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

April 15, 1993

MEMORANDUM FOR: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque

FROM: Dennis K. Rathbun, Director
Office of Congressional Affairs DR

SUBJECT: PROPOSED WITNESS LIST FOR GLENN HEARING

The staff of the Senate Governmental Affairs Committee has informed us of the following tentative witness list for the April 22 hearing on the regulation of radiation medicine.

Panel 1 - Chairman and NRC Commissioners

Panel 2 - Bruce Burlington, Director Center for Devices
Food and Drug Administration
Department of Health and Human Services
accompanied by officials of
Center for Disease Control
National Institute for Occupational Safety and Health

Panel 3 - Aubrey Godwin on behalf of the Conference of Radiation Control Program Directors (CRCPD)
accompanied by Charles Hardin, Executive Director

The Committee staff also expects a number of individuals and groups to file testimony for the record.

Attached for your information is an early draft of testimony to be presented by Mr. Godwin on behalf of CRCPD.

Additional information will be provided to you as it becomes available.

Attachment:
As stated

Contact: Tom Combs, 504-1776

cc: EDO
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Medical
Vol. 1

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 14, 1993

MEMORANDUM FOR: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: EVALUATION OF THERAPEUTIC MISADMINISTRATION DATA FOR 1990-1992

During a briefing to the Commission on January 22, 1993, the staff described the current practice for followup of patients subject to a therapeutic misadministration. The Commission questioned: 1) the extent of the Nuclear Regulatory Commission's confirmation of notification of the patient and/or referring physician of a misadministration; 2) the frequency of use of medical consultants for misadministrations; and 3) the underlying root causes of each misadministration. Information responding to these questions has been obtained from the NRC regional offices and analyzed for therapeutic misadministrations involving NRC-licensed material for calendar years (CY) 1990 through 1992. A summary of the analysis is provided in Enclosure 1.

A detailed breakdown of the data for individual incidents may be found in Enclosure 2. This analysis is based on a review of inspection findings, licensee reports, and in some cases, direct communication with the licensee if the report did not contain sufficient information. There was a change in the definition of misadministrations and notification requirements with the implementation of the "Quality Management Program and Misadministrations" (QM) Rule, effective January 27, 1992. Regional personnel contacted licensees and subsequently indicated that there was some confusion regarding the licensee's responsibility to send written notification to the patient, especially before implementation of the QM rule. The staff notes that many reasons given for not notifying the patient do not meet the criteria in 10 CFR 35.33(a)(3), i.e., that in the medical judgment of the referring physician, telling the patient would be harmful. The data show that invalid reasons include: "dose within acceptable limits;" "no adverse effects were expected;" "no medical benefit to the patient;" "not in the patient's best interest;" or that "the patient has died." It should be noted that providing written notification has significantly improved, from 46 percent before January 27, 1992, to 76 percent after that date, which may reflect a change in the rule language regarding the requirement for the licensee to provide a written report to the patient.

The root cause analysis was based primarily on a review of the licensee's written report and inspection findings. The four categories used are those described in the statements of consideration for the QM rule. Specifically, the root causes of misadministrations could be characterized primarily as

deficient procedures or failure to follow procedures, inattention to detail, and inadequate training. Some misadministrations were a result of more than one of these causes. Although the regions did not identify insufficient supervision as a root cause of any misadministration, inadequate supervision was a likely contributing cause in many instances where failure to follow procedures or inadequate training were involved.

The staff is currently preparing an Information Notice for all NRC medical licensees, reemphasizing the importance of the requirements for notifications, reports, and records of misadministrations in 10 CFR 35.33. This notice will point out that many reasons given for not notifying the patient do not meet the criteria in 10 CFR 35.33, i.e., that, based on the medical judgment of the referring physician, telling the patient would be harmful. In addition, the notice emphasizes that there is no basis for the belief that the misadministration notification requirements cease upon the death of a patient. Licensees are advised that if there is any confusion as to the identity of the patient's "responsible relative," licensees have the responsibility to identify that person. A memorandum was sent to all NRC regions on April 5, 1993, addressing the importance of ensuring that the licensee has complied with all requirements in 10 CFR 35.33, including patient notification after a misadministration. Furthermore, the staff is currently reviewing the cases wherein the patient was not provided with a written notification to determine if enforcement action is warranted.

Original signed by
James M. Taylor

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Summary of Misadministration data fr CY90-92
2. Therapeutic Misadministration data fr CY90-92

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NRC File Ctr	IMNS Central File	NMSS DirOf r/f	IMAB r/f
EJordan, AEOD	JMPiccone	PRathbun	BHayes, OI
TechEd	EDO R/F	JLieberman, OE	
EKraus	Taylor		
02/25/93	Thompson		

*See previous concurrence

OFC	IMAB	E	IMAB*	E	IMAB*	N	D/IMNS*	
NAME	PKHolahan		LWCamper		JEGlenn		RECunningham	
DATE	03/ /93		03/05/93		03/05/93		03/08/93	

OFC	*OGC		DD/NMSS		D/NMSS		DEDS		EDO	
NAME	STreby		GArlotto		RMBernero		HThompson		JMTaylor	
DATE	04/08/93		04/ 9/93		04/12/93		04/14/93		04/ /93	

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SUMMARY OF THERAPEUTIC MISADMINISTRATION DATA FOR NRC LICENSEES DURING 1990 - 1992

	Number of occurrences	Percentage
Notification of referring physician within 24 hr	70[1]/72	97
Verbal notification of patient or relative	52[2,3]/72	72
Written notification provided to patient (if informed verbally)	29[4]/52	56[5]
Medical consultant used	23/72	32
Root cause analysis[6]:		
1. Insufficient supervision	0/72	0
2. Deficient procedures or failure to follow procedures	29/72	40
3. Inattention to detail	31/72	43
4. Inadequate training	11/72	15
5. Other[7]	9/72	12

[1] In two of these cases, notification was not within 24 hr; notification is unknown in one of two cases; in one other of the two where the referring physician was not notified, the patient was notified verbally.

[2] In 50/52 cases, notification was made within 24 hr; in 7/20 cases, the referring physician made a medical judgment that informing the patient would be harmful. In 2/20 cases when the patient was not informed, the patient died prior to determination that a misadministration occurred; in 4/20 cases, no reason was provided; and in the remaining 7/20 cases, the reasons included: no adverse effects expected; not in patient's best interest; or the dose was within acceptable clinical limits.

[3] In 1/52 misadministrations, 12 patients were involved. Only one of these patients was not notified because the physician believed it would result in undue patient stress.

[4] In 2 of the remaining 23 cases, it is unknown if the patient received a written report. For the 21 cases in which the patient did not receive written notification, the primary reason provided by the licensee was a lack of understanding of the requirement.

[5] It should be noted that after January 27, 1992, 76 percent of the patients that were informed verbally also received written notification.

[6] Some misadministrations may have been attributed to more than one root cause so that the summed percentage exceeds 100 percent.

[7] Other reasons included lack of management oversight, recordkeeping, technical problems, and patient intervention.

THERAPEUTIC MISADMINISTRATION DATA FOR NRC LICENSEES DURING 1990 - 1992

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	NOTIFICATION[3] PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
Ball Memorial Hospital (2-6-90)	B	5-Kink in Catheter	Y	Y	N	Y	Dose to any significant structure not of clinical significance	
Berkshire Medical Center (11-91)	T	3	Y	Y	N	N		
Beth Israel Hospital (8-23-90)	B	5-Lack of Mgmt,RSC,RSO oversight	N	N*		N		NRC identified during 92' inspection *-licensee did not consider a misadmin. - patient died before NRC identified
Bothwell Regional Hospital (3-18-92)	T	2	Y	Y	Y	N		
Brigham & Women's Hospital (7-19-90)	R	3	Y	Y	Y	N		
Carlisle Hospital (1-13-92)	T	4	Y	Y	N	N		
Christ Hospital (5-29-92)	B	5-difficulty with new technology	Y	Y	N	Y	Low probability of damage to rectal tissues- greater risk of tumor recurrence	

Enclosure 2

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	NOTIFICATION[3] PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
Clara Maass Medical Center (3-28-91)	R	2	Y	Y	N	Y	-No significant effect - rapid clearance	
Cleveland Clinic Foundation (2-6-90)	T	2	Y	N[b]		N		[b]-misadmin. only in technical sense - not relevant to pt. care
Cleveland Clinic Foundation (4-24-91)	B	3	Y	Y	Y	N		
Cleveland Clinic Foundation (1-17-92)	B	2	Y	Y	N	Y	No evidence of acute adverse reactions	
Cooper Hosp/Univ. Medical Center (1-24-92)	B	3	Y	N[c]		N		[c]-dose within acceptable clinical limits
Cooper Hosp/Univ. Medical Center (9-17-90)	B	2	Y	N		Y	No adverse effects	[d]-no adverse effects, did not want extra patient stress
Frankford Hospital (8-1-90)	R	3	Y	Y	N	N		
Geisinger Medical Center (2-19-90)	T	2	Y	Y (not in 24 hr)	N (?)	Y	Some risk of radiation myelitis 6-24 mos.; possible spinal cord lesion.	
Geisinger Medical Hospital (7-25-91)	R	5 (dose was off)	N (?)*	N*		N		* Questionable misadministration

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	NOTIFICATION[3] PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
Greenwich Hospital (10-22-92)	T	3	Y	N[f]		N		[f]-based on medical judgement
Hahnemann University (2-22-91)	B	3	Y	N[g]		N		[g]-medical judgement that administration within clinical parameters - no adverse effects
Harper Hospital (2-24-92)	T	2	Y	N[h]		N		[h]-may cause patient unhealthy increase in anxiety
Hospital Metropolitano (3-24-92)	B	4, 2, 3 5- recordkeeping	Y	Y	Y	Y(INEL)		
Indiana Univ School of Medicine (5-14-90)	T	3	Y	Y	Y	Y	no significant deleterious medical effects expected	
Indiana Univ School of edicine (11-13-92)	T	2	Y	Y	Y	Y		
Jane Phillips Episcopal-Memorial Medical Center (10-29-92)	T	3, 4	Y	Y	Y	N		

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	NOTIFICATION[3] PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
Jersey Shore Hospital (11-3-92)	T	2	Y	N[i]		N		[i]-not in patient's best interest
John F. Kennedy Memorial Hospital (3-16-90)	B	4	Y	Y	Y	Y	Kerato-conjunctivitis (may have been viral-induced)	
Lahey Clinic Foundation (10-14-92)	B	3	Y	Y (not in 24 hrs)	N	N		
Massachusetts General Hospital (7-15-92)	T	2	Y	N[j]		N		[j]-not in patient's best interest
Medical Center of Delaware (8-11-92)	T	2	Y	Y	Y	N		
Medical Center Hospital Vermont (1-31-92)	T	3	Y	Y	Y	N		
Memorial Hospital of Laramie County (10-22-92)	B	2, 4	Y	N[k]		Y (INEL)		[k]-based on medical judgement, telling patient would be harmful
Monogahela Valley Hospital (1-17-90)	B	2	Y	Y	N	Y	No adverse effects expected	

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	NOTIFICATION[3] PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
Muskogee Regional Medical Center (3-12-90)	T	3	Y	N[t]		N		[t]-based on medical judgement, telling patient would be harmful.
Ohio State University (11-13-91)	B	4	Y	Y	Y	N		
Oncology Services Corporation (11-18-92)	B	4	Y	Y	Y	Y	Radiation was a contributing cause of death	
Parkview Memorial Hospital (3-21-90)	B	5 - patient intervention	Y	?		N		
Queen's Medical Center (2-12-92)	B	5-bend in catheter	Y	Y	Y	N		
Radiology-Ultrasound-Nuclear Consultants (2-28-92)	T	3	Y	Y	Y	N		
Riverside Methodist Hospital (8-2-91)	R	3	Y	Y	N	N		
Riverside Regional Medical Center (3-16-90)	T	4	Y	Y	Y	N		

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	NOTIFICATION[3] PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
St. Clares Riverside Medical Center (10-2-92)	B	4	Y	Y	N	Y		
St. Francis Medical Center (4-17-90)	R	3	Y	Y	N	N		
St. John Medical Center (1-13-92)	T	4	Y	Y	Y	Y (INEL)		
St. John's Regional Medical Center (4-11-91)	T	3 5 - wedge factor not used	Y	Y[m]	N	N		- 12 patients [m]-1 patient not notified because of undue patient anxiety
St. John's Medical Center (11-6-92)	T	2	Y	Y	Y	Y (2)[n]	5% risk of radiation neurosis in 4-12 months	[n]-reevaluation by second consultant
St. Joseph's Hospital/Medical Center (10-25-91)	B	2	Y	Y	N	N		
St. Joseph's Hospital/Medical Center (7-16-92)		2	Y	Y	N	N		
St. Joseph's Hospital (9-19-91)	B	2	Y	Y	Y	N		

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
St. Lukes Hospital (5-7-90)	T	3	Y	Y	N	N		
St. Lukes Hospital (6-22-90)	T	3	Y	Y	N	N		
St. Mary's Medical Center (3-19-90)	T	2	Y	Y	Y	Y	Low probability of radiation necrosis of thoracic spine in 6 mos. - 4 yrs.	
St. Vincent Health Center (7-10-90)	R	2	Y	Y	N[o]	N		[o]-physician received written report
Scott AFB, USAF (7-18-91)	R	3	Y	Y	Y	N		
Sharlin Radiology Associates (11-13-92)	T	3	Y	Y	Y	N		
Tripler Army Medical Center (10-16-87)	B	2, 3, 4	Y (10 days late)	N[p]		N		-identified during QA audit on 4/24/91 -unaware of reporting requirements [p]-patient died 2/11/90
University Hosp of Cleveland (5-31-91)	B	5-patient intervention	Y	Y	Y	N		

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	NOTIFICATION[3] PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
University of Cincinnati (8-30-90)	B	5-difficulty with new technology	Y	Y	Y	N		
University of CT Health Center (8-4-92)	T	2	Y	Y	Y	N		
Univ Pittsburgh Presbyterian Hospital (9-14-90)	T	3	Y	Y	Y	N		
Univ Pittsburgh Presbyterian Hospital (11-21-91)	T	3	Y	Y	N	N		
Univ Pittsburgh Presbyterian Hospital (6-26-91)	B	3	Y	Y	N	N		
University of Wisconsin-Madison (2-7-90)	B	3	Y	Y	Y	Y	-no significant medical consequences	
University of Wisconsin-Madison (3-15-90)	B	3	Y	Y	? - patient deceased	Y	-no significant medical consequences	
University of Wisconsin (11-27-91)	B	2	Y	Y	Y	Y	-no significant reaction expected	

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
VA Loma Linda (12-9-90)	R	2 (authorized user)	Y (11/92)	N[q]		N		-OGC determined misadministration - referring physician notifed 11/92 [q]- no adverse effects observed in 5/92
Valley Hospital (6-4-90)	R	2	Y	A - N[r] B - ?		Y	-no adverse effects expected -1 patient had decreased WBC, platelets	-2 patients involved [r]-not notified b/c no adverse effects - no medical benefit to inform
Washington Hospital Center (1-16-90)	T	2	Y	N[s]		N		[s]-physician did not feel appropriate
Washington Hospital Center (2-5-91)	T	2	Y	Y	N	N		
West Virginia Univ. Hospital (5-28-91)	B	2	Y	N[t]		N		[t]-knowledge of lower dose might decrease palliative effect
William Beaumont Hospital (10-10-90)	R	3	Y	Y	Y	Y	-no adverse medical effects expected	
William Beaumont Army Med Center (8-30-91)	R	3	Y	N[u]		N		[u]-based on medical judgement, telling patient would be harmful

FACILITY (DATE)	TYPE[1]	ROOT CAUSE[2]	NOTIFICATION[3] PHYSICIAN	PATIENT	WRITTEN NOTIFICATION	MEDICAL CONSULTANT	CONSULTANT FINDINGS	COMMENTS
Yale New Haven Hospital (12-2-92)	B	2	Y	Y	Y	Y	-no report yet.	
Yale New Haven Hospital (7-5-91)	B	3	Y	N[v]		N		[v]-not in patient's best interest

1. Type of misadministration: T = teletherapy; B = brachytherapy; R = radiopharmaceutical therapy

2. Root cause was attributed to 5 general categories: 1) insufficient supervision; 2) deficient procedures or failure to follow procedures; 3) inattention to detail; 4) inadequate training; and/or 5) other.

3. Y = yes; N = no. In those instances where the licensee provided a reason for not informing the patient, the licensee's reason is indicated under Comments. This does not infer that these reasons meet the criteria in 10 CFR 35.33, i.e., that based on the medical judgment of the referring physician, telling the patient would be harmful.