PRM-35-1

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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Mr. Ed Podolak
Radiological Safety

(44)

Gentlemen:

Re: Docket No. PRM-35-1 (44FR26817)

We believe that in the case of approved low-risk diagnostic radiopharmaceuticals, the physician should, in the interest of good medical judgment, not be required to follow the package insert for all clinical procedures utilizing these drugs. We, therefore, support and endorse the referenced petition.

In the specific instance cited in the petition, namely the use of $^{99m}$Tc-DTPA in aerosol form, some concern has been expressed about the radiological safety aspects of the radiodiagnostic in this form. Comparison has been made with gaseous $^{133}$Xe, which has safety considerations different from those of the usual IV-injected liquid drugs. It is desired to point out that the aerosol form of DTPA (and similar agents) is typically a fine mist of liquid droplets with particle sizes around 1-2 micrometers. This aerosol is easily controlled and, unlike xenon gas, is easily trapped with 100% efficiency. Further, unlike xenon, which is merely delayed in passage by a charcoal trap, the trapping of an aerosol is permanent. The main-flow bacterial filters that are used in inhalation therapy to filter out 0.2 μm pathogenic bacteria have been found to be completely effective in trapping exhaled radioactive aerosols. In fact, there are commercially available units for producing and trapping such aerosols that employ bacterial filters. Other safety advantages of $^{99m}$Tc aerosols derive from the limited dispersion of the droplets which, unlike a gas, do settle by impaction and gravity, and from the much shorter half-life of $^{99m}$Tc compared to $^{133}$Xe.

An early and favorable action on this petition is considered to be a positive contribution to good health care and to the diagnosis of life threatening illnesses.

Very truly yours,

K. D. George
Senior Development Scientist

cc: Dr. George V. Taplin

KDG/smf

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