



June 23, 2022

RE: FDA Form 2579

Dear Registrant,

This letter is in reference to the notification requirement in 180 NAC 2-011. The State of Nebraska X-Ray Registration Program will accept electronic or faxed versions of this notification. If electronic submission is not available, mailing a paper copy is still acceptable. The notification can be emailed to [dhhs.radiationprograms@nebraska.gov](mailto:dhhs.radiationprograms@nebraska.gov) or faxed to 402-471-0169.

Below is some important information for Service Provider's in Nebraska regarding the notification requirement:

- 1) Your company must be registered with the State of Nebraska to be allowed to install any x-ray equipment at any Nebraska facility; Regulatory Guide 2.1 provides guidance on registering with the Department. The NRH-9 application must be submitted for this process.<sup>1</sup>
- 2) Each individual providing services must be listed on the registration.<sup>2</sup>

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<sup>1</sup> 180-NAC 005.03 SERVICE TYPES. Applicants must be registered and be trained to provide each of the types of services they perform. The types of services are: (A) INSTALLATION OR SERVICE. Installation or service includes installation and assembly, including initial calibration, and the service or repair of radiation generating equipment and associated radiation generating equipment components. It also includes the measurement of radiation generating equipment output. A person performing installation or service must meet the requirements of 180 NAC 15-014

<sup>2</sup> 180-NAC 005.02 DOCUMENTATION. The applicant must specify for each individual providing services on the registration application: (A) That each individual has read and understands the requirements of this chapter; and (B) The services each individual is applying for; and (C) The training and experience that qualifies the individual to perform the services that have been specified on the application for that individual. The applicant must submit to the Department documentation of the specific training and experience, as required by 180 NAC 15-004, or 15-014, or both, that qualifies each individual to provide the type of service they will be providing.

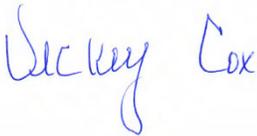
3) Notification of the service provided must be made to the Department within 15 days.<sup>3</sup>

Please note that the Form FDA 2579 may be submitted as notification of services.<sup>4</sup>

If you have any questions, concerns, or comments, please submit or contact me.

Thank you for your services.

Sincerely,



Vickey Cox, X-Ray Registrar  
X-Ray Registration  
301 Centennial Mall South  
Lincoln, NE 68504  
[vickey.cox@nebraska.gov](mailto:vickey.cox@nebraska.gov)  
402-471-0563

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<sup>3</sup> 180 NAC 2.011. ASSEMBLER OR TRANSFER OBLIGATION. A person who sells, leases, transfers, lends, disposes, assembles, or installs radiation generating equipment or components which affect radiation output in this State must notify the Department within 15 days of:

- (A) The full name and address of persons who have received this equipment;
- (B) The manufacturer, model, and serial number of each radiation generating equipment transferred; and
- (C) The date of transfer of radiation generating equipment.

<sup>4</sup> 180 NAC 2.011.01 ASSEMBLER'S REPORT. In the case of diagnostic x-ray systems which contain certified components, the registrant may submit a copy of the assembler's report (Form FDA 2579) prepared in compliance with requirements of 21 CFR §1020.30(d), in place of any other report by the assembler.