

April 6, 2000

MEMORANDUM TO: George Pangburn, Director
 Division of Nuclear Materials Safety, RI

Douglas M. Collins, Director
 Division of Nuclear Materials Safety, RII

Cynthia D. Pederson, Director
 Division of Nuclear Materials Safety, RIII

Dwight D. Chamberlain, Director
 Division of Nuclear Materials Safety, RIV

FROM: John W. Hickey, Chief /RA/
 Materials Safety and Inspection Branch
 Division of Industrial and
 Nuclear Materials Safety, NMSS

SUBJECT: STATUS OF SEALED SOURCE AND DEVICE REQUEST FOR
 REGISTRATION

Attached is a listing of the sealed source and device pending cases as of April 4, 2000.

Attachment 1 contains actions that were submitted as a Technical Assistance Report from Headquarters or the Regions, and Attachment 2 lists all actions that have been filed directly by the vendor and regions for product evaluation and registration.

Attachments: As stated

CONTACT: Traci Kime, NMSS/IMNS/MSIB
301-415-8140

DISTRIBUTION: w/enclosures

V. Campbell, RIV	J. Kinneman, RI	J. Madera, RIII
M. Lesser, RII	C. Frazier, RIII	L. J. Baynard, PMDA
NMSS-02 PUBLIC	L. Howell, RIV	S. Moore, MSIB
C. Hosey, RII	M. Shanbaky, RI	F. Costello, RI
S. Villar, RI	C. Cain, RIV	R. Caniano, RIII
NMSS r/f	M. Phillips, RIII	S. Kimberley, LFDCEB
B. Prange, RIV	T. Decker, RII	B. Spitzberg, RIV
IMNS r/f	J. Piccone	D. Cool
G. Wright, RIII		

DOCUMENT NAME: H:\Traci\Regions. Reg ML 003700077

OFC	MSIB	C	MSIB	MSIB
NAME	Traci Kime <i>JK</i>		Fritz Sturz	John Hickey
DATE	4/4/00		4/5/00	4/6/00

OFFICIAL RECORD COPY

Pending Sealed Source & Device Actions
Actions received during the period 01/01/1901 to 04/04/2000
 For actions recorded as of Tuesday, April 04, 2000

Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
01/06/1998	98-05 Jankovich	1	Seaman Nuclear Corp.	C-300	To Fees on 1/7/98. Case has been reassigned to S.Lee on 1/29/98. Rtrned frm fees on 2/2/98. Def. ltr sent on 4/16/98. Response rec'd on 6/3/98. Def. ltr sent on 10/19/98. Waiting for Commission decision.
03/05/1999	99-18 Burgess	1	Advanced Detection Tech.	303-2160, 313-2180, 312-2280	To Fees 3/5/99. Ret'd from Fees 3/12/99.
03/11/1999	99-19 Burgess	2	US Dept of Transportation	MC-DMD & CMD-1	To Fees 3/11/99. Ret'd from Fees 3/15/99.
04/19/1999	99-26 Burgess	1	Apgee Corporation	LB 6600 Series	To Fees 4/20/99. NR-112-D-105-S to inactive status.
04/21/1999	99-27 Jankovich	1	GRAY*STAR, INC.	GS-42	To Fees 4/21/99. Modifications of the Gray*Star and GS-42 Sealed Source. Ret'd from Fees 4/26/99. Graystar briefed staff 5/11/99. Memo sent to J. Craig 6/1/99. Acceptance review completed, ltr sent 6/22/99. Def. ltr sent 7/26/99. Environmental Request to OGC 5/27/99. GrayStar requested, in ltr dtd 8/12/99, an extension til 9/26/99, to respond to the def. ltr. Ltr sent 9/10/99 informing GrayStar of acceptance to extend response time to 9/27/99. Team review of response completed 11/2-4/99. Office Director briefed 12/21/99.
04/30/1999	99-31 Burgess	1	Air Products & Chemical	IMA-1A	

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Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
09/01/1999	99-53 Bhachu	1	Mine Safety Appliances, Co	03-ACAMS-SF/AF, OEM-FIS	To Fees 9/1/99. Adm. review completed 9/1/99. Tech. acceptance review complete 9/14/99. Def. ltr sent 11/22/99. Extension to def. ltr - response has been granted. Def. response rec'd 2/1/2000.
10/18/1999	99-58 Burgess	1	Web Research Company	MS9 Series	To Fees 10/18/99. Application for Mossbauer sources containing Tin-119m to be distributed only to specific licensees in accordance with 10 CFR 32.210. Fee sent in for \$1,580.00. Check #3438. Ret'd frm Fees 10/25/99. Acceptance review ok 10/28/99 (MLB).
10/29/1999	99-61 Burgess	1	Department of the Army	GID-3	Amendment to become custom user as two Federal Agencies. See 7/27/99 e-mail attached. To Fees 10/29/99. Acceptance review ok 11/2/99 (MLB). Rec'd from Fees 11/18/99. First part of info sent 12/22/99. Given to Michele Burgess to review after the 1st of January 2000.
11/10/1999	99-62 Burgess	7	Agilent Technologies	G1223A, G1533, 19233 etc.	To Fees 11/10/99. Amendment to NR-348 registration certs. Acceptance review ok'd 11/15/99. Rec'd from Fees 11/18/99. Partial response sent 2/23/2000.
12/15/1999	99-64 Burgess	1	Department of the Army	GID-3	To Fees 12/15/99. Amendment to NR-155-D-125-S. Ret'd from Fees 12/20/99.

Pending Sealed Source & Device Actions
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Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
12/22/1999	99-65 Bhachu	1	MDS Nordion	C-188 Series	To Fees 12/22/99. Amendment to NR-220-S-103-S to include a new Type 13 configuration. Acceptance review completed 1/3/00. Seung Lee was second reviewer on this case. Seung will speak with Ujagar on this the week of 1/31/00. Def. ltr sent 2/8/2000. Partial resp. rec'd 2/23/2000. (resp. ltr dtd 1/27/2000.) Resp. to def. ltr rec'd 3/7/00.
01/19/2000	00-03 Bhachu	1	GE Medical Systems	V-TransACT	To Fees 1/24/2000. Registration of their V-TransACT Rod Unit. (NR-1049-D-102-S). Ret'd from Fees 2/15/2000.
02/01/2000	00-07 Kirkwood	3	Hochiki America Corp.	SIJ and AIE Series	Amendment to License 04-14886-01E plus an amendment to NR-355-D-105-E and NR-355-D-106-E. Small entity fee paid in the amount of \$1800.00 sent directly to Fees. Tech. Acc. Review completed 2/14/2000. Ret'd from Fees 2/15/2000. Def. call made 2/29/00.
02/01/2000	00-08 Bhachu	1	Sampling Technology	IMS Analyzer	To Fees 2/2/00. AR-101-D-101-G will be going inactive. Ret'd from Fees 2/15/2000.
02/07/2000	00-09 Kirkwood	1	Grinnell Fire Protection	612I & 912I Ionization Chamber Smoke Detector	Amendment of License 34-23772-02E. To Fees 2/7/2000. Ret'd from Fees 2/15/2000. Tech. Acc. review completed 2/22/2000. Def. call made 2/23/00.

Pending Sealed Source & Device Actions
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Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
02/17/2000	00-12 Kirkwood	2	Intelligent Detector Sys.	Ion Mobility	To Fees 2/23/2000. Ret'd from Fees 2/25/2000. Modification to license 54-23849-01E and reg. cert. NR-1018-D-101-E. Tech. Acc. Review completed 3/8/2000.
02/17/2000	00-11 Bhachu	1	Stocker & Yale	SY-183	To Fees 2/17/2000. Inactivating reg. cert. NR-622-D-102-E.
02/23/2000	00-13 Lee	1	DraxImage, Inc.	LS-1	New application for a new device. Check sent in amount of \$1580.00 (ck #08136) To Fees 2/24/2000. Tech. Acc. Review completed 3/1/2000. Ret'd from Fees 3/22/00.
03/02/2000	00-14 Burgess	3	Department of the Army	MA3A1, CAM/ICAM, & ACADA/GID/3	Amendment to: NR-155-D-118-S, NR-155-D-119-S, and NR-155-D-125-S. To Fees 3/2/2000. Ret'd from Fees 3/13/2000.
03/14/2000	00-15 Kirkwood	2	Environmental Technologies	ADP 2000	Application for new exempt distribution license. To Fees 3/14/2000.
03/14/2000	00-16 Lee	1	Lite Pro	AA, C	Application for a new device containing gaseous tritium light sources. Check #1050112530 rec'd for \$5200.00. Ret'd from Fees 3/22/00. Acceptance Review completed 3/23/00. Def. ltr given to U. Bhachu for 2nd concurrence 4/4/00.

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Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
03/20/2000	00-17 Jankovich	1	MDS Nordion	TheraSphere Y-90 Glass Microspheres	Requesting amendment to NR-220-D-113-S for their TheraSphere Y-90 Glass Microspheres. To Fees 3/20/2000. Ret'd from Fees 3/22/00.
03/21/2000	00-20 Lee	1	GE Medical Systems	VG Gamma Camera	Application for a new device. To Fees 3/22/2000.
03/21/2000	00-18 Lee	2	MDS Nordion	Model 780C & 1000	Name Change & Amendment to NR-687-D-101-S & NR-687-D-105-S. To Fees 3/22/2000. Ret'd from Fees 3/28/00.
03/21/2000	00-19 Lee	4	MDS Nordion	C-146/C-196, C-151/C-152, XC-325, Ther 780-19	Name Change on: NR-687-S-102-S, NR-687-S-103-S, NR-687-D-107-S, & NR-687-S-108-S. To Fees 3/22/2000. Ret'd from Fees 3/28/00.

Total Open Case(s) is 26 Totaling 43 Action(s)

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 01/01/1901 to 04/04/2000

Actions recorded as of Tuesday, April 04, 2000

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1 Case(s) Assigned to Reviewer(s) Totaling 2 Action(s)

Control Number	Assign. # Actions	Reviewer	Company	Model Numbers
0	00-12 2	Kirkwood	Intelligent Detector Sys.	Ion Mobility

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 01/01/1901 to 04/04/2000

Actions recorded as of Tuesday, April 04, 2000

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25 Case(s) Assigned to Reviewer(s) Totaling 41 Action(s)

Control Number	Assign. # Actions	Reviewer	Company	Model Numbers
0	98-05 1	Jankovich	Seaman Nuclear Corp.	C-300
0	99-18 1	Burgess	Advanced Detection Tech.	303-2160, 313-2180, 312-2280
0	99-19 2	Burgess	US Dept of Transportation	MC-DMD & CMD-1
0	99-26 1	Burgess	Apgee Corporation	LB 6600 Series
0	99-27 1	Jankovich	GRAY*STAR, INC.	GS-42
0	99-31 1	Burgess	Air Products & Chemical	IMA-1A
0	99-53 1	Bhachu	Mine Safety Appliances, Co	03-ACAMS-SF/AF, OEM-FIS
0	99-58 1	Burgess	Web Research Company	MS9 Series
0	99-61 1	Burgess	Department of the Army	GID-3
0	99-62 7	Burgess	Agilent Technologies	G1223A, G1533, 19233 etc.
0	99-64 1	Burgess	Department of the Army	GID-3

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 01/01/1901 to 04/04/2000

Actions recorded as of Tuesday, April 04, 2000

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25 Case(s) Assigned to Reviewer(s) Totaling 41 Action(s)

Control Number	Assign. # Actions	Reviewer	Company	Model Numbers
0	99-65 1	Bhachu	MDS Nordion	C-188 Series
0	00-03 1	Bhachu	GE Medical Systems	V-TransACT
0	00-07 3	Kirkwood	Hochiki America Corp.	SIJ and AIE Series
0	00-08 1	Bhachu	Sampling Technology	IMS Analyzer
0	00-09 1	Kirkwood	Grinnell Fire Protection	612I & 912I Ionization Chamber Smoke Detector
0	00-11 1	Bhachu	Stocker & Yale	SY-183
0	00-13 1	Lee	DraxImage, Inc.	LS-1
0	00-14 3	Burgess	Department of the Army	MA3A1, CAM/ICAM, & ACADA/GID/3
0	00-15 2	Kirkwood	Environmental Technologies	ADP 2000
0	00-16 1	Lee	Lite Pro	AA, C
0	00-17 1	Jankovich	MDS Nordion	TheraSphere Y-90 Glass Microspheres

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 01/01/1901 to 04/04/2000

Actions recorded as of Tuesday, April 04, 2000

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25 Case(s) Assigned to Reviewer(s) Totaling 41 Action(s)

Control Number	Assign. # Actions	Reviewer	Company	Model Numbers
0	00-18 2	Lee	MDS Nordion	Model 780C & 1000
0	00-19 4	Lee	MDS Nordion	C-146/C-196, C-151/C-152, XC-325, Ther 780-19
0	00-20 1	Lee	GE Medical Systems	VG Gamma Camera

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 01/01/1901 to 04/04/2000

Actions recorded as of Tuesday, April 04, 2000

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25 Case(s) Assigned to Reviewer(s) Totaling 41 Action(s)

Control Number	Assign. # Actions	Reviewer	Company	Model Numbers
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Total Open Case(s) for All Regions is 26 Totaling 43 Action(s)