MEMORANDUM TO:

George Pangburn, Director

Division of Nuclear Materials Safety, RI

February 2, 2000

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 original signed by: F. Sturz for:

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 February 1, 2000. There are no pending actions that were submitted as a Technical Assistance Report from the Regions, and the attachment lists all actions that have been filed directly by the vendors 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

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

T. Decker, RII

S. Kimberley, LFDCB

B. Prange, RIV

B. Spitzberg, RIV

IMNS r/f

J. Piccone

D. Cool

G. Wright, RIII

DOCUMENT NAME: H:\Traci\Regions. Reg

| OFC | MSIB | С | MSIB 10) | C | MS(B) | |
|------|------------|---|-------------------|----------|-------------|---|
| NAME | Traci Kime | _ | Fritz Sture 10 fc | % | John Hickey | |
| DATE | 2/ / /00 | • | 2/ /00 | | 2/1/00 | · |

OFFICIAL RECORD COPY

Pending Sealed Source & Device Actions

Actions received during the period 1/1/1901 to 2/1/2000

For actions recorded as of Tuesday, February 01, 2000

| Date | Assign. # | | _ | | |
|-----------|--------------------|---------|--|------------------------------|--|
| Received | Reviewer | Actions | Company | Model Numbers | Status |
| 1/6/1998 | 98-05 | | | | |
| 1707 1830 | 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. Itr sent on 4/16/98. Response rec'd on 6/3/98. |
| | | | | | Def. itr sent on 10/19/98. Waiting for Commission decision. |
| | | | | | |
| 3/5/1999 | 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. |
| 3/11/1999 | 99-19 | | | | |
| | Burgess | 2 | US Dept of Transportation | MC-DMD & CMD-1 | To Fees 3/11/99. Ret'd from Fees 3/15/99. |
| 4/19/1999 | 99-26 | • | | | |
| | Burgess | 1 | Apgee Corporation | LB 6600 Series | To Fees 4/20/99. NR-112-D-105-S to inactive status. |
| 4544000 | | | | | * |
| 4/21/1999 | 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, itr sent 6/22/99. |
| | | | | | Def. Itr sent 7/26/99. |
| | | | | | Environmental Request to OGC 5/27/99. |
| | | | | | GrayStar requested, in itr dtd 8/12/99, an extension til |
| | | | | | 9/26/99, to respond to the def |
| | | | • | | ttr. 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. |
| 4/30/1999 | 99-31 | | | | |
| | Burgess | 1 | Air Products & Chemical | IMA-1A | |
| | | | J. O. ROW | | |

Pending Sealed Source & Device Actions

Actions received during the period 1/1/1901 to 2/1/2000 For actions recorded as of Tuesday, February 01, 2000

| Date Received | Assign. # Reviewer | Actions | Company | Model Numbers | Status |
|------------------|-----------------------|---------|-------------------------------|-------------------------|--|
| 5/21/1999 | 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. Working on. Will be sending def. ltr. Def. ltr sent 12/20/99. |
| 7/7/1999 | 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. SJL gave Fritz memo on 11/1/99 to OGC asking for interpretation. def. letter to Maria Schwartz of OGC for concurrence on 12/1/99. Revised def. letter given to Maria Schwartz (OGC) for concurrence 12/13/99. Def. Itr sent 12/20/99. |
| 9/1/1999 | 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. itr sent 11/22/99. Extension to def. itr - response has been granted. |
| 9/13/1999 | 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. Def. Itr sent 1/10/2000. |
| 9/17/1999 | 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. This case is tied with a licensing action that TKirkwood is working on. ASK wrote rejection letter and waited for OGC concurrence. Casework to be terminated. |

Pending Sealed Source & Device Actions

Actions received during the period 1/1/1901 to 2/1/2000 For actions recorded as of Tuesday, February 01, 2000

| Date | Assign.# | | | | |
|------------|------------------|---------|-------------------------|---------------------------|--|
| Received | Reviewer | Actions | Company | Model Numbers | Status |
| 0/04/4000 | | | | | |
| 9/24/1999 | 99-56 Burgess | . 2 | Air Products & Controls | Husman 520 | To Fees 9/24/99. |
| | 20.8000 | _ | | | 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. 1/21/00 def. call |
| | | • | | | 1/21/00 def. resp. (rec'd |
| | | | | | 1/27/00). |
| | | | | | File is with S. Lee for 2nd sig. |
| 10/18/1999 | 99-58 | . 1 | Web Research | MCO Corios | T- F 404000 |
| | Burgess | 1 | 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 | | | | |
| 1012011000 | Burgess | 1 | | GID-3 | Amendment to become |
| | | | Army | | 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 |
| ٠ | | | • | | 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. |
| | 7 | | | · | |

Pending Sealed Source & Device Actions

Actions received during the period 1/1/1901 to 2/1/2000 For actions recorded as of Tuesday, February 01, 2000

| Date Received | Assign. # Reviewer | Actions | Company | Model Numbers | Status |
|------------------|-----------------------|---------|------------------------|-----------------------|---|
| 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. |
| 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. |
| 1/18/2000 | 00-02 Lee | 1 | Metorex | SUPS 0484 & SUPS 2476 | To Fees 1/24/2000. U.Bhachu will be 2nd reviewer on this. |
| 1/19/2000 | 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). |
| 1/24/2000 | 00-04 Jankovich | 1 | MDS Nordion | TheraSphere | Applicant requesting a new TheraSphere device. Follow-up to 99-44. |
| 1/27/2000 | 00-05 Bhachu | 2 | | · 500A, Series | To Fees 1/27/2000. Amendment to NR-547-D-101-E & License #12-15023-02E. |
| 2/1/2000 | 00-07 Unassigned | 2 | Hochiki America Corp. | SIJ and AIE Series | Amendment to License 04-14886-01E plus an SSD review as part of a cross-training endeavor requested by F. Sturz. |

Total Open Case(s) is 22 Totaling 34 Action(s)

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 1/1/1901 to 2/1/2000 Actions recorded as of Tuesday, February 01, 2000

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22 Case(s) Assigned to Reviewer(s) Totaling 34 Action(s)

| Control | Assign. # | Devley | | |
|---------|--------------|-----------|----------------------------|------------------------------|
| Number | Actions | Reviewer | Company | Model Numbers |
| 0 | 98-05 1 | Jankovich | Seaman Nuclear Corp. | C-300 |
| o | 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 |
| o | 99-31 1 | Burgess | Air Products & Chemical | IMA-1A |
| • 0 | 99-37 1 | Bhachu | Hemisphere Forwarding, Inc | EI100BUS, EI |
| 0 | 99-45 1 | Lee | Environmental Tech. Group | Gas/Aerosol Detector |
| . 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 |

Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 1/1/1901 to 2/1/2000 Actions recorded as of Tuesday, February 01, 2000

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22 Case(s) Assigned to Reviewer(s) Totaling 34 Action(s)

| | Control Number | Assign. # Actions | Reviewer | Company | Model Numbers | |
|---|-------------------|----------------------|------------|-------------------------|---------------------------|--|
| | 0 | 99-56 2 | Burgess | Air Products & Controls | Husman 520 | |
| | . 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 | |
| | 0 | 99-65 1 | Bhachu . | MDS Nordion | C-188 Series | |
| ſ | 0 | 00-02 1 | Lee | Metorex | SUPS 0484 & SUPS 2476 | |
| | 0 | 00-03 1 | Bhachu | GE Medical Systems | V-TransACT | |
| | . 0 | 00-04 1 | Jankovich | MDS Nordion | TheraSphere | |
| | 0 | 00-05 2 | Bhachu | | 500A, Series | |
| | o | 00-07 | Unassigned | Hochiki America Corp. | SIJ and AIE Series | |

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Pending Sealed Source & Device Actions Tied to Licensing Actions

By Region for the period 1/1/1901 to 2/1/2000 Actions recorded as of Tuesday, February 01, 2000

| SSSS 22 Case(s) / | Assigned to F | leviewer(s) T | otaling 34 Action(s) | | |
|----------------------|---------------|---------------|----------------------|---------------|--|
| Control Number | | Reviewer | Company | Model Numbers | |

Total Open Case(s) for All Regions is 22 Totaling 34 Action(s)