VERMONT
Department of Health

Radiological Health Program
Safety and Compliance Inspection Report

Registrant:

Location:

Registrant Representative:

Registrant Representative Email:

Date(s) of Inspection: **Type of Inspection:**

Registrant:

The inspection was an examination of the activities conducted as they relate to radiation safety and compliance with the Vermont Department of Health (VDH) Radiological Health Rule pursuant to 18 V.S.A. Chapter 32. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ Based on the findings, no violations were identified. Please sign and submit on page 9.

☐ Previous violations were closed. Please sign and submit on page 9.

☐ The violations, specifically described to you by the inspector as non-cited violations, are **not being cited** because they were self-identified, non-repetitive, and corrective action has been taken, and the remaining criteria in the VDH enforcement procedure to exercise discretion, were satisfied. Non-cited violations were discussed involving the following requirements listed in "Cited and Non-cited Violations" on page(s) 8 and/or 9. Please sign and submit on page 9.

☐ During the inspection certain safety and compliance measures, as described below in the "Cited and Non-cited Violations" on page(s) 8 and/or 9, were in violation of VDH requirements and **are being cited** in accordance with VDH enforcement policy. This form is Notice of Violation, which may be posted in accordance with Radiological Health Rule 7.17.1.4.

If cited violations are marked above, the registrant shall submit a written corrective action plan, on page(s) 10-12, addressing these violations within 30 days of the date of the transmission of notice. For each violation, include the corrective actions that have been completed to date and any additional procedures, controls, or safeguards that will be established to prevent the recurrence of similar violations in the future. Please sign and submit on page 12.

Please refer to the complete Radiological Health Rule for each inspection item listed below. Note that the radiation emitting machines listed below are intended for general dental facility use and may not be applicable to all facilities.

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Administrative Items (5.0, 7.0, and 8.0)

X-Ray Registration

1. Current x-ray registration certificate (5.4).
2. Certificate properly posted (7.17.1.2).
3. Total number of units at facility:
4. All x-ray units registered (8.2.1).
5. Intraoral: Pan: Pan/Ceph: Pan/CBCT: Pan/Ceph/CBCT: CBCT: Handheld:
6. Unit(s) in storage, exempt from registration, made physically inoperable through inactivation or dismantling electrical circuitry (4.1.6).

Observations

Licensure

7. Valid state of Vermont professional license for individuals operating radiation machines (8.2.6).

Observations

Notification of Incidents

8. Immediate notification, no later than 4 hours, (7.14.1) after the discovery of an event involving cause or threat for an individual to receive a total effective dose equivalent of 25 rem or more (7.14.1.1.1).
9. Notification within 24 hours (7.14.2) after the discovery of an event involving cause or threat for an individual to receive a total effective dose equivalent exceeding 5 rem (7.14.2.1.1).
10. Notification of an event in which equipment is disabled or fails to function to prevent radiation exposures that exceed regulatory limits (7.14.2.2.1).

Observations

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Public Dose Compliance

10. Compliance with dose limits to the public (7.6).

Observations

Occupational Monitoring

11. Demonstration, or alternative demonstration (7.8.2.1) and documentation retention (7.12.4) that the operator will not receive a dose in excess of 10% of the annual dose limit (7.8.1.1) with the total effective dose equivalent equal to 5 rem (7.2.1.1.1).

12. Dosimeters worn: 13. Dosimeters worn properly: 14. Dosimeters stored properly:

15. Dosimeters are processed and evaluated by NVLP accredited laboratories (7.7.3.1).

16. Demonstration and documentation retention that declared pregnant workers do not receive a deep dose equivalent in excess of 0.1 rem during the entire pregnancy (7.8.1.3).

17. Demonstration and documentation retention (7.12.3) that the dose equivalent to an embryo/fetus of a declared pregnant worker does not exceed 0.5 rem (7.5.1).

Observations

Procedures

18. Written safety procedures for x-ray operators (8.4.1).

19. Written standard operating procedures (SOP) on radiation protection (8.10.1.1):

A. Reviewed annually and updated as needed by management (8.10.1.1).

B. Written documentation that employees have completed SOP policy and procedure review (8.10.1.2).

C. At least 3-year record retention (8.10.1.3).

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20. Documentation and implementation of radiation protection program (7.1.1, 7.10.1.1).

A. Annual registrant review (7.1.3).

B. At least 3-year record retention (7.10.2) of audits and reviews of program content and implementation (7.10.1.2).

Observations

Lead

21. Individual shielding available to reduce scatter radiation exposure (8.9.5.1).

Observations

Service

22. All x-ray units and components have met FDA approval for sale, use and distribution (Report of Assembly FDA 2579 [21 CFR 1020.30(d)(1)]) (8.2.3).

23. Service providers are registered with the Radiological Health Program (8.2.4).

24. Facility follows the manufacturer's maintenance specifications and schedule (8.14.2).

25. Service records (8.2.3.3).

26. 5-year record retention of survey measurements, calibrations, maintenance, modifications, evaluations, and corrective actions for each x-ray imaging system (8.7.1) according to manufacturer's maintenance schedule (8.14.2).

27. All monitors used for primary diagnosis are evaluated according to the manufacturer's recommendations, qualified medical physicist, AAPM, ACR, NCRP, or The Joint Commission (8.10.9).

Observations

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Machine Requirements for *all* Dental X-Ray Machines (8.0 and 8.14)

28. Legible machine and control panel labels that say (8.2.3):
    Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed [21 CFR 1020.30(j)].
29. Written technique readily available or anatomically programmable controls used (8.3.1).
30. Useful beam shall be limited to the area of clinical interest (8.12.2).
31. Operator must be able to see the x-ray control panel from the operator's protected position when x-rays are being taken (8.6.3.4.1, 8.14.4.3.1).
32. A signal that the operator can hear from their protected position when an x-ray exposure is completed (8.6.3.4.2, 8.14.4.3.2).

Observations

Intraoral and Panoramic X-Ray Machines (8.14)

In addition to **all dental X-Ray machine requirements**, intraoral and panoramic machines have the following additional requirements:

33. Tube and pointer cone are stable and maintain their position without drift or vibration (8.14.3.2.5).
34. All locking, holding and centering devices are functioning as designed (8.6.3.3.1).
35. Source to skin distance (SSD) no less than 20 centimeters (8.14.3.2.2).
36. With a minimum 20-centimeter SSD, the X-ray field beam shall have a diameter of no more than 7 centimeters (8.14.3.2.3).
37. X-ray control permanently mounted in a separated area behind a whole-body protective barrier or the operator can stand at least 6ft. from the patient, tube, and beam (8.14.4.2.2.2.1).
38. An exposure control such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less (8.14.4.2.2.1).

Observations

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Cephalometric X-Ray Machines (5.0 and 8.14)

In addition to **all dental X-Ray machine requirements and intraoral and panoramic X-ray machine requirements**, cephalometric machines have the following additional requirements:

39. The facility has a scaled drawing (5.3.4.2) and shielding evaluation performed by a qualified expert for (8.5 and 8.14.3.1):

    A. New facility construction (8.5.1.3.1) or new installations of CBCT/volumetric and cephalometric x-ray machines in an existing facility (8.5.1.3.3).

    B. Renovation or modification of existing facilities for installation of 3D CBCT/volumetric and cephalometric x-ray machines that have potential to reduce the effectiveness of existing shielding (8.5.1.3.2).

Observations

Cone-Beam CT (3D CBCT)/Volumetric Machines (5.0, 8.14 and 8.17)

In addition to **all dental X-Ray machine requirements**, 3D CBCT machines have the following additional requirements:

40. Operators have been trained specifically to use the machine (8.17.4.1.1).

41. Periodic calibrations and annual quality control tests are performed according to the manufacturer's specifications (8.14.5.2), including additional or more frequent testing as recommended by a Qualified Medical Physicist with annual review (8.14.5.3).

42. Operator must be able to safely view patient and avoid direct line of sight while taking an exposure using a mirror, shielded window, whole body protective barrier or other method (8.17.3.2.2).

43. The facility has a scaled drawing (5.3.4.2) and shielding evaluation performed by a qualified expert for (8.5 and 8.14.3.1):

    A. New facility construction (8.5.1.3.1) or new installations of 3D CBCT/volumetric and cephalometric x-ray machines in an existing facility (8.5.1.3.3).

    B. Renovation or modification of existing facilities for installation of 3D CBCT/volumetric and cephalometric x-ray machines that have potential to reduce the effectiveness of existing shielding (8.5.1.3.2).

Observations

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Handheld Dental X-Ray Machines (8.15)

In addition to **all dental x-ray machine requirements**, handheld dental x-ray machines have the following additional requirements:

44. Device is approved for use by the Health Department (8.15.4.1)
45. Documentation of user training (8.15.4.3).
46. Use of a lead apron by operator (8.15.4.5).
47. The device has a built-in locking mechanism when the device is on but not active and the lock/safety is always engaged between exposures (8.15.4.15).
48. Device is not left unattended without locking the unit, room, or building (8.15.4.13).
49. Backscatter shield is in place (8.15.4.5.1).
50. Battery charge indicator on unit (8.15.4.11).
51. Immediate notification, with written documentation received 24 hours after notification, of missing or stolen handheld device (8.15.4.14).

Observations

Dental Facilities Using Traditional X-Ray Film (8.10 and 8.14)

52. Quality control and quality assurance have been performed and documented according to the manufacturer's recommendations, including:
    A. Follow recommended time and temperature specifications (8.14.5.1.1).
    B. Measure and log the temperature of chemicals each day x-rays are developed (8.14.5.1.2).
    C. Documentation showing that developer chemicals are changed at least once a month (8.14.5.1.3).
    D. Automatic film processors are adjusted and maintained to meet technical development specifications for the film used (8.10.5.1).

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53. Manual film processing:

A. The manufacturer's recommendation for developing time and chemical temperature is followed (8.10.6.1).

B. Measure and log developer chemical temperature each day it is used (8.10.6.2).

C. Written documentation that the developer chemicals are changed at least once every month (8.10.6.3).

D. Film storage and pass boxes are light tight and have adequate shielding to protect against stray radiation (8.10.8).

Observations

Cited and Non-cited Violations

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Registrant Representative Name	Signature	Date

VDH Inspector Name	Signature	Date

Email:

VDH Radiation Control Program Director Name	Signature	Date

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Corrective Action Plan

To be completed by registrant if cited violations are marked on page 1. The registrant shall submit a written corrective action plan below, addressing these violations within 30 days of the date of the transmission of notice. For each violation, include the corrective actions that have been completed to date and any additional procedures, controls, or safeguards that will be established to prevent the recurrence of similar violations in the future. Please sign and submit on page 12.

Violation:

Corrective Steps:

Violation:

Corrective Steps:

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Corrective Steps:

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Violation:

Corrective Steps:

Violation:

Corrective Steps:

Registrant Representative Name | Signature | Date