



# American Association for Nuclear Cardiology, Inc.

*Professionals Dedicated to Diagnostic Accuracy*

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US Mail

Radiation Safety Administrator  
Nuclear Regulatory Commission  
Region III  
801 Warrenton Road  
Lisle, IL 60532-4351

Dear Radiation Safety Colleague:

It has been called to our attention that there appears to be no uniform standards for the approval of computer programs designed for nuclear medicine facilities. These programs are used for radioisotope records (ordering, receipt, use, disposal), safety records (exposure and contamination surveys), instrumentation records (calibration, constancy, accuracy, geometry) and in some cases, virtually all nuclear medicine administrative activities. These computer systems are purchased from dealers or "given" to sites by suppliers (radiopharmacies) in exchange for other business considerations. We have determined that the programs all appear to "work," however, there seems to be several issues that may need to be addressed.

1. There is not "standard" for how often the data must be backed up. We have found sites that have neither data back-up or hard copy of the records. It appears they are "one-crash" from having no operational records.
2. The systems can be "defeated" to permit the entering of data; i.e., records of use, surveys, etc., with the incorrect date as well as, of course, false data. Accuracy/calibration records can be entered weeks/months after they were due and the date changed to show apparent compliance.

We have concluded that requiring a printed record on a daily or weekly basis would greatly assist in preventing both data loss and fabrication of records. Furthermore, we feel the printed data must be signed by the person responsible for the records to verify the responsibility.

Does your agency have any regulations or operational guides relating to this issue? Are you interested in developing such guides or implementing any checks and balances relating to these records?

Sincerely,

*Charles H. Rose*

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Executive Director