TABLE 1
Radiochemical Purity of Fractionated MAG3 and MIBI Kits Relative to Storage Time

		Kit			
Storage time (days)		MAG3 1	MAG3 2	MIBI 1	MIBI 2
0	RP (%) ± s.d.	98.1 ± 0.79	97.2 ± 0.79	98.1 ± 0.71	97.9 ± 0.54
Immediate use	n	17	10	8	4
	n below RP limit	0	0	0	0
1–6	RP (%) ± s.d.	98.1 ± 1.43	63.6 ± 47.8	97.9 ± 0.71	94.9 ± 10.1
	n	10	11	5	6
	n below RP limit	0	3	0	1
Longer than 6	RP (%) ± s.d.	98.6 ± 1.39	23.9 ± 40.0	96.9 ± 2.51	96.1 ± 6.0
	n	11	10	4	5
	n below RP limit	0	8	0	1

Numbers 1 and 2 refer to generator eluate. n = number of preparations.

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## **Problems with Fractionated Cold Kits**

TO THE EDITOR: Cost-effective preparation of  $^{99m}$ Tc radiopharmaceuticals by fractionated use of expensive cold kits has been explored extensively in recent years and has been discussed at a Society of Nuclear Medicine annual meeting (I-3). Methods have been published for HM-PAO (4,5,6), MIBI (2,7), MAG3 (7,8) and ECD (3). In general, the kits are reconstituted with saline, divided into several fractions, transferred to sterile vials and stored at -10 to  $-70^{\circ}$ C. In our department, we have used this approach for MAG3 and MIBI. By changing our generator system from TECEGEN S<sup>TM</sup> (CIS/Behring, Marburg, Germany; reference activity 8 and 20 GBq, generator 1) to ULTRATECHNEKOW<sup>TM</sup> (Mallinckrodt, Petten, The Netherlands; reference activity 12.9 and 10.6 GBq, generator 2), we found an unexpected high rate of an unacceptable low radiochemical purity (RP) of longer-stored kits, which had never been observed before.

MAG3 kits were reconstituted in 10 ml nonbacteriostatic, low-dissolved-oxygen (LDO) saline (i.e., nitrogen purged for 15 min) and split into four fractions, 2.5 ml each. The fractions were stored in a freezer at -10°C for up to 30 days. For labeling, the kits were thawed at room temperature and, after the addition of 740-1110 MBq 99mTc-pertechnetate (generator in growth less than 24 hr, eluate not older than 2 hr) in 1.5 ml (final volume 4 ml), boiled for 10 min. Determination of RP was performed using the SEPPAK method recommended by the producer of the United States kit; the RP limit for the European kit is 96%. MIBI kits were dissolved in 3 ml LDO saline and split into three fractions, 1 ml each, and stored up to 7 days. After thawing the kit at room temperature, labeling was performed by adding 3-4 GBq [99mTc]pertechnetate (generator in growth less than 24 hr, eluate not older than 2 hr) in 1.0 ml (final volume 2 ml) and boiling for 10 min. Radiochemical purity was determined using the recommended TLC method (Baker flex Aluminia foils/Ethanol), with a RP limit of 90%.

Using the eluate from generator 1, an excellent RP of  $98.3\% \pm 1.02\%$  (mean  $\pm$  SD; n = 38) for  $^{99m}$ Tc-MAG3 and  $97.8\% \pm 1.3\%$  (mean  $\pm$  s.d.; n = 17) for  $^{99m}$ Tc-MIBI was found in all preparations independent of the storage time. For up to 30 days of storage no RP decrease was found. Labeling performed with eluate from generator 2, however, resulted in an unacceptable low RP for MAG3 kits stored more than 1 wk. Of 10 MAG3 kits, only two had a RP greater than 96% (mean = 23.9%). Also, at shorter storage times, 3 of 11 preparations failed to yield the required RP limits (mean = 63.6%). The use of fractionated MIBI kits labeled with eluate from generator 2 resulted in a higher stability, but two preparations stored for longer times failed to give the required RP. The results are summarized in Table 1.

Many arguments could be found to explain a reduced stability of kits for 99mTc labeling using a different generator eluate. It may be due, for instance, to a higher amount of dissolved oxygen in the eluate oxidizing the tin(II) in the kit. Differences in the generator technology of the two described generators may also play a role. Another reason for the observed low RP levels in the fractionated kits is that storage can significantly reduce the amount of tin(II). This also explains why fractionated MAG3 kits caused more problems than fractionated MIBI kits, as the theoretical amount of tin(II) in the former (10  $\mu$ g as SnC12.2H2O) is much lower than that in the latter (25  $\mu$ g as SnC12.2H2O). Although the problem can be eliminated by adding additional amounts of tin(II), as has been described for HMPAO (4), MIBI (2) and ECD (3), or by changing the storage conditions (7), we want to stress that kit fractionation must only be performed under a strict quality control program, which should include RP determination before application and sterility testing. Small changes in the original tested protocol such as changing the generator, using different vials for storage or changing volumes or activity can lead to unexpected results and to an unsafe product. Also, keeping in mind legal considerations, it should be emphasized that cold-kit fractionation must remain in the hands of individuals with proven radiopharmacy experience.

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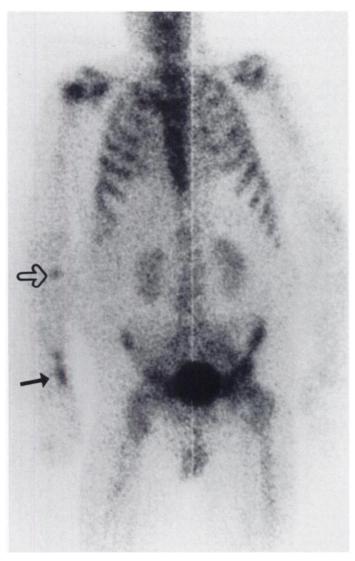
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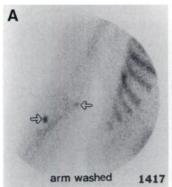
### Lymph Node Visualization in the Elbow Region

**TO THE EDITOR:** We read with great interest the article by Ongseng et al. (1) on ipsilateral axillary lymph node visualization due to extravasation of <sup>99m</sup>Tc-MDP. There was, however, no description of lymph node uptake in the elbow region in their results listing 48 of 2435 (2%) of axillary lymph node visualization. We encountered a patient who had extravasation of a bone imaging agent in the wrist region resulting in visualization of lymph nodes in the ipsilateral elbow region on bone scintigraphy.

In a 73-yr-old man with a 40+ yr history of smoking referred for bone scintigraphy because of lung cancer in the right upper lobe with mediastinal lymphadenopathy and right pleural effusion, a total-body anterior bone image (Fig. 1) acquired 3 hr after intravenous administration of 22



**FIGURE 1.** Total-body anterior bone image shows increased uptake in the right shoulder, suggestive of increased uptake in the left acetabulum and linearly increased radioactivity near the right wrist (arrow). Note the focal area of increased uptake near the elbow, possibly in the right proximal radius (open arrow).





**FIGURE 2.** (A) Anterior image of the right elbow with slight rotation shows two discrete areas of uptake (open arrows) being separated from the joint or bone structure; the medial area is located in the superficial area of the soft tissue. (B) Posterior image of the right elbow shows focal uptake (open arrow) in the forearm in the superficial soft tissue and a suggestive lesion is seen in the right 10th rib posteriorly.

mCi <sup>99m</sup>Tc-HMDP showed increased uptake in the patient's right shoulder. We also observed an area of activity in the right wrist, which was the known injection site with infiltration.

The abnormal area of activity near the elbow was thought to be urine contamination. Therefore, the patient's forearm and elbow regions were washed; two additional images were then obtained (Fig. 2).

Incidental axillary lymph node visualization after radiotracer subcutaneous infiltration of <sup>99m</sup>Tc-MDP into the antecubital region has been well documented (2-6). Our patient had extravasation of radiopharmaceutical around the dorsal part of the wrist leading to superficial lymphatic drainage to the lymph node near the elbow. The lymph node visualization might be misinterpreted as a lesion in the radius or as urinary contamination. After the patient's forearm and elbow were washed, two additional images depicted two discrete superficial foci in the elbow region, which were separated from the overlying bony structure, the elbow joint or were located in the superficial area of subcutaneous tissue. These foci were concluded to result from lymphatic drainage from the subcutaneous infiltration near the wrist.

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# Effective Communication on Radiation Risk: Who Is at Fault?

TO THE EDITOR: This communication addresses the Editorial "Scatter: Invasion from Mars" in the October 1995 JNM. I find it remarkably inconsistent with your previous professional writings. The use of generalizations and an attack on the issues of ignorance toward realistic radiation