

August 9, 2023

MEMORANDUM

X-Ray Facilities & Vendors Proposing to Sell, Install or Utilize Intraoral Hand-Held X-ray TO: Systems

Chrissy Chavis, Director, Division of Electronic Products $\begin{cal}C\end{cal}$ FROM:

Bureau of Radiological Health

SC Department of Health and Environmental Control

SUBJECT: Regulatory Requirements for Intraoral Hand-held X-ray Systems-Updates to R.61-64, Xrays (Title B)

The Department of Health and Environmental Control, Bureau of Radiological Health previously granted conditional approvals for the sale and marketing of dental hand-held x-ray devices and issued exemptions from certain regulatory requirements of Regulation 61-64, X-Rays to facilities for the use of these devices.

South Carolina Regulation 61-64, X-rays, (Title B) was recently revised and became effective May 26, 2023. As part of this revision, and to remove the need for conditional approvals and exemptions, RHB 1.2.7 "Prohibited Use" was revised and RHB 4.5.13 "Hand-Held X-ray System-Intraoral Equipment" was recodified. Therefore, previously issued exemptions are now void and no longer required. Facilities utilizing intraoral hand-held x-ray systems must comply with all applicable requirements of South Carolina Regulation 61-64, X-rays, (Title B).

If you have questions regarding this matter, please feel free to contact the Bureau of Radiological Health at 803-545-4400.

To access the current version of Regulation 61-64, X-Rays (Title B), please refer to our website www.scdhec.gov, and search "xray regulations" or scan the QR code.

