October 6, 2016

DENTAL HAND-HELD REQUIREMENTS FOR SERVICE PROVIDERS

To: NC Registered Service Providers for Sales of Hand-held Dental Radiation Generating Devices (RGDs)

From: Jenny Rollins, Radiology Compliance Branch Manager
NC DHHS, Division of Health Service Regulation, Radiation Protection Section (RPS)

Subject: Requirements Prior to Sale, Installation or Delivery

It has come to the attention of this agency that dental hand-held radiation generating devices (RGDs) are being sold, installed or delivered to facilities prior to the facility submitting an application for a hand-held waiver and the waiver approval letter being issued. This practice is in violation of the North Carolina Rules Against Radiation Protection, 10A NCAC 15 .210(a), which states:

No person registered pursuant to Rule .0205 of this Section for x-ray sales or installations shall make, sell, lease, transfer, lend, assemble, or install radiation machines or equipment used in connection with such machines unless such machines and equipment when placed in operation shall meet the applicable requirements of these Rules.

Currently our rules do not allow for the use of hand-held dental RGDs therefore a waiver of our rules must be obtained. It is the responsibility of the service provider to let the facility or registrant know that they have to complete a waiver application with conditions. It is also the responsibility of the facility or registrant, not the service provider, to complete the waiver application and represent the use or intended use of the dental hand-held RGD. The facility must also represent how they will secure it. The most current waiver application can be found at, http://www.ncradiation.net/Xray/documents/handheldappl.pdf. Facilities that do not use the most current application may have their request delayed or denied.

Furthermore, it is the responsibility of the service provider to ensure that the facility has a valid hand-held waiver approval letter that is issued by this agency prior to the hand-held unit being sold, installed or delivered to the facility. The service provider should always contact the facility to verify if the hand-held waiver request has been approved. RPS should only be contacted as a last resort, so we do not become overwhelmed with requests which will affect our productivity.

Beginning January 1, 2017, RPS will begin citing any NC service provider that sales, installs or delivers hand-held dental units that do not have a valid hand-held waiver approval letter that is issued by this agency. A hand-held waiver approval letter will be required for EACH MANUFACTURER of the hand-held that is sold, installed or delivered. A penalty may be recommended for repeat offenders.

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