Expiration Times for Tc-99m

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Expiration times of Tc-99m eluates may be shortened by the presence of Mo-99. Based on current limits for Mo-99 contamination, calculations are presented that establish expiration times for Tc-99m eluates.

The presence of Mo-99 breakthrough in the Tc-99m eluate of a Mo-99/Tc-99m generator is always a possibility. For this reason, the Nuclear Regulatory Commission (NRC) has recently formulated regulations that require the determination of Mo-99 contamination in each elution of a generator (*1*). The NRC goes on to specify the maximum limits for Mo-99 contamination as not more than "1 microcurie of molybdenum-99 per millicurie of technetium-99m, or more than 5 microcuries of molybdenum-99 per administered dose, at the time of administration. . . ." (*1*).

The United States Pharmacopeia (USP), in its 20th official revision effective July 1, 1980, states that, "the expiration date is not later than 48 hours after time of manufacture." (*2*). It continues with: "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." (*2*). Assuming a maximum Tc-99m dose of 30 mCi, this limit would be 4.5 μCi per administered dose as compared with the NRC limit of 5 μCi per administered dose.

Calculations

In an effort to determine the expiration time of Tc-99m eluates, which contain sufficient Mo-99 to exceed established USP limits before 48 hr, the following calculations were performed:

Let M = microcuries of Mo-99.

Let T = millicuries of Tc-99m.

Let t = time in hours.

The decay constant of Mo-99 = 0.01034 hr^{-1}.

The decay constant of Tc-99m = 0.1155 hr^{-1}.

Substituting into the decay formula,

$$M = M_O e^{-0.01034t} \quad (1)$$

and

$$T = T_O e^{-0.1155t} \quad (2)$$

The USP limit is 0.15 μCi Mo-99 per mCi Tc-99m at the time of administration.

$$\therefore 0.15 = \frac{M}{T} \text{ or } M = 0.15\,T.$$

Substituting this into Eq. 1,

$$0.15\,T = M_O e^{-0.01034t}. \quad (3)$$

And substituting Eq. 2 into Eq. 3,

$$0.15\,T_O e^{-0.1155t} = M_O e^{-0.01034t}.$$

$$0.15\,e^{-0.1155t} = \frac{M_O}{T_O} e^{-0.01034t}.$$

$$\ln(0.15\,e^{-0.1155t}) = \ln\left(\frac{M_O}{T_O} e^{-0.01034t}\right).$$

$$(\ln 0.15) + (-0.1155t) = \ln\left(\frac{M_O}{T_O}\right) + (-0.01034t).$$

$$-1.897 - 0.1155t = \ln\left(\frac{M_O}{T_O}\right) - 0.01034t.$$

$$1.897 + 0.1155t = -\ln\left(\frac{M_O}{T_O}\right) + 0.01034t.$$

$$0.1155t - 0.01034t = -\ln\left(\frac{M_O}{T_O}\right) - 1.897.$$

$$0.10516t = -\ln\left(\frac{M_O}{T_O}\right) - 1.897.$$

$$t = \frac{-\ln\left(\frac{M_O}{T_O}\right)}{0.1052} - 18.03. \quad (4)$$

The expiration time (less than 48 hr) of any Tc-99m eluate can be calculated using Eq. 4, where (M_O/T_O) is the initial μCi Mo-99 per mCi Tc-99m and t is the time in hr.

Table 1 provides hourly expiration times for Tc-99m along with their corresponding Mo-99/Tc-99m and Tc-99m/Mo-99 ratios.

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TABLE 1. Expiration Times for Tc-99m

Initial μCi Mo-99/mCi Tc-99m	Initial mCi Tc-99m/μCi Mo-99	Expires (hr)	Initial μCi Mo-99/mCi Tc-99m	Initial mCi Tc-99m/μCi Mo-99	Expires (hr)
0.135	7.4	1	0.0108	92.5	25
0.122	8.2	2	0.0097	103.0	26
0.109	9.1	3	0.0088	114.0	27
0.098	10.2	4	0.0079	127.0	28
0.089	11.3	5	0.0071	141.0	29
0.080	12.5	6	0.0064	157.0	30
0.072	13.9	7	0.0058	174.0	31
0.065	15.5	8	0.0052	193.0	32
0.058	17.2	9	0.0047	215.0	33
0.052	19.1	10	0.0042	238.0	34
0.047	21.2	11	0.0038	265.0	35
0.042	23.6	12	0.0034	294.0	36
0.038	26.2	13	0.0031	327.0	37
0.034	29.1	14	0.0028	363.0	38
0.031	32.3	15	0.0025	403.0	39
0.028	35.9	16	0.0022	448.0	40
0.025	39.9	17	0.0020	498.0	41
0.023	44.3	18	0.0018	553.0	42
0.020	49.2	19	0.0016	614.0	43
0.018	54.7	20	0.0015	683.0	44
0.016	60.7	21	0.0013	758.0	45
0.015	67.5	22	0.0012	842.0	46
0.013	74.9	23	0.0011	936.0	47
0.012	83.3	24	<0.0010	>1040.0	48

Basis:

1 July 80 USP: not greater than 0.15 μCi Mo-99 per mCi Tc-99m at time of injection.

$$t = \frac{-\ln (Mo/To)}{0.1052} - 18.033$$

where Mo/To is the initial μCi Mo-99/mCi Tc-99m and t = time in hr.

Discussion

Application of new USP expiration criteria may result in considerably decreased shelf-lives of Tc-99m eluates. Nigg recently reported results of a retrospective evaluation of Tc-99m eluate shelf-lives based on the new USP criteria (*3*). The mean shelf-life was 13.56 hr; individual shelf-lives ranged from only 3.5 hr to over 24 hr. Because of this wide range, it is important that the shelf-life be individually determined for each eluate.

Conclusion

The expiration time of Tc-99m eluates may be shortened by the presence of Mo-99. An equation and a table provide methods for quickly establishing expiration times.

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References

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2. *The United States Pharmacopeia, Twentieth Revision* (official from July 1, 1980). Rockville, United States Pharmacopeial Convention, Inc., 1979; 764–65.
3. Nigg K. Shelf-life of Tc99m eluates based on the new USP criteria for Mo99 contamination. *The Monthly Scan*, College of Pharmacy, University of New Mexico, Albuquerque, NM 1980, 2.