TABLE 2
Radiochemical Purity Results with Refrigerated Fractions

	Times				
	0 min	60 min	120 min	180 min	240 min
% [^{99m}Tc]HM-PAO Lipophilic	(Fraction 1) 97.0 ± 0.7	(Fraction 2) 96.6 ± 0.4	(Fraction 3) 92.6 ± 1.6	(Fraction 4) 89.0 ± 5.2	(Fraction 5) 79.8 ± 9.9
% [^{99m}Tc]HM-PAO Lipophilic	(Fraction 1) 97.0 ± 0.7	(Fraction 1) 82.6 ± 10.3	(Fraction 1) 68.9 ± 17.5	(Fraction 1) 47.8 ± 8.7	(Fraction 1) 31.5 ± 12.2

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Radioactivity Variations in Cobalt-57 Cyanocobalamin Capsules

TO THE EDITOR: In a letter published recently in the February 1989 issue of the *Journal of Nuclear Medicine*, concern was raised about the variation in radioactivity between cobalt-57 cyanocobalamin capsules.

The U.S. Pharmacopeia Drug Standards Division and the U.S.P. Radiopharmaceutical Advisory Committees brought this information to the attention of the Food and Drug Administration (FDA), Division of Drug Quality Evaluation, Office of Compliance. We have been told that the current standards are adequate for good manufacturing practices of cyanocobalamin, although a letter dated August 11, 1989, from the Compendial Operations Branch of the FDA Center for Drug Evaluation and Research, indicates that "it would certainly be advisable to assay each capsule prior to use."

10 CFR 35.53 now requires dose calibrator assays of photon emitting doses only in excess of 10 μCi. We have been informed that the FDA will propose to the NRC a modification of 10 CFR 35.53 to require a dose calibrator assay of all photon emitting human doses, regardless of the amount of activity.

We bring this to your attention, so that your readers might know that the U.S.P. and Society of Nuclear Medicine Pharmacopeia Committee will respond to all concerns expressed in this area.

Edward B. Silberstein
Chairman, Pharmacopeia Committee
Society of Nuclear Medicine