



Equipment Performance Evaluations Guidance for Service Companies

SCOPE AND PURPOSE

The Department of State Health Services (the Agency) regulates the use of x-ray equipment as identified in Chapter 401 of the Texas Health and Safety Code. Persons who are in the business of providing radiation machine services are subject to the provisions of 25 Texas Administrative Code as specified on their Certificate of Registration with the Agency.

This document provides guidance to service companies registered with the Agency to ensure compliance with the Equipment Performance Evaluation (EPE) requirements outlined in §289.226(o)(5).

§289.226(o) Responsibilities of assemblers and/or installers.

(5) Equipment performance evaluations shall be performed as follows:

(A) on all medical, chiropractic or podiatric radiation machines within 30 days after the initial installation, re-installation, and after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, power supply, and thereafter, in accordance with §289.227(o)(1) of this title; and

(B) on all dental radiation machines and radiation machines used in veterinary medicine within 30 days after the initial installation, re-installation, and after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, and power supply, and thereafter, in accordance with §289.232(i)(7) and §289.233(i)(5)(N) of this title.

(Complete rules can be found at <https://www.dshs.texas.gov/radiation/x-ray/laws-rules.aspx>)

Registrants using radiation machines in the healing arts, dental, and veterinary medicine are also held to EPE requirements outlined in §289.227, §289.232, and §289.233. The intent of the EPE rule for service companies is to ensure compliance for the health and safety of the general public and radiation workers. Although the facility and the service company are jointly responsible for ensuring compliance, only one EPE needs to be performed as outlined in the rule.

Installation/reinstallation of a radiation machine:

An Equipment Performance Evaluation (EPE) is due within 30 days of the installation date.

The Agency suggests the following:

- Discuss the EPE requirement with the facility during the purchase phase of a new unit and document who will perform the EPE.
- Obtain the contact information for a person at the facility with signature authority.
- If a facility refuses your services for an EPE, notification of the EPE requirement and refusal by the facility should be documented and signed by the most responsible party at the time of the installation – preferably the Radiation Safety Officer (RSO). If the RSO is not available, a copy of the signed refusal can be emailed to the RSO by the service company.
- A service company should be able to provide documentation upon request that a facility has declined their involvement in obtaining an EPE. If a service company is unable to obtain a refusal signature at the time of installation, it will need to provide evidence of due diligence in notifying the facility that an EPE is due within 30 days of installation.

Repair of a Radiation Machine:

An Equipment Performance Evaluation (EPE) is due within 30 days after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, and/or power supply.

The Agency suggests the following:

- Service notes should document clearly whether the repair affects the radiation output (e.g. replacement of FDA certified components).
- If the repair has possibly affected the radiation output of the unit, document that facility was notified that their physicist needs to determine if an EPE is required (see installation guidance above regarding recommended signatures and documentation).

FAQs

Is a physicist required for dental/veterinary EPEs?

No, EPEs of dental and veterinary equipment does not require involvement of a physicist. These EPEs can be performed by a service company qualified to do so.

What is the penalty for an EPE violation?

The initial violation for not performing an EPE within 30 days of installation/repair is a Severity Level III violation, which typically does not incur an administrative penalty. Repeat violations may be subject to elevation of severity level, which may incur an administrative penalty. For more information about administrative penalties and violation severity levels, refer to §289.205(j)-(k)

<https://www.dshs.texas.gov/radiation/x-ray/laws-rules.aspx>

What needs to be documented on the repair notes of a radiation machine?

The current regulations do not require documentation but it is recommended that the service ticket documentation of the service performed is sufficient enough for a physicist to be able to determine if an EPE is required.

My company does work for a large hospital system that employs their own physicists to complete their EPEs. Can I obtain a blanket refusal?

Yes. You may obtain a signed letter from the Radiation Safety Officer (RSO) that they assume responsibility for obtaining an EPE for any installations and/or repairs over a given time frame. It is recommended to review this statement periodically to ensure the RSO has not changed. The statement must be available to the Agency upon request.

What if the RSO is unavailable at the time of service?

You may work with the most responsible party available at the time of the installation.

What if the customer refuses to name their RSO?

Every registrant must name an RSO in order to obtain a Certificate of Registration from the Agency. This information is public record and can be obtained directly from the Agency through an open records request.

Information about open records requests can be found at:

<https://www.dshs.texas.gov/radiation/open-records.aspx>

Can an assembler/installer determine if an EPE is needed?

An EPE is required following all new installations or re-installations. Whether or not an EPE is necessary following a repair should be determined by a licensed medical physicist.

FAQs Continued

How can a facility locate a licensed medical physicist?

As the intent of the rule is for the installer to have a role in the completion of an EPE, it is recommended that manufacturers develop a list of licensed medical physicists by consulting with The American Association of Physicists (www.aapm.org), the Texas Medical Board (www.tmb.state.tx.us), or physicists affiliated with local hospitals.

What if a customer is unresponsive to communication regarding EPEs?

It is recommended that you retain documentation of your attempts to contact the customer to provide to the Agency upon request.