

MEMORANDUM TO:

George Pangburn, Director
Division of Nuclear Materials Safety, RI

November 2, 1999

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 [orig. signed by]
Materials Safety and Inspection Branch
Division of Industrial and
Nuclear Materials Safety, NMSS

SUBJECT: STATUS OF SEALED SOURCE AND DEVICE REQUEST FOR
REGISTRATION

Attached are listings of the sealed source and device pending cases as of
November 1, 1999. 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

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301-415-8140

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V. Campbell, RIV	J. Kinneman, RI	J. Madera, RIII
M. Lesser, RII	C. Frazier, RIII	G. Shear, RIII
L. J. Baynard, PMDA	NEO2-SSD-7	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, LFDCB	B. Prange, RIV	M. Meenan, RIII
T. Decker, RII	B. Spitzberg, RIV	IMNS r/f
J. Piccone	D. Cool	

DOCUMENT NAME: H:\Traci\Regions. Reg

OFC	MSIB	C	MSIB	MSIB	N
NAME	Traci Kime <i>JK</i>		Fritz Sturz <i>JS</i>	John Hickey <i>JH</i>	
DATE	11/1/99		11/1/99	11/3/99	

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PDR RC

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 1/1/01 to 11/1/99

Actions recorded as of Monday, November 01, 1999

RI

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

Control Number	Assign. # Actions	Reviewer	Company	Model Numbers
0	99-50 1	Bhachu	Mills Biopharmaceutical	125SL & 125SH

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 1/1/01 to 11/1/99

Actions recorded as of Monday, November 01, 1999

SSSS

22 Case(s) Assigned to Reviewer(s) Totaling 33 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	99-23 1	Lee	GE Medical Systems	ATC Rod Unit
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	99-35 1	Bhachu	Graseby STI	4000
0	99-37 1	Bhachu	Hemisphere Forwarding, Inc	EI100BUS, EI
0	99-44 1	Jankovich	MDS Nordion	TheraSphere Yttrium-90 Glass Microspheres
0	99-45 1	Lee	Environmental Tech. Group	Gas/Aerosol Detector

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 1/1/01 to 11/1/99

Actions recorded as of Monday, November 01, 1999

SSSS

22 Case(s) Assigned to Reviewer(s) Totaling 33 Action(s)

Control Number	Assign. # Actions	Reviewer	Company	Model Numbers
0	99-46 1	Jankovich	Mb-Microtec	100/4
0	99-47 1	Jankovich	Metorex	SIPS Probe
0	99-51 4	Burgess	Nuclear Research Corp.	SH-300 SERIES, LS 101, NRC-D-701049
0	99-53 1	Bhachu	Mine Safety Appliances, Co	03-ACAMS-SF/AF, OEM-FIS
0	99-54 2	Bhachu	Barringer Instruments, Inc	Ion Scan
0	99-55 2	Lee	IDS Intelligent Detector	Ion Mobility
0	99-56 2	Burgess	Air Products & Controls	Husman 520
0	99-57 4	Bhachu	Stocker & Yale	13208E4680, 100/1 & SY-183
0	99-58 1	Burgess	Web Research Company	MS9 Series
0	99-59 2	Lee	Dynalec Corporation	IC/SF, IC/SFD, 3464
0	99-60 1	Bhachu	BSI Instruments	NW-201 Series

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 1/1/01 to 11/1/99

Actions recorded as of Monday, November 01, 1999

SSSS

22 Case(s) Assigned to Reviewer(s) Totaling 33 Action(s)

Control Number	Assign. # Actions	Reviewer	Company	Model Numbers
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Total Open Case(s) for All Regions is 23 Totaling 34 Action(s)

Pending Sealed Source & Device Actions

Actions received during the period 1/1/01 to 11/1/99

For actions recorded as of Monday, November 01, 1999

Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
1/6/98	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.
3/5/99	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.
3/11/99	99-19 Burgess	2	US Dept of Transportation	MC-DMD & CMD-1	To Fees 3/11/99. Ret'd from Fees 3/15/99.
4/5/99	99-23 Lee	1	GE Medical Systems	ATC Rod Unit	To Fees 4/5/99. Def. ltr sent 5/5/99. Def. ltr 7/7/99.
4/19/99	99-26 Burgess	1	Apgee Corporation	LB 6600 Series	To Fees 4/20/99. NR-112-D-105-S to inactive status.
4/21/99	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 is scheduled for 11/2-4/99.

Pending Sealed Source & Device Actions

Actions received during the period 1/1/01 to 11/1/99

For actions recorded as of Monday, November 01, 1999

Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
4/30/99	99-31 Burgess	1	Air Products & Chemical	IMA-1A	
5/12/99	99-35 Bhachu	1	Graseby STI	4000	To Fees 5/12/99. AR-101-D-101-G Ret'd from Fees 5/24/99.
5/21/99	99-37 Bhachu	1	Hemisphere Forwarding, Inc	EI100BUS, EI	To Fees 5/21/99. Adding Model Number SS-668 to NR-1040-D-101-E. Ret'd from Fees 7/21/99. Def. response rec'd 9/29/99.
7/7/99	99-45 Lee	1	Environmental Tech. Group	Gas/Aerosol Detector	To Fees 7/7/99. Ret'd from Fees 7/12/99. Transferred to S. Lee 9/8/99.
7/7/99	99-44 Jankovich	1	MDS Nordion	TheraSphere Yttrium-90 Glass Microspheres	To Fees 7/7/99. Check 2047767 sent in the amount of \$910.00. Acceptance review completed and ok 8/11/99. Ret'd from Fees 9/1/99. Draft def. ltr given to M. Burgess on 9/2/99 for 2nd review. Still waiting for 2nd review. Affidavit sent to Ann Warbick 10/26/99.
7/20/99	99-46 Jankovich	1	Mb-Microtec	100/4	To Fees 7/20/99. Amendment to NR-446-D-103-E - Materials License 331-23712-01E. Acceptance review ok 7/30/99. Ret'd from Fees 8/27/99. Def. ltr sent 8/31/99. Received response to def. questions on 9/17/99. Requested additional drawings on 10/21/99.

Pending Sealed Source & Device Actions

Actions received during the period 1/1/01 to 11/1/99

For actions recorded as of Monday, November 01, 1999

Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
7/20/99	99-47 Jankovich	1	Metorex	SIPS Probe	To Fees 7/20/99. Amendment to NR-0701-D-104-B. Paid registration fee in the amount of \$590.00 (Check #23747). Returned from Fees 7/30/99. Acceptance review complete 7/30/99. Draft def. ltr and draft certificate was given to M. Burgess on 8/31/99 for 2nd review. Still waiting on 2nd review.
8/11/99	99-50 Bhachu	1	Mills Biopharmaceutical	125SL & 125SH	To Fees 8/11/99. Ret'd from Fees 8/16/99. Transferred to S. Lee 9/8/99. Def. ltr sent 9/23/99.
8/17/99	99-51 Burgess	4	Nuclear Research Corp.	SH-300 SERIES, LS 101, NRC-D-701049	To Fees 8/17/99. Name change and ownership change. (NR-504-D-109-B, NR-504-D-111-B, NR-504-D-117-S & License #37-02401-05E.) Ret'd from Fees 9/1/99. Acceptance review completed 8/30/99. 9/10/99 def. response.
9/1/99	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.
9/13/99	99-54 Bhachu	2	Barringer Instruments, Inc	Ion Scan	To Fees 9/14/99. Also need to amend License #29-28620-02G Ret'd from Fees 9/17/99.
9/17/99	99-55 Lee	2	IDS Intelligent Detector	Ion Mobility	To Fees 9/20/99. Tony Kirkwood has the licensing part of it (License # 54-23849-01E). Ret'd from Fees 9/27/99.

Pending Sealed Source & Device Actions

Actions received during the period 1/1/01 to 11/1/99

For actions recorded as of Monday, November 01, 1999

Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
9/24/99	99-56 Burgess	2	Air Products & Controls	Husman 520	To Fees 9/24/99. Name Change to NR-1060-D-101-E and to License #21-23805-02E. (License amended by Raeann Shane 9/24/99). Returned from Fees 9/29/99. Acceptance review ok 10/5/99. 10/6/99 def. call.
9/30/99	99-57 Bhachu	4	Stocker & Yale	13208E4680, 100/1 & SY-183	To Fees 9/30/99. Stocker & Yale will be selling their assets to Commenga Associates. Will be changing the following: Reg. Certs.: NR-210-D-101-E, NR-622-D-102-E Licenses: 21-26460-02-E & 28-23842-03E. (Will assign these to Tony Kirkwood). Returned from Fees 10/8/99.
10/18/99	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).
10/20/99	99-59 Lee	2	Dynalec Corporation	IC/SF, IC/SFD, 3464	To Fees 10/20/99. Change to registry NR-1051-D-101-E and to License 31-23861-01-E (T. Kirkwood). Rtd from Fees 10/25/99.

Pending Sealed Source & Device Actions

Actions received during the period 1/1/01 to 11/1/99

For actions recorded as of Monday, November 01, 1999

Date Received	Assign. # Reviewer	Actions	Company	Model Numbers	Status
10/26/99	99-60 Bhachu	1	BSI Instruments	NW-201 Series	To Fees 10/27/99. Request for amendment to NR-186-D-117-B which was issued on October 13, 1999.

Total Open Case(s) is 23 Totaling 34 Action(s)