

November 3, 2006

Dear Medical Use Licensee:

As we previously reported, on March 14, 2006, 32 Ill. Adm. Code Part 335 was approved by the Illinois State Legislature (effective date April 28, 2006). This rulemaking was implemented to ensure compatibility with U.S. Nuclear Regulatory Commission regulations and to ensure that the latest technologies were available to the medical community while also protecting patient and public health and safety. New requirements for medical events, written directives, use of dose calibrators, outpatient treatments, clinical trials of new products, approval for emerging medical technologies and use of gamma stereotactic radiosurgery were among those addressed in this rulemaking. Quality assurance for use of these technologies was also specifically addressed. The revised Part 335 can be obtained by accessing our website at <http://www.state.il.us/iema/legal/regs/radmtl.asp>.

Enclosed is a summary of the changes included in this rulemaking to facilitate the transition to the new requirements. We have also indicated which changes may require amendments to current radioactive materials licenses (underlined italics). Please be aware that these recommendations for amendment are not all-inclusive, and each Administrator/Radiation Safety Officer should review their programs to ensure compliance with these requirements. If the regulations conflict with the licensee's radiation safety program as identified in its license, the regulations shall apply, unless the statements, representations, conditions, and procedures in the license are more restrictive. However, if that licensee exercises its privilege to amend its license, the portion amended must comply with the requirements of the regulations. Applications for renewal and expedited renewal should also be reviewed thoroughly to ensure that your program is reflective of the new requirements.

In order to allow for the effective implementation of the new rules, the agency has determined a phased approach to inspection and enforcement of the revised rules is appropriate. Violations of those rules, which have become effective since April 28, 2006, will be noted to the licensee through April 28, 2007, when inspections are conducted. Noted items will not necessarily be cited as items of violation unless a substantially similar rule or license condition was in effect before the time of the rulemaking. It is our intent to bring new regulatory items to licensees' attention, allow them an opportunity understand the revised/new rule and to make program changes prior to the next routine inspection.

We appreciate your cooperation on this matter and hope that the new regulations facilitate the medical use of radioactive material while also protecting patient and public health and safety. If you have any questions, please feel free to contact Gibb Vinson for licensing concerns or Daren Perrero for enforcement issues (217) 785-9947.

Sincerely,

Joseph G. Klinger, Head  
Radioactive Materials Section

Enclosure