AA73-1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

Norm McElroy, NMSS MAR 26 1985

Just a short note to confirm, in writing, the information I gave you concerning the number of beds for NRC medical licensees. This information was submitted to us in response to our survey of materials licensees.

No. Beds	No. Licensees	Cumulative No. L.
1-50	50	50
51-100	186	236
101-150	246	482
151-200	184	666
201-250	190	856
251-300	130	986
301-350	118	1104
351-400	84	1118
401 +	360	1548

Let me know if you have any questions.

Mike Lesar

Michael Lesar
RPB, DRR, ADM

rec'd 5/27/85 mlm

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rec'd from Rachel
2 25 85

turnaround time (days)

CALENDAR YEAR 1984

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
-TAT NRC	132	136	54	47	42	62		46	66	74	54	46
New Licenses:												
-Rcvd NRC	9	8	16	14	12	7		13	13	10	11	8
- TAT NRC	66	77	46	56	55	63		58	56	56	56	70
Amendments:												
-Rcvd NRC	159	131	141	109	125	121		157	103	146	95	82
-TAT NRC	143	130	99	137	102	154		172	162	158	129	169
Renewals:												
-Rcvd NRC	36	30	34	37	36	32		41	37	54	39	34
-TAT NRC	51	41	53	117	29	33		39	86	30	135	28
Terminations:												
-Rcvd NRC	6	8	2	4	3	0		5	3	2	1	1

μ 55d.

N
8 × 12/11 = 123

μ 60d

A
1493

μ 141d

R
447

2063 actions

from monthly log books

	1983	1984
N	143	123
R	647	447
A	1772	1493

a sterile solution of pentetic acid that is complexed with ^{99m}Tc in Sodium Chloride Injection. It is suitable for intravenous administration, and may contain buffers. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{99m}Tc as the pentetic acid complex expressed in microcuries or millicuries per ml at the time indicated in the labeling. Other chemical forms of radioactivity do not exceed 10.0 percent of the total radioactivity.

Packaging and storage — Preserve in single-dose or in multiple-dose containers, at a temperature between 2° and 8°.

Expiration date — The expiration date is not later than 6 hours after time of manufacture.

Labeling — Label it to include the following, in addition to the information specified for *Labeling* under *Injections* ⟨1⟩: the time and date of calibration; the amount of ^{99m}Tc as labeled pentetic acid complex expressed as total millicuries or microcuries and concentration as microcuries or millicuries per ml at the time of calibration; the expiration date; and the statement, "Caution—Radioactive Material." The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay and also indicates that the radioactive half-life of ^{99m}Tc is 6.0 hours.

pH ⟨791⟩: between 4.0 and 7.5.

Other requirements — It meets the requirements of the tests for *Radionuclide identification* and *Radionuclidic purity* under *Sodium Pertechnetate Tc 99m Injection*. It meets the requirements under *Injections* ⟨1⟩, except that it may be distributed or dispensed prior to completion of the test for *Sterility*, the latter test being started on the day of manufacture, and except that it is not subject to the recommendation on *Volume in Container*. It meets also the requirements for *Pyrogen*, *Radiochemical purity*, *Biological distribution*, and *Assay for radioactivity* under *Technetium Tc 99m Iron Ascorbate Pentetic Acid Complex Injection*.

Technetium Tc 99m Sodium Gluceptate Injection

D-*glycero*-D-*gulo*-Heptonic acid, technetium-^{99m}*Tc* complex.
Technetium-^{99m}*Tc* D-*glycero*-D-*gulo*-heptonate complex

» Technetium Tc 99m Sodium Gluceptate Injection is a sterile, aqueous solution, suitable for intravenous administration, of sodium gluceptate and stannous chloride that is labeled with ^{99m}Tc. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{99m}Tc as stannous gluceptate complex expressed in microcuries or millicuries per ml at the time indicated in the labeling. It may contain antimicrobial agents and buffers. Other chemical forms of radioactivity do not exceed 10.0 percent of the total radioactivity.

Packaging and storage — Preserve in single-dose or in multiple-dose containers, at a temperature between 2° and 8°.

Expiration date — The expiration date is not later than 48 hours after time of manufacture.

Labeling — Label it to include the following, in addition to the information specified for *Labeling* under *Injections* ⟨1⟩: the time and date of calibration; the amount of ^{99m}Tc as labeled stannous gluceptate expressed as total microcuries or millicuries and concentration as microcuries or millicuries per ml at the time of calibration; the expiration date and time; and the statement, "Caution—Radioactive Material." The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of ^{99m}Tc is 6.0 hours.

Pyrogen — It meets the requirements of the *Pyrogen Test* ⟨151⟩.

pH ⟨791⟩: between 4.0 and 8.0.

Radiochemical purity — Place a measured volume of Injection, appropriately diluted, such that it provides a count rate of about 20,000 counts per minute, about 25 mm from one end of a 25- × 300-mm strip of chromatographic paper (see *Chromatography* ⟨621⟩), and allow to dry in air. With no delay, develop the chromatogram over a suitable period of time by ascending chromatography, using acetone that has been purged with oxygen-free nitrogen for not less than 10 minutes. Allow the chromatogram to dry, and determine the radioactivity distribution by scanning with a suitable collimated radiation detector. Not less than 90.0% of the total radioactivity is found as stannous gluceptate (at the point of application).

Biological distribution — Inject intravenously between 5 mCi and 7.5 mCi of the Injection in a volume not exceeding 0.3 ml into the caudal vein of each of two 150-g and 250-g rats. Approximately 1 hour after the injection, decapitate the animals, and drain the blood into a suitable container. Dissect the animals, and place the kidney, liver, gastrointestinal tract, and a 10-g specimen of blood, accurately weighed, in separate, suitable counting containers, and determine the radioactivity, in counts per minute, in each container with an appropriate detector using the same counting geometry. Determine the percentage of radioactivity in the kidney, liver, and gastrointestinal tract by the formula $100(Ai/A)$, in which Ai is the net radioactivity, in mCi, in the organ, and A is the total radioactivity, in mCi injected, both corrected to injection time. Determine the percentage of radioactivity in the blood by the formula $[100(B/W_S)0.07(W_R)]/A$, in which B is the net radioactivity, in mCi, in the specimen of blood, and A is the total radioactivity, in mCi injected, both corrected to injection time, W_S is the weight, in g, of the blood specimen, W_R is the weight, in g, of the rat, and 0.07 is the assumption that the total blood weight of the rat is 7% of the total body weight. Not less than 15.0% of the radioactivity is found in the kidney, not more than 3.0% of the radioactivity is found in the blood, not more than 5.0% of the radioactivity is found in the gastrointestinal tract, and not more than 5.0% of the radioactivity is found in the liver.

Other requirements — It meets the requirements for *Radionuclide identification* and *Radionuclidic purity* under *Sodium Pertechnetate Tc 99m Injection*. It meets also the requirements under *Injections* ⟨1⟩, except that it may be distributed or dispensed prior to completion of the test for *Sterility*, the latter test being started on the date of manufacture, and except that it is not subject to the recommendation on *Volume in Container*.

Assay for radioactivity — Using a suitable counting assembly (see *Selection of a Counting Assembly* under *Radioactivity* ⟨821⟩), determine the radioactivity, in μCi per ml, of Technetium Tc 99m Sodium Gluceptate Injection by use of a calibrated system as directed under *Radioactivity* ⟨821⟩.

Sodium Pertechnetate Tc 99m Injection

Pertechnetic acid ($H^{99m}TcO_4$), sodium salt.
Sodium pertechnetate ($Na^{99m}TcO_4$) [*23288-60-0*]

» Sodium Pertechnetate Tc 99m Injection is a sterile solution, suitable for intravenous or oral administration, containing radioactive technetium (^{99m}Tc) in the form of sodium pertechnetate and sufficient Sodium Chloride to make the solution isotonic. Technetium 99m is a radioactive nuclide formed by the radioactive decay of molybdenum 99. Molybdenum 99 is a radioactive isotope of molybdenum and may be formed by the neutron bombardment of molybdenum 98 or as a product of uranium fission.

Sodium Pertechnetate Tc 99m Injection contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{99m}Tc at the date and hour stated on the label. Other chemical forms of ^{99m}Tc do not exceed 5 percent of the total radioactivity.

Packaging and storage — Preserve in single-dose or in multiple-dose containers.

Expiration date — The expiration date is not later than 48 hours after time of manufacture.

Labeling — If intended for intravenous use, label it with the infor-

mation specified for *Labeling* under *Injections* (1). Label it also to include the following: the time and date of calibration; the amount of ^{99m}Tc as sodium pertechnetate expressed as total millicuries and as millicuries per ml on the date and at the time of calibration; a statement of the intended use, whether oral or intravenous; the expiration date; and the statement, "Caution—Radioactive Material." If the Injection has been prepared from molybdenum 99 produced from uranium fission, the label so states. The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of ^{99m}Tc is 6.0 hours.

Radionuclide identification [see *Radioactivity* (821)]—Its gamma-ray spectrum is identical to that of a specimen of ^{99m}Tc that exhibits a major photopeak having an energy of 0.140 MeV.

pH (791): between 4.5 and 7.5.

Radiochemical purity—Place a volume of Injection, appropriately diluted, such that it provides a count rate of about 20,000 counts per minute, about 25 mm from one end of a 25- × 300-mm strip of chromatographic paper (see *Chromatography* (621)). Develop the chromatogram over a suitable period of time by ascending chromatography, using a mixture of 80 volumes of acetone and 20 volumes of 2 *N* hydrochloric acid. Allow the chromatogram to dry in air. Determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector. The radioactivity of the pertechnetate band is not less than 95% of the total radioactivity in the test specimen. The R_f value for the pertechnetate band (approximately 0.9) falls within ±10.0% of the value found for a known sodium pertechnetate Tc 99m specimen when determined under identical conditions.

Radionuclidic purity—Using a suitable counting assembly (see *Selection of a Counting Assembly* under *Radioactivity* (821)), determine the radioactivity of each radionuclidic impurity, in μCi per mCi of technetium 99m, in the Injection by use of a calibrated system as directed under *Radioactivity* (821).

For Injection prepared from technetium 99m derived from parent molybdenum 99 formed as a result of neutron bombardment of stable molybdenum—

MOLYBDENUM 99—The presence of molybdenum 99 in the Injection is shown by its characteristic gamma-ray spectrum. The most prominent photopeaks of this radioactive nuclide have energies of 0.181, 0.740, and 0.780 MeV. Molybdenum 99 decays with a radioactive half-life of 66.0 hours. **The amount of molybdenum 99 is not greater than 0.15 μCi per mCi of technetium 99m per administered dose of the Injection, at the time of administration.**

OTHER GAMMA-EMITTING RADIONUCLIDIC IMPURITIES—The total amount of other gamma-emitting radionuclidic impurities does not exceed 0.5 μCi per mCi of technetium 99m, and does not exceed 2.5 μCi per administered dose of the Injection, at the time of administration.

For Injection prepared from technetium 99m derived from parent molybdenum 99 formed as a result of uranium fission—Gamma- and beta-emitting impurities—

MOLYBDENUM 99—The Injection meets the requirements set forth for the Injection prepared by neutron irradiation of stable molybdenum (see foregoing).

IODINE 131—The most prominent photopeak of this radioactive nuclide has an energy of 0.364 MeV. Iodine 131 decays with a radioactive half-life of 8.08 days. The concentration of iodine 131 is not more than 0.05 μCi per mCi of technetium 99m, at the time of administration.

RUTHENIUM 103—The most prominent photopeak of this radioactive nuclide has an energy of 0.497 MeV. Ruthenium 103 decays with a radioactive half-life of 39.5 days. The concentration of ruthenium 103 is not more than 0.05 μCi per mCi of technetium 99m, at the time of administration.

STRONTIUM 89—Determine the presence of strontium 89 in the Injection by a counting system appropriate for the detection of particulate radiations. Strontium 89 decays by a beta emission with a maximum energy of 1.463 MeV, and a radioactive half-life of 52.7 days. Strontium 89 may be present in a concentration of not more than 0.0006 μCi per mCi of technetium 99m, at the time of administration.

STRONTIUM 90—Determine the presence of strontium 90 in the Injection by a counting system appropriate for the detection of particulate radiations. Strontium 90 decays by a beta emission with a maximum energy of 0.546 MeV, and a radioactive half-life of 27.7 years. Strontium 90 may be present in a concentration of not more than 0.00006 μCi per mCi of technetium 99m, at the time of administration.

ALL OTHER RADIONUCLIDIC IMPURITIES—Not more than 0.1 μCi of all other beta and gamma emitters per mCi of technetium 99m is present at the time of administration. Not more than 0.001 nCi of gross alpha impurity per mCi of technetium 99m is present at the time of administration.

Pyrogen—It meets the requirements of the *Pyrogen Test* (151).

Other requirements—It meets the requirements under *Injections* (1), except that the Injection may be distributed or dispensed prior to the completion of the test for *Sterility*, the latter test being started on the day of manufacture, and except that it is not subject to the recommendation on *Volume in Container*.

Chemical purity—

Aluminum (To be determined if separation is accomplished by an alumina column in the preparation of the Injection)—

ALUMINUM STANDARD SOLUTION—Dissolve 35.17 mg, accurately weighed, of aluminum potassium sulfate dodecahydrate in water to make 1000.0 ml. Each ml of this solution contains 2 μg of Al.

PROCEDURE—Pipet 10 ml of *Aluminum standard solution* into each of two 50-ml volumetric flasks. To each flask add 3 drops of methyl orange TS and 2 drops of 6 *N* ammonium hydroxide, then add 0.5 *N* hydrochloric acid, dropwise, until the solution turns red. To one flask add 25 ml of sodium thioglycolate TS, and to the other flask add 1 ml of disodium ethylene-diaminetetraacetate TS. To each flask add 5 ml of eriochrome cyanine TS and 5 ml of acetate buffer TS, and add water to volume. Immediately determine the absorbance of the solution containing sodium thioglycolate TS at the wavelength of maximum absorbance at about 535 nm, with a suitable spectrophotometer, using the solution containing the disodium ethylenediaminetetraacetate TS as a blank. Repeat the procedure using two 1.0-ml aliquots of Sodium Pertechnetate Tc 99m Injection. Calculate the quantity, in μg per ml, of aluminum in the Injection by the formula $20(T_I/T_S)$, in which T_I and T_S are the absorbances of the solution from the Injection and the solution containing the aluminum standard, respectively. The concentration of aluminum ion in the Injection is not greater than 20 μg per ml for Injection prepared from molybdenum 99 derived from the neutron irradiation of stable molybdenum, and not greater than 10 μg per ml for Injection prepared from molybdenum 99 formed as a result of uranium fission.

Methyl ethyl ketone (To be determined if separation is accomplished by liquid-liquid extraction in the preparation of the Injection)—Place 1.0 ml of the Injection in a suitable container, and dilute with water to 20.0 ml. Add 2.0 ml of 1 *N* sodium hydroxide, mix, then add 2.0 ml of 0.1 *N* iodine, dropwise, and again mix. At the same time, prepare a standard by placing 1.0 ml of a solution of methyl ethyl ketone (1 in 1000) in a similar container and diluting with water to 20.0 ml. Add 2.0 ml of 1 *N* sodium hydroxide, mix, then add 2.0 ml of 0.1 *N* iodine, dropwise, and again mix. After 2 minutes, the turbidity of the test specimen does not exceed that of the standard (0.1%).

Assay for radioactivity—Using a suitable counting assembly (see *Selection of a Counting Assembly* under *Radioactivity* (821)), determine the radioactivity, in mCi per ml, in Sodium Pertechnetate Tc 99m Injection by use of a calibrated system as directed under *Radioactivity* (821).

Technetium Tc 99m Pyrophosphate Injection

» Technetium Tc 99m Pyrophosphate Injection is a sterile, aqueous solution, suitable for intravenous administration, of pyrophosphate that is labeled with ^{99m}Tc. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of ^{99m}Tc as pyrophosphate expressed in microcuries or millicuries per ml at the time indicated in the labeling. It may contain antimicrobial agents, buffers, reducing agents, and stabilizers. Other chemical forms of radioactivity do not exceed 10.0 percent of the total radioactivity.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, at a temperature between 2° and 8°.