



4814 South 40th Street

Phoenix, Arizona 85040-2940

(602) 255-4845
Fax (602) 437-0705

November 21, 2016

ARRA INFORMATION NOTICE **2013-IN-04**: THE NEED TO PERFORM PREVENTIVE MAINTENANCE ON A PARTICLE ACCELERATOR USED IN THE PRACTICE OF MEDICINE

ADDRESSES

All registrants who use particle accelerators (PA) to treat human disease are obligated to ensure a therapy system is operating optimally. In this regard, the American Association of Physicists in Medicine issued a Code of Practice for Radiotherapy Accelerators in AAPM Report No. 47 in September 1994. The recommendations are as valid today as they were when this report was issued almost 20 years ago (even with the increasing sophistication and complexity of today's radiation therapy systems).

PURPOSE

The Arizona Radiation Regulatory Agency is issuing this information notice (IN) to inform PA registrants of the Agency's concern for some registrants making the decision to suspend this very integral part of a comprehensive quality management program (QM). A QM program is needed to ensure the radiation dose administered is as prescribed and that injury to normal tissue surrounding the treatment volume is kept to a minimum.

DESCRIPTION OF CIRCUMSTANCES

With the down-turn in the economy, changing medical insurance coverage and increasingly stringent Medicare payment schedules, radiation therapy centers are finding it more difficult to make ends meet. Some radiation therapy centers are trying to find ways to cut costs and improve their "bottom-line" by doing away with what is perceived as unnecessary safety/QA practices. Good patient care does not include this type of thinking and should be left for those centers that are no longer in the business of providing medical care to patients.

DISCUSSION

AAPM Report No. 47 recommends that radiation therapy providers carry out a program of routine maintenance as well as making emergency repairs as necessary. The report recommends that vendor-outlined preventative maintenance program be performed twice a year. The Agency agrees with this recommendation.

2013-IN-04

CONCLUSION

A Quality Management (QM) program is approached in R12-1-904(E) and includes preventive maintenance items. In addition, the AAPM has made a QM program a cornerstone of a sound radiation therapy program.

The Agency currently asks a new radiation therapy applicant to describe its proposed QM program in the registration application. As part of the inspection process, the Agency will be asking the registrant to describe its preventative maintenance program. The registrant is expected to respond appropriately to all inspection questions, including those concerning preventive maintenance. **Should a registrant find the Agency's position unacceptable, a written request for a variance should be sent to the Agency stating the AAPM standard is not acceptable, why it is not acceptable, with a description of the maintenance program that will be employed.**

If there are any questions or concerns regarding this informational notice, please contact Brian Goretzki at 602-255-4845 ext 234.