Eur J Nucl Med (1986) 12:41–46

European Journal of Nuclear Medicine

Chemical, radiochemical, and radionuclide purity of eluates from different commercial fission $^{99}Mo/^{99m}Tc$ generators*

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Abstract. Seven $^{99}Mo/^{99m}Tc$ generators (using fission ^{99}Mo) obtained from seven different manufacturers were studied in 1984 and 1985 to test the quality of the eluates. We present the findings concerning the elution efficiency, radionuclide purity, ^{99}Mo breakthrough, radiochemical purity, pH, and aluminium content of the eluates. One generator was overloaded with ^{99}Mo by about 40%, while one generator had ^{99m}Tc yields of only about 80%. The eluates generally (although with some exceptions) exhibited a high and satisfactory radionuclidic purity and good radiochemical purity. The low-level determination of ^{99}Mo breakthrough using a commercially available dose calibrator with a ^{99}Mo assay shiled indicated a misleadingly high ^{99}Mo content. All of the eluates had pH values of between 5.0 and 5.5, and the aluminium content was always below the detection limit of 1 μg per milliliter of eluate. The generators performed well and proved their capability of functioning as reliable sources of sodium pertechnetate Tc99m. In all cases, the pertechnetate produced met the requirements of the European Pharmacopeia.

Key words: Quality control – Radioisotope generators – ^{99}Mo – ^{99m}Tc

At present, ^{99m}Tc is the most commonly used radionuclide in nuclear medicine. It is usually obtained in the form of sodium pertechnetate Tc99m by saline elution in molybdenum Mo99 technetium Tc99m generators, in which ^{99}Mo is fixed on aluminium oxide columns as ammonium molybdate. Because of the radiation risk to the patient resulting from radionuclide impurities, e.g., ^{99}Mo, ^{131}I, ^{103}Ru, etc., or radiochemical impurities present as contaminants in the eluate of such generators, many researchers have investigated ways of checking and eliminating such impurities (Müller and Steinnes 1971; Meinhold et al. 1973; Briner and Harris 1974; Billinghurst and Hreczuch 1976; Vinberg and Kristensen 1976, 1980; Vlcek et al. 1976; Väyrynen et al. 1981; Näsman and Väyrynen 1983; McAuley et al. 1985).

In many cases, the application of ^{99m}Tc depends on the quality of the generator eluate, which may vary considerably not only between different generators but also between eluates obtained from the same generator. In order to provide a basis for dose calculations and to obtain accurate knowledge about available radiation exposure, we performed a detailed investigation of the radioactive contamination produced by radionuclide generators. The following parameters were investigated:

1. The elution efficiency (calculated from the stated ^{99}Mo or ^{99m}Tc content), i.e., the activity of the eluted fraction, which characterizes the generator with regard to possible ^{99}Mo overloading, as well as the ineffective recovery of ^{99m}Tc from the column
2. The radionuclide purity of the eluates, with respect to possible ^{99}Mo breakthrough and the presence of other radionuclides
3. The radiochemical purity of the eluates, with reference to the valency state of the eluted ^{99m}Tc
4. The pH of the eluates
5. The aluminium content of the eluates, which may be detrimental when special labeling procedures are used

Materials and methods

We investigated $^{99}Mo/^{99m}Tc$ generators supplied by seven manufacturers (listed in Table 1; all generators were stated to contain fission-produced ^{99}Mo). Following the manufac-

Table 1. Data concerning the generators studied

Manufacturer	Generator type	Activity on day of reference (GBq)
A Hoechst (FRG)	Tecegen S	2.0 (54)
B Mallinckrodt (Netherlands)	Ultratechnekow FM	1.85 (50)
C Amersham (USA)	Amertec	2.78 (75)
D Squibb (FRG)	Minitec 2000	1.85 (50)
E IRE (Belgium)	Elutec	3.7 (100)
F CIS (France)	Elumatic III	1.85 (50)
G ZfK (GDR)	Rotop	1.85 (50)

Numbers in parentheses indicated the activity in milicuries

* This report is based on work conducted within the scope of a research poject devised by the Ministry of the Interior of the Federal Republic of Germany (Hammermaier et al. 1985). The present report reflects the opinions of the authors and does not necessarily express the views of the Federal Ministry of the Interior

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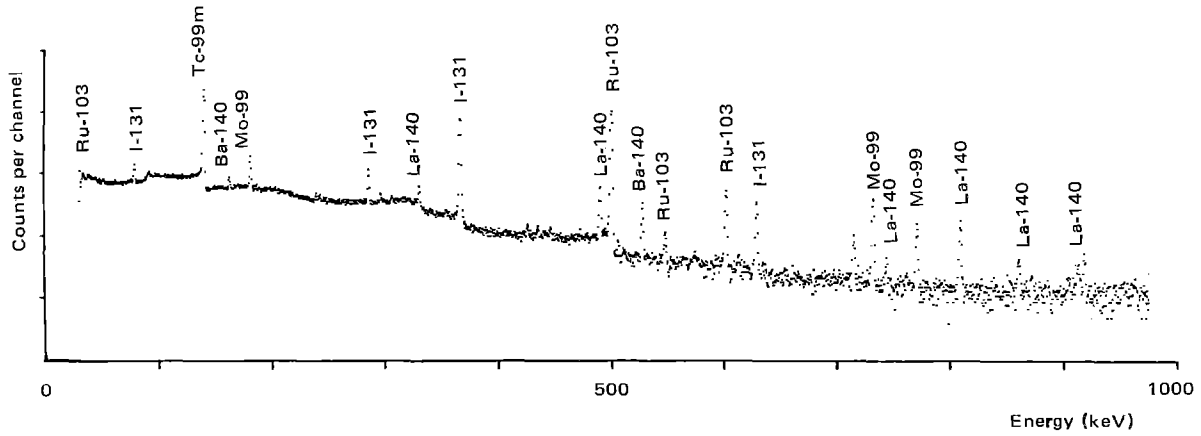

Fig. 1. Gamma spectrum of a ^{99m}Tc eluate (C1) showing characteristic peaks for ^{99}Mo, ^{131}I, ^{103}Ru, ^{140}La, and ^{140}Ba

turers' instructions, all generators were eluted ten times on consecutive weekdays, starting the morning after the generator had been received. Elutions were performed at 24-h intervals according to the manufacturers' instructions. The eluates were stored in vials closed with rubber stoppers.

^{99m}Tc-Generator elution efficiencies calculated from the stated ^{99}Mo content

The total gamma activity of the eluted fractions was measured immediately after elution using a dose calibrator. This instrument was calibrated with ^{99m}Tc standard solutions. The apparent elution efficiencies were then calculated from the stated ^{99}Mo content. The supposed ^{99}Mo activity of each generator was stated on the label. The elutable ^{99m}Tc activity is dependent on the ^{99}Mo activity at the time of elution and the time that has elapsed since the last elution (24 h).

It should be noted that, when calculating the ^{99m}Tc efficiency of the first elution of the generator, the time that had elapsed between the control elution at the manufacturer's and the first elution after receipt was assumed to be 24 h.

Nuclidic impurities in ^{99m}Tc-generator eluates Gamma-emitting nuclidic impurities in ^{99m}Tc-generator eluates. Gamma-energy analyses were carried out using a Ge(Li) detector connected to a 4096-channel pulse-height analyzer. A 7-ml eluate was placed in a glass vial and measured about 11–40 days after elution in an upright position with the bottom of the vial on the surface of a coaxial Ge(Li) detector. Usually, ^{99m}Tc decay and a decrease in the activity of some interfering radionuclides, especially ^{131}I, had already occurred. The energy range of 35 keV to 2.0 MeV was examined, and the measuring time was 20,000–90,000 s. Energy calibrations and efficiency determinations were performed using standard solutions of different radioisotopes (standard mixture from PTB, Braunschweig, FRG).

By taking into account the decay scheme of the corresponding radionuclide, it was possible to calculate the activity of all radionuclides. The content of impurities was calculated according to the time of elution. The energies and decay characteristics were taken from the findings of Lederer and Shirley (1978) and Kocher (1981). Figure 1 shows the spectrum of a ^{99m}Tc eluate measured using a Ge(Li) spectrometer 14 days after elution.

Rapid determination of ^{99}Mo contamination in eluted $^{99m}TcO_4^-$. A rapid, accurate technique for determining ^{99}Mo contamination in pertechnetate eluates using a commercially available dose calibrator and a ^{99}Mo assay shield has been described elsewhere (Richards and O'Brien 1969; Williams et al. 1981). Because of the great difference in the energies of the gamma rays emitted by ^{99m}Tc (140 keV) and ^{99}Mo (740 keV), ^{99}Mo levels in the eluate can easily be determined from two activity measurements, i.e., with and without a 5-mm-thick lead shield. This shield blocks the gamma rays of ^{99m}Tc to a considerable extent. Nearlly all commercial dose calibrators are equipped with a suitable lead shield, and are supplied with instructions for the calculation of the amount of ^{99}Mo. A 5-mm-thick lead canister reduces the ^{99m}Tc reading to 0.002% of the unshielded reading, while the ^{99}Mo reading is reduced by approximately 50%. Limitations of this technique are explained in the Results and Discussion.

Determination of radiochemical purity using thin-layer chromatography

To separate pertechnetate and other valency states of ^{99m}Tc, we used thin-layer chromatography (TLC) in acetone on silica gel (Heide et al. 1979, 1980, 1981, 1983; Knöpnadel et al. 1984; Robbins 1984) immediately after elution. This solvent system was found to be most suitable for the chromatographic separation of pertechnetate ions from the other oxidation states of ^{99m}Tc. The chromatograms were allowed to develop for 30 min, i.e., until the solvent front had moved 12 cm. After each run, the chromatograms were dried in a current of warm air. The activity distribution on the plates was measured using an LB-283 TLC linear analyzer (F. Berthold, Wildbad, FRG; Hammermaier et al. 1984) as shown in Fig. 2. The R_f value for pertechnetate (RPH) was found to be 0.9–1.0. The R_f value of reduced ^{99m}Tc (VU) was 0.

In order to study the behavior of lower oxidation states of technetium, Tc (IV) was obtained by the reduction of Tc (VII) using concentrated hydrochloric acid. In our system using acetone on silica, the R_f values obtained for Tc (IV) and Tc (VII) were 0 and 1.0, respectively. The main peak was found at the same R_f, as was also the case for untreated eluates, thus confirming that the main valency state of ^{99m}Tc obtained in generator eluates is pertechnetate.

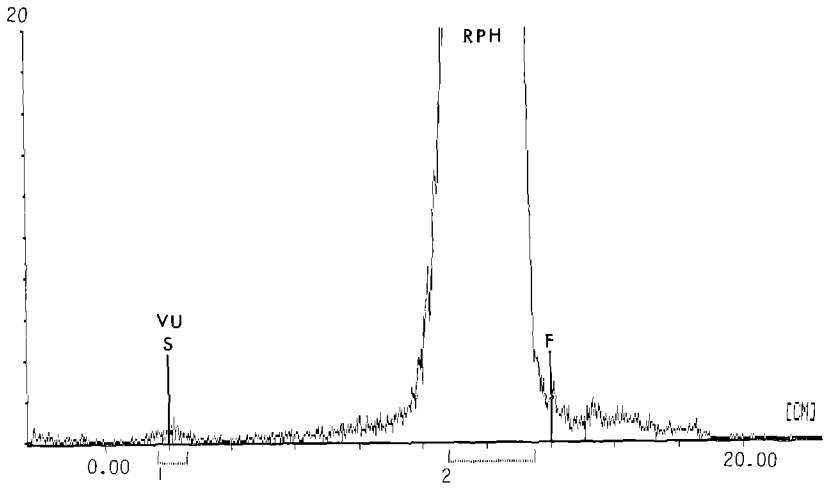

Fig. 2. Typical thin-layer radiochromatogram of a pertechnetate eluate (A6). *RPH*, pertechnetate; *VU*, reduced pertechnetate; *S*, origin; *F*, solvent front; *1....1*, regions of interest

pH of ^{99m}Tc-generator eluates

The pH of the solutions was measured using various pH papers, the accuracy being ± 0.5.

Aluminium levels in the eluates

The presence of aluminium in ^{99m}Tc-pertechnetate hinders the labeling of blood cells and influences the biodistribution of pertechnetate and sulfur colloids (Weinstein and Smoak 1970; Shukla et al. 1977). Tests to check the aluminium content of pertechnetate can be found in all pharmacopoeias. A classical method is the chinalizarin-based spot test on filter paper, as described by Feigl (1958). Recently, there have been several attempts to quantify the aluminium content of eluates. In general, these have involved a two-step procedure, i.e., after localization of the aluminium by a spottest, the exact amount is determined by atomic-absorption (Vinberg and Kristensen 1980; Shukla et al. 1977; Lin et al. 1971) and/or activation analysis (Müller and Steinnes 1971).

Quantitative determinations of the amount of aluminium present in undiluted eluates were made about 14 days after elution using an atomic-absorption spectrometer. Standards containing 1, 2, 5, 10, 25, 50, and 100 ppm Al in 0.9% saline were used for the development of calibration graphs. A solution of 0.9% saline without aluminium was used as a blank. The limit of detection was 1 ppm Al, i.e., 1 μg Al (3+) per milliliter of eluate.

Results and discussion

A summary of the results obtained for the seven generators over a period of 10 days is given in Table 2. We now discuss aspects of the quality of the generators (referred to as A–F; see Table 1).

Elution efficiency

The eluates were assayed immediately after elution using a dose calibrator. This instrument had been calibrated by the manufacturer, and the calibration was tested for different ^{99m}Tc solutions. Differences with regard to counting efficiency (due to different elution volumes) were not corrected, because all generators were eluted with maximum elution volumes (ranging from 10 to 15 ml). The apparent elution efficiencies were then calculated from the stated ^{99}Mo activity (products A–E) or from the stated ^{99}Mo activity (products F and G). The yield was fairly constant for each of these seven generators during the period of the study, but the elution efficiency was low for generator C (80%). Generator D was overloaded with ^{99}Mo (about 40%). The apparent elution efficiencies of the other generator eluates (products A, B, E–G) varied between 100% and 115%.

Radionuclide purity

Measurements and evaluations of radionuclide purity (gamma-emitting nuclides) using a Ge(Li) detector revealed the presence of ^{99}Mo, ^{131}I, ^{103}Ru, ^{140}La, and ^{140}Ba in the eluates. The activity of these radionuclides was expressed in nanocuries per millicurie of ^{99m}Tc corresponding to the time of elution, T(O).

^{99}Mo. The presence of ^{99}Mo was detected in all eluates examined, except the eluates obtained from generators E and G; this was because, for these two generators, Ge(Li)-detector measurements were performed about 40 days (20 half-lives of ^{99}Mo) after elution, so that the ^{99}Mo content had decreased below the detection limit. The lowest ^{99}Mo content in eluates was found in generator B, this ranging from 0.55 nCi per millicurie of ^{99m}Tc (first eluate) to 0.05 nCi per millicurie of ^{99m}Tc (ninth eluate). The highest ^{99}Mo content in all eluates examined was found in generator D, this ranging from 60.80 nCi per millicurie of ^{99m}Tc (first eluate) to 85.03 nCi per millicurie of ^{99m}Tc (ninth eluate).

^{131}I. ^{131}I was detectable in all of the examined eluates. The lowest levels of ^{131}I ranged from 0.0002 to 0.0005 nCi per millicurie of ^{99m}Tc in generator-B eluates, with the highest levels being from 0.03 to 0.27 nCi per millicurie of ^{99m}Tc in generator-D eluates.

^{103}Ru. ^{103}Ru could not be identified in eluates from generator A, but a later Ge(Li)-detector measurement of the column revealed the presence of ^{103}Ru. Also, ^{103}Ru was only detectable in the first eluate from generator F. The eluates from generator D contained the highest levels of ^{103}Ru,

Table 2. Results concerning eluates of $^{99m}TcO_4^-$ obtained from seven generators

Generator	Day after receipt	1	2	3	4	5	6	7	8	9	10
A	Elution efficiency (%)	105.1	117.9	113.9	113.8	115.3	115.6	114.4	114.8	114.6	116.3
	$^{99}Mo/^{99m}Tc$[a]	1.37		1.92		2.01		2.67		2.93	
	$^{131}I/^{99m}Tc$[a]	0.006		0.009		0.018		0.027		0.030	
	$^{103}Ru/^{99m}Tc$[a]	N.D.		N.D.		N.D.		N.D.		N.D.	
	Radiochemical purity (%)	100		99.99			99.92				
	Aluminium Al(3+) µg/ml	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
B	Elution efficiency (%)	101.5	109.9	112.1	112.3	111.1	109.2	113.5	112.6	110.8	112.9
	$^{99}Mo/^{99m}Tc$[a]	0.55		0.15		0.09		0.09		0.05	
	$^{131}I/^{99m}Tc$[a]	0.0002		0.0002		0.0003		0.0004		0.0005	
	$^{103}Ru/^{99m}Tc$[a]	0.0001		0.0001		0.0001		0.0002		0.0003	
	Radiochemical purity (%)					99.93			99.83		
	Aluminium Al(3+) µg/ml	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
C	Elution efficiency (%)	80.7	79.4	80.4	81.2	79.5	83.7	80.0	82.3	82.7	81.7
	$^{99}Mo/^{99m}Tc$[a]	0.21		0.12		0.12		0.11		0.08	
	$^{131}I/^{99m}Tc$[a]	0.0165		0.0086		0.0099		0.0091		0.0132	
	$^{103}Ru/^{99m}Tc$[a]	0.0093		0.0034		0.0040		0.0066		0.0120	
	Radiochemical purity (%)		99.75					99.90			
	Aluminium Al(3+) µg/ml	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
D	Elution efficiency (%)	143.7	138.7	141.3	139.2	143.6	137.8	141.7	140.5	139.9	139.8
	$^{99}Mo/^{99m}Tc$[a]	60.80		35.62		48.91		66.39		85.03	
	$^{131}I/^{99m}Tc$[a]	0.03		0.06		0.07		0.11		0.27	
	$^{103}Ru/^{99m}Tc$[a]	0.069		0.019		0.012		0.020		0.027	
	Radiochemical purity (%)		99.99				99.55				
	Aluminium Al(3+) µg/ml	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
E	Elution efficiency (%)	111.7	105.4	104.3	103.7	102.9	108.7	105.9	103.3	106.1	106.7
	$^{99}Mo/^{99m}Tc$[a]	+		+		+		+		+	
	$^{131}I/^{99m}Tc$[a]	0.0030		0.0018		0.0030		0.0019		0.0045	
	$^{103}Ru/^{99m}Tc$[a]	0.00006		0.0001		0.0022		0.0001		0.0003	
	Radiochemical purity (%)		100							99.90	
	Aluminium Al(3+) µg/ml	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
F	Elution efficiency (%)	103.8	107.3	103.1	104.6	106.0	105.7	105.4	101.2	105.0	106.6
	$^{99}Mo/^{99m}Tc$[a]	6.47		0.35		0.20		0.29		N.D.	
	$^{131}I/^{99m}Tc$[a]	0.036		0.024		0.047		0.083		0.082	
	$^{103}Ru/^{99m}Tc$[a]	0.0001		N.D.		N.D.		N.D.		N.D.	
	Radiochemical purity (%)			99.50					100		
	Aluminium Al(3+) µg/ml	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
G	Elution efficiency (%)	101.2	95.5	105.9	96.0	100.9	98.7	108.0	97.9	99.6	98.2
	$^{99}Mo/^{99m}Tc$[a]	+		+		+		+			
	$^{131}I/^{99m}Tc$[a]	0.022		0.022		0.029		0.048			
	$^{103}Ru/^{99m}Tc$[a]	0.0128		0.0012		0.0006		0.0006			
	Radiochemical purity (%)			100			100			100	
	Aluminium Al(3+) µg/ml	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1

[a] Nanocuries of γ-emitting nuclide per millicurie of ^{99m}Tc
N.D., not detectable; +, not detectable (half-life $\ll$age of the sample)

these ranging from 0.069 to 0.027 nCi per millicurie of ^{99m}Tc.

Other gamma-emitting substances. Only in generator C were detectable amounts of other gamma-emitting substances (parent-daughter system $^{140}La/^{140}Ba$) found, the amounts ranging from 0.0018 to 0.0121 nCi per millicurie of ^{99m}Tc for ^{140}La, and from 0.0018 to 0.0098 nCi per millicurie of ^{99m}Tc for ^{140}Ba.

Breakthrough of ^{99}Mo (assay shield)

A ^{99}Mo breakthrough is to be understood as ^{99}Mo transfer into the ^{99m}Tc eluate. This is most likely to happen in a newly operating generator when the inner container has been damaged during transport or assembly. As a consequence, it is advisable to check each new generator prior to using it for the first eluate. An eluate may be administered to patients only when the ^{99}Mo activity does not exceed 0.1% of the ^{99m}Tc activity.

The determination of ^{99}Mo breakthrough in a ^{99m}Tc eluate immediately after elution is possible in the following ways:

1. By Ge(Li)-detector measurement of a shielded eluate in a lead pot. Unfortunately, since this type of spectrometer is expensive and not usually available, it may be impossible to apply this procedure in most laboratories.
2. By dose-calibrator measurement using a suitable ^{99}Mo assay shield. For this, the eluate is placed behind a 5-mm-

thick lead shield and, when subsequent measurement using a counter reveals activity levels well above the background level, it is safe to assume that a certain amount of ^{99}Mo is present. ^{131}I and ^{103}Ru impurities were similarly detected, since for these radio-nuclides, the 50%-absorption thickness for a lead shield is also in the range of 5–7 mm.

As shown by Ge(Li)-detector measurements, the 5-mm-thick lead shielding used for the eluate would not have been sufficient for assaying high ^{99m}Tc activities in a dose calibrator: a lead thickness of 10 mm would be more appropriate, but a 10-mm-thick lead pot cannot be placed in our or most commercially available dose calibrators. Other authors have also remarked (Vinberg and Kristensen 1976; Williams et al. 1981) that commercially available dose calibrators with a 4- to 5-mm-thick ^{99}Mo assay shield allow excessive penetration of lower-energy ^{99m}Tc photons, so that such calibrators indicate a misleadingly high level of ^{99}Mo activity in high-activity eluates, even when the measured ^{99}Mo content does not exceed the limit set in the European Pharmacopeia. However, in the absence of interfering factors, such a calibrator performed satisfactorily when ^{99}Mo/^{99m}Tc equilibrium standard mixtures were used.

Radiochemical purity

Trace amounts of reduced pertechnetate ($R_f = 0$) were found in most of the eluates examined. In all cases, we found the radiochemical purity to be above 95%, i.e., within the requirements of the European Pharmacopeia, but an impurity level of more than 0.5% was never found.

pH values

All of the eluates had pH values of between 5.0 and 5.5 (European Pharmacopeia, pH 4–8), the accuracy being ± 0.5.

Aluminium levels

Although the limit specified in the European Pharmacopeia is 20 μg/ml [and all of the eluates tested contained less than the detection limit of 1 μg Al (3+) per milliliter of eluate], it is well known that smaller amounts of Al in eluates may cause a decrease in the quality of certain ^{99m}Tc-labeled compounds.

Supplementary information

No operational instructions were supplied with generators D, E, and G.

In generator A, the stock container for the eluent had a capacity of 150 ml, and therefore only ten elutions with the 13-ml vial were possible. The operational instructions supplied with this generator stated that the stock container holds 230 ml eluent.

The calibration (in milliliters) on the evacuated vials from generator G was badly printed, so that the elution volume could only be estimated.

When generator F arrived (January 1985), the temperature had been −30° C on the day before; no elution was possible because the column and stock contained were frozen. After allowing the generator to thaw for 3 h, normal elution was possible.

Table 3. Requirements of the European Pharmacopeia for sodium pertechnetate Tc^{99m} injection (fission)

Parameter	Requirements
Elution efficiency	90%–110% of the declared technetium Tc 99m radioactivity at the date and hour stated on the label
Radionuclide purity	^{99}Mo ≤ 1 μCi/mCi ^{99m}Tc ^{131}I ≤ 50 nCi/mCi ^{99m}Tc ^{103}Ru ≤ 50 nCi/mCi ^{99m}Tc All other gamma emitters ≤ 100 nCi/mCi ^{99m}Tc ^{89}Sr ≤ 600 pCi/mCi ^{99m}Tc ^{90}Sr ≤ 60 pCi/mCi ^{99m}Tc Alpha emitters 1 pCi/mCi ^{99m}Tc
Radiochemical purity	≥ 95% TcO_4^-
pH	4.0–8.0
Al (3+)	≤ 20 μg/ml
Sterility	Sterile

Quality-control parameters

In generator-produced eluates, the purity and chemical parameters must conform with special requirements. Appropriate pharmaceutical reference volumes, e.g., the European Pharmacopeia, the United States Pharmacopeia, the British Pharmacopeia, and DIN 6854, state the required purity for ^{99m}Tc eluates. The required radionuclide purity of sodium pertechnetate injection solutions differs according to whether they are obtained from either fission or nonfission ^{99}Mo. All other quality criteria are identical. The requirements of the European Pharmacopeia for sodium pertechnetate Tc99m injection (fission) are listed in Table 3. The requirements of the United States Pharmacopeia XX and DIN 6854 deviate in certain respects from those of the European Pharmacopeia. For example, the former species a ^{99}Mo level of less than 0.15 μCi per millicurie of ^{99m}Tc, the level of all other beta and gamma emitters to be less than 100 nCi per millicurie of ^{99m}Tc, and the level of aluminium to be less than 10 μg/ml. In DIN 6854, the nominal activity corresponds to the received ^{99}Mo activity at a certain point in time (reference time); a maximum deviation of 10% from the level of ^{99}Mo at the reference time is allowed. The actual eluted activity should not be less than 70% for elutions at 24-h intervals. Also, DIN 6854 specifies that the level of alpha emitters should not exceed 6 pCi per millicurie of ^{99m}Tc.

Conclusions

The seven generators examined in our study were subjected to tests – partly based on those of the European Pharmacopeia – to examine the quality of ^{99m}Tc eluates obtained from fission molybdenum. In all cases the pertechnetate produced net the requirements of the European Pharmacopeia. Tests for alpha- and beta-emitting impurities, sterility, and pyrogens were not included in our study.

We also determined the accuracy of ^{99}Mo-breakthrough measurements obtained using a commercially available dose calibrator with a 5-mm-thick assay shield. The ^{99}Mo assay

shield allowed penetration by lower-energy ^{99m}Tc photons as well as by ^{131}I and ^{103}Ru, thus resulting in a misleadingly high measurement of the ^{99}Mo activity present in high-activity ^{99m}Tc eluates. Therefore, we recommend that generator-produced eluates should be monitored immediately after elution using either a high-resolution spectrometer or a dose calibrator and a ^{99}Mo assay shield with a lead thickness of more than 5 mm.

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Received August 3, 1985 / October 26, 1985