



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

June 20, 1997

ALL AGREEMENT STATES  
OHIO, OKLAHOMA, PENNSYLVANIA

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-97-047)

Your attention is invited to the enclosed correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION.....

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION..... XX 99MO/99mTc SUPPLIES  
INTERRUPTED

OTHER INFORMATION .....

Supplementary information: MDS Nordion of Canada, a major North American supplier of molybdenum to U.S. 99Mo/99mTc generator manufacturers, announced that a strike on Thursday June 19, 1997 has closed its medical production reactor interrupting supplies of molybdenum. U.S. generator manufacturers are seeking alternative sources of molybdenum from foreign suppliers. We understand, however, that foreign suppliers may not be able to meet the North American demand. (Starting on Tuesday June 24 the supply to the United States may be only 30-70% of United States needs.)

In 1991, when a similar interruption was expected, NRC took action to issue a temporary waiver to allow licensees to elute generators beyond the manufacturers' recommended expiration date. At that time, NRC regulations required radiopharmacies and hospitals to follow the package inserts in the 99Mo/99mTc generators. These inserts contained an expiration date for the generators beyond which 99mTc could no longer be withdrawn from the generator. Such action by NRC today is not needed because 10 CFR 35.200 was amended by the Radiopharmacy Rule to remove the requirement that package inserts be followed. Given that most States may not have adopted the Radiopharmacy Rule, you may want to evaluate and consider the need to issue such a waiver to your licensees. A copy of the 1991 NRC waiver and a MDS Nordion communique are enclosed for your use.

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PDR STPRG ESGGEN  
PDR

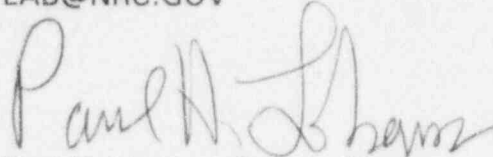


SP-A-4

JUN 20 1997

If you have any questions regarding this correspondence, please contact me or the individual named below.

POINT OF CONTACT:	Lloyd A. Bolling
TELEPHONE:	(301) 415-2327
FAX:	(301) 415-3502
INTERNET:	LAB@NRC.GOV



Paul H. Lohaus, Deputy Director  
Office of State Programs

Enclosures:  
As stated

JUN 20 1997

If you have any questions regarding this correspondence, please contact me or the individual named below.

POINT OF CONTACT: Lloyd A. Bolling  
TELEPHONE: (301) 415-2327  
FAX: (301) 415-3502  
INTERNET: LAB@NRC.GOV

**Original Signed By:**  
**PAUL H. LOHAUS**

Paul H. Lohaus, Deputy Director  
Office of State Programs

Enclosures:  
As stated

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OFFICE	OSP	OSP:DD	OSP:D				
NAME	LABolling.gd	PHLohaus	RLBangart				
DATE	06/20/97	06/20/97	06/20/97				

OSP FILE CODE: SP-A-4



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555

URGENT

TO ALL NRC MEDICAL LICENSEES, NUCLEAR PHARMACIES AND  
RADIOPHARMACEUTICAL MANUFACTURERS

Enclosed is Temporary Waiver of Compliance for licensees authorized to possess and use molybdenum-99/technetium-99m generators and prepare reagent kits.

The enclosed waiver does not relieve licensees from current molybdenum-99 breakthrough testing or maintaining compliance with the rules and regulations of the Food and Drug Administration.

Because this Temporary Waiver of Compliance is effective immediately, it is important that you notify your appropriate personnel immediately, and retain this Temporary Waiver of Compliance with your license records. Questions and comments may be directed to your nearest NRC regional office.

This Temporary Waiver of Compliance is effective through February 4, 1991.

Sincerely,

A handwritten signature in cursive script, reading "Robert M. Bernero", is written over a horizontal line.

Robert M. Bernero, Director  
Office of Nuclear Material Safety  
and Safeguards

Enclosure: Temporary Waiver of  
Compliance

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
WASHINGTON, D.C. 20555

TEMPORARY WAIVER OF COMPLIANCE (EFFECTIVE JANUARY 15, 1991)

I

The Commission authorizes licensees to possess and use molybdenum-99m generators and prepare reagent kits, by license condition and regulations in accordance with the manufacturer's instructions.

II

There is no domestic supply of molybdenum-99 for radiopharmaceutical production and the sole source for the United States is Atomic Energy of Canada Limited (AECL). Because of problems affecting molybdenum-99 production, at the AECL NRU facility at Chalk River Laboratories, there is a potential for disruption of the supply of radiopharmaceuticals needed for medical diagnosis. Accordingly, the Director, Office of Nuclear Material Safety and Safeguards, has found that the public health, safety, and interest requires that this Temporary Waiver of Compliance be made effective for the period January 15, 1991, through February 4, 1991, inclusive.

III

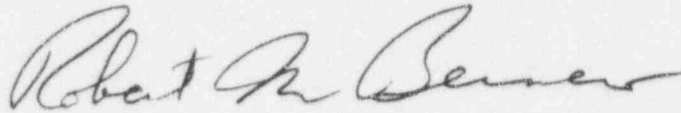
Accordingly, the Nuclear Regulatory Commission has concluded that it will not enforce license conditions or regulations requiring licensees authorized to possess and use molybdenum-99/technetium-99m generators and prepare reagent kits to follow manufacturer's instructions to allow use of generators for up to 21 days, use of technetium-99m eluant for up to 24 hours, and preparation of pooled reagent kits ("super kits"), provided that:

- a. the molybdenum-99 concentration is determined for each technetium-99m eluate and meets the requirements of 10 CFR 35.204(a) and 10 CFR 30.34(g);
- b. aluminum breakthrough testing is performed as currently required; and
- c. preparation of each "super kit" includes radiochemical purity (% Tag) testing 20 minutes after each preparation.

IV

This does not relieve licensees from maintaining compliance with the rules and regulations of the Food and Drug Administration (FDA).

FOR THE NUCLEAR REGULATORY COMMISSION

A handwritten signature in cursive script, appearing to read "Robert M. Bernero".

Robert M. Bernero, Director  
Office of Nuclear Material Safety  
and Safeguards

Dated at Rockville, Maryland  
This 15 day of January, 1991

JUN 19 '97 17:22 FR

TO 19107165839

P.01/01

417 March Road  
Kanata, Ontario  
Canada K2K 1X8



Post-It® Fax Note	7671	Date	97.6.19	# of pages	1
To	JOHN LONG	From	S.C. DEANS		
Co./Dept.		Co.			
Phone #		Phone #	613 592 2790		
Fax #	910 716 5639	Fax #			

### COMMUNIQUE STRIKE AT CHALK RIVER LABORATORIES

1. The Atomic Energy Allied Council (a group of several unions, primarily support services such as electricians, security, bus drivers etc.) at Atomic Energy of Canada's Chalk River Laboratories began a legal strike at 00:01 Thursday June 19.
2. AECL and the Allied Council had reached a tentative agreement which was subsequently rejected by the union membership.
3. In anticipation of a strike AECL began the orderly shutdown of the NRU reactor (at Chalk River) on June 17. As a consequence, the production of key medical isotopes - Mo-99, I-125, I-131 and Xe-133 has stopped at Chalk River.  
  
MDS Nordion is attempting to purchase Mo-99 from other suppliers but the quantities available to us will meet only a portion of our requirements. We are making plans to source I-131 and Xe-133 from our facilities in Belgium. Isotopes such as Ir-192 (for gamma radiography sources) and I-125 are being sought from other suppliers.
4. MDS Nordion supplies greater than 60% of the molybdenum-99 for use in the production of radiopharmaceuticals in North America. Plans are in place to meet all requirements for Mo-99 up to and including Sunday June 22. Starting June 23 product will be on allocation.
5. More than 90% of the radiopharmaceutical medical procedures performed use technetium-99m (a derivative of molybdenum-99). These include various diagnostic procedures relating to cancer, AIDS, heart disease and other illnesses. This equates to 9 million medical procedures per year, or 36,000 per day.
6. The major radiopharmaceutical manufacturers in the United States are: Amersham Medi-Physics; DuPont Merck; and Mallinckrodt Medical.
7. MDS Nordion has a fleet of approved type B shipping containers that it will make available to potential suppliers in order to facilitate shipments.
8. Your Account Manager and Customer Representative will be in touch with you to discuss further details on supply.

Dated 19 June 1997

S.C. Deans  
Manager, Commercial Operations

U.S.A. Canada



**U. S. NUCLEAR REGULATORY COMMISSION  
OFFICE OF STATE PROGRAMS**

**OFFICE OF STATE PROGRAMS FAX: (301) 415-3502**

**NUMBER OF PAGES: 7 including this page**

**DATE: JUNE 20, 1997**

**TO: RADIATION CONTROL PROGRAM DIRECTORS IN  
AGREEMENT STATES, OHIO, OKLAHOMA, PENNSYLVANIA  
  
NRC REGIONAL STATE AGREEMENTS OFFICERS  
NRC REGIONAL STATE LIAISON OFFICERS**

**FROM: PAUL H. LOHAUS, DEPUTY DIRECTOR  
OFFICE OF STATE PROGRAMS**

**SUBJECT: SP-97-047 99Mo/99mTc SUPPLIES INTERRUPTED**

**VERIFICATION - 415-3340**



## &lt; TRANSACTION REPORT &gt;

06-20-1997(FRI) 19:44

## [ BROADCAST ]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
32800	6-20	18:15	610 337 5324	7	0° 02' 44"	NORM.E	OK
32801		18:18	404 562 4955	7	0° 02' 50"	NORM.E	OK
32802		18:21	7085151096	7	0° 05' 17"	NORM.E	OK
32803		18:26	817 860 8122	7	0° 02' 41"	NORM.E	OK
32804		18:29	5109750381	7	0° 03' 07"	NORM.E	OK
32805		18:33	334 613 5387	7	0° 04' 54"	NORM.E	OK
32806		18:38	602 437 0705	7	0° 02' 50"	NORM.E	OK
32807		18:41	5016612466	7	0° 03' 03"	NORM.E	OK
32808		18:45	0111916 3243610	7	0° 02' 43"	NORM.E	OK
32809		18:48	303 343 3697	7	0° 03' 04"	NORM.E	OK
32810		18:51	904 487 0435 -OK- Florida-FL	5	0° 02' 34"	NORM.E	U010
32811		18:54	404 362 2653	7	0° 02' 44"	NORM.E	OK
32812		18:57	217 524 4724	7	0° 02' 49"	NORM.E	OK
32813		19:00	515 242 6284	7	0° 02' 45"	NORM.E	OK
32814		19:03	913 296 0984	7	0° 02' 57"	NORM.E	OK
32815		19:07	502 564 6533	7	0° 02' 44"	NORM.E	OK
32816		19:10	LOUISIANA	7	0° 03' 05"	NORM.E	OK
32817		19:13	MAINE	7	0° 04' 33"	NORMAL	OK
32818		19:18	410 631 3198	7	0° 03' 09"	NORMAL	OK
32819		19:21	601+354+6167	7	0° 04' 15"	NORMAL	OK
32820		19:26	402 471 9449	7	0° 02' 43"	NORM.E	OK
32821		19:29	7026875751	7	0° 04' 17"	NORMAL	OK
32822		19:34	603 225 2325	7	0° 02' 49"	NORM.E	OK
32823		19:37	5058271544	7	0° 04' 08"	NORMAL	OK
32824		19:41	518 458 6434	7	0° 02' 47"	NORM.E	OK
				173	1° 21' 32"		

## &lt; TRANSACTION REPORT &gt;

06-20-1997(FRI) 20:56

## [ BROADCAST ]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
32825	6-20	19:45	915 571 4148	7	0° 02' 46"	NORM.E	OK
32826		19:46	701 328 5200	7	0° 02' 40"	NORM.E	OK
32827		19:51	503 731 4081	7	0° 02' 40"	NORM.E	OK
32828		19:54	401 277 2456	7	0° 04' 43"	NORM.E	OK
32829		19:59	8037377412	7	0° 02' 48"	NORM.E	OK
32830		20:02	615 532 7938	7	0° 02' 47"	NORM.E	OK
32831		20:05	5128346708	7	0° 02' 57"	NORM.E	OK
32832		20:08	801 533 4097	7	0° 03' 28"	NORM.E	OK
32833		20:12	360 753 1496	7	0° 02' 40"	NORM.E	OK
32834		20:15	518 457 2225	7	0° 02' 46"	NORM.E	OK
32835		20:18	518 457 5545	7	0° 03' 06"	NORM.E	OK
32836		20:22	NEW YORK CITY	7	0° 02' 47"	NORM.E	OK
32837		20:25	502 227 7862	7	0° 03' 18"	NORMAL	OK
32838		20:29	AECB (613) 995-5066	7	0° 03' 05"	NORMAL	OK
32839		20:32	WASHINGTON DC	7	0° 02' 41"	NORM.E	OK
32840		20:35	7996726	7	0° 02' 43"	NORM.E	OK
32841		20:38	217 782 1328	7	0° 03' 24"	NORM.E	OK
32842		20:42	512 239 6362	7	0° 02' 50"	NORM.E	OK
32843		20:45	4024714840	7	0° 04' 05"	NORMAL	OK
32844		20:53	912 262 3143	7	0° 03' 14"	NORMAL	OK
				140	1° 01' 28"		

# < TRANSACTION REPORT >

06-20-1997(FRI) 17:06

## [ BROADCAST ]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
32796	6-20	16:44	OHIO	7	0° 02' 49"	NORM. E	OK
32797		16:48	405 271 8425	7	0° 02' 39"	NORM. E	OK
32798		17:04	PENNSYLVANIA	0			U000
32799		17:06	MASSACHSETTS <i>-OK 6/21</i>	0			U000
				14	0° 05' 28"		

# < TRANSACTION REPORT >

06-23-1997(MON) 07:11

[ TRANSMIT ]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
32847	6-23	07:08	NYSERDA	7	0° 03' 25"	NORMAL	OK
			<i>Spoken, NY</i>	7	0° 03' 25"		

# < TRANSACTION REPORT >

06-21-1997(SAT) 09:30

[ TRANSMIT ]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
32845	6-21	09:27	004 487 0435	7	0' 02' 55"	NORM.E	OK
			Florida	7	0' 02' 55"		

# < TRANSACTION REPORT >

06-21-1997(SAT) 09:37

[ TRANSMIT ]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
32846	6-21	09:33	617 522 9860	7	0° 04' 05"	NORMAL	OK
			<i>Massachusetts</i>	7	0° 04' 05"		

# < TRANSACTION REPORT >

06-23-1997(MON) 09:06

[ TRANSMIT ]

NO.	DATE	TIME	DESTINATION STATION	PG.	DURATION	MODE	RESULT
32851	6-23	09:03	PENNSYLVANIA	7	0° 02' 58"	NORM.E	OK
				7	0° 02' 58"		