall.
Make a copy of the doctor's license, RDH license, and/or assistant license or credentials. Inspectors will ask to see them so if a copy is in the notebook it will make the inspection run smoothly.
Make a divider labeled OPERATING AND SAFETY INSTRUCTIONS. It is OK to use what is in the state regulation however this copy is much easier to understand. It will take some personalization and fill in the blanks. These instructions are to be briefed to the staff once a year.
Operating and Safety Procedures for ____________________________
The designated RSO for this office is ____________________________

1. Purpose. These are procedures that will minimize radiation exposure to patients and employees.

2. Responsibilities.
   a. The Radiation Safety Officer (RSO) will brief the staff on these procedures annually and document the briefing on an attendance roster.
   b. The RSO has the responsibility and authority for assuring safe radiation practices and is the point of contact between this facility and DSHS Radiation Control.
   c. The RSO will insure the following are accomplished within required time guidelines and are documented in the radiation notebook.
      i. Equipment Performance Evaluations.
      ii. Image processing quality control.
      iii. Conduct annual inventory of x-ray units.
      iv. Notify Radiation Control Branch, Licensing division of an increase of x-ray units or change of physical address of this office.
   d. The staff will comply with these procedures in the daily discharge of their duties.

3. References.
   b. Manufacturer’s literature.

4. Procedures.
   a. Operator and patient safety.
      i. All operators of x-ray units must meet the requirements of the Texas State Board of Dental Examiners.
      ii. Individuals who operate only dental x-ray units are exempt from individual monitoring requirements (film badges).
      iii. Film holding devices will be used whenever possible. If it is necessary to hold the film or a patient, the staff will wear protective apron and position themselves out of the direct beam. Pregnant staff members are prohibited from holding the film during exposure.
      iv. Staff will not hold or stabilize the tube head during exposure.
   b. Posting notices.
      i. The “Notice to Employees” sign is posted ____________________________
      ii. The Certificate of Registration, Operating and Safety Instructions, and violations involving radiological working conditions are located ____________________________
      iii. Rights and obligations as a radiation worker are found in TAC 289.232(i)(4)(D) and (k)(1) located ____________________________
      iv. Our facility does not post a “Caution Radiation Area” because our operators have continuous surveillance and access control to the radiation area.
   c. Dose to operators
i. Occupational dose limits are found in TAC 289.232(i)(4)(A).
ii. A staff member who is or becomes pregnant may voluntarily inform the RSO in writing. The RSO must ensure that the dose not exceed 0.5 rem during the entire pregnancy.
iii. Any radiation incident or overexposure will be reported immediately to the RSO.
d. Operation of the x-ray units and image/film processing
   i. No x-ray exam shall be taken unless ordered by Doctor(s).
   ii. During exposure the staff must be able to continuously see, hear, and communicate with the patient. The staff must be at least six feet from the useful beam or behind a protective barrier.
   iii. If exposure settings are not programmed into the x-ray unit, a technique chart will be posted next to the controller.
e. Beam limiting devices that are a part of the x-ray unit (tube head cone and filters) will not be removed.
f. Portable x-ray units are mounted on a permanent base with wheels or hand-carried.
   i. During exposure the staff will be positioned to make exposure minimal and be out of the direct line of the beam.
g. This office does / does not use a film processor.
   i. Unexposed film will be stored
   ii. Processor chemical temperature will be in accordance to manufacturer's specifications. Temperature will be checked at the beginning of the day and films will not be developed unless the temperature is ______ or the “temperature ready” light is on. Manual processing temperature will be checked throughout the day.
   iii. A cleaner film will be run through the film processor at the beginning of the day to ensure the rollers do not contaminate the exposed film.
   iv. Expiration dates on film and chemicals will be checked periodically to ensure expired items are not used. Always use the oldest items first.
   v. Chemicals will be replaced by __________ according to manufacturer's recommendations. Chemicals will not exceed three months without complete replacement.
   vi. Lighting in the darkroom will not be altered without the approval of the RSO.
      1. Filter type __________________________
      2. Bulb wattage __________________________
      3. Distance from work surfaces __________________________
   vii. If a light leak is discovered, notify the RSO. A light leak check will be conducted and documented semi-annually by __________
h. Alternative processing systems are / are not used in this facility.
i. Processing will be done according to manufacturer's specifications.

ii. Digital imaging is/is not used in this facility.

i. Quality control of images will be conducted and documented by

ii. Processing of images will be according to manufacturer's specifications.
Make a divider labeled INVENTORY. The radiation safety officer is required to do a physical inventory check and sign it to document all x-ray units are the same.
<table>
<thead>
<tr>
<th>MACHINE MANUFACTURER</th>
<th>CONTROL PANEL MODEL NUMBER</th>
<th>CONTROL PANEL SERIAL NUMBER</th>
<th>ROOM ID OR NUMBER</th>
<th>TOTAL X-RAY TUBES FOR THIS CONTROL PANEL</th>
<th>AVERAGE NUMBER OF X-RAY FILMS OR EXPOSURES TAKEN PER WEEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENDEX</td>
<td>EXPERT DC</td>
<td>40-1864608DP</td>
<td>ROOM 1</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>PROGENY</td>
<td>PREVA</td>
<td>DK10507</td>
<td>ROOM 2 &amp; 4</td>
<td>1</td>
<td>40</td>
</tr>
<tr>
<td>GENDEX</td>
<td>EXPERT DC</td>
<td>300659</td>
<td>ROOM 3</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>GENDEX</td>
<td>765</td>
<td>15-1768686DP</td>
<td>ROOM 10</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>ARIXEX</td>
<td>NOMAD PRO 2</td>
<td>XD-130618-08</td>
<td>DENTAL</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>SORDEX</td>
<td>CRANEX 3D</td>
<td>SE-1100082</td>
<td>PAN EXAM</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>

COMPLETED BY RSO DATE 13/25/13

COMPLETED BY RSO

COMPLETED BY RSO

COMPLETED BY RSO

COMPLETED BY RSO

COMPLETED BY RSO

COMPLETED BY RSO

COMPLETED BY RSO
Make a divider labeled **FOR EACH ROOM**. Example here is ROOM 1, ROOMS 2&4, ROOM 3, ROOM 10, MOBILE 1, and PANOREX. File the most current on top, the previous form, and the original installation form (FDA Form 2579 sometimes called the pink slip). If a certified component has been replaced there will be a form for that. In case the original installation form cannot be located put a copy of the invoice from when that x-ray unit was purchased. If that is not available make a memo for record that states “On or about [date] make, model, SN# was installed in room [blank]. The RSO must sign this memo for record.

Mobile hand held x-ray units do not need installation since they are ready to use out of the box. Therefore an FDA Form 2579 Report of Assembly of a Diagnostic X-Ray System will not be issued. The Certificate of Conformance and your MWD invoice will be used to establish the installation date.
DIVIDER AND TAB
FOR
THIS X-RAY
DENTAL EQUIPMENT PERFORMANCE EVALUATION

42700 Commerce Street
Wichita Falls, TX 76301
800-766-2025 R17773

Survey instrument used: Unifors 512
Calibration date: 3/1/2011
Ion chamber: External [x]

X-RAY UNIT INFORMATION

Manufacturer: Gendex
Model: Expert DC
Serial Number: 40-1864805DP

TIMER ACCURACY

Regulation - 25 TAC 289.232(9)(h)(j): The accuracy of the timer shall meet the manufacturer's specifications. If the manufacturer specifications are not obtainable, the timer accuracy shall be +/- 10% of the indicated time with the testing performed at 0.5 second.

<table>
<thead>
<tr>
<th>Timer Measurements:</th>
<th>Time Selected: 0.5 Seconds</th>
<th>Pulses</th>
<th>Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial 1: 0.494 Seconds or 1 Pulsed</td>
<td>Deviation 1.20%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial 2: 0.494 Seconds or 1 Pulsed</td>
<td>Deviation 1.20%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial 3: 0.494 Seconds or 1 Pulsed</td>
<td>Deviation 1.20%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial 4: 0.494 Seconds or 1 Pulsed</td>
<td>Deviation 1.20%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

EXPOSURE REPRODUCIBILITY

Regulation - 25 TAC 289.232(9)(i)(j): When all technique factors are held constant, the coefficient of variance of exposures for both manual and AEC systems shall not exceed 0.05. See TRC Form 60-3 Pg. 4 for explanation.

Technical Factors Selected: 7 mA 65 kVp 0.5 Seconds 1 Pulses

Output Measurements:
| Trial 1: 481.6 mR |
| Trial 2: 481.6 mR |
| Trial 3: 481.7 mR |
| Trial 4: 481.5 mR |

Exposure Variability Coefficient of Variation: 0.0002

KVP TEST

Regulations - 25 TAC 289.232(9)(i)(j): If the registrant possesses the manufacturer's kilovolt peak specifications, the radiation machine shall meet those specifications. Otherwise, the indicated kVp shall be accurate to within +/-10% of the indicated setting at no less than three points over the usual operating range of the machine. For units with fewer than three fixed kVp settings, the units shall be checked at those settings.

<table>
<thead>
<tr>
<th>Manufacturer's Specifications</th>
<th>+/- 10% of indicated setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial 1: Indicated kVp 65</td>
<td>Measured kVp 61.0</td>
</tr>
<tr>
<td>Trial 2: Indicated kVp 65</td>
<td>Measured kVp 61.2</td>
</tr>
<tr>
<td>Trial 3: Indicated kVp 65</td>
<td>Measured kVp 61.1</td>
</tr>
<tr>
<td>Trial 4: Indicated kVp 65</td>
<td>Measured kVp 60.9</td>
</tr>
</tbody>
</table>

KVP Accuracy Pass [x] Fail [ ]
TUBE STABILITY

Regulations - 25 TAC 289.232(l)(6)(K): The tube shall remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant shall assure proper and free movement of the unit.

<table>
<thead>
<tr>
<th>Tube stable in all orientations</th>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free movement where designed</td>
<td>Pass</td>
<td>Fail</td>
</tr>
</tbody>
</table>

COLLIMATION

Regulations - 25 TAC 289.232(l)(6)(L): Field Limitation shall meet the requirements of 25 TAC 289.3(l)(12)

Intraoral:
Minimum source to skin distance (SSD) = 20.32 cm.
Field size at tip of cone = 7 cm.
Field size <= 7 cm: If the minimum SSD is 18 cm or more
Field size <= 6 cm: If the minimum SSD is less than 18 cm

<table>
<thead>
<tr>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
</table>

Panoramic:
X-ray field misalignment at image receptor slit: _______ inch x _______ inch
transverse vertical

Misalignment = 0.0 inches in the tranverse axis:
Misalignment <= 0.5 inches in the vertical axis:

<table>
<thead>
<tr>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
</table>

Cephalometric:
Source to image distance (SID) = _______ inches or _______ cm.
Indicated field size: _______ in. X _______ in. or _______ cm. X _______ cm.
Measured field size: _______ in. X _______ in. or _______ cm. X _______ cm.
Misalignment: _______ in. X _______ in. or _______ cm. X _______ cm.
Misalignment allowed:
Misalignment within 2% of the SID:

<table>
<thead>
<tr>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
</table>

ENTRANCE EXPOSURE

Regulations - 25 TAC 289.232(l)(6)(L): EE Limits - Limit 450 mR for 60 kVp and above / 600 mR for less than 60 kVp

<table>
<thead>
<tr>
<th>Technique Factors selected:</th>
<th>65 kVp</th>
<th>7 mA</th>
<th>0.16 Seconds</th>
<th>Pulses</th>
</tr>
</thead>
<tbody>
<tr>
<td>intraoral bitewing only</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source to skin distance (SSD) = 8 1/2 inches 9 1/2 cm.
Source to detector distance (SSDD) = 8 1/2 inches cm.
Is tip of cone positioned 1/2 inch or less from surface of instrument housing or probe? x Yes

EE = _______ 307 mR Direct Measurement _______ mR Calculated Measurement

Entrance exposure within limits: x Pass Fail

Name of Surveyor: Date: 02/03/12

Signature of Surveyor: 

Page 2
FOR FDA USE ONLY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
REPORT OF ASSEMBLY
OF A DIAGNOSTIC X-RAY SYSTEM

1. EQUIPMENT LOCATION
   a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED
   b. STREET ADDRESS
   c. CITY
   d. STATE
   e. ZIP Code
   f. TELEPHONE NUMBER

2. ASSEMBLER INFORMATION
   a. COMPANY NAME
   b. STREET ADDRESS
   c. CITY
   d. STATE
   e. ZIP Code
   f. TELEPHONE NUMBER

3. GENERAL INFORMATION
   a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Check appropriate boxes)
      y NEW ASSEMBLY - FULLY CERTIFIED SYSTEM
      x MEASURABLY CERTIFIED SYSTEM
   b. INTERVENTIONAL OTHER SPECIFIC FUNCTION
      y GENERAL PURPOSE RADIOTHERAPY
      x PURITY
      x OTHER (Specify)
   c. THE X-RAY SYSTEM IS (Check one)
      y MOBILE
      x STATIONARY
      x OTHER (Specify)
   d. THE MASTER CONTROL IS IN ROOM
   e. DATE OF ASSEMBLY

4. COMPONENT INFORMATION (If additional space is needed for this section use another form, replacing the preprinted number with this Form Number and complete Items 1, 4, and 5 only)
   a. A NEW INSTALLATION
   b. A REPAIR OR MODIFICATION
   c. NUMBER OF SYSTEMS OR MAINTENANCE ACTIONS
   d. SYSTEM MODEL NAME
   e. MANUFACTURER
   f. CONTROL MODEL NUMBER
   g. CONTROL SERIAL NUMBER
   h. SYSTEM SERIAL NUMBER

5. ASSEMBLER CERTIFICATION
   a. I certify that all certified components associated with this report are as listed above and that the statements made therein are true and correct.

COMMENTS
DIVIDER AND TAB
FOR
THIS X-RAY
1. EQUIPMENT LOCATION

HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED

2. ASSEMBLER INFORMATION

COMPANY INFORMATION

MIDWEST DENTAL EQUIPMENT R17773
2700 COMMERCE ST.
WICHITA FALLS, TX 79301, US
Telephone:(940) 322-4392

3. GENERAL INFORMATION

THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE

(*) New Assembly-Fully Certified System
( ) Reassembly-Mixed System (Both certified and non-certified components)
( ) Replacement Components in an Existing System
( ) An Addition to an Existing System

INTENDED USES

[ ] General Purpose Radiology
[ ] General Purpose Fluoroscopy
[ ] Tomography (other than CT)
[ ] Angiography
[ ] Podiatry
[ ] Other

THE X-RAY SYSTEM IS

(*) Stationary  ( ) Mobile

THE MASTER CONTROL IS IN ROOM

ROOMS 2 & 4

DATE OF ASSEMBLY
01/02/2014

4. COMPONENT INFORMATION

THE MASTER CONTROL IS

(*) A New Installation
( ) Existing (Certified)
( ) Existing (Non-certified)

CONTROL MANUFACTURER
PROGENY

CONTROL SERIAL NUMBER
DK10607

DATE MANUFACTURED
12/2013

CONTROL MODEL NUMBER
PREVA

SYSTEM MODEL NAME (CT Systems Only)

MANUFACTURER
PREVA

MODEL NUMBER

SELECTED COMPONENT

DATE MFGRD
12/2013

OTHER CERTIFIED COMPONENTS (Number of each installed)

[ ] X-ray Control
[ ] High Voltage Generator
[ ] Vertical Cassettes Holder
[ ] Tube Housing Assembly
[ ] Dental Tube Head
[ ] Cephalometric Device
[ ] Image Receptor Support Device
[ ] Other

[ ] Cradle
[ ] Film Changer
[ ] Image Intensifier
[ ] Spot Film Device
[ ] Fluoroscopic Imaging Assembly
[ ] Image Receptor
[ ] Fluoroscopic Air Kerma Display Device

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with the provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.

PRINTED NAME
DENNIS WEST

SIGNATURE
Jeff Lathrop

DATE
01/02/2014

6. COMMENTS

R18520

Copy - Purchaser
DIVIDER AND TAB
FOR
THIS X-RAY
1. EQUIPMENT LOCATION

HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED

2. ASSEMBLER INFORMATION

COMPANY INFORMATION

3. GENERAL INFORMATION

THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE

INTENDED USES:

[ ] General Purpose Radiology
[ ] General Purpose Fluoroscopy
[ ] Tomography (other than CT)
[ ] Angiography
[ ] Podiatry
[ ] Other

[ ] Urology
[ ] Mammography
[ ] Chest
[ ] Chiropractic
[ ] CT Head scanner
[ ] Cholangiography
[ ] Dental Panoramic
[ ] CT Head scanner
[ ] Dental-CT

THE X-RAY SYSTEM IS

(*) Stationary  ( ) Mobile

THE MASTER CONTROL IS IN ROOM

ROOM 3

DATE OF ASSEMBLY

11/28/2012

4. COMPONENT INFORMATION

THE MASTER CONTROL IS

( ) A New Installation
(*) Existing (Certified)
( ) Existing (Non-certified)

CONTROL MANUFACTURER

GENDEX

CONTROL SERIAL NUMBER

300859

DATE MANUFACTURED

07/2011

CONTROL MODEL NUMBER

EXPERT DC

SYSTEM MODEL NAME (CT Systems Only)

DELETED COMPONENTS

OTHER CERTIFIED COMPONENTS (Number of each unit)

[ ] X-Ray Control
[ ] High Voltage Generator
[ ] Vertical Cassettes Holder
[ ] Tube Housing Assembly
[ ] Dental Tube Head
[ ] Cephalometric Device
[ ] Image Receptor Support Device
[ ] Other

[ ] Grailde
[ ] Film Changer
[ ] Image Intensifier
[ ] Spot Film Device
[ ] Fluoroscopic Imaging Assembly
[ ] Image Receptor
[ ] Fluoroscopic Air Kerma Display Device

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with the provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.

PRINTED NAME

ALLEN ELLIOTT

SIGNATURE

Jeff Lathrop

DATE

11/28/2012

Digitally Signed Oct. 11/28/2012, 02:05:55 PM

6. COMMENTS

REPLACED TUBEHEAD SN# 2108560.
1. EQUIPMENT LOCATION: R13118

2. ASSEMBLER INFORMATION: R17773
   a. COMPANY NAME: Midwest Dental Equipment
   b. STREET ADDRESS: 2700 Commerce St
   c. CITY: Wichita Falls
   d. ZIP CODE: 76301
      1. TELEPHONE NUMBER: (940) 322-4592

3. GENERAL INFORMATION:
   a. NEW ASSEMBLY - FULLY CERTIFIED SYSTEM
   b. INTENDED USERS (check matrix)
      i. GENERAL PURPOSE RADIOGRAPHY
         ii. GENERAL PURPOSE FLUOROSCOPY
         iii. TOMOGRAPHY ( Cone or CT )
         iv. ANGIOSCOPY
         v. RADIOLOGY
   c. THE X-RAY SYSTEM IS (check one)
      i. STATIONARY
      ii. MOBILE
   d. THE MASTER CONTROL IS IN ROOM:
      Room 3
   e. DATE OF ASSEMBLY: 07/20/2011

4. COMPONENT INFORMATION:
   a. THE MASTER CONTROL IS:
      i. A NEW INSTALLATION
      ii. EXISTING (REMAKE)
   b. CONTROL MANUFACTURER: Gendex
   c. CONTROL MODEL NUMBER: EXPERT DC
   d. CONTROL SOCIAL SECURITY NUMBER: 300659
   e. DATE MANUFACTURED: July 2011
   f. SYSTEM MODEL NAME (CT System Only):

   Completing the following information for the selected components listed below which you installed. For beam limiting devices, tables and CT gantries, enter the manufacturer and model number in the indicated spaces. For other certified components, enter the appropriate blocks how many are on the system.

   0. SELECTED COMPONENTS
      a. MANUFACTURER: Gendex
         b. MODEL NUMBER: EXPERT DC
         c. DATE MANUFACTURED: July 2011
   d. MANUFACTURER:
      e. MODEL NUMBER:
         f. DATE MANUFACTURED:
   e. MANUFACTURER:
      f. MODEL NUMBER:
         g. DATE MANUFACTURED:
   f. MANUFACTURER:
      g. MODEL NUMBER:
         h. DATE MANUFACTURED:

5. ASSEMBLER CERTIFICATION:
   a. All components herein were installed by the assembler.

6. COMMENTS:

FORM FDA 2679 (5/10) PREVIOUS EDITIONS MAY BE USED

Printed Name: Allen Elliott
Signature: Allen Elliott
Date: 7/20/11

White Original - FDA Document Mail Center - WDCS-0269 - 10503 New Hampshire Avenue Silver Spring, MD 20993-0002
DIVIDER AND TAB
FOR
THIS X-RAY
DENTAL EQUIPMENT PERFORMANCE EVALUATION

Survey instrument used: Unfors 512 135234
Calibration date: 3/1/2011
Ion chamber: External [X] In housing []

X-RAY UNIT INFORMATION

Manufacturer: Gendex  Model: 765  Film:  Hand Held Unit [ ]
Serial Number: 15-1766363DP  Location RM10  Digital: [X]

TIMER ACCURACY

Regulation - 25 TAC 289.232(i)(6)(h)(i): The accuracy of the timer shall meet the manufacturer's specifications. If the manufacturer specifications are not obtainable, the timer accuracy shall be +/- 10% of the indicated time with the testing performed at 0.5 second.

Reference for Accuracy (select one)

- Manufacturer's Specifications: [ ]
- +/- 10% @ 0.50 second timer setting: [X] 0.5 [ ]
- Preheat time: [ ]

Timer Measurements: Time Selected: 0.5 Seconds Pulses

Trial 1: 0.494 Seconds or [ ] Pulses Deviation 1.20%
Trial 2: 0.494 Seconds or [ ] Pulses Deviation 1.20%
Trial 3: 0.494 Seconds or [ ] Pulses Deviation 1.20%
Trial 4: 0.494 Seconds or [ ] Pulses Deviation 1.20%

Timer within manufacturer's specifications: Pass [X] Fail [ ]

EXPOSURE REPRODUCIBILITY

Regulation - 25 TAC 289.232(i)(6)(j): When all technical factors are held constant, the coefficient of variance of exposures for both manual and AEC systems shall not exceed 0.05. See TRC Form 80-3 Pg. 4 for explanation.

Output Measurements:

Technical Factors Selected: 7 mA 65 kVp 0.5 Seconds Pulses

Trial 1: 508.5 mR
Trial 2: 508.9 mR
Trial 3: 498.4 mR
Trial 4: 497.5 mR

Coefficient of Variation: 0.0119

Exposure Reproducible: Pass [X] Fail [ ]

KVP TEST

Regulations - 25 TAC 289.232(i)(6)(j): If the registrant possesses the manufacturer's kilovolt peak specifications, the radiation machine shall meet those specifications. Otherwise, the indicated kVp shall be accurate to within +/- 10% of the indicated setting at no less than three points over the usual operating range of the machine. For units with fewer than three fixed kVp settings, the units shall be checked at those settings.

Manufacturer's Specifications OR +/- 10% of indicated setting

Trial 1: Indicated kVp 65  Measured kVp 60.7  Deviation 6.62%
Trial 2: Indicated kVp 65  Measured kVp 60.7  Deviation 6.62%
Trial 3: Indicated kVp 65  Measured kVp 60.5  Deviation 6.92%
Trial 4: Indicated kVp 66  Measured kVp 60.5  Deviation 6.92%

kVp Accuracy: Pass [X] Fail [ ]

Page 1
TUBE STABILITY

Regulations - 25 TAC 286.232(j)(6)(K): The tube shall remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant shall assure proper and free movement of the unit.

- Tube stable in all orientations: Pass [X] Fail [ ]
- Free movement where designed: Pass [X] Fail [ ]

COLLIMATION

Regulations - 25 TAC 286.232(j)(6)(L): Field Limitation shall meet the requirements of 25 TAC 286(j)(12)

Intraoral:
- Minimum source to skin distance (SSD): 20.32 cm.
- Field size at tip of cone: 7 cm.
- Field size <= to 7cm: If the minimum SSD is 18 cm or more: Pass [X] Fail [ ]
- Field size <= to 6cm: If the minimum SSD is less than 18 cm: Pass [X] Fail [ ]

Panoramic:
- X-ray field misalignment at image receptor slit: ___ inch X ___ inch
  - Transverse: Pass [ ] Fail [ ]
  - Vertical: Pass [ ] Fail [ ]

- Misalignment = 0.0 inches in the tranverse axis: Pass [ ] Fail [ ]
- Misalignment <= 0.5 inches in the vertical axis: Pass [ ] Fail [ ]

Cephalometric
- Source to image distance (SID): ___ in. X ___ in. or ___ cm. X ___ cm.
- Indicated field size: ___ in. X ___ in. or ___ cm. X ___ cm.
- Measured field size: ___ in. X ___ in. or ___ cm. X ___ cm.
- Misalignment: ___ in. X ___ in. or ___ cm. X ___ cm.
- Misalignment allowed: Pass [ ] Fail [ ]
- Misalignment within 2% of the SID: Pass [ ] Fail [ ]

ENTRANCE EXPOSURE

Regulations - 25 TAC 286.232(j)(6)(M): EE Limits - Limit 450 mR for 60 kVp and above / 600 mR for less than 60 kVp

- Technique Factors selected: 65 kVp 7 mA 0.5 Seconds 8 Pulses intraoral biteewing only
- Source to skin distance (SSD): 8 inches 20 cm.
- Source to detector distance (SDD): 8 inches 20 cm.
- Is tip of cone positioned 1/2 inch or less from surface of instrument housing or probe? [X] Yes

EE = 321.9 mR Direct Measurement mR Calculated Measurement

- Entrance exposure within limits: Pass [X] Fail [ ]
- Name of Surveyor: [Signature]
- Date: 02/03/12
- Signature of Surveyor: [Signature]
DENTAL EQUIPMENT PERFORMANCE EVALUATION

Clinic Name: DR. X
Address: 2700 Commerce Street
City, State, Zip: Wichita Falls, TX 76301
Telephone: 800-766-2025 R17773
Registration: RN

Survey instrument used: Radial 4075D
Calibration date: April 2007

Ion chamber: External

X-RAY UNIT INFORMATION
Manufacturer: GENDEX
Model: 765
Serial Number: 15-1766833
Film: 
Location RM9
Hand Held Unit
Digital: X

TIMER ACCURACY

Regulation - 25 TAC 286.232(i)(6)(f)(J): The accuracy of the timer shall meet the manufacturer's specifications. If the manufacturer specifications are not obtainable, the timer accuracy shall be +/- 10% of the indicated time with the testing performed at 0.5 second.

Reference for Accuracy (select one)

Manufacturer's Specifications: OR X +/- 10% @ 0.50 second timer setting

Preheat time

Timer Measurements: Time Selected: 0.5 Seconds

Pulses

Trial 1: 0.498 Seconds or ___ Pules Deviation 0.40%
Trial 2: 0.498 Seconds or ___ Pules Deviation 0.40%
Trial 3: 0.498 Seconds or ___ Pules Deviation 0.40%
Trial 4: 0.498 Seconds or ___ Pules Deviation 0.40%

Timer within manufacturer's specifications: Pass X Fail

EXPOSURE REPRODUCIBILITY

Regulation - 25 TAC 286.232(i)(6)(f)(L): When all technique factors are held constant, the coefficient of variance of exposures for both manual and AEC systems shall not exceed 0.05. See TRC Form 60-3 Pg. 4 for explanation.

Technical Factors Selected: 7 mA 65 kVp 0.5 Seconds ___ Pulses

Output Measurements:
Trial 1: 368.0 mR
Trial 2: 369.0 mR
Trial 3: 369.0 mR
Trial 4: 370.0 mR

Coefficient of Variation 0.0014

Exposure Reproducible: Pass X Fail

KVP TEST

Regulations - 25 TAC 286.232(i)(6)(J): If the registrant possesses the manufacturer's kilovolt peak specifications, the radiation machine shall meet those specifications. Otherwise, the indicated KVP shall be accurate to within +/-10% of the indicated setting at no less than three points over the usual operating range of the machine. For units with fewer than three fixed KVP settings, the units shall be checked at those settings.

[Manufacturer's Specifications OR ___ +/- 10% of indicated setting

KVP Accuracy Pass X Fail

Page 1
TUBE STABILITY

Regulations - 25 TAC 289.232(l)(6)(K): The tube shall remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrent shall assure proper and free movement of the unit.

- Tube stable in all orientations: Intraoral only
  - Pass: X
  - Fail: 

- Free movement where designed: Panoramic only
  - Pass: 
  - Fail: X

COLLIMATION


Intraoral:
- Minimum source to skin distance (SSD) 20.32 cm.
- Field size at tip of cone 7 cm.
- Field size <= 7 cm: If the minimum SSD is 18 cm or more
  - Pass: X
  - Fail: 

- Field size <= 6 cm: If the minimum SSD is less than 18 cm
  - Pass: 
  - Fail: X

Panoramic:
- X-ray field misalignment at image receptor slit: ______ inch X ______ inch
  - Transverse
  - Vertical
- Misalignment = 0.0 inches in the transverse axis:
  - Pass: 
  - Fail: X

- Misalignment <= 0.5 inches in the vertical axis:
  - Pass: 
  - Fail: 

Cephalometric
- Source to image distance (SID) ______ inches or ______ cm.
- Indicated field size ______ in. X ______ in. or ______ cm. X ______ cm.
- Measured field size ______ in. X ______ in. or ______ cm. X ______ cm.
- Misalignment ______ in. X ______ in. or ______ cm. X ______ cm.
- Misalignment allowed: 
- Misalignment within 2% of the SID: 

ENTRANCE EXPOSURE

Regulations - 25 TAC 209.232(l)(8)(M): EE Limits - Limit 450 mR for 60 kVp and above / 600 mR for less than 60 kVp

- Technique Factors selected: 65 kVp 7 mA 0.5 Seconds Pulses intraoral bitewing only

- Source to skin distance (SSD) 8 inches
- Source to detector distance (SDD) 8 inches
- Is tip of cone positioned 1/2 inch or less from surface of instrument housing or probe? X Yes

EE = 114 mR Direct Measurement
  - mR Calculated Measurement

- Entrance exposure within limits: X Pass 
  - Fail: 

Name of Surveyor: Bill Parker

Signature of Surveyor: 

Date: 02/08/08
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
REPORT OF ASSEMBLY
OF A DIAGNOSTIC X-RAY SYSTEM

1. EQUIPMENT LOCATION

a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED:

b. STREET ADDRESS:

c. CITY:

d. STATE:

e. ZIP CODE:

f. TELEPHONE NUMBER:


2. ASSEMBLER INFORMATION

a. COMPANY NAME:

b. STREET ADDRESS:

c. CITY:

d. STATE:

e. ZIP CODE:

f. TELEPHONE NUMBER:


3. GENERAL INFORMATION

a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE:

   [ ] NEW ASSEMBLY—FULLY CERTIFIED SYSTEM
   [ ] REASSEMBLY—FULLY CERTIFIED SYSTEM
   [ ] REASSEMBLY—MINIMIZED SYSTEM (both certified and non-certified components)
   [ ] REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM
   [ ] AN ADDITION TO AN EXISTING SYSTEM

b. INTENDED USE:

   [ ] GENERAL PURPOSE RADIOGRAPHY
   [ ] GENERAL PURPOSE FLUOROSCOPY
   [ ] TOMOGRAPHY (cone or flat CT)
   [ ] ANGIOSCOPY
   [ ] RADIOLOGY
   [ ] OTHERS

[ ] THE X-RAY SYSTEM IS:

   [ ] STATIONARY
   [ ] MOBILE

[ ] THE ASSEMBLER CONTROL IS IN ROOM

[ ] THE ASSEMBLER CONTROL IS APPROXIMATELY 27 FEET AWAY

4. COMPONENT INFORMATION

   (If additional space is needed for this section, use another form, replacing the preprinted number with this Form Number, and complete Items 1, 4, and 5 only)

b. CONTROL MANUFACTURER:

c. CONTROL MANUFACTURER MODEL NUMBER:

d. DATE MANUFACTURED:

[ ] SYSTEM MODEL NAME (CT Systems Only):

Complete the following information for the components listed below which you installed. For beam limiting devices, scales and CT gantries enter the manufacturer and model number in the indicated spaces. For other certified components, enter in the appropriate boxes how many of each you installed in this system.

6. SELECTED COMPONENTS

   a. MANUFACTURER:
   b. MODEL NUMBER:
   c. DATE MANUFACTURED:

[ ] OTHER CERTIFIED COMPONENTS

   [ ] X-RAY CONTROL
   [ ] CRANE
   [ ] MOBILE X-RAY UNIT
   [ ] MONITOR/VIDEO MONITOR
   [ ] VERTICAL CASSETTE HOLDER
   [ ] IMAGE INTENSIFIER
   [ ] TUBE HOUSING ASSEMBLY
   [ ] DENTAL X-RAY UNIT
   [ ] DENTAL X-RAY TUBE
   [ ] OTHER (Specify):

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type received by the manufacturer(s), were of the type required by the instructions of the manufacturer(s), and were installed in accordance with subsections of 21 CFR Part 1020 and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and within 15 days from the date of assembly, been copy of this report will be returned to us at the bottom of each copy.

6. PRINTED NAME:

7. SIGNATURE:

8. DATE:

COMMENTS:

[XXXXXXXXXX]

FORM FDA 2579 (7/02) PREVIOUS EDITION IS OBSOLETE
DIVIDER AND TAB
FOR
THIS X-RAY
Certificate of Conformance

Product: NOMAD Pro 2
Serial #: XD-130618-08
Mid Date: June 2013

This product is designed and manufactured to conform to the following US and International standards: 21 CFR 1020.30, 21 CFR 1020.31, IEC 60801-1, IEC 60801-1-2, IEC 60801-1-3, IEC 60801-1-4, IEC 60801-2-7, IEC 60801-2-28

Performance Results:

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<th>Test Description</th>
<th>Acceptance Limits</th>
<th>Timer Setting</th>
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<td>20ms</td>
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<tr>
<td>KV (mV) Accuracy</td>
<td>60.0kV ± 10%</td>
<td>58.5</td>
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<tr>
<td>KV (mV) Reproducibility</td>
<td>CV &lt; 0.05</td>
<td>0.001</td>
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<td>Timer Accuracy</td>
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<tr>
<td>Timer Reproducibility</td>
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<tr>
<td>Linearity</td>
<td>CL &lt; 0.1</td>
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<td>HVL</td>
<td>&gt;1.5mm Al</td>
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<tr>
<td>Radiation Leakage</td>
<td>&lt;0.02mGy/h'</td>
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Measurement Method: Final performance measurements are made using a NERO mAX, model 8000 x-ray meter from Viatoraex. Tube current (mA) is sensed across a series connected resistor with an accuracy of ±1% and measured using a digital multimeter, prior to encapsulation; NOMAD Pro has no provision for external measurement of beam current after final manufacture. Exposure time is measured during the entire exposure, referenced to 75% rise/fall, using the NERO mAX 8000 x-ray meter. Accelerating voltage (kV) is measured at both peak (kVp) conditions and effective conditions (kVeF), which is the equivalent kV as if the kV were constant through the whole exposure time. Linearity is calculated per IEC 60801-2-7, 60.102.2a.

I have reviewed the above data and have verified that this data represents an accurate summary of the actual test results.

Quality Assurance: [Signature]
Date: 6/28/13

www.aribex.com
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**10% DOWN VIA CREDIT CARD / BALANCE - PAY PROMPTLY**

**NOTES**

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<td>CANTILEVER - WAL - ALARM</td>
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**WITH EVERY USE**

**INDISPENSABLE RESOURCES FOR PROVIDING ACCESS TO CARE SAFELY AND CONVENTIONALLY**

**COMMUNITY'S VIEW OF THE NONAD AG BOLLY A TRIBLY DISRUPTIVE TECHNOLOGY AND**

**PRODUCTS, THE PRO 2 IS THE NEXT LOGICAL STEP TO REINFORCE THE DENTAL**

**RESEARCH LIMITATIONS AND HUMANITARIAN HEROES WHO USE THE NONAD AG IMPROVES THE SYSTEM'S DURABILITY AND**

**TOGETHER WITH A NEW CHARGING CABLE IMPROVES THE SYSTEM'S DURABILITY AND**

**THE PRO 2 REMOVES DISCONNECTED HANDSET WITH INFRARED CONNECTIONS.**

**NOMAD PRO 2 XRAY UNIT-WHITE**

**RETAIL LIST**

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**Midwest Dental**

**DEPARTMENT: SERVICES - SUPPLIES**

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<td>ABC</td>
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</tbody>
</table>
DIVIDER AND TAB FOR THIS X-RAY
1. EQUIPMENT LOCATION

HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED

[Address Information]

2. ASSEMBLER INFORMATION

COMPANY INFORMATION

MIDWEST DENTAL EQUIPMENT R17773
2700 COMMERCE ST.
WICHITA FALLS, TX 76301, US
Telephone:(940) 322-4652

3. GENERAL INFORMATION

THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE

( ) New Assembly-Fully Certified System
( ) Reassembly-Fully Certified System
( ) Reassembly-Mixed System (Both certified and non-certified components)
( ) Replacement Components In an Existing System
( ) An Addition to an Existing System

INTENDED USE(S)

[ ] General Purpose Radiology
[ ] General Purpose Fluoroscopy
[ ] Tomography (other than CT)
[ ] Angiography
[ ] Pediatry
[ ] Other

THE X-RAY SYSTEM IS

( ) Stationary ( ) Mobile

THE MASTER CONTROL IS IN ROOM
PANOREX EXAMINATION AREA

DATE OF ASSEMBLY 12/02/2013

4. COMPONENT INFORMATION

THE MASTER CONTROL IS

( ) A New Installation
( ) Existing (Certified)
( ) Existing (Non-certified)

CONTROL MANUFACTURER SORDEX
CONTROL SERIAL NUMBER SE-1100082
DATE MANUFACTURED 10/2011

CONTROL MODEL NUMBER CRANEX 3D
SYSTEM MODEL NAME (CT Systems Only)

SELECTED COMPONENTS

<table>
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<tr>
<th>MANUFACTURER</th>
<th>MODEL NUMBER</th>
<th>DATE MFRD</th>
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<tr>
<td>SORDEX</td>
<td>CRANEX 3D</td>
<td>10/2011</td>
</tr>
</tbody>
</table>

OTHER CERTIFIED COMPONENTS (Number of each installed)

[ 0] X-Ray Control [ 0] Cradle
[ 0] High Voltage Generator [ 0] Film Changer
[ 0] Vertical Cassettes Holder [ 0] Image Intensifier
[ 0] Tube Housing Assembly [ 0] Scot Film Device
[ 0] Dental Tube Head [ 0] Fluoroscopic Imaging Assembly
[ 0] Cephalometric Device [ 0] Image Receptor
[ 0] Image Receptor Support Device [ 0] Fluoroscopic Air Karmir Display Device
[ 0] Other

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with the provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.

PRINTED NAME CHARLIE McGAFF
SIGNATURE Jeff Lathrop
DATE 12/02/2013

6. COMMENTS

[Signature]
Make a divider labeled **DISPOSAL FORMS**. Any x-ray unit that has been taken down must have a disposal form. It does not matter if it was thrown away, saved for parts, or left on the wall. This form indicates it cannot be turned on and energized.
The following x-ray units have been transferred, disposed of, or rendered inoperable by Midwest Dental Equipment and Supply.

Registrant Name: DR. MARK SMITH
Address: 55 Commerce St., Ste X
          Wichita Falls, TX 76301
Registration Number: 000000

Manufacturer: SS WHITE MARKSMAN 1
Control Serial Number: 01005

Manufacturer: Control Serial Number:

Manufacturer: Control Serial Number:

Manufacturer: Control Serial Number:

Manufacturer: Control Serial Number:

Manufacturer: Control Serial Number:

Date: 8/25/2007
Make a divider labeled QUALITY CONTROL. This is where you keep information on the step wedge test or darkroom light leak test.
QUALITY ASSURANCE/QUALITY CONTROL PROTOCOL FOR IMAGE PROCESSING

1. PURPOSE:

   The purpose of this operating instruction is to assure that quality assurance/quality control procedures for determining diagnostic quality of images are followed. Good image quality is of utmost importance so needless exposures are taken on patients.

2. RESPONSIBILITIES:
   a. The Radiation Safety Officer will assure that only properly trained personnel are permitted to take x-ray images.
   b. Staff who takes x-ray exposures will follow manufacturer's guidelines, regulatory requirements, and/or our Operating & Safety Instructions.

3. REFERENCES:
   a. Manufacturer's literature
   b. TAC 289.232(i)(16)
   c. Office Operating & Safety Instructions

4. PROCEDURES:
   a. Imaging plates that are not new will be subjected to a periodic phantom test. Five plates will be selected randomly and tested monthly. The Radiation Safety Officer will review the images and make the determination to keep or discard the sensors. Test images will be kept on file for review.
   b. Imaging plates will be visually examined prior to use on a patient. If any defects are noted that imaging plate will be discarded prior to use and a new one will be used.
   c. When the dentist reviews the image if there is any indication diagnostic quality is compromised that imaging plate will be discarded.
PROCEDURES FOR QUALITY CONTROL FOR IMAGE PROCESSING

1. Darkroom light leak test (film based only) Required twice a year
   a. Go into the darkroom, shut the door, and turn out the light or use the daylight loader
   b. Use a periapical film that has not been exposed
   c. Open the film and wait 60 seconds
   d. Process the film in the normal manner
      i. If the film comes out clear then there is no light leak
      ii. If the film comes out gray or black there is a white light leak
          1. Fix the light leak and retest
   e. Keep the films in a full mouth mount for an inspector to review

2. Step wedge (this is required once a year) Also referred to as a phantom
   a. A step wedge can be purchased commercially or the head of an amalgam carrier can be substituted
      i. Film based
         1. Using a periapical film take a shot of the step wedge for each x-ray unit and file in a full mouth mount
      ii. Digital
         1. Take an image using each sensor and capture the image to be saved on a computer file that can be reviewed by an inspector.
Make a divider labeled INSPECTIONS. Keep the last inspection on file. Also keep any inspection that had a violation to show the next inspector the discrepancy did not happen again.
Dear Mr. [Redacted]:

We have reviewed your letter dated January 17, 2011 informing us of the steps taken to correct the violation. Your corrective actions appear to bring your radiation safety program into compliance.

This correspondence should be retained as part of your permanent records. If you have any questions, you may contact me at (512) 834-6770, ext. 2061.

Sincerely,

Chris Myers
Quality Assurance Specialist
Radiation Group
Policy/Standards/QA Unit

CM:ls

cc: File
Date

From: (your office)

To: TDSHS

Attn: [redacted]
Inspection No. [redacted]

Violation 1: Equipment Performance Evaluations were not conducted by the required date.
Severity Level III
Corrective Action: EPE due dates have been entered into a scheduling program to insure compliance.

Violation 2: The Agency was not notified within 30 days of increase in number or radiation machines.
Severity Level IV
Corrective Action: This requirement is included in our Operating and Safety Procedures as a reminder of the duties of the RSO.

Violation 3: The Remote inspection was not signed by the RSO.
Severity Level IV
Corrective Action: This requirement is included in our Operating and Safety Procedures as a reminder of the duties of the RSO.

(signed)
[redacted], DDS
Radiation Safety Officer
**NOTICE OF VIOLATION**

**September 20, 2013**

---

**License No.** R31165-000

**Inspection No.** 101360Y

**Inspection Date:** December 06, 2012

**Inspector:** Tony Thompson

**Inspection Location:** 1615 EKAHRT ST, RIO HONDO, TX 77802

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The following alleged violations were found during an inspection of operations under the registration number above:

1. **Violation of 25 TAC §289.232(i)(7)(A):**
   
The equipment performance evaluation was not conducted as required for the following machine(s).

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model No.</th>
<th>Serial No.</th>
<th>Date EPE Due</th>
<th>Date EPE Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siemens</td>
<td>Heliodent</td>
<td>04 702 902</td>
<td>02/13/2011</td>
<td>01/14/2013</td>
</tr>
<tr>
<td>Dental-EZ</td>
<td>DX</td>
<td>XR0306020</td>
<td>02/13/2011</td>
<td>01/14/2013</td>
</tr>
<tr>
<td>Gendex</td>
<td>GX-770</td>
<td>770-1153133</td>
<td>02/13/2011</td>
<td>01/14/2013</td>
</tr>
</tbody>
</table>

   This is a Severity Level III Violation. Code 37 HR

   **Note:** Please establish written procedures to prevent exceeding the interval in the future. Your corrective actions will be verified at the next on-site inspection performed by an inspector from this Agency. Repeat violations will result in the severity level being escalated.

2. **Violation of 25 TAC §289.232(b)(5)(D)(ii):**
   
The Agency was not notified in writing, within 30 days of the increase in number of radiation machines.

   This is a Severity Level IV Violation. Code 51

3. **Violation of 25 TAC §289.232(k)(1)(T)(ii):**
   
The Dental Remote Inspection Form issued on December 6, 2012 was not signed by the Radiation Safety Officer (RSO). Code 39 HR, RSO.

   This is a Severity Level IV violation. Code 20

It will not be necessary to submit a written response to this notice. This closes inspection action 1011183 only. Any pending actions concerning registration or fees must meet compliance with the appropriate department. If you have any questions, please contact Michelle Brown at 512-334-6770, extension 2859.

Violation 1 is health related, or potentially health related and should be corrected immediately. **25 Texas Administrative Code, Chapter 289** requires this notice be made available for employee review.

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An Equal Opportunity Employer and Provider
You are required to have TAC289.232. It is not necessary to print this regulation as it is quite lengthy. All that is required is to have access to this state regulation. Go to this website and scroll down to the regulation. You can save it on your computer or have the link in your favorites.

http://www.dshs.state.tx.us/radiation/rules.shtm