



X-ray Facility Data/Survey Sheet Division of Electronic Products

Facility Name: _____

Registration #: _____ Survey Date: _____

Street Address: _____ City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Person Contacted During Inspection: _____ Title: _____

Administrator/Owner (If different from above): _____ Title: _____

Mailing Address: _____ City: _____ State: _____ Zip: _____

Inspection Type: Initial Re-inspection Follow-up

Number of tubes in report: _____ Number of controls in report: _____

SURVEY EQUIPMENT

Manufacturer	Model	Serial No.	Calibration Due Date

FACILITY INSPECTION FINDINGS:

IMAGE PROCESSING Type: Automatic Manual Digital Daylight
 Darkroom: Light Tight _____ Safelight Adequate _____ Film Storage Adequate _____

DIGITAL PROCESSING Type: CR DR
 Current Manual Available _____ Manufacturer Protocol Followed _____

<p>AUTOMATIC PROCESSING</p> <p>Developer Temperature Indicated _____</p> <p>How often is processor cleaned _____</p> <p>Records _____</p>	<p>MANUAL PROCESSING</p> <p>Dedicated Darkroom: Thermometer _____ Timer _____</p> <p>Time/Temperature Chart _____</p> <p>Sight Developing _____ Chemicals Changed Records _____</p>
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PERSONNEL MONITORING

Number of occupationally exposed _____ Number monitored _____ Badges appropriately worn _____

Monitoring system employed: Never Current Discontinued Company _____ Reporting Period _____

Records: Kept _____ Available _____ Previous occupational exposure _____ Multiple facilities _____

Personnel routinely holds patients/film _____

Badges: Lost Damaged Late Unused _____

Comments: _____

Inspector(s): _____ Date: _____

Registration #: _____ - _____

QUALITY ASSURANCE

Equipment Performance Test: Records _____ Vendor _____

Date of last test _____ Adequate _____

Repeat analysis frequency _____ Densitometry/Sensitometry _____ Cassettes cleaned _____ Documented _____

ADMINISTRATIVE

*** Doctor only operator

Operator Qualification: SCRQSA Certificate _____ Available to Public _____ Training (Dental/Veterinary) _____

Documentation _____

Facility specific equipment/procedures training _____ Documentation _____

Written Operating Procedures: Available _____ Complete _____
(Patient holding, Pregnant workers, Pregnant patients, Gonadal shielding, Personnel monitoring, Training plan, Quality Assurance)

Facility Registration Approval: Adequate _____

Report of Change: Not Reported _____

OTHER REQUIREMENTS

RHA-20 posted _____ Pregnancy poster posted _____ Radiation area sign posted _____

Protective clothing/Gonadal shielding available _____ Adequate _____ Inspected _____ Documented _____

Patient log _____ Adequate _____

COMMENTS:

Next equipment performance test(s) due: _____

Violation page attached: Yes No

Supplementary page attached: Yes No

In accordance with Regulation R61-64, X-rays (Title B), the items indicated identify the violation(s) found at your facility. All violations must be corrected within sixty (60) days. You are required to notify the Department, in writing, of the action taken to correct the violations. You are also required to address any recommendations that have been made. Each violation and recommendation must be addressed individually. All correspondence should be sent to: DHEC, Division of Electronic Products, 2600 Bull Street, Columbia, SC, 29201.

Any questions concerning this inspection should be addressed to _____ at (803)545-4400.

Your notice of corrective action is due, in writing, by: _____
The above violations and recommendations, if any, have been discussed with me, and I agree to correct the violations and address any recommendations.

Report received by: _____ Date: _____

Inspector(s): _____ Date: _____

FACILITY VIOLATION/RECOMMENDATIONS

Facility Name: _____

Registration #: _____

Violation	Recommendation	DESCRIPTION OF VIOLATION / RECOMMENDATION
		RHB 4.2.16.2 - Darkroom. The darkroom is not light tight.
		RHB 4.2.17.2.4 - Safelight. If a safelight is used, it shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.
		RHB 4.2.17.2.9 - Quality Assurance - Records of Processor Quality Assurance. There were no records of processor quality assurance available for review.
		RHB 4.2.17.1 - Manual Film Processing Requirements. The following were not present for use with the manual developing system: <input type="checkbox"/> A dedicated darkroom thermometer. <input type="checkbox"/> A dedicated darkroom timer. <input type="checkbox"/> A time/temperature processing chart.
		RHB 3.3.2 - Personnel Monitoring. The registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).
		RHB 3.20.6 - Records of Personnel Monitoring. Records of personnel monitoring are not being maintained.
		RHB 3.12, 4.12.3.2 - Personnel Monitoring. Personnel monitoring, or film badges, are required, but not being provided.
		RHB 3.4.4 - Records of Exposure at Multiple Facilities. There are no records of exposure received by an employee at another facility.
		RHB 3.20 - Records of Prior Occupational Dose During This Current Year. There are no records of exposure received by an employee at any previous facility.
		RHB 4.2.16.1- Quality Assurance – Equipment Performance Tests. Your x-ray unit(s) have not been tested on the required frequency. Your x-ray unit(s) will need to be tested _____.
		RHB 4.2.16.1- Quality Assurance - Records of Equipment Performance Tests. There were no records of previous tests available for review.
		RHB 4.2.16.1 - Quality Assurance – Equipment Performance Tests. A test was performed on your unit, but it is not adequate. You must contact your vendor concerning this requirement.
		RHB 4.3.12.1 - Digital Imaging. Protocol established by the manufacturer of the digital imaging acquisition system is not being followed.
		RHB 4.3.12.2 - Digital Imaging. The current manufacturer's operating manual is not available.
		RHB 4.2.16.4 - Repeat Analysis. A repeat analysis is not being performed or the repeat analysis program is not adequate. An analysis of repeats shall include, at a minimum, the overall repeat rate and the causes for all repeats. At your facility, the repeat analysis shall be done_____.

Inspector(s): _____ Date: _____

FACILITY VIOLATION/RECOMMENDATIONS

Facility Name:		Registration #:
Violation	Recommendation	DESCRIPTION OF VIOLATION/RECOMMENDATION
		RHB 4.2.17.3.3 - Screen Cleaning. Cassettes and screens are not being cleaned on a routine basis, or the cleaning is not being documented.
		RHB 4.2.2 - Operator Training. X-ray operators do not possess a current, valid certificate from the South Carolina Radiation Quality Standards Association.
		RHB 4.2.2.6 - Operator Training. Each operator's current certificate is not displayed in public view. Certificates or posting of notice was not available.
		RHB 4.2.2.7 - Operator Training. Operators have not received training specific to the equipment and procedures in use at this facility, or this training has not been documented for _____.
		RHB 4.2.2.8- Certificates. Dentists and their auxiliaries must meet the requirements of the South Carolina Dental Practice Act. At the time of inspection certificate(s) were not available for _____.
		RHB 4.12.22 - Operator Training. Operators and/or holders in veterinary facilities have not received adequate training. At the time of inspection documentation of training was not available for _____.
		RHB 4.2.3 - Operating Procedures. Written operating procedures were not available. The procedures must include all items specified in RHB 4.2.3. At the time of inspection, your operating procedures did not include: <ul style="list-style-type: none"> <input type="checkbox"/> Policies and procedures for Pregnant Workers <input type="checkbox"/> Policies and procedures regarding the Use of Gonadal Shielding <input type="checkbox"/> Policies and procedures for Pregnant Patients <input type="checkbox"/> Policies and procedures for Personnel Monitoring <input type="checkbox"/> Procedures for Training New Employees <input type="checkbox"/> Methods for Quality Assurance <input type="checkbox"/> Policies and procedures for Patient Holding
		RHB 4.2.3 - Operating Procedures. Although written operating procedures are available, they are not being followed for _____.
		RHB 2.4.1.4 – Facility Registration Approval. Facility registration has not been issued for this facility.
		RHB 2.5.3 - Report of Change. A change of status affecting this x-ray facility was not reported within thirty (30) days.
		RHB 2.5.4 - Using an Unregistered Vendor. A vendor was used who is not registered with the Department to provide x-ray services.
		Other Required Items. One or more of the following required items is not present: <ul style="list-style-type: none"> <input type="checkbox"/> "Notice to Employees" sign is not posted. - RHB 10.2.1 <input type="checkbox"/> A pregnancy poster is not posted. - RHB 4.2.7 <input type="checkbox"/> Protective clothing/gonadal shielding is not available. - RHB 4.2.10, 4.2.12 <input type="checkbox"/> Lead aprons and gloves shall be checked and documented annually. - RHB 4.2.8 <input type="checkbox"/> The patient log does not contain all required items. - RHB 4.2.15 <input type="checkbox"/> A radiation area sign is not posted. - RHB 3.15 <input type="checkbox"/> A warning label containing the statement in RHB 4.3.1 is not present.

Inspector(s): _____ **Date:** _____

Division of Electronic Products
X-ray Facility Data/Survey Summary Sheet
DHEC 3457

PURPOSE:

The purpose of DHEC Form 3457 is to provide a record of items of non-compliance that are found on the regulatory inspection of x-ray facilities and x-ray equipment. This form will also serve as a report to the facility for their use in responding to items of non compliance found on inspection.

EXPLANATION AND DEFINITION:

Item by Item Instructions:

1. The first part of the form is to record general information about the facility. Record the facility name, registration number, and survey date. Record the facility's street address, telephone number, and FAX number. Record the name and title of the person contacted during the inspection. Record the administrator/owner's name and title if it is different from the person contacted during the inspection. Record the mailing address, if it is different from the location address.
2. Indicate the inspection type. Initial inspection is for a facility that has never been inspected. A reinspection is the routinely scheduled inspection of an x-ray facility. A follow-up inspection is a specially scheduled inspection to follow up on problems cited on a previous inspection.
3. Write in the number of tubes that were inspected that are reported on this form. Write in the number of controls that were inspected that are reported on this form.
4. Under "Facility Inspection Findings," place a check in the appropriate violation or recommendation column for any of the citations listed that are present at the facility.
5. Write in the name of the company that provides routine servicing on the equipment.
6. Write in the date that the next equipment calibration is due. For dental facilities, the next calibration date should be two years after the DHEC inspection. For all other facilities, the next calibration is due one year after the previous calibration, or sixty (60) days after the DHEC inspection, if no calibration has been performed during the preceding twelve months. Indicate whether a supplementary sheet is included with the report. A supplementary page is not required, but may be used to list additional violations and recommendations.
7. Record the name of the contact person at DHEC that the facility should call if questions arise. Write the date that notice of corrective action is due, which is sixty (60) days after the inspection date.
8. Have the contact person at the facility sign and date the form where indicated.
9. The inspector(s) signs and dates the form at the bottom of the second page.

OFFICE MECHANICS AND FILING:

After completion, the form is separated, and the white copy is given to the facility. The yellow copy is placed in the facility's file. The facility files are maintained in the file room located in the Bureau of Radiological Health.