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Notice to the Director Members of a QA/QC Issue with Certain GE Pristina Mammography Systems

CRCPD has become aware of a potential quality assurance/quality control issue affecting certain GE Pristina mammography systems. State radiation control program directors are asked to share this notice promptly with their mammography teams, particularly mammography inspectors, so they can alert facilities operating GE Pristina units.

The issue involves the Pristina Quality Control Test for AOP/SNR when using QC Manual 5845677-8EN_2 and software versions 7.70.28 and 7.70.51, M3-5.

Reported concerns include:

- The AOP/SNR quality control test displaying an overall “pass” result even when individual results indicate a “failure”
- SNR baseline data displaying “no data”
- The SNR deviation being recorded as “0.00,” which may not accurately reflect the test results

CRCPD understands that some facilities contacting GE have been instructed to perform a new five-day average to establish a new baseline, reset the data, and populate the SNR deviation with valid values. Facilities should contact GE directly to determine whether their equipment and software are affected and to obtain the manufacturer’s current instructions.

Mammography inspectors are encouraged to bring this issue to the attention of facilities operating GE Pristina units and ask them to:

1. Review their AOP/SNR quality control test results for the conditions described above
2. Contact GE for information regarding the scope of the issue and whether their system is affected
3. Request GE’s current corrective-action instructions and anticipated resolution timeline
4. Document any guidance received from GE and actions taken by the facility

This notice is intended to increase awareness and does not replace instructions or technical guidance provided by the equipment

manufacturer. Questions regarding corrective actions, software updates, or interpretation of quality control results should be directed to GE.

CRCPD is sharing this information to support accurate quality control testing and quality mammography imaging for patients across the country and beyond.

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