PROVIDENCE HOSPITAL
RADIATION SAFETY OFFICE
(202) 562-2211 EXT 5415

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Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
ATTENTION: Docketing and Service Branch

Gentlemen:

Please find below comments which were solicited with regard to the proposed Revision 2 to Regulatory Guide 10.8 "Guide for the preparation of applications for medical programs".

With regard to Appendix N, "Model procedure for Area Surveys", and Appendix P "Model procedure for radiation safety during therapuetic use of radiopharmaceuticals." :

Both of these appendices set forth the requirement that instrumentation be capable of detecting removeable contamination levels of 200 d.p.m. . Since all nuclear medicine departments must perform surveys weekly for removeable contamination, or if therapy utilizing radiopharmacueticals is to be performed, this instrumentation must be posessed by the licensee or alternatively the licensee must have immediate access to such instrumentation.

In appendix H "Model procedure for Leak-testing Sealed sources" page H-2, the description of the instrumentation necessary to detect the .005 microcurie action level required for the leak test is described.

However, appendices N and P provide no description of the instrumentation necessary to detect the 200 d.p.m. levels as required for removeable contamination surveys.
Two hundred d.p.m. is equivalent to .000901 microcuries.

Since the computation of d.p.m. involves not not only calculation of the energy efficiency of the instrumentation but also the relative gammas per disintegration or (yield) it is necessary not only to know the efficiency but also the particlular radionuclide which is being measured.

(continued)

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For example:

Isotope	counts per minute	energy efficiency	gammas per disintegration	d.p.m.
X	15	20%	1	75
Y	15	20%	.1	750

Consequently it becomes necessary to know what radionucide is present before it is possible to calculate d.p.m.

Although it is theoretically possible to derive the radionuclide in question by performing a measurement of half-life, it is not practical. Due to the length of the half-lives and to the fact that in most institutions many different radionuclides are used with half-lives which are nearly the same. If the contamination is mixed then it becomes nearly impossible and exceedingly labor intensive to determine the relative amounts and identities of the radionuclides present.

Therefore: It is my position that to comply with the regulations requiring a 200 d.p.m. detectability limit. Possession or immedate access to a multichannel analyzer is necessary. Not only because of the sensitivity necessary but also the apparent impossibility of calculating d.p.m. while not knowing what radionuclide the contaminant represents.

I believe therefore that the appendices listed above should be ammended to reflect a description of the necessary instrumentation required.

With regard to Appendix L page L-1 under Model procedure item #1, last sentence: I believe that the limit noted as .01 millicurie/100 cm2 should read .01 microcurie/100 cm2. I hope that this is a typographic error. If not it represents a relaxation of the previous limit by a factor of 1000.

Sincerely,

Jim Littell
Health Physics Assistant
Radiation Safety Office
Providence Hospital
3200 Providence Drive
Anchorage, Alaska
99516