(18)

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of DIFFERING PROFESSIONAL OPINION -- CINCINNATI HOSPITAL	ASLBP NO. DPO-1, ASLBP No. 90-611-01-SP

STATEMENT OF PETER G. CRANE

FILED: June 11, 1990

Release as bracketed
Ex. 6

June 11, 1990

MEMORANDUM FOR: Judge Margulies
Judge Kline
Judge Foreman

FROM: Peter Crane

SUBJECT: UNIVERSITY OF CINCINNATI CASE

I appreciate the opportunity to present this panel with additional materials and a further statement of my views. While the panel already has my memorandum of March 9, 1990, addressed to Bill Kennedy, of the Office of the Executive Director for Operations, that memo deliberately avoided any mention of the role of the NRC staff in dealing with the incident, so as not to compromise the Inspector General's ongoing investigation of the staff's actions. (Some of the evidence pointing most strongly to misconduct on the part of the staff also indicates most clearly that the hospital misrepresented facts in its submissions to the NRC.) In addressing this panel, however, there is no reason to present anything but the full picture of the case, as it appears to me. Ms. Raspa of the Inspector General's office has confirmed in a telephone call that there is no objection to my furnishing the panel with materials I have previously written about the case, including memos to the Inspector General's office and its predecessor, the Office of Inspector and Auditor. I have therefore included a number of documents that I hope may be helpful to the panel; not all are cited to specifically in this memorandum.

I do not intend in this [illegible] have already had to say about the case [illegible] few points either not [illegible] previously.

NOTE: SEE NEXT PAGE FOR RETYPE OF ILLEGIBLE PORTIONS

1. Ben Hayes' [illegible] that the correctness of [illegible] evidence" to support [illegible] contention, since [illegible] misstated. [illegible] headquarters [illegible] conclusion [illegible] evidence. [illegible] memo, subsequent [illegible] saw fit to correct [illegible] which he continues to stand.

[illegible] should [illegible] just as [illegible] that the [illegible]

(retyping of illegible material on p. 1)

I do not intend in this memorandum to rehash all that I have already had to say about the case, but rather to make a few points either not made, or not sufficiently emphasized, previously.

1. Ben Hayes' memo to the panel of June 5, 1990, suggests that the correctness of the report's conclusion -- "no evidence" to support the allegation -- is not a matter in contention, since OI advised me last year that it was misstated. It is true that one member of the OI headquarters staff told me early in 1989 that the report's conclusion should never have been framed in terms of "no evidence." But as Mr. Pawlik points out in his August 1989 memo, subsequent reviews by OI headquarters never saw fit to correct the report's "no evidence" conclusion, by which he continues to stand.

Moreover, in stating what the report's conclusion should have been, Mr. Hayes' memo misstates the allegation, just as the OI report did. The allegation that I made, and that the Commission asked OI to investigate (enclosure D),

was that the hospital did not know of the patient's contamination as early as their submissions to the NRC claimed (August 28 or 29, 1984), and that it was therefore doubtful that there had ever been a "medical decision" based on the knowledge that a seed was leaking. The allegation that OI Region III ultimately chose to investigate, however, was that a physician "changed his original prescription to cover up the possible misadministration." If one asks the wrong question, it is not surprising that one arrives at the wrong answer.

2. Though OI concluded otherwise, I believe that the interviews conducted by OI contained enough evidence of wrongdoing to meet the low threshold for a referral. But in reviewing the allegation, and OI's resolution of it, the issue is not merely whether the evidence that was gathered substantiated the allegation; the question is also whether OI, with the information in its possession, pursued the investigation appropriately or instead stopped short prematurely. The burden was not on me personally to prove the allegation beyond a reasonable doubt; rather, the burden was on OI to deal in an appropriate way with the information I provided to it.

3. OI seems to have relied almost exclusively on the testimony of [redacted] as to the "medical decision," and to have ignored all the evidence that suggested that that "medical decision" might have been a story concocted after the fact, or at least greatly exaggerated. Yet there was good reason not to accept that testimony uncritically, but instead to look for more information that would either corroborate or refute it. For example:

a. From notes found at the hospital on May 3, 1989, we know that on October 30, 1984, hospital staff (including [redacted] and NRC staff (Axelson, Mullauer, Srenawski) reached an understanding by which the hospital would report its "medical decision" in writing and the NRC would find no misadministration. (See enclosures B and V.) Ex 6

b. We therefore know that [redacted] was lying to the OI investigator when he said that his letter of November 2, 1984, describing the "medical decision," had "nothing to do" with whether a misadministration would be found to have occurred. (See enclosure V.) (We also have grounds to doubt the NRC staff's claim, in its handout of December 15, 1986, that the decision to call the event a non-misadministration was not made until early December, 1984. See enclosure J.)

c. There is further reason to doubt [redacted] credibility, because he claims that "iodine leakage" in his November 2 letter does not refer to leakage in the patient, when it plainly does, because of its reference to the possibility of harm to the thyroid. (Second [redacted] interview, p. 3.)

d. The staff had discussed the case with both [redacted] after learning that there would be an OI investigation, and before OI had interviewed them. We know this from Axelson's interview with OIA and from the EDO's memo of November 28, 1986 to the Commission (enclosure H). OI was well aware of the indications that the staff and the hospital had concocted the original story (see enclosure N); it should have recognized the possibility that the fallback story (of leaking seeds merely "suspected," and a medical decision made on the basis of that suspicion) might also be the product of collusion.

e. There are discrepancies between the testimony of the two doctors. Dr. [redacted] endorses the plain meaning of the letter, saying that at the time it was written, they had ruled out all sources of contamination other than a leak in the patient. But Dr. [redacted] makes no such claim, and goes to pains to say that at the time of the decision described in the letter, all the evidence they had pointed away from the patient. How much evidentiary value does Dr. [redacted] endorsement of the letter have, to the extent it goes beyond what the letter's author says that he meant?

f. We also know that 3M (enclosure C) vigorously disputed the hospital's claim that 3M had admitted that the incident was the fault of the seeds, and could have happened anywhere. 3M says that its records show that hospital personnel were instead advised that reusable seeds should not go on being used at U. of Cincinnati because the hospital lacked adequate facilities and health physics support. Considering that 3M went on marketing the seeds, it is hardly credible that it would have blamed the incident on an inherent flaw in its product, but that need not be resolved here: the point is that the controversy was another reason to be wary of taking the hospital's statements on faith.

Yet OI wrote its investigation report and reached its conclusion <u>without even asking to see the patient's chart or the hospital's records on the incident.</u> It was only after I

raised that point that a return visit to the hospital was scheduled, in May 1989. Though that visit turned up much evidence casting doubt on there having been any "medical decision" during the treatment period, OI Region III insisted that there was no reason to alter the report's conclusions.

4. One of the things learned at the May 1989 visit to the hospital is that the patient's 5-year-old daughter was tested and found to have been irradiated. (The nurses' notes indicate that she visited her mother on the evening of August 31.) The hospital reported -- and the Commission reported to the Congress, in the May 1987 Abnormal Occurrence Report (enclosure L) -- that the patient, her friend, and 60 hospital staff were irradiated. Why was the daughter left off the list? Is that not a subject of regulatory concern, and does that not constitute a material false statement? Are we to assume, without probing further, that the omission of the one person whose exposure was most embarrassing to admit was mere inadvertence?

5. Either the doctors were extraordinarily casual in protecting the patient and others, or they were lying when (with the advance approval of the NRC staff) they reported their "medical decision." Let us suppose for a moment that they did not know, but merely had a strong suspicion, that the seeds were leaking in the patient's head, and decided to let the treatment go on anyway. We must therefore believe that they then chose:

-- not to note this in the patient's chart, which still said "sources intact," a notation made on the day of the negative wipe test, August 29 (enclosure A, p. 3);
-- not to take an immediate urine count to check for radioactivity;
-- not to administer a thyroid blocker;
-- not to ask the thyroid specialist, Dr. [redacted] to examine the patient at the time that he examined the exposed technologists;
-- not to warn the nurses of possible exposure to the patient's daughter, other visitors, or themselves;
-- not to warn the surgeon who was to perform the explant, Dr. [redacted] that the seeds might be leaking; and
-- not to mention the decision in the note on the treatment written by Dr. [redacted] on September 12.

Is that the way in which doctors at U. of Cincinnati Hospital commonly do business? If so, one must tremble for patients, staff, and visitors alike. If not, there is an inference that someone is not telling the truth.

6. I would like to draw special attention to the issue of the patient's child. Anyone who has ever been treated with radioactive iodine knows that patients with free radioiodine

in their systems are cautioned about close physical contact with others, and especially with children, whose thyroids are more radiosensitive. The major risk is from bodily fluids -- saliva, sweat, urine -- and thus one is warned not to kiss one's children or to handle food that others will eat. Although I-125 emits less energy than I-131, from the standpoint of ingestion the risks are similar. Thus is it extremely difficult to credit that doctors who believed the patient to be a potential hazard nevertheless allowed her to have a visit from her daughter (on the evening of August 31, according to the nurses' notes) without so much as uttering a warning about close physical contact. It is one thing to let a terminally ill patient have her thyroid exposed to radiation, on account of the benefits of treatment; it is quite another to let an otherwise healthy five-year-old be exposed.

7. Even if it is determined that the hospital did strongly suspect a leaking seed and nevertheless make a conscious decision to allow the treatment to continue, that is a far cry from what they reported to the NRC in 1984. My allegation of August 1986 was responding to the original story, not the fallback. The fact that it pushed the hospital and the staff into providing revised accounts of the event is in itself grounds for considering the allegation at least partially substantiated.

8. Though it is not directly probative of the issue before this panel, a recent memorandum from the EDO to the Commission sheds some light on how the Radiation Safety Office at the University of Cincinnati Hospital has discharged its responsibilities over the past several years. (Enclosure X.)

9. The Director of Region III OI has been candid, in one of the memoranda provided to the panel by Hugh Thompson, in voicing his irritation that I continue to take issue with OI's report, and I am sure that in his position I would feel the same. It may well appear to some as though I am simply being stubborn in refusing to accept the professional judgment of experienced investigators. Perhaps, therefore, I should conclude by explaining why I continue to press the matter.

First, I want justice for the patient's daughter. She herself was negligently exposed to radiation, and her mother might well have had a malpractice suit against the hospital. The patient was a single mother, living on welfare, and when she died at 26, I can't imagine that she left much money for the upbringing of her then 6-year-old daughter. I cannot in conscience let this matter drop while I see strong evidence that collusion between the hospital and the NRC was responsible for keeping this girl and her guardians ignorant of her possible right to redress. It is a bitter joke at

the expense of a motherless child that two years after the Commission told Congress and announced in the Federal Register that the event was a "therapeutic medical misadministration," Dr. Saenger, the head of the hospital's Radiation Safety Committee (and a longtime consultant to the NRC staff) could object to a question about the 1984 "misadministration" on the grounds that no one at the NRC had ever advised him that the incident constituted a misadministration. (See interview of May 3, 1989.) It is, of course, the finding of a misadministration that triggers the patient notification requirement of the regulation.

Second, I think it is extremely important for the NRC's own integrity and health that this incident be correctly understood and appropriate actions taken. The NRC's business should be to protect the public from being injured through the actions of its licensees, not to protect licensees from having to face the consequences of negligently injuring the public. I realize that the Inspector General has yet to complete its investigation of the staff's role in the case, and may arrive at conclusions about the incident different from OI's. However, I do not think that fact diminishes the importance of assuring that OI's determinations on the matter be sound.

Third, I am keenly aware that between the actions of the NRC staff and those of OI, the investigation was crippled from the start. First, the staff contacted key witnesses in the fall of 1986, after learning that the Commission had directed that there be an investigation. Then the OI regional office, to which the case had been referred by OI headquarters, closed out the investigation without conducting a single interview, for reasons I do not know. (I did not learn of this until 1989.) In mid-1987, after I raised with OI headquarters the unexplained delay of the investigation, it was revived, but on the basis of an incorrectly framed allegation (see the Pawlik to Hayes Request for Investigation of December 22, 1986). The problems with the investigation itself I have already suggested. The result of all the above is that almost four years have passed since the original allegation; the statute of limitations has passed for false statements made in 1984; and even if the case were to be prosecuted on a theory of continuing conspiracy, it would be difficult to prove a case on the basis of events occurring so long ago. As a practical matter, therefore, any wrongdoers in the case have probably escaped justice. But that very fact makes me all the more convinced that even if only for the record, the nature of their actions should be understood correctly.

My view of the case may be wrong, and the allegation may in fact be without substance; but if so, I would like that determination to be made on the basis of an independent

review, not by persons who are in the position of evaluating their own prior actions, or who have anything to gain or lose from any particular outcome. I am confident that this panel will provide that independent review.

LIST OF ENCLOSURES

A. Patient's chart, 8/27/84 through 9/2/84
B. Handwritten notes of [redacted] 10/30/84
C. 3M letter to Heltemes, 2/11/86
D. Memo, Roberts to Hayes, 9/26/86
E. Memo, Hayes to Commissioners, 10/30/86
F. Draft memo, Stello to Zech, undated (c. 11/26/86)
G. Memo, Crane to Malsch, 11/26/86
H. Memo, Stello to Zech, 11/28/86
I. Crane's notes in preparation for NRC staff briefing, 12/15/86
J. NRC staff briefing handout, 12/15/86
K. Crane memo to files, 12/19/86
L. Abnormal Occurrence Report, 52 Fed. Reg. 17855, 5/12/87
M. Memo, Crane to Connelly, 7/6/87
N. Memo, Crane to Walker, 7/29/87
O. Memo, Crane to Logan, 2/5/88
P. Memo, Crane to Logan, 2/19/88
Q. Memo, Crane to Rathbun, 11/7/88
R. Crane notes on OI interviews, undated (c. 11/15/88)
S. Memo, Crane to Connelly, 11/20/88
T. Memo, Crane to Walker, 4/5/89
U. Memo, Crane to Thompson, 8/4/89
V. Memo, Crane to Scinto, 9/28/89
W. Memo, Crane to Williams, 3/10/90
X. Memo, Taylor to Commissioners, 6/4/90
YZ Miscellaneous documents obtained from U. of Cincinnati Medical Center pursuant to OI subpoena, 5/3/89

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University of Cincinnati Hospital

HISTORY, PHYSICAL AND PROGRESS NOTES

ENTER PROBLEM NO. AND TITLE WHEN RECORDING PROBLEM ORIENTED PROGRESS NOTES

W4058

OS-959 CAF
E 191
/FOUNDAS.
1501 KINNEY AVE 45231
000000012863 CINTI. OH

LABS: 143 | 102 | 15
4.6 | 35 | 0.8

ALC: 0.3 H/H 11.5/35.6 PLT 307
39-5 ; 18-5 ; 33 PT/PTT 11.3/0.7

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HISTORY, PHYSICAL AND PROGRESS NOTES

ENTER PROBLEM NO. AND TITLE WHEN RECORDING PROBLEM ORIENTED PROGRESS NOTES

082684 4W405B

676 677

[illegible]-7-2394 10-05-959 CAF
[illegible], JENNIFER E /91
SOUR SAWAYA, R /FOUNCAS.
1501 KINNEY AVE 45231
000000012863 CINTI, OH

[illegible] [illegible] [illegible]
[illegible] Up to [illegible] ... [illegible]
[illegible]
[illegible]
No abnormal [illegible]
[illegible]
[illegible] [redacted]

8-28-84 11-7A -
asleep most of night. Easy to arouse - up to bathroom
ē assist - very unsteady gait - V.S. stable - No c/o pain.
No new drainage at implant site - HOB ↑ 30° [redacted]

8/28 Nsg Note 7-3:30 PM
VSS. Up to BR ē max assist of one, N: C/O pain or dizziness
today. Diet taken adequately for breakfast and poorly for lunch.
Hemovac remains on. [illegible] - alert and oriented. Rt side strong
L arm [illegible]. L leg weak. Pupils = and reactive at 3mm. [redacted]
In good spirits.

8/28/84 1530
S: Pt. queries ē radiation hazard to boyfriend and very pregnant sister. Advised that hazard to these two [illegible] [illegible] no greater than for other persons... no additional Rad. Tx precautions indicated. Otherwise, pt. [illegible] but ē other c/o.
O: T - 98.6 P - 94-100 R - 20 BP - 114-120 / 74-70

Pupils 5+/5+ Ø Nystagmus absent, lateral gaze or pursuit
Motor strength of UE's ↓ (3/5) on Ⓛ } no signif[illegible]
of LE ↓ (2/5) on Ⓛ } from admi[illegible]
Reflexes brisk on Ⓛ upper & lower Ext.
4 beats of ankle clonus elicited on Ⓛ
Pt. c/o ↓ sensation to pinprick, vibration, cold, heat, positi[on]
diffusely over Ⓛ [illegible].
Chest; Lungs clear Heart: RRR
Other systems: WNL.
A/P #1 S/P radionuclide implant pt stable
② Pt neurologically un Δ'ed from initial exam
P ① Pt consult (done) ② [illegible] this day [redacted]

8/28/84 Oncology Staff -

Pt → ~ 5wks post CCNU
+ still ~ 1500 granulocytes. Will
see pt in clinic in 2 wks c plts
for CCNU at 50% dose at that.

[redacted]
Thanks

8-28-84 Nsg Note:
3-11:30 Up to BR x 2 c very unsteady gait. Visitors in. Ate well for dinner & asked for an hs snack. Helped off much of the time as she claims it makes her head hurt. Head dsg c drainage. No % HA.

[redacted]

8-29-84 Nsg Notes
11-7 Slept well thru night. VSS. Afebrile. Denied c/o ambulation to BR x 2. @ w + l extremities weak. Helped put on c encouragement.

[redacted]

8/29/84 Red One.
Sources intact & pt tolerating implant well.
Plan 5 days Clins to be removed Saturday 9/1/84 @ 5pm to deliver 8000R to Tina.

[redacted]

8-29-84 Nsg. Progress Note 7-3 P/N
ISS. Up to bathroom for one final assist of one. C/O a little nausea when up walking @ about 2 PM. Mental status is the same as c/e. Same except R pupil is slightly larger than L. Dr. notified. Pt has been like this before. Appetite is fair. Able to do own ROM exercises c minimal assist. Continues to keep bland in when personnel on room.

[redacted]

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HISTORY, PHYSICAL AND PROGRESS NOTES

ENTER PROBLEM NO. AND TITLE WHEN RECORDING PROBLEM ORIENTED PROGRESS NOTES

8 27 84

676 677

OPERATIVE NOTE

[illegible] JEANNETTE [illegible] 191
[illegible] SUE SAWAYA, R [illegible] ROUBERS, S
501 RIGHLY AVE 45231
[illegible] CINTI, OH

Preoperative Diagnosis Rt. Parietal Glioblastoma

Postoperative Diagnosis Same

Operation Implantation of 2 catheters of I^{125} for local radiotherapy

Surgeons Dr. [redacted] Assist. [redacted]

Findings 2 Catheters in place.

[illegible] Tumor None

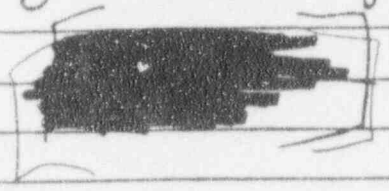
None

[redacted]

9-1-84 Rad Onc

^{125}I seeds removed at 5:15 PM

Survey shows some activity present over pt thyroid (<cal) We will contact her next visit re: obtaining an exact thyroid count.



9-1-84 Staff

Catheters & seeds removed without difficulty

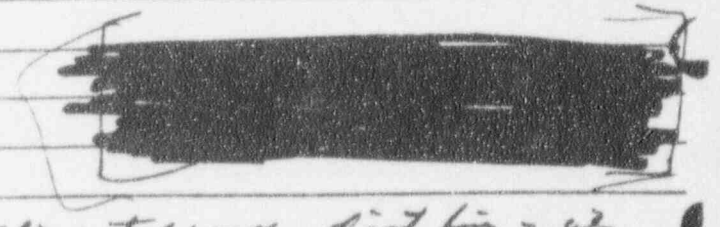
2 stitches placed & covered with dressing

Condition stable

Discharge instruction sheet given

Continue present medication at drug

PO TID



9-7-84 NAME 3-11-20

ISS. husband removed a tube of pt's tooth paste - dirt for - at first brought in by mother - upset at visit - up in al. chair and back by Solarium to watch TV - keeping after family home in A.M. - no complaints

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HISTORY, PHYSICAL AND PROGRESS NOTES

ENTER PROBLEM NO. AND TITLE WHEN RECORDING PROBLEM ORIENTED PROGRESS NOTES

083084 4W405E

676 677

[illegible] 10-09-954 C
HEIG, JENNIFER E /S
ADUR SAWAYA, B /FOUNDAS
1501 KINNEY AVE 45231
OCOOOCO12863 CINTI, OH

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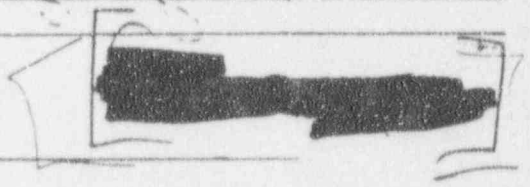
University of Cincinnati Medical Center
Cincinnati General Hospital

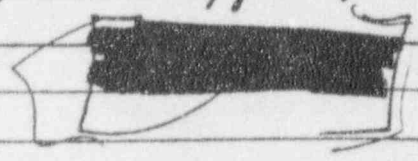
PHYSICAL/OCCUPATIONAL THERAPY PROGRESS NOTES

Heeg, Jennifer
12-?-63



6/1/84 Nursing Notes

9-3PM. Afebrile V.S. stable. Alert, oriented but very sleepy this pm. took both meals well. Up to BR & ambulating on + Guard assist. Needs a great deal of reassurance. Very tearful when walking. Had episode of dizziness while in room today. Pale in color. Assisted to bed. B.P. 130/84 P 100 - P episode of dizziness. Resting quietly. States "she feels better"



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HISTORY, PHYSICAL AND PROGRESS NOTES

ENTER PROBLEM NO. AND TITLE WHEN RECORDING PROBLEM ORIENTED PROGRESS NOTES

083084 4W405B

676 677 1

[redacted]
25577-2394 10-05-959 CAF
MEEG, JENNIFER E /9/
ASUR SAWAYA, R /FOUNCAS.
1501 KINNEY AVE 45231
000000012863 CINTI, OH

8-30-84 Nsg Note:
8-31-84 Up to BR c assist & cane. Very ataxic. Ate fair & had episode of nausea, but no vomiting. Helmet on most of the time. Double vision still pronounced & wearing eye patch. Pupils +7. Hand splint on for part of evening.

[redacted]

8/32/84 S: 0 POD#3
O: VSS dressing dry
pt stable neurologically
A: Stable.
P: Participate toward radionuclides PM Saturday

[redacted]

8-31-84 NPN 11pto7A
VS Stable. Took meds + swallowed easily minimum water. Very slow to awaken per pt's wife. However, LOC normal. PT stated later that slow awakening is normal for her. To BR c much assist by use of 4-pronged cane. Quite ataxic

[redacted]

8/33/84 S: 0
O: VSS afebrile comfortable
dressing intact
pt stable neurologically
A: Pt. stable
P: Remove radionuclides PM Saturday.
Anticipate DC 9/2
will [illegible] Dicodan 5 mg q 6°
with Cardizem 4.1

[redacted]

DD Nrsg Notes

7-1-3 | Pt slept [illegible] rental room, vital signs & med @ 8pm, no complaints voiced @ that time, helmet on per nurse's request. Awake @ noon, ate part of B'fast tray + part of lunch. Up to bathroom x 2 for standby & BR x 1, gait very ataxic, pt uses quad cane but needs constant attendance. Pt alert + oriented, bath per mother then back to bed & sitting up in chair for appx 20 mins. [redacted]

8-31-84 3-11 30/p | Neg note: VSS after. Dozing off + on most of shift. Wears helmet & visitors in room. Daughter up tonight for short period. Up to BR x 1 assist due to ataxic gait even w quad cane. A+O x 3 watched TV tonight had all meds & + call light within reach. [redacted]

9-1-84 | NPN 11p to 7a
Ambulated to BR x 1 assist x 2, ataxic gait, quad cane, BATAXIC, but pt tries hard to ambulate. Swallows meds & water well. Eager to go home in few days. Mental Nsg Focus: d/c planning. Had visit from daughter. Yukon RN vs Stable. [redacted]

9/4/87 | S E
O VSS pt ambulating with walker to BR ~ 7 ft x 2 assist
A: Stable pt.
P: Seen out today / pt ambulating. [redacted]

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HISTORY, PHYSICAL AND PROGRESS NOTES

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676 677 mid

726-3777 Heeg, Jennifer

1100 8/29/89 S: Pt c/o double vision + lightheadedness of N/V. States that has occurred c previous radiation/surgery. No other c/o voiced.
O: T 98, P-96 R-20 BP-114/77

Heeg

pupils 7+/6+
Ø nystagmus
motor strength of UE's 4 (3/5) c Ⓒ
and LE's 4 (2/5) c Ⓓ
Reflexes 3+ with Ⓐ only.
Ankle clonus x 4 beats c Ⓓ
Sensory to light touch intact throughout c Ⓐ & Ⓑ only.
Other PE: WNL.
Ⓐ Ⓑ Ⓒ Ⓓ Ⓔ Hx S/P radionuclide implant stereotactically placed.
Ⓐ 3 weeks from previous exam.
Ⓐ Ⓔ Case as ordered continue.

[redacted]

Lab Addendum
CBC - 6.0, Indices WNL x MCH 32.1(L)
RBC - 3.27
H/H - 10.9/32.3 6.6/15
PLT - 288 11/8

Neurosurg Neuro Oncology service

[redacted]

8-29 Recheck WBC of 6,000 is very surprising and could be an error will repeat

[redacted]

8-84	Nsg Note:
1430	Up to BR x 2 - once in W/C, once c assist + cane. Much more steady when using cane. Emesis x 1 c felt much better afterward. Ate some cheese crackers later. Helmet on + head dsg s drainage. No c/o pain, but feeling weaker + has pronounced double vision. Wearing eye patch to alternating eyes. [redacted]
7-30-84	Nsg Note
1-7#	Ambulate part 2. Supervise remainder of night. Pt to BR x 2 c cane + assist. Good strength & Coordination, went to G. Pupils equal @ 5. VSS. Afebrile. Postural drop dizziness [redacted] Elevation c pupils in room
1130	Physical Therapy. Pt to be seen + tube fed a complete regimen to follow. Ogal Riddle L.P.T.
30.	Staff: CBC Todays WBC = 4.1 [redacted]
8 30	Occupational Therapy Pt was fitted with a Safe position hand splint to be worn as ordered. Pt was instructed in skin inspection and wear + care of splint. She has exercise program, home therapy + later she performs them on her own. Will cont until discharge. [redacted]
	Dd Nrsg Notes
8-30-84	Pt took mid early Am then slept until 11 a/p ate cereal + milk, voided per Commode + rousted c/c. Next urine spec for Radiation Dept. Gait very ataxic needs assist to bathroom. Eye nurse + walker. Remains in bed rest of afternoon, visitors. Refused bath this time. Felt not well while visitors present. Pleasant [redacted] Encouraged to proceed

Rev 8/78

HISTORY, PHYSICAL AND PROGRESS NOTES

ENTER PROBLEM NO. AND TITLE WHEN RECORDING
PROBLEM ORIENTED PROGRESS NOTES

(11)

083084 4X405E

676 677

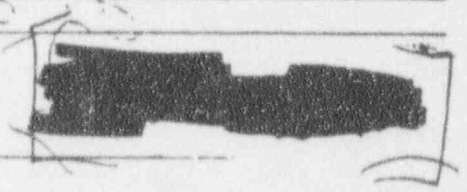
[illegible] 1-239[illegible] 10-09-454 C
REG. JENNIFER E /9
ASUK SAWAYA, R /FOUNDAS
1501 KINNEY AVE 45231
OCCOOCC012863 CINTI, OH

CGH-126
Rev 8/78

University of Cincinnati Medical Center
Cincinnati General Hospital

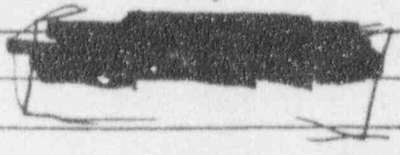
PHYSICAL/OCCUPATIONAL THERAPY PROGRESS NOTES

Reg. Jennifer
12-63



9/1/84 Nursing Notes

9-3PM. Afebrile. V. stable. Sfoebbe. Alert-oriented but very sluggy this am. Took both meds well. Up to BR & assistance of one. Gait good c assistance. Needs a great deal of assistance. Very steady when walking. Had episode of dizziness while on commode. Pale in color. Returned to Bed. B/P 120/80 P 110 - P episode of dizziness. Pt. is very quiet by states "she feels better"



(12)

HISTORY, PHYSICAL AND PROGRESS NOTES

ENTER PROBLEM NO. AND TITLE WHEN RECORDING
PROBLEM ORIENTED PROGRESS NOTES

083084 4W405E

676 677

[illegible] 7-239[illegible] 10-09-959 C
MILLER, JENNIFER E /9
ASUK SAMAYA, R /FOUNDAS
1501 BINNEY AVE 45231
OCC000012863 CINTI, OH

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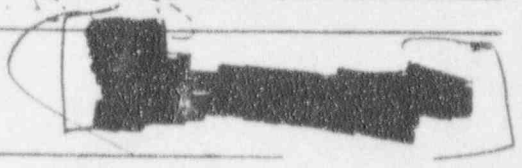
University of Cincinnati Medical Center
Cincinnati General Hospital

PHYSICAL/OCCUPATIONAL THERAPY PROGRESS NOTES

8/30/84

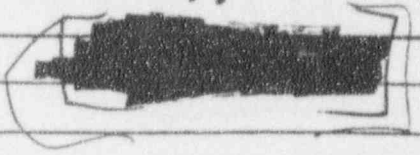
[illegible]

Miller, Jennifer
13-963



9/1/84 Nursing Notes

9-3 PM. Ambulated V. min assist. Steady. Alert, oriented but very sluggish this am. Took both meals well up to BR & assistance of one V general care needs a great deal of encouragement. Very slow when walking. Had episode of dizziness while in commode. Pale in color. Complained to Rn. B/P 120/80 P 110 - P episode of dizziness. Patient finally states "she feels better"



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(13)

HISTORY, PHYSICAL AND PROGRESS NOTES

ENTER PROBLEM NO. AND TITLE WHEN RECORDING PROBLEM ORIENTED PROGRESS NOTES

083084 4 4058

676 677

[illegible] 10-09-45[illegible] C[illegible]
MEEG, JENNIFER E /9
ASUK SAWAYA, R /FOUNTAS
1501 KINNEY AVE 45231
OCCOOCO12863 CINTI, OH

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Rev 8/78

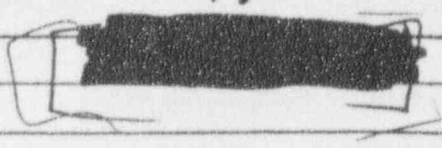
University of Cincinnati Medical Center
Cincinnati General Hospital

PHYSICAL/OCCUPATIONAL THERAPY PROGRESS NOTES

Meeg, Jennifer
13:63

9/1/84 Nursing Notes

9-3 Pm. Ambulated [illegible] Stable. Alert oriented but very sluggish this pm. took both meals well up to BR c assistance of one + Guard cane. Needs a great deal of reassurance. Very slow in when walking. Had episode of dizziness while in room. Pale in color. Assisted to BR. B/P 120/80 P 110 - P episode of dizziness. Resting quietly states "she feels better"



CGH-76
Rev. 6/78

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(14)

HISTORY, PHYSICAL AND PROGRESS NOTES

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PROBLEM ORIENTED PROGRESS NOTES

W4058

05-959 CAI
E 191
MEEG. /FOUNDAS.
NSUP SAWR...
1501 KINNEY AVE 45231
000000012863 CINTI, OH

LABS: 143/102/15
4.6/35/6

WBC 8.3 H/H 11.5/35.6 PLT 317
39-5; 18-5; 33.

PT/PTT 11.3/24

8/27/84 Neg 3-11 30 pm
VSS. Pt'd taken well. Up to bathroom
c assistance. Alert & oriented. IV
infusing well @ arm. NPO @ 24 H.
for CT. [redacted]

UNIVERSITY HOSPITAL RADIOLOGY DEPT.
C. T. SCAN PERFORMED
DATE: 8-27-84
TYPE: CT Head
TECH: [redacted]

8/27/84 Rad Onc.
2 catheters implanted in tumor area in Rt
brain. 5 seeds ~35-38 mCi each in lateral catheter
c 5 mm spacing in between seeds.
3 seeds ~35-38 mCi each in medial catheter
c 7 mm spacing in between seeds.
Pt sent to Room c complications.
Plan ~ 8000R to tumor volume.
Estimate 5 days + 6 hrs.
to be delivered ~ 1 pm Saturday [redacted]

UNIVERSITY HOSPITAL RADIOLOGY DEPT.
C. T. SCAN PERFORMED
DATE: 8-22-84
TYPE: Head
TECH: [redacted]

Axelson
Jan Sullum
Dan Sroczynski

[redacted]

10/30/86

Ex. 1

Promise in writing - no difference in treatment of leakage found earlier (8/29/84) - medical decision made

Items of non-compliance

survey of area - one in store room - high bay.

- April 10, 1984 - Comm. appointment meeting

Toilet paper not to be opened

HP. Journal Sept. 1984

Working on corrective action

I-3

Ex 6

PC's notes in preparation for 12/15/86 briefing

Possible questions:

1. The memo says that the decision not to call it a misadministration was based in part on discussion among regional and headquarters staff. Did that include any lawyers, and if so, what was their judgment?

[Apparently, Tom Dorian was asked at the time and said that it was a misadministration.]

2. If the legal advice was that it was a misadministration, why was that advice disregarded? Whose decision was that?

3. The memo speaks on p. 1 of the "protocol" for cutting open and removing sealed sources, and of the need for the licensee to be "more careful" in handling the sealed sources. But the IE inspection report, at p. 8, indicates that the person who removed the sources from the catheter reported that he had never been told that the sources would be used again. Doesn't that indicate a problem more serious than simply not being careful, if the person performing the protocol has never been told that the purpose of the protocol is to remove the seeds for future use?

1/6

4. If the licensee suspected on August 29 that the implanted seeds were the source of the I-125 contamination, why was the patient not immediately given a thyroid blocker.

such as potassium iodide, which could have kept the thyroid dose to a minimum?

5. If the licensee suspected on August 29 that the implanted seeds were source of the I-125 contamination, why were numerous licensee personnel counted as early as August 30 and August 31, and the patient and the patient's friend not counted until September 5, according to the licensee's Appendix B?

6. Isn't it rather misleading of the licensee to say in its chronology for August 30, 1984, that "The results of thyroid counting on more than sixty (60) hospital personnel and the patient's friend ranged from 0.04 to 209 nCi; there was 557 mCi found in the patient. (See Appendix B).", when the count of the patient did not occur until September 5, 1984?

7. If a urine sample was collected from the patient on August 31 (see IE report at 11), why did it take them until September 5 to count it? It didn't take five days to count other people's urine.

8. The IE inspectors interviewed the technicians responsible for checking the instruments before and after implants and explants. See p. 5 of the IE report. There is nothing in there to suggest that by the time of the explant, the licensee had identified the leaking seed as the source.

or that special precautions were taken with regard to that seed.

9. Dr. [redacted] the radiation oncologist, dictated a note on September 12, 1984, in which he says that the iodine leak was discovered "several days after" the implantation of the seeds (which occurred on August 27), and that "the patient was later checked for radiation exposure and was found to have an estimated dose in the thyroid of 2087 rads." He says that "we" (presumably, the Department of Radiation Oncology) "feel that this dose to the thyroid may cause some hypothyroidism in this patient which can be handled with exogenous thyroid replacement but would not cause harm to her overall condition." If in fact the decision to leave the seeds in had been deliberate, and had occurred on August 29, wouldn't you expect Dr. [redacted] to mention this fact? Dr. [redacted] account seems to point to a very different set of facts, which the staff rejects: namely, that the contamination was discovered several days after the implant and was not traced to the patient until after the seeds were removed. Dr. [redacted] note is Appendix E of the licensee's report.

10. If they had traced the contamination to the patient by August 29, why were the first urinalyses of nurses treating the patient based on urine collected September 7?

11. If they knew on September 1 that the patient was a walking source of radiation, capable of exposing other people with whom she came in contact, why did they let her out of the hospital? The result of doing so was that the patient's friend was also exposed. What cautions were given to the patient's friend?

12. Is the patient still alive? Did anyone at NRC talk to her back in 1984 or more recently to find out what she was told and when? Do we know who her referring physician was?

12. Taking together the time of the urine counts, the absence of a thyroid blocker, the early release from the hospital, and Dr. [redacted] contemporaneous account of the facts, don't they all point to the licensee's not figuring out about the leaking seed and the unintended dose to the patient's thyroid until September 4, and then calling her back to the hospital for testing?