

May 9, 2005

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Mr. Bryan Parker
U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Licensing Section
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Radioactive Materials License #24-04206-01MD, Mail Control # 136604	03032995
Radioactive Materials License #24-04206-13MD, Mail Control # 136605	03032954
Radioactive Materials License #24-04206-14MD, Mail Control # 136607	03032951
Radioactive Materials License #24-04206-15MD, Mail Control # 136608	03032952
Radioactive Materials License #24-04206-16MD, Mail Control # 136612	03032971
Radioactive Materials License #24-04206-17MD, Mail Control # 136613	03033157
Radioactive Materials License #24-04206-19MD, Mail Control # 136614	03033578
Radioactive Materials License #24-04206-22MD, Mail Control # 136615	03035461

Mr. Parker:

Pursuant to your telephone conversation with April Chance on April 13, 2005, Mallinckrodt is providing additional information regarding our amendment request dated March 10, 2005.

- In accordance with Section 8.10.12 of NUREG-1556, volume 13 a revised table showing radiation profile data is provided as Attachment A. Radiation levels were calculated using the MicroShield[®] software (Grove Engineering, Rockville, MD). The table provides the following data for each radioactive drug currently distributed:
 - Radionuclide and maximum activity for each type of container, e.g., vial, syringe;
 - Type and thickness of the "transport radiation shield" for each type of container; and
 - The maximum radiation level expected at the surface of each "transport radiation shield" at maximum activity.

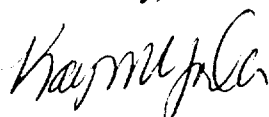
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NMSS/RGNI MATERIALS-002

- In accordance with Section 8.10.11 of NUREG-1556, volume 13, the following information is being provided about the prescription labels:
 - For description of labels, see sample provided in Attachment B of March 10, 2005 request. Only changes pertaining to information required by 10 CFR 32.72(a)(4) will be submitted in the future.
 - The label for the transport radiation shield must contain the following:
 - The radiation symbol;
 - "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL;"
 - Name or abbreviation of the radioactive drug; and
 - Quantity of radioactivity at a specified date and time
 - The label for the syringe or vial must contain the following:
 - The radiation symbol;
 - "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL;" and
 - An identifier that correlates the inner container with the transport radiation shield.
 - Mallinckrodt agrees to affix the required labels to the "transport radiation shields" and each container used to hold radioactive drugs.

All other items relating to our established Radiation Safety Program remain unchanged at this time. Please contact April Chance, Manager, Radiological Affairs, at (314) 654-7960 for further information to support this request. Thank you for your prompt assistance regarding this matter.

Sincerely,



Kay M. Yoder
Director, Radiation, Environment, Health & Safety – Mallinckrodt Inc.

Attachment

cc: B. Means, R.Ph., RSO (Harrisburg, PA) C. Brunner, R.Ph., RSO (Bethlehem, PA)
 A. Gerner, R.Ph., RSO (Folcroft, PA) M. Mezeivtch, R.Ph., RSO (Pittsburgh, PA)
 M. Marinock, R.Ph., RSO (Pine Brook, NJ) T. Hays, R.Ph., RSO (Altoona, PA)
 R. Hylinski, R.Ph., RSO (Milford, CT) M. Loiseau, R.Ph., RSO (Wilkes-Barre, PA)
 A. Chance, Manager, Radiological Affairs (Hazelwood, MO)
 J. Schuh, Manager, EHS, Pharmacy Operations (Hazelwood, MO)

**ATTACHMENT A
RADIATION PROFILE DATA**

Isotope	Source Carrier Geometry	Shield Identification	Maximum Activity (mCi)	Contact^a Exposure Rate (mR/hr)
Tc-99m	5cc Syringe	0.25" Pb Biodex Syringe Pig	2200	<1
Tc-99m	5cc Syringe	0.19" Pb Mallinckrodt Syringe Pig	2200	2
Tc-99m	3cc Syringe	0.19" Pb Mallinckrodt Syringe Pig	2200	5
Tc-99m	Vial	0.125" Pb	14000	938
Tc-99m	Vial	0.25" Pb	14000	<1
Tc-99m	Vial	0.125 + 0.25" Pb	14000	<1
Tc-99m	Vial	0.5" Pb	14000	<1
Cr-51	3cc Syringe	0.125" Pb Biodex Syringe Pig	0.77	16
Cr-51	5cc Syringe	0.25" Pb Biodex Syringe Pig	0.77	3
Cr-51	5cc Syringe	0.19" Pb Mallinckrodt Syringe Pig	0.77	5
Cr-51	3cc Syringe	0.19" Pb Mallinckrodt Syringe Pig	0.77	7
Sr-89	3cc Syringe	0.125" Pb Biodex Syringe Pig	4	1
Sr-89	5cc Syringe	0.25" Pb Biodex Syringe Pig	4	<1
Sr-89	5cc Syringe	0.19" Pb Mallinckrodt Syringe Pig	4	1
Sr-89	3cc Syringe	0.19" Pb Mallinckrodt Syringe Pig	4	1
Sm-153	3cc Syringe	0.125" Pb Biodex Syringe Pig	140	182
Sm-153	5cc Syringe	0.25" Pb Biodex Syringe Pig	140	47
Sm-153	5cc Syringe	0.19" Pb Mallinckrodt Syringe Pig	140	74
Sm-153	3cc Syringe	0.19" Pb Mallinckrodt Syringe Pig	140	107
I-125, Isotrex	5cc Syringe	0.25" Pb	600	<1
I-131	Vial, Solution	0.697" Pb	92	423
I-131	Vial, Solution	0.25" + 0.625" Pb	275	569
I-131	Vial, Capsule	0.697" Pb	92	477
I-131	Vial, Capsule	0.25" + 0.625" Pb	200	464
I-131, Bexxar	Vial	0.5" Pb	20	191
I-131, Bexxar	Vial	0.875" Pb	160	259
I-131, Bexxar	60 cc syringe	0.5" Pb + 0.5" stainless	125	300

^a Contact exposure rates calculated at 1 cm from surface of container.