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FDA Sends Philips Warning on Manufacturing Facilities

The FDA has sent Philips Healthcare of North Andover, Mass, a warning letter noting that the manufacturing methods used at its Cleveland facilities do not conform with the required current good manufacturing processes required of it.The facility manufactures the Brilliance, Big Bore, iCT and the MX-16 slice families of CT systems and the Gemini, Gemini, LXL/TF, BrightView, JetStream and Precedence families of nuclear medicine systems. An inspection of the facility from Aug. 25, 2010 to Dec. 3, 2010 revealed 16 violations, including the following three:

* Failure to establish and maintain procedures for implementing corrective and preventive action such as incorrect scaling for infant scans on the Brilliance 64 CT. Although Philips has submitted planned revisions, these have not been approved or implemented.
* Failure to adequately implement and record changes in methods and procedures needed to correct and prevent identified quality problems.
* Failure to establish and maintain adequate procedures to verify the design of the device in order to ensure that design output meets the design input requirements specified.

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