

ORIGINAL
OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: U.S. Nuclear Regulatory Commission

Title: Incident Investigation Team

Docket No.

INTERVIEW OF: Edwin A. Balliet, Jr.

LOCATION: Indiana, Pennsylvania

DATE: Saturday, December 5, 1992

PAGES: 1 - 31

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ADDENDUM/ERRATA SHEET

Page	Line	Correction and Reason for Correction
13	18	Boren spelled incorrectly should be ^{Eds} be spelled Boren.
26	1	him should be her, Dr. Boren is female.

1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION

3
4 OFFICE OF INVESTIGATIONS

5 - - - - -X

6 In the Matter of: :

7 INVESTIGATIVE INTERVIEW :

8 Edwin A. Balliet, Jr. :

9 (CLOSED) :

10 - - - - -X

11
12 Scenery Hill Manor Nursing Home

13 R.D. 5

14 Indiana, Pennsylvania

15 Saturday, December 5, 1992

16
17 The above-entitled matter commenced at 1:00
18 o'clock p.m., when were present:

19 RON LLOYD, Investigator

20 CYNTHIA G. JONES, Section Chief, IMNS

21 PENNY NESSEN, Health Physicist

22 Nuclear Regulatory Commission
23
24
25

P R O C E E D I N G S

[1:00 p.m.]

MS. JONES: It is Saturday, December 5th, at exactly one o'clock. My name is Cynthia Jones, and I am a Section Leader in the Operations Branch, Division of Industrial Medical Nuclear Safety at our headquarters office, which is located in Rockville, Maryland.

What I would like each of you to do is please state your name, spell your last name, and give us your title?

THE INTERVIEWEE: My name is Edwin Balliet, B-a-l-l-i-e-t. I am the Administrator for the nursing facility.

MR. LLOYD: My name is Ron Lloyd with the U.S. Nuclear Regulatory Commission in Bethesda, Maryland. My last name is spelled L-l-o-y-d.

MS. NESSEN: Penny Nessen, the last name is N-e-s-s-e-n. I am a Health Physicist in the Medical Inspection Section for Region I of the NRC.

MS. JONES: As we discussed earlier, the subject incident is being investigated by what we call an Incident Investigation Team or IIT.

These teams are established at the highest level of the Nuclear Regulatory Commission to establish what happened, to identify probable causes of the incident, to

1 provide any appropriate feedback to the industry or licensee
2 regarding any lessons that we learn from the incident.

3 We are here conducting interviews, and taking
4 notes of interviews with a stenographer to ensure that we
5 can have the facts for useful purposes later on so that we
6 can look at a document, an interview, and determine what
7 exactly was said.

8 We are interviewing people with regard to their
9 personal actions and observation of personnel or situations
10 in the area who were directly involved with the event.

11 The transcripts that will be made of our
12 conversation will be available for your review in about 24
13 hours, and Ron has a copy of Exhibit 3.1 which include some
14 information for you, along with the telephone number of our
15 hotel, and room number on the top. Marsha K., when you call
16 that phone number, will be able to tell you if the
17 transcript is ready for you to review. You will get an
18 opportunity to look at it, and to correct any statements
19 that you feel were incorrect or wrong, and you can correct
20 those in about 24 hours.

21 I just recommend that you call first and see if
22 they are available, because we are doing a number at the
23 same time. The corrections, and any clarifications that you
24 make will be included as part of the transcript, just so you
25 know that.

1 The transcripts will be made publicly available in
2 the NRC's Public Document Room, both in our regional office
3 in King of Prussia, and in our headquarters offices in
4 Washington, D.C. They will be issued after the team report,
5 which will be in probably 45 days from now. It takes about
6 that long for us to assimilate all the information and fact
7 finding and put it in the report.

8 What I guess we would like to do is, in your own
9 way and description of events, how you can describe in your
10 own way the events that occurred shortly before the patient
11 was sent over on Monday, November 16th, to the Cancer Center
12 for treatment, what was she like here, and then just go one
13 from there?

14 THE INTERVIEWEE: I have no direct resident
15 contact other than just visiting, so as far as any physical
16 health, she was alert and oriented, she was able to speak to
17 you and talk to you.

18 MS. JONES: Let me back up a second. Tell us what
19 your training and experience is, and your experience and
20 responsibilities here?

21 THE INTERVIEWEE: I am a Licensed Nursing Home
22 Administrator with the State of Pennsylvania. I have a
23 Bachelor's Degree in Health Administration, and I have been
24 the administrator here for approximately 16 months.

25 MS. JONES: And before that?

1 THE INTERVIEWEE: I was an Associate Administrator
2 at another facility. Prior to that, I was the Administrator
3 for Research for the Veterans' Administration.

4 MS. JONES: So how many years of experience do you
5 have in this field?

6 THE INTERVIEWEE: In long-term care?

7 MS. JONES: Yes.

8 THE INTERVIEWEE: Approximately three.

9 MS. JONES: Has there been any retraining that you
10 have taken since obtaining your degree?

11 THE INTERVIEWEE: I do the standard required in-
12 services that the State requires and the Federal government
13 requires for me to keep my license, yes.

14 MS. JONES: Do you provide any training here to
15 personnel in long-term care?

16 THE INTERVIEWEE: Yes, we do. We do in-services
17 here at the facility. We also send our staff out for in-
18 servicing either to Indiana University of Pennsylvania, or
19 to other seminars that they wish to attend.

20 MS. JONES: What kinds of training?

21 Would they be for both nursing staff and the
22 other?

23 THE INTERVIEWEE: Yes. Any of the departments may
24 attend an in-service, if they find one that they wish to
25 attend outside the facility. The in-services within the

1 facility, we have several that are yearly requirements, and
2 others that we do simply to refresh skills.

3 MS. JONES: Could you tell us the background
4 history on the patient that was in question here earlier?

5 THE INTERVIEWEE: The individual patient was
6 admitted here three times in this calendar year, 1992. The
7 original admission was for treatment of radiation burns from
8 previous radiation treatments that she had received.

9 The second admission was due to a possible
10 fractured hip, and the last admission was an admission for
11 treatment and care dealing mainly with her diagnosis which,
12 at this time, had been infection and secondary cancer.

13 MS. JONES: Do you happen to have the dates of
14 those admissions, or records of them?

15 THE INTERVIEWEE: Yes, I do.

16 MS. JONES: We will ask you to supply us with a
17 copy of that information.

18 THE INTERVIEWEE: Okay.

19 MS. JONES: Did you note any -- on the last
20 admission date to this facility, did you note any activity
21 changes in the patient, or did -- I know that you normally
22 don't work with the patient, as you mentioned before, was it
23 brought to your attention?

24 THE INTERVIEWEE: No, it wasn't. If there is any
25 changes, they would be in either the nursing notes or the

1 social servicing activity notes.

2 MS. JONES: What is the number of staff on each
3 shift, and what type of staff are on each shift?

4 THE INTERVIEWEE: On the seven to three shift, we
5 staff an RN, an LPN, and anywhere from four to six nursing
6 assistants. On the three to eleven shift, there is an RN,
7 an LPN, and anywhere from three to four nursing assistants,
8 possibly on some days there would be five. On the eleven --

9 MS. JONES: Excuse me, on Sundays or some days?

10 THE INTERVIEWEE: Possibly on some days, excuse
11 me.

12 MS. JONES: I am sorry.

13 THE INTERVIEWEE: That's okay.

14 On the eleven to seven shift, there is an LPN,
15 from time to time there may be an RN in place of the LPN,
16 and two to three nursing assistants.

17 MS. JONES: What is the total number of people
18 that are employed at the facility?

19 THE INTERVIEWEE: It varies from time to time.
20 Currently, I believe it is 51.

21 MS. JONES: Do you have, besides nurses or nursing
22 assistants, any other type of employees?

23 THE INTERVIEWEE: We have dietary employees,
24 housekeeping employees, maintenance. We have a physical
25 therapy technician, and, of course, social services

1 activities and secretarial support.

2 MS. JONES: What was your contact, if any, with
3 the doctor of the patient here, and also the doctor at the
4 Cancer Treatment Center?

5 THE INTERVIEWEE: The doctor of the patient here
6 is our medical director, so I have contact with her
7 concerning policy issues, individual issues, and simply
8 seeing her. She is in the facility itself.

9 The physician from the Treatment Center I have
10 only spoken to once on the phone briefly.

11 MS. JONES: Do you have or have you had at this
12 facility other patients who were treated with catheters?

13 THE INTERVIEWEE: Not to my knowledge. We have
14 had other individuals here treated with radiation
15 treatments, and we have had other individuals who have had
16 true implants, but, to the best of my knowledge, I am not
17 aware that we had anyone with catheters before.

18 MS. JONES: Do you know if any of the nurses or
19 assistants on your staff have had training with catheters?

20 THE INTERVIEWEE: No. I am not aware if they have
21 or not.

22 MS. JONES: As far as the day to day routine of
23 red bag waste or medical waste is concerned, could you step
24 me through if a patient had medical waste, what happens to
25 it or what the nurses or assistants would consider what they

1 would do with it, would it stay in the patient's room, and
2 so forth?

3 THE INTERVIEWEE: Any item that would be
4 considered biohazardous medical waste in our facility would
5 be placed in a one gallon hazardous waste bag, which is red
6 in color. The bag would be tied and sealed at the top and
7 then carried to a utility room where we have a step can with
8 another biohazardous waste bag in that and the bag would be
9 placed in there.

10 Each day between 3:00 and 3:15 one of our two
11 maintenance men would then take that bag, tie the top, and
12 take it out to an outside entrance to a storage center where
13 it is placed into a biohazardous box which again has a red
14 bag liner in it.

15 When a box becomes filled, the top is sealed with
16 tape and it is dated and our facility name is put on the top
17 of it.

18 MS. JONES: Okay. How often does it get picked
19 up? What happens at that point?

20 THE INTERVIEWEE: The boxes themselves are picked
21 up once per month on a Wednesday by the licenced carrier
22 that we have a contract with to pick it up.

23 MS. JONES: Okay. Of the treatment shipping paper
24 that I made a copy of here and that you had seen, too,
25 yesterday. It was the one that had a difficult date to look

1 at and I'll speak with [Ron Ressler], who is listed on there.
2 We had a question trying to read the date and it was listed
3 the 23rd, which we noted was a Monday rather than a
4 Wednesday.

5 Can you explain or is it just --

6 THE INTERVIEWEE: No, to the best of my knowledge
7 they have always been here on a Wednesday.

8 MS. JONES: Okay, so if we needed to, is it
9 possible if we corrected this you would be able to sign and
10 certify that it was on Wednesday or --

11 THE INTERVIEWEE: I can't certify that it occurred
12 on that Wednesday. I was not here at the time it was picked
13 up.

14 MS. JONES: Okay.

15 THE INTERVIEWEE: But I do know that every time
16 that I am aware that they have been here it has always been
17 on a Wednesday.

18 MS. JONES: Okay. What I'll do is have [Ron] look at
19 that and if he can ensure me that's a Wednesday, then we'll
20 have him sign and state that this was just an incorrect
21 date, they come on a Wednesday, and if he can sign and date
22 that we'll put that into the record.

23 That date, just for people's information, was the
24 day before Thanksgiving, so there was probably a lot of
25 activity going on.

1 THE INTERVIEWEE: I would say it's probably a
2 daily occurrence.

3 MS. JONES: And the children would be any sort of
4 age, babies to --

5 THE INTERVIEWEE: Certainly. We have infants here
6 that come in and visit family members.

7 MS. JONES: In addition to the nurses' notes that
8 you have here, are there any other notes or records from the
9 physician or from other physicians that may have attended
10 the patient in question?

11 THE INTERVIEWEE: The Physicians Orders and the
12 Physician Progress Notes are part of the clinical record
13 here as well.

14 MS. JONES: Okay. We'd like to get a copy of
15 those for the record. Any copies --

16 MR. LLOYD: Question.

17 MS. JONES: Yes.

18 MR. LLOYD: Would this include Dr. Boren or Dr.
19 Bauer or both?

20 THE INTERVIEWEE: It would definitely include Dr.
21 Boren. Dr. Boren was the physician, attending physician
22 here. MR. ORLANDO:

23 MR. LLOYD: Okay, so the notes you are referring
24 to would be those of Dr. Boren?

25 THE INTERVIEWEE: Yes.

1 Did you have anything?

2 MR. LLOYD: No.

3 MS. JONES: After the patient came back from the
4 Cancer Treatment Center on the 16th, she was here for a
5 period of time and received care. Do you have records of
6 the patients that were in rooms adjacent next to her and
7 across the way -- any for that period of time from the 16th
8 through the 21st?

9 THE INTERVIEWEE: Yes, we do.

10 MS. JONES: Okay. We would like to get a copy of
11 the patients that were in the facility at that time.

12 THE INTERVIEWEE: Okay.

13 MS. JONES: I guess in addition to the ones that
14 are adjacent to her, probably a list of the patients that
15 could have been in the area or an estimate of the number of
16 patients who were here would be helpful.

17 THE INTERVIEWEE: Okay.

18 MS. JONES: If you -- I have asked you this
19 question before, but just for the record, do you have any
20 Visitors Logs that are at the facility?

21 THE INTERVIEWEE: No, we do not.

22 MS. JONES: Okay. If you had an idea or could
23 estimate when people visit the most at the facility, when
24 would that be? Is there any peak on certain days, hours?

25 THE INTERVIEWEE: At this facility, no. There

1 seems to be visitors here at any given time between 10:00
2 a.m. and perhaps 7:30 p.m.

3 MS. JONES: So those would be the core hours?

4 THE INTERVIEWEE: Those are the core hours,
5 between there.

6 MS. JONES: Okay. Is there anyone on your staff
7 that would be knowledgeable of visitors or an estimate of
8 visitors that I could ask?

9 THE INTERVIEWEE: I don't believe one of my Staff
10 would be able to give you an estimate of the number that are
11 in on any given day. It depends on again whether it is a
12 holiday or perhaps there are more on a weekend than there
13 would be during the week.

14 MS. JONES: What types of notification, if any,
15 was made to the family after the patient died?

16 THE INTERVIEWEE: It's noted in the nursing notes
17 who was notified and at what time.

18 MS. JONES: Okay. Let's see. Do you know if
19 there is very many children that visit the facility for
20 people, I mean it's their grandparents or --

21 THE INTERVIEWEE: We do have children who visit
22 the facility, yes.

23 MS. JONES: Do you have any estimate or would
24 someone here have an estimate if that is -- would that be
25 considered very rare, infrequent, frequent, or --

1 MS. JONES: Is there -- do you happen to know the
2 names of the relatives that have been notified or will be
3 notified of the deceased?

4 THE INTERVIEWEE: That she became deceased or of
5 this event?

6 MS. JONES: Of this event.

7 THE INTERVIEWEE: No. We were told that was being
8 handled by the Treatment Center.

9 MS. JONES: Okay, so the Treatment Center has
10 indicated they would call the people.

11 THE INTERVIEWEE: Yes.

12 MS. JONES: Did someone tell you that from the
13 Treatment Center?

14 THE INTERVIEWEE: I was told that by the Medical
15 Director.

16 MS. JONES: [Dr. Boren?]

17 THE INTERVIEWEE: Yes.

18 MS. JONES: Okay. If possible, we would like to
19 get a copy of the names of the relatives. I myself don't
20 have that information. We can check with the other people
21 on the team to see if they have that, so that if we need to
22 contact them, we can.

23 THE INTERVIEWEE: Okay.

24 MS. JONES: Do you know if they are in the area?
25 Do they --

1 THE INTERVIEWEE: Yes, they do.

2 MS. JONES: Okay. What was the feeling of the
3 Staff at the nursing home concerning the death of the
4 patient?

5 THE INTERVIEWEE: They felt sad to see her go. As
6 I said, she had been here three times so the patient was
7 known very well by the entire Staff.

8 THE INTERVIEWEE: Okay. Is there anyone else that
9 you think we should talk to or perhaps would have additional
10 information that could help us put together time and motion
11 studies for determining where people are at certain times of
12 the day, routines, that kind of thing?

13 THE INTERVIEWEE: I think you are going to get
14 most of that information off of our scheduling sheets and
15 our nursing assistants flow sheet.

16 MS. JONES: Okay, and if you could just again tell
17 me the scheduling sheets have what types of information on
18 them?

19 THE INTERVIEWEE: The schedule sheet would say who
20 was working that evening or that morning or whichever the
21 shift is for a specific day and also which rooms the
22 individual had to take care of that day.

23 MS. JONES: The Certified Nurses Assistants, as
24 Nurse Joyner told me, are rotated for different patients or
25 either the parts of the wing. Can you explain a little bit

1 more in detail how that works?

2 THE INTERVIEWEE: Sure. We rotate our nursing
3 staff in our building so that the same resident does not
4 have the same nursing assistant each day, so an individual
5 may have a certain number of rooms on the specific wing
6 section tonight but have another set of rooms on another
7 wing section tomorrow night.

8 They would not have the same set of rooms each
9 night.

10 MS. JONES: So would it be fair to say that if a
11 nurse, a Certified Nursing Assistant, had one wing one
12 night, the next -- North Wing, the next night, and then came
13 back to that same wing again the third night?

14 THE INTERVIEWEE: It could be the third night or
15 it may be four or five nights later, depending on the
16 rotating of the shifts.

17 MS. JONES: Okay. Okay, great.

18 How long would it take to go through a full
19 rotation in one shift?

20 THE INTERVIEWEE: Do you mean an individual who
21 would have had this resident how many days would it be until
22 they had them again?

23 MS. JONES: Yes.

24 THE INTERVIEWEE: There is no way of knowing. It
25 depends on requested days off. They may have that person,

1 two days later they may not have that person, if there are
2 three nursing assistants on in the evening for three or four
3 days, or on day shift, they may not see them for a week.

4 MS. JONES: Penny, did you have any questions that
5 you wanted to ask?

6 MS. NESSEN: Actually quite a few. Can I ask
7 questions?

8 MS. JONES: Sure.

9 MS. NESSEN: You are the Administrator of the
10 nursing home, correct?

11 THE INTERVIEWEE: Yes, I am.

12 MS. NESSEN: What are your duties as an
13 administrator?

14 THE INTERVIEWEE: My duties are the overall
15 running of the facility itself to oversee all the serv.
16 that we provide here in the facility, to ensure smooth
17 running from day to day, to give direction to the department
18 heads, and I also personally oversee the admissions.

19 MS. NESSEN: You stated that you have 51 employees
20 currently at the nursing home.

21 THE INTERVIEWEE: Yes.

22 MS. NESSEN: Does this include part-time
23 employees?

24 THE INTERVIEWEE: Yes, it does.

25 MS. NESSEN: And what about people from training

1 programs, maybe from community colleges around here?

2 THE INTERVIEWEE: No, that is not included.

3 MS. NESSEN: How many part-time employees do you
4 have?

5 THE INTERVIEWEE: Approximately five from the top
6 of my head, and we consider part-time anyone under 30 hours
7 per week.

8 MS. NESSEN: Thank you.

9 You said that the maintenance man comes and picks
10 up the bio-hazard waste and takes it outside to the storage
11 room. Is this particular duty assigned to one maintenance
12 man, and if he is off that day you have to try to rearrange
13 the schedule?

14 THE INTERVIEWEE: No, it is not. We have two
15 full-time maintenance men here, and no one is specifically
16 assigned to it on any given day.

17 MS. NESSEN: Would there be an occasion when both
18 of those individuals would be off for a day?

19 THE INTERVIEWEE: No, we have a maintenance man
20 here seven days a week.

21 MS. NESSEN: Your waste hauler that picks up the
22 bio-hazard waste, how do they gain access to that outside
23 storage?

24 THE INTERVIEWEE: The maintenance gentleman that
25 is on that day opens the door for them.

1 MS. NESSEN: And the maintenance man has a key to
2 all of the rooms around here?

3 THE INTERVIEWEE: Yes.

4 MS. NESSEN: We had discussed before what the
5 walls between the patients rooms and between the outside
6 storage area for the bio-hazard waste and the recreation
7 room were made of. If you could describe first the walls
8 between the patient rooms for me?

9 THE INTERVIEWEE: The walls between the patient
10 rooms is our standard wood and stud wall with three-quarter-
11 inch drywall on each side, and quarter-inch wood panelling
12 on top of that.

13 MS. NESSEN: And now the --

14 THE INTERVIEWEE: The wall between the storage
15 room for the waste and the activities room is a cinderblock
16 wall.

17 MS. NESSEN: There is a lounge that is located
18 adjacent to the soiled utility room, do you have an idea of
19 how often that is used, or how long someone may stay in that
20 area?

21 THE INTERVIEWEE: The lounge is used everyday. It
22 is used by visitors, it is used by residents. The average
23 person in the lounge may be there an hour. If a resident is
24 sitting there reading a book, she may be there for an hour-
25 and-a-half to two hours. To the best of my knowledge, no

1 one would be in there longer than two hours.

2 MS. NESSEN: Would any of your employees use that
3 area as an office space to work?

4 THE INTERVIEWEE: It would not be used as an
5 office space, but some of the staff may complete their notes
6 in there at the end of shift, which would be approximately
7 20 minutes.

8 MS. NESSEN: And the recreation room is located
9 adjacent to the outside storage room?

10 THE INTERVIEWEE: Yes.

11 MS. NESSEN: I notice that there was a desk in
12 that room, is that used for --

13 THE INTERVIEWEE: That is the activity director's
14 desk.

15 MS. NESSEN: How long are they at that position in
16 the day?

17 THE INTERVIEWEE: She would be at the desk
18 approximately two to two-and-a-half hours a day.

19 MS. NESSEN: If you could just explain what that
20 room was used for, the recreation room?

21 THE INTERVIEWEE: The recreation room is a multi-
22 purpose room. All of our resident activities are in there.
23 We have musical groups who come in and play music for us.
24 We have movies that we show on the VCR. They have a card
25 club in there, and crafts, aerobics, those types of things.

1 MS. NESSEN: Next to the soiled utility room,
2 there is bathing room?

3 THE INTERVIEWEE: Yes.

4 MS. NESSEN: How long would an individual, one of
5 your residents or one of the nurses, how long would they
6 spend in that room?

7 THE INTERVIEWEE: A resident would not be in the
8 room for more than approximately 20 minutes, probably less
9 than five to disrobe and be lowered into the tub, less than
10 ten minutes in the tub, and another five to be brought out,
11 dried and dressed before she left the room.

12 The staff members would be in there with her at
13 that time, then they would escort that individual back to
14 their room, and perhaps one of those two nursing assistants
15 would go back in with the second resident, but a separate
16 nursing assistant would also be in there at that time. So
17 they do rotate through the tub room as well.

18 MS. NESSEN: The nurses rotate?

19 THE INTERVIEWEE: The nursing assistants, yes.

20 MS. NESSEN: And who are the staff members, who
21 would that include?

22 THE INTERVIEWEE: The nursing assistants, anyone
23 who would be on the day shift, or the three to eleven shift.

24 MS. NESSEN: Okay.

25 MS. JONES: For the recreation room schedule, you

1 indicated that there are activities that are done probably
2 throughout a daily basis, is it possible to get a list of
3 activities that were performed on the dates of November 16
4 through the 21st?

5 THE INTERVIEWEE: Yes, I can give you a calendar
6 and it shows the activities that were there.

7 MS. JONES: And in regards to the room that
8 contains -- in the interim here, that would have the red bag
9 waste, is there a possibility that that could have filled up
10 earlier in the day, or do you have maybe more than one bag
11 throughout the day rather than waiting until 3:15 to 3:30?

12 THE INTERVIEWEE: If the bag would have been full,
13 nursing staff would have told the maintenance director, or
14 the maintenance assistant, and they would have taken the bag
15 out and placed a new bag in.

16 MS. JONES: Is there a possibility that maybe the
17 nursing staff, if they couldn't reach the maintenance man,
18 would have taken the bag out themselves, do they have a key?

19 THE INTERVIEWEE: No. They would not have taken
20 it out themselves.

21 MS. JONES: Can we take a brief recess for a
22 second?

23 [Brief recess at 1:25 p.m.]

24 MS. JONES: Let's go back on the record.

25 When were you first aware or heard about the

1 situation with the patient and the fact that there was a
2 source that was in the patient for a period of time while
3 that patient was here?

4 THE INTERVIEWEE: When we were first aware that
5 the source was in the patient?

6 MS. JONES: And how did you find that information
7 out?

8 THE INTERVIEWEE: We found that information out
9 on -- I believe it would have been Thursday morning, because
10 we were not aware that the source had been found in the
11 catheter until then. We had been aware of the situation,
12 but we were not aware that the source had been found in the
13 catheter.

14 MS. JONES: So last Thursday morning, so December
15 3rd?

16 THE INTERVIEWEE: Yes.

17 MR. LLOYD: How did you find that out?

18 THE INTERVIEWEE: We were told when the NRC team
19 arrived here.

20 MS. JONES: Did anyone contact you from the Cancer
21 Treatment Center, to your knowledge, before that?

22 THE INTERVIEWEE: We had talked to them two days
23 prior to that concerning the information from BFI, but they
24 had not told us where the source had been found, no.

25 MS. JONES: Do you know who BFI talked to at this

1 facility when they called up?

2 THE INTERVIEWEE: Yes.

3 MS. JONES: And who was that?

4 THE INTERVIEWEE: [Sara Ferguson,] she is an RN.

5 MS. JONES: Have you talked with [Sara] to

6 understand what was in the conversation with BFI?

7 THE INTERVIEWEE: Yes. BFI told her that one of
8 our boxes had shown to be radioactive at the treatment
9 facility, and had told her that they would call me back
10 later that morning. I was not in in the morning when they
11 called.

12 MS. JONES: And did they call you back?

13 THE INTERVIEWEE: No, they did not.

14 MS. JONES: Did you have a phone number where you
15 could reach them?

16 THE INTERVIEWEE: Yes, I did.

17 MS. JONES: Did you contact them?

18 THE INTERVIEWEE: No, I did not. I contacted the
19 Cancer Treatment Center.

20 MS. JONES: And what was the reason for contacting
21 the Cancer Treatment Center?

22 THE INTERVIEWEE: I was trying to determine why
23 our garbage would have shown radioactivity.

24 MS. JONES: At that point, was there any other
25 patients here who would have gone through radiation

1 treatment?

2 THE INTERVIEWEE: Not at the present time, no.

3 MS. JONES: What happened at that point?

4 THE INTERVIEWEE: I did not get to make the phone
5 call to the Cancer Treatment Center. I was on another line,
6 and I had my Director of Nursing contact them. She spoke to
7 an individual named [Pat] who assured her that it was
8 impossible for our waste to have been radioactive from a
9 resident that we had had here.

10 MS. JONES: Do you know what happened after that?

11 THE INTERVIEWEE: From our standpoint, we then
12 telephoned our electric company to see if it might have been
13 some sort of magnetism that might have set off their alarm,
14 since the boxes are near our electrical system. They
15 assured me that it was impossible from their standpoint, and
16 I then was waiting for BFI to call me back.

17 That same day, at approximately five to twelve,
18 the Cancer Treatment Center called and asked for me, and
19 asked for the name and telephone number of our waste hauler,
20 which I then gave them.

21 MS. JONES: And do you know what happened after
22 that?

23 THE INTERVIEWEE: What happened after that is
24 Wednesday morning. This had all occurred on Tuesday. On
25 Wednesday morning, I telephoned the Medical Director and

1 told him that I had not heard anything yet.

2 MS. JONES: The Medical Director, Dr. Boren?

3 THE INTERVIEWEE: Of our facility, yes, Dr. Boren.

4 That I had not heard anything yet, but that there had seemed
5 to have been a problem with our medical waste, and it was
6 shortly after that that we were told that there had been a
7 problem.

8 MS. JONES: Then what happened after that?

9 THE INTERVIEWEE: What happened after that is, our
10 Medical Director was contacted by Dr. Flynn, and we, at that
11 point, set up for blood testing to be done on our staff on
12 Thursday.

13 MS. JONES: Do you remember how many staff had
14 blood samples?

15 THE INTERVIEWEE: The original numbers were
16 approximately 43, but I do not know from Dr. Flynn how many
17 samples he actually had drawn.

18 MS. JONES: And did you have blood samples taken?

19 THE INTERVIEWEE: Yes, I did.

20 MS. JONES: What direction or information was
21 given to your staff regarding why the blood samples were
22 taken, and who did that?

23 THE INTERVIEWEE: Myself and the Director of
24 Nursing explained to our staff that there was a possibility
25 of one of our residents having been exposed to a high level

1 of radiation and, as a precaution, and to prove to the staff
2 for piece of mind that everything was fine here, that we
3 were going to be done blood testing. That they would be
4 able to see the results, and discuss them with our Medical
5 Director, and the independent oncologist, and that they
6 would be more than welcome to show them to their physician.

7 MS. JONES: So the blood samples were taken on
8 Thursday, and that would be December 3rd.

9 And have you received your results back, and have
10 your staff?

11 THE INTERVIEWEE: Yes, we did. The results were
12 faxed to us on that evening, approximately 9:00 p.m., and
13 all of the staff members had been notified that Dr. Flynn
14 had reviewed them and had stated that all of the results
15 were within normal ranges.

16 MS. JONES: Do you know if [Dr. Boren] has also
17 reviewed those results?

18 THE INTERVIEWEE: [Dr. Boren] was notified by Dr.
19 Flynn, but I am not aware if she has actually seen the
20 results or not.

21 MS. JONES: Can you think --

22 THE INTERVIEWEE: Also on that Thursday is when
23 the building itself was tested with the counters, and we
24 were told at that point that we were not registering any
25 radiation.

1 MS. JONES: That was done by?

2 THE INTERVIEWEE: The Department of Environmental
3 Resources.

4 MS. JONES: Is that of Pennsylvania.

5 THE INTERVIEWEE: Yes.

6 MS. JONES: Do you have any questions?

7 MR. LLOYD: Yes, I have a couple of questions.
8 Have you known Dr. Bauer in the past?

9 THE INTERVIEWEE: No, I do not.

10 MR. LLOYD: So when was the first time that you
11 had any contact or knew of his presence?

12 THE INTERVIEWEE: I have heard of his name before
13 through the Treatment Center, but I have never personally
14 met him.

15 MR. LLOYD: Has he ever been in this facility at
16 all, whether you were here or not here?

17 THE INTERVIEWEE: He may have been to our facility
18 at some point, but I am not aware of him being here in the
19 year and four months that I have been here.

20 MR. LLOYD: Has he requested the nurses' record,
21 the attending physician's records, and so on of the patient?

22 THE INTERVIEWEE: We have not had a formal request
23 for the records, no.

24 MR. LLOYD: Has the Nursing Home had any
25 complaints filed against it since you have been here, or

1 that you know of?

2 THE INTERVIEWEE: I am not sure if I understand
3 what you mean by complaints.

4 MR. LLOYD: People complaining about the service
5 given to the residents?

6 THE INTERVIEWEE: We have had one complaint, which
7 stemmed from an incident approximately a year-and-a-half ago
8 to a year-and-three-quarters ago which was investigated as
9 part of a standard survey by the Department of Health in
10 January of '92, and we were told at that time that there was
11 nothing to substantiate those findings, and that dealt with
12 the resident who was sent to a hospital, and the hospital
13 was not aware if it was a correct discharge or not.

14 MR. LLOYD: Anything else?

15 MS. JONES: In your opinion, is it usual or
16 unusual to receive instructions from doctors, or outside
17 doctors, in this case, for patients that are in care at this
18 facility?

19 THE INTERVIEWEE: Well, we do not have physicians
20 that are employees of our facility. All of our physicians
21 are the individual residents' primary physician, so all of
22 the orders that come through here would be from the outside
23 physician.

24 MS. JONES: We mentioned earlier that the catheter
25 use at this facility was unusual, that you hadn't had any --

1 THE INTERVIEWEE: To the best of my knowledge.

2 MS. JONES: -- to the best of your knowledge,
3 here. Do you know if there were instructions from the
4 doctor to your nursing staff about catheter use?

5 THE INTERVIEWEE: To my knowledge, I am not aware
6 if there was or not, but it would be listed in the nursing
7 notes.

8 MS. JONES: You mentioned before, earlier to me,
9 yesterday, when we were walking around, that the facility is
10 undergoing construction, or will undergo some construction.
11 Do you think there has been anyone at the facility who is a
12 construction worker, and electrician, an outside person who
13 would not work at the facility and enter the facility and
14 walk around?

15 THE INTERVIEWEE: No, I don't. The individuals
16 who -- all the renovations we are doing are cosmetic. The
17 individuals who had started them did not arrive here until
18 after the 21st.

19 MS. JONES: Okay.

20 THE INTERVIEWEE: I am not sure of the exact date,
21 but they actually started Thanksgiving morning.

22 MS. JONES: Do you have any questions for us?

23 THE INTERVIEWEE: No.

24 MS. JONES: Do you have anything else?

25 MS. NESSEN: No.

1 MS. JONES: Ron?

2 MR. LLOYD: No.

3 MS. JONES: I think concludes the interview. It
4 is now 1:40.

5 [Whereupon, at 1:40 p.m., the interview was
6 concluded.]

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REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

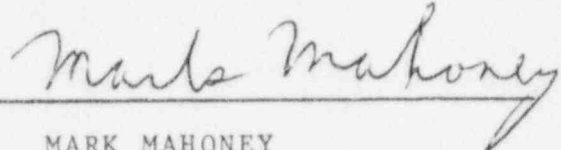
in the matter of: Incident Investigation Team

NAME OF PROCEEDING: Int. of: Edwin A. Balliet, Jr.

DOCKET NUMBER:

PLACE OF PROCEEDING: Indiana, Penn.

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Official Reporter
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OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: U.S. Nuclear Regulatory Commission

Title: Incident Investigation Team

Docket No.

INTERVIEW OF: IIT MEDIA BRIEFING
With Dr. CARL PAPERIELLO
And Dr. DANIEL F. FLYNN

LOCATION: Indiana, Pennsylvania

DATE: Friday, December 4, 1992

PAGES: 1 - 14

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1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION

3
4 OFFICE OF INVESTIGATIONS

5 - - - - -X

6 In the Matter of: :

7 IIT MEDIA BRIEFING :

8 With Dr. Carl Paperiello and :

9 Dr. Daniel F. Flynn :

10 - - - - -X

11
12 Best Western University Inn

13 1545 Wayne Avenue

14 Indiana, Pennsylvania 15701

15 Friday, December 4, 1992
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P R O C E E D I N G S

MR. ABRAHAM: I am Carl Abraham, the NRC Region I Public Affairs Officer. Region I covers the whole Northeast United States.

You all have a sheet of paper with the proper names and proper titles. Dr. Paperiello is going to be the first speaker, he is a Ph.D. Health Physicist, and his colleague is a physician, a doctor.

Dr. Paperiello, would you please start?

DR. PAPERIELLO: I am Carl Paperiello. I am the Deputy Regional Administrator for the NRC Region III Office which is outside of Chicago, which is my normal position. I am currently the Team Leader for this NRC Incident Investigation Team.

The IIT is a formal process conducted by the NRC for the purpose of accident prevention. This includes the gathering and analysis of information, a determination of findings and conclusions including the determination of probable causes of events concerning significant matters of operation. We disseminate the information to the NRC, to the industry and to the public.

The incident that we are investigating is the apparent failure of a device for placing a fairly intense radiation source into a tumor for cancer treatment. The source did not retract back into the device after treatment,

1 instead the tip of the wire containing the source, that is
2 approximately one-half inch long in length, remained in the
3 patient. This was not identified by the clinic, and the
4 patient was returned to the nursing home where she resided.
5 This occurred on November 16th.

6 On November 20th, the source in a catheter was
7 discharged by the patient. It was placed in a bio-hazards
8 waste container, and treated as a bio-hazard. Eventually,
9 it was detected at an incinerator for biological waste in
10 Warren, Ohio, and sent back to Carnegie, Pennsylvania.

11 The source was retrieved by the medical physicist
12 for the clinic, and the NRC was notified of this around
13 December 1.

14 In response to the event, the NRC, as I said, has
15 initiated an incident investigation team. The team includes
16 radiation specialists, engineers, administrative support
17 from the regions and headquarters, a medical consultant, and
18 engineers and other support people from the Idaho National
19 Engineering Laboratory.

20 IITs are initiated by the highest level of NRC
21 management. In this case, it was initiated due to the
22 complexity of the event and the possibility of significant
23 public involvement with a radiation source. There are also
24 generic issues, high dose rate, remote afterloaders for
25 Brachytherapy are a relatively new treatment mode.

1 The process that we will engage in is, we will
2 determine the time sequence of events, we will attempt to
3 determine what actually happened, and why it happened. Our
4 goal is to determine the cause of the source failure,
5 determine if it is generic, determine why the failure was
6 not detected, and determine the radiological exposure.

7 This IIT is somewhat different from others in that
8 inspection efforts by Region I and the consultants were
9 already underway when the preliminary results raised the
10 level of this event within the NRC Q&IIT.

11 Our investigations have only begun, but we do have
12 some significant initial findings based on a review of the
13 medical data, and I am going to introduce our medical
14 consultant, Dr. Flynn, who is a radiation oncologist, to
15 discuss what these results appear to be.

16 Dr. Flynn.

17 DR. FLYNN: My name is Dr. Daniel Flynn. I am a
18 radiation oncologist.

19 I was asked by the NRC to serve as an independent
20 consultant to review the medical records, and render my own
21 opinion as to the effects of the radiation event on the
22 patient.

23 The patient was an elderly woman with recurrent
24 cancer of the pelvis which was not curable. My review of
25 the medical records indicates that everyone involved in her

1 care was concerned to help her. She received two prior
2 courses of radiation which, on review of the records at that
3 time, did definitely benefit her.

4 On November 16th, an incident occurred at a cancer
5 facility which resulted in a much higher dosage than
6 intended. I was asked to review the medical records before
7 and after that treatment to the time of her death on
8 November 21st.

9 Much of her records are at the nursing home, where
10 I spent most of my time. The care provided at the nursing
11 home was excellent. The recordkeeping was detailed, and
12 very helpful to me. There is nothing that could have been
13 done at the nursing home to change the outcome.

14 A radiation source intended to stay in place for
15 minutes stayed in place for many hours. In retrospect, the
16 symptoms and the timing of the symptoms was consistent with
17 a severe acute radiation syndrome.

18 In my opinion, the radiation event that occurred
19 outside the nursing home was a probable contributing cause
20 to the death of the patient.

21 That is the end of my patient.

22 QUESTION: Doctor, was there an autopsy done?

23 DR. FLYNN: No.

24 QUESTION: How do we know how she died?

25 DR. FLYNN: I said probable contributing cause to

1 the death of the patient. An autopsy would make a very
2 definitive finding, in my opinion.

3 QUESTION: She was buried?

4 DR. FLYNN: Yes.

5 QUESTION: [Inaudible.]

6 DR. FLYNN: I can't comment on that. I am not a
7 licensed physician in Pennsylvania.

8 QUESTION: What kind of effects of radiation would
9 we find in the people who were exposed to her, and the
10 person who took out the catheter?

11 DR. FLYNN: I questioned, at the nursing home,
12 everyone involved in her care. I questioned the Medical
13 Director. I questioned the Head of Nursing. There was no
14 one at the nursing home, either working there or patients,
15 who exhibited any side effects attributable to radiation.

16 I asked the Medical Director, on my advice, to get
17 blood counts on everyone who worked there as precautionary
18 to reassure them to alleviate the anxiety, which is the
19 primary thing I was looking for, and that was done.

20 The blood results are back on everyone who works
21 there. They are all normal. All results are normal.

22 QUESTION: [Inaudible.]

23 DR. FLYNN: I can comment only on the acute
24 effects of radiation, and the fact that the blood counts
25 that were done on everyone there was normal, and the doses

1 that I would expect would be calculated in terms of what
2 doses these individuals received would be exceedingly low.

3 But I would reserve that comment to the NRC Staff
4 who will reenact the time/motion studies and determine the
5 dosimetry on everybody involved. I am certainly, in my own
6 opinion, very confident that no one at the nursing home was
7 harmed in any way.

8 QUESTION: Could anybody else elsewhere be harmed?

9 DR. FLYNN: I have no knowledge of the events
10 outside the nursing home. I directed my study to the
11 medical records of the patient before, during and after
12 treatment.

13 QUESTION: What is the half-life for Iridium-192,
14 how long is it radioactive?

15 DR. FLYNN: Approximately 74 days is the half-
16 life.

17 QUESTION: Doctor, we had a tape run out on us,
18 could you repeat what your findings were in the last part of
19 your prepared statement?

20 DR. FLYNN: There was nothing that could have been
21 done at the nursing home between November 16th and November
22 21st that could have changed the outcome.

23 In my opinion, the radiation event that occurred
24 outside the nursing home was a probable contributing cause
25 to the death of the patient.

1 QUESTION: How were you even able to trace the
2 catheter to this particular woman?

3 DR. PAPERIELLO: The catheter was discharged from
4 the woman's body, placed in a bio-hazards bag, and then
5 placed in the storage area next to the nursing home. After
6 the woman died, the three remaining catheters were removed,
7 wrapped in a separate gauze and put into the same bag.

8 The material, and I don't have all the timing on
9 this, and this is part of our study to review the movement
10 and the exact dates and times of movements, the material was
11 picked up by a bio-hazards waste disposal company. When it
12 got to the incinerator, the company has radiation monitors
13 at the incinerator, they received an alarm. They knew where
14 the bag came from.

15 The medical physicist from the clinic retrieved
16 the bag and found one catheter with the source in it in the
17 bag, and the other three catheters were wrapped in the
18 gauze. That is my understanding, they were wrapped. They
19 were just separate, and they did not have the source in
20 them. The waste hauler knew where the bag was picked up,
21 and that is how it was identified.

22 QUESTION: [Inaudible.]

23 DR. FLYNN: I can comment on the effects as a
24 radiation oncologist in practice, this is a very valuable
25 form of treatment that has helped many, many patients, and

1 it will continue to be used to help many patients.

2 As far as any policy decisions, or any regulatory
3 guides that might be given to the users to cope with a rare
4 event that was not expected by those of us who treat
5 patients, I will let the NRC make those determinations.

6 But, certainly, this is a very valuable form of
7 treatment. We have one million individuals a year in the
8 United States who get cancer. Approximately 50 percent,
9 500,000 get radiation each year as part of their treatment
10 for their cancer. Many patients, not all, are cured. There
11 is no magic cure for cancer. There are several million
12 Americans walking around right now with no evidence of
13 cancer who were treated with radiation.

14 This is a new form of treatment which is going to
15 be very valuable for treating other patients who have very
16 difficult tumors to treat, tumors that are recurrent, tumors
17 that can be implanted locally to give them comfort and care
18 even if they have incurable disease. The treatment was
19 totally appropriate in terms of the planning, and this is a
20 very valuable form of treatment.

21 QUESTION: If the company knew, then they are
22 obviously going to have to make some changes in the way that
23 they do things?

24 DR. FLYNN: I am sorry, I am not an engineer, and
25 I can only comment on the medical treatment and what I

1 anticipate will happen in the future.

2 QUESTION: Dr. Paperiello, can I ask you to
3 follow-up on that?

4 DR. PAPERIELLO: Yes.

5 QUESTION: Do you think it is possible for
6 somebody other than at the nursing home could have been
7 affected by the radiation?

8 DR. PAPERIELLO: The major portion of my
9 activities here will be to assess the exposures to people
10 who could have come in contact with the source, and I have
11 radiation specialists with me to assist me in that
12 particular task.

13 This is very preliminary, but I think the best
14 estimates are, the people who probably had the greatest
15 contact with the source in terms of time and distance would
16 be people at the nursing home. I cannot preclude that
17 somebody else may not have come closer to the source, but I
18 don't believe it.

19 The nursing home probably has the greatest
20 exposure to date, but I don't know. That is very
21 preliminary, and that is what we are now in the process of
22 determining.

23 QUESTION: The people at the Cancer Treatment
24 Center, the officials there, what has been their level of
25 cooperation?

1 DR. PAPERIELLO: Everybody that we have dealt with
2 has been very cooperative.

3 QUESTION: [Inaudible.]

4 DR. PAPERIELLO: This, to my knowledge, is the
5 first event of this type that I am aware of with this
6 particular device, but we have a lot of licensees who use a
7 number of devices for radiation therapy, and there have been
8 failures before.

9 I was partially involved in an event several years
10 ago in which a mechanical failure of a cobalt unit caused
11 the death of a patient, not the radiation, but the
12 mechanical failure.

13 As Dr. Flynn noted, radiation therapy is a very
14 valuable and useful way of treating cancer. It is the NRC's
15 job to ensure that the rules that we have in place allow
16 this to be done safely. A purpose of this investigation is
17 to determine if we have to change some of our rules. Is
18 there something in our rules that, if it were different,
19 would have precluded this from happening, and that is goal
20 of this. From a safety viewpoint, that is what the goal of
21 this investigation is.

22 The event happened, and I can't change that. For
23 the purpose of a public record, I have to determine
24 precisely what happened, and then recommend to the
25 Commission, and I will personally have to brief the five

1 Commissioners on recommendations to preclude this from
2 happening in the future.

3 QUESTION: You will not be placing blame then as a
4 result of your investigation?

5 DR. PAPERIELLO: The purpose of my investigation
6 is not to assess blame. If there are violations of NRC
7 requirements that resulted in this event, that matter will
8 be referred to Region I, and they will then have to take
9 action on that, I don't.

10 But the goal of this investigation is safety, and
11 to understand what happened. It is not a compliance
12 inspection.

13 QUESTION: Meanwhile, what about the use of this
14 particular device?

15 DR. PAPERIELLO: We have an agreement with both
16 the manufacturer of this device, who is right now testing
17 it, as well as the Institute that this particular device
18 will not be used until we know why it failed.

19 QUESTION: Can you give us the name of the
20 manufacturer?

21 DR. PAPERIELLO: It is Omnitron.

22 QUESTION: Would you be able to spell that?

23 DR. PAPERIELLO: Could somebody on my staff spell
24 that?

25 NRC STAFF MEMBER: O-m-n-i-t-r-o-n.

1 QUESTION: Doctor, I understand the radioactivity
2 of this particular element is about 3.7 Curies?

3 DR. PAPERIELLO: It was reported to me to be 3.7,
4 but I think that may have been at the time it was found, and
5 I believe it was 4.2 on the day of the treatment.

6 QUESTION: Can you give us an idea in layman's
7 terms or compare it to something that would be --

8 DR. PAPERIELLO: I don't know if this helps you
9 out, it is equivalent to about four grams of radium. I
10 would say that any source in excess of a Curie is a large
11 source for something that is relatively small.

12 I know what you need. The radiation dose at one
13 yard from this source is approximately two rem per hour.
14 The allowable dose to a member of the general population in
15 a year is one-half of a rem. So in 15 minutes, at one yard,
16 you could get the exposure limit for a member of the public
17 under our regulations.

18 Now this does not mean there is an acute effect.
19 These are limits that we have put for everybody in the
20 country for year-in and year-out. The threshold for acute
21 effects is somewhere on the order of about 100 to 150 rems,
22 and that depends upon the dose rate. The faster the dose,
23 the lower the level before you will get any kind of physical
24 detectable effect, but that is for comparison.

25 It is a source that always has to be shielded.

1 Are there any other questions?

2 QUESTION: The reason the patient was not
3 identified, is that at the request of the family?

4 DR. PAPERIELLO: It is the normal policy of the
5 NRC that we don't reveal the identity of individuals who
6 have been exposed to radiation, period, and our report will
7 not identify anybody by name.

8 MR. ABRAHAM: There is a good probability, when
9 the team completes its field work, which right now looks to
10 be sometime next week, that we will try to arrange a
11 briefing which will allow Dr. Flynn and Dr. Paperiello to
12 give you some of the preliminary findings of the team, and
13 we will put out an advisory on that as we have this one.

14 If there is somebody here who didn't get our
15 advisory in the form of a fax, please give me a fax number
16 and I will see that you get on the list to make sure you get
17 the next one.

18 Thank you very much for coming.

19 [Whereupon, the media briefing was concluded.]

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