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OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: U.S. Nuclear Regulatory Commission
Office of Investigations

Title: Investigative Interview of:
Anthony J. Bradshaw
(Closed)

Docket No.

LOCATION: Houston, Texas

DATE: Thursday, December 17, 1992

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF INVESTIGATIONS

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In the Matter of: :

INVESTIGATIVE INTERVIEW :

Anthony J. Bradshaw :

(CLOSED) :

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Omnitron International, Inc.
8990 Kirby, Suite 200
Houston, Texas 77054

Thursday, December 17, 1992

The above-entitled matter commenced at 2:35
o'clock p.m., when were present:

RON LLOYD, Investigator

THOMAS W. RICH, Mechanical Engineer, IMNS

Nuclear Regulatory Commission

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1 Also Present:

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REBECCA D. FULLER, Investigator

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MARIELLE P. ARCE, Investigator

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U.S. Food and Drug Administration

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JAMES KNAUSS, Director, Product Assurance

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Omnitron International, Inc.

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P R O C E E D I N G S

[2:25 p.m.]

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3 MR. LLOYD: My name is Ron Lloyd. I'm the Section
4 Chief in the Incident Investigation Program, U.S. Nuclear
5 Regulatory Commission. This is an incident investigation.
6 The purpose is to look into the event that occurred in
7 Indiana, Pennsylvania, concerning the loss of the source.

8 So, we're here in Houston to interview as many
9 people that had any knowledge of the Omnitron 2000 in their
10 particular positions and get as many facts as we can.

11 As we go through and one of us asks questions, if
12 you could answer to the best of your ability and to your
13 direct knowledge. If you're not sure of something, just
14 indicate that you're not sure, that's somebody else's
15 responsibility.

16 The reason we're transcribing these is to get the
17 facts as closely to what you say as possible rather than us
18 relying on notes and going back to the office and writing a
19 report. You will have an opportunity within a short period
20 of time to request a copy of your transcript, to take a look
21 at it and see what was asked of you and how you responded.

22 If you have any questions concerning what you had
23 to say, you can make corrections by way of an errata sheet.
24 At the close of this day of interviews, we will drop off a
25 name and address that you can write to, if you care to get a

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1 copy of your transcripts.

2 Initially we would like to introduce those that
3 are listening in, at least, if everyone could state their
4 name and position and where they're from. We'll start with
5 you.

6 MR. BRADSHAW: Tony Bradshaw, Vice President,
7 Product Development, for Omnitron.

8 MR. LLOYD: Okay.

9 MR. RICH: Tom Rich, U.S. Nuclear Regulatory
10 Commission, with the Sealed Source Safety Section.

11 MR. KNAUSS: James Knauss, Director of Product
12 Assurance, Omnitron.

13 MS. ARCE: Marielle Arce, Investigator, Food and
14 Drug Administration.

15 MS. FULLER: Rebecca D. Fuller, Investigator, U.S.
16 Food and Drug Administration.

17 MR. LLOYD: Okay. We have Wanda, who is our
18 stenographer.

19 THE REPORTER: Wanda Gross.

20 MR. LLOYD: Initially if you could tell us how
21 long you have been with Omnitron and what your
22 responsibilities are here.

23 THE INTERVIEWEE: I think my start date was August
24 of '91. My responsibilities are Product Development,
25 including the -- and applicators and worked on the wire

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1 development --- mechanically oriented -- three-
2 dimensionally-oriented design.

3 MR. LLOYD: Where were you before you came to
4 Omnitron?

5 THE INTERVIEWEE: Georgia Tech.

6 MR. LLOYD: Georgia Tech.

7 THE INTERVIEWEE: Uh-uh.

8 MR. LLOYD: Who is your immediate supervisor here?

9 THE INTERVIEWEE: Richard Calfee.

10 MR. LLOYD: Richard Calfee.

11 What is your educational background?

12 THE INTERVIEWEE: Industrial design, B.S.

13 MR. LLOYD: From Georgia Tech?

14 THE INTERVIEWEE: Uh-huh.

15 MR. LLOYD: What's the span of your
16 responsibilities here? Do you have people that work for
17 you? Or are you by yourself?

18 THE INTERVIEWEE: Yes, uh-huh.

19 MR. LLOYD: How many individuals do you supervise?

20 THE INTERVIEWEE: Currently one full-time person
21 and a consultant.

22 MR. LLOYD: How long have they been here?

23 THE INTERVIEWEE: The consultant has been here, I
24 guess, since probably January, or December of '91 --
25 December '91, January '92, somewhere through there. The

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1 other person, the full-time person, has been here for about
2 three months.

3 MR. LLOYD: What's the background of the
4 consultant?

5 THE INTERVIEWEE: He's a Ph.D., Mechanical
6 Engineer, graduate and undergraduate.

7 MR. LLOYD: What's your background with the after
8 loader itself? Have you had any other experience with
9 similar-type devices?

10 THE INTERVIEWEE: No.

11 MR. LLOYD: How did you get the job then?

12 THE INTERVIEWEE: Russ Chambers called my boss at
13 Georgia Tech and asked if he could recommend somebody to do
14 some consulting, design consulting, so he referred me. So I
15 entered into a consulting agreement with Omnitron at that
16 time, to do consulting work, prototype development.

17 MR. LLOYD: Then they turned you into a full-time
18 employee?

19 THE INTERVIEWEE: Right.

20 MR. LLOYD: What's your duties and
21 responsibilities outside of this immediate Houston Office.
22 Do you perform regular conversations or trips to various
23 clinics or hospitals that have the Omnitron 2000?

24 THE INTERVIEWEE: I do, I guess, a fair amount of
25 visiting over at Methodist. They have different kinds of

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1 applications that come up. I work on, you know, new
2 applications for the device as well. I've been to some
3 other sites, but that's not on a regular basis.

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MR. LLOYD: We have a series of questions, like we mentioned here when we first started, if you could answer them as accurately as possibly. We'll just kind of go through those. You're free to ask questions of us.

THE INTERVIEWEE: Okay.

MR. LLOYD: If you think you need to clarify any questions, go ahead.

MR. RICH: Okay. Can explain to us why the machine is limited to 250 cycles?

THE INTERVIEWEE: That was the original spec from, I think, in 1988 -- submission. It was part of the

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1 application.

2 MR. RICH: What was his name?

3 THE INTERVIEWEE: Darrell Hodgson.

4 MR. RICH: Where is he from?

5 THE INTERVIEWEE: California, southern California
6 -- Sunnyvale.

7 MR. RICH: Okay. Did Omnitron, or anybody
8 representing Omnitron, do an audit of this vendor and that
9 material?

10 THE INTERVIEWEE: No, not that I know of.

11 MR. RICH: Did you supply the vendor with any
12 specifications that you wanted built to, like an ASME code
13 or your our specific specifications?

14 THE INTERVIEWEE: No, he recommended some alloys.
15 That's what we did development testing with, as far as the
16 process. You know, that's what we wanted specified.

17 MR. RICH: Okay. The alloys he recommended, did
18 anybody test analysis of those alloys?

19 THE INTERVIEWEE: No.

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13 THE INTERVIEWEE: Yes, I watched production.

14 MR. RICH: Are you aware of any nickel titanium or
15 stainless steel wires that have cracked, bent, or broken
16 that were manufactured by Omnitron or for Omnitron, besides
17 these two recent wire cables?

18 THE INTERVIEWEE: No.

19 MR. RICH: What about for prototype wires? Have
20 any prototyped wires failed?

21 THE INTERVIEWEE: Yeah, we tested a lot of them
22 for failure.

23 MR. RICH: Do you have documented results on that?

24 THE INTERVIEWEE: I've got, yeah, some notes in my
25 notebook on the various tests.

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1 THE INTERVIEWEE: No.

2 MR. RICH: Did you do them in-house or outside?

3 THE INTERVIEWEE: In-house.

4 MR. RICH: What equipment did you use here to do
5 those tests?

6 THE INTERVIEWEE: The microscope. It's a
7 production room in there.

8 MR. RICH: What magnification does that go to?

9 THE INTERVIEWEE: I believe it's 38.

10 MR. RICH: Thirty-eight?

11 THE INTERVIEWEE: Uh-huh.

12 MR. RICH: You talked about doing cycling tests on
13 nickel titanium wire. What equipment was used for that?
14 Did you actually use an afterloader or did you have a
15 separate device?

16 THE INTERVIEWEE: An afterloading.

17 MR. RICH: Okay. You said it was roughly 3,500
18 cycles; is what you said?

19 THE INTERVIEWEE: I don't know --

20 MR. RICH: Did you ever test a wire to failure?

21 THE INTERVIEWEE: Yes.

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9 THE INTERVIEWEE: Uh-huh.

10 MR. LLOYD: -- where was that failure on the wire?

11 THE INTERVIEWEE: The bottom of the hole.

12 MR. LLOYD: The same place as the failure on the
13 two units at Pennsylvania?

14 THE INTERVIEWEE: Right. I haven't seen the one
15 from Pittsburgh. Was it --

16 MR. LLOYD: It was at the bottom of the hole.

17 THE INTERVIEWEE: -- at the bottom of the hole?

18 MR. RICH: You mentioned that you discussions with
19 the vendor when choosing this wire. Who was present from
20 Omnitron during those discussions?

21 THE INTERVIEWEE: Nobody.

22 MR. RICH: You just had them over the phone?

23 THE INTERVIEWEE: Uh-huh.

24 MR. RICH: It was a conference call or just
25 yourself?

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1 THE INTERVIEWEE: Just myself.

2 MR. RICH: Who approves the final use of this
3 wire? Was it done solely by you? Did the President have
4 something to say about the quality?

5 THE INTERVIEWEE: The President.

6 MR. RICH: Who designed the construction of the
7 wire, the depth of the whole, the diameter to use?

8 THE INTERVIEWEE: I guess that's a combination of
9 myself and Sam Liprie and John Edison.

10 MR. RICH: Okay. Was such a small cavity wall
11 chosen?

12 THE INTERVIEWEE: The goal was to be within a
13 certain gauge of the diameter and then the size of the
14 iridium dictated the inner-bore. So, the OD was dictated by
15 the gauge of the needle that we wanted to go into. The ID
16 was dictated by the iridium diameter.

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1 THE INTERVIEWEE: To get the roundness better than
2 we were able to -- the raw scale wire. The raw wire is an
3 oxide and scaling iron from manufacturing.

4 MR. RICH: Is that inspected after it's ground?

5 THE INTERVIEWEE: Yes.

6 MR. RICH: How is that inspected?

7 THE INTERVIEWEE: Microscopically.

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THE INTERVIEWEE: No.

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1 MR. RICH: Are there operating procedures either
2 by the vendor or specified by you for the EDM operation
3 itself?

4 THE INTERVIEWEE: Of -- ask it again?

5 MR. RICH: Are there operating procedures, either
6 the vendor has them, or specified by Omnitron, for the EDM
7 operation itself?

8 THE INTERVIEWEE: The process?

9 MR. RICH: The process.

10 THE INTERVIEWEE: He has he own.

11 MR. RICH: Has he given you a copy of those
12 procedures, or has he allowed you to review those
13 procedures?

14 THE INTERVIEWEE: I've seen them visually.

15 MR. RICH: Okay.

16 THE INTERVIEWEE: Or I've witnessed them.

17 MR. RICH: Can you describe what they are, from
18 what you remember?

19 THE INTERVIEWEE: It's quite a lengthy process,
20 the stage that you go through. I can get my notes if you
21 want to --

22 MR. RICH: Okay. We can get those later, then.

23 For each of the machines that had a source wire
24 failure, what were the number of cycles; do you know?

25 THE INTERVIEWEE: No.

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1 MR. LLOYD: Are you going to get that information?
2 Are you working on that?

3 THE INTERVIEWEE: On that?

4 MR. LLOYD: Yes. The last --

5 THE INTERVIEWEE: Personally I'm not. I mean, I
6 saw the --

7 MR. LLOYD: The last individual that we talked to
8 mentioned that in-between, you know, the source
9 replacements, you could do it anywhere from five cycles to
10 245 cycles.

11 THE INTERVIEWEE: What's that?

12 MR. LLOYD: Each time the source wire is changed,
13 on a quarterly basis, there's a counter that indicates how
14 many cycles the active wires have.

15 THE INTERVIEWEE: Uh-huh.

16 MR. LLOYD: You mentioned that that could be
17 anywhere from five cycles to 245 cycles.

18 THE INTERVIEWEE: 245. I don't follow what you're
19 saying. There is a limitation of the counter on there,
20 right. The counter -- there's a print-out we can get. We
21 know how many it's been through. But I don't know what they
22 are.

23 MR. LLOYD: This is what he was stating. So, I
24 was wondering --

25 THE INTERVIEWEE: Well, Indiana, you know, I was

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1 the wire would withstand?

2 THE INTERVIEWEE: Uh-uh. No, we don't know those
3 numbers.

4 MR. RICH: Okay. Has anybody examined the wire
5 after the final test to Sam Liprie's lab? I know he has his
6 calibration. He does a wipe test and he does a cycling
7 test. Has anybody examined the wire after that final test?

8 THE INTERVIEWEE: I think there's a wipe done at
9 installation, but I'm not familiar with the exact details of
10 the wire installer's process other than the wipe they take
11 and install. That's all I know.

12 MR. RICH: I'm sorry. I guess you misunderstood.
13 When the wire goes from the Houston facility to the
14 Louisiana facility, Sam finishes the manufacturing. He puts
15 the iridium wire into the nickel titanium wire. He welds
16 the plug in place. He goes ahead and sends it to be
17 calibrated to the afterloader. Then it sends it back to be
18 wipe tested. Then he sends it through a critical bend
19 radius.

20 Has anybody looked or inspected that wire after
21 it's gone through that last critical bend radius?

22 THE INTERVIEWEE: I think the wipe test is the
23 inspection at that point.

24 MR. RICH: But there is no physical examination of
25 the wire?

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1 MR. RICH: What were you looking for?
2 THE INTERVIEWEE: Clamp pressure.
3 MR. RICH: How did you determine the clamp
4 pressure?
5 THE INTERVIEWEE: How did I determine it?
6 MR. RICH: Yes.
7 THE INTERVIEWEE: What it is?
8 MR. RICH: How did you specify the pressure?
9 Then, how did you measure that pressure?
10 THE INTERVIEWEE: Well, we took the pressure
11 coming from the airlines and broke it down to what our
12 service area was -- the factor friction.
13 MR. RICH: Okay. Do you have calculations showing
14 that?
15 THE INTERVIEWEE: No, I didn't do it personally.
16 MR. RICH: Okay.
17 THE INTERVIEWEE: It was just there.
18 MR. RICH: Do you have those pressures documented
19 anywhere -- the standard operating pressures that lab should
20 be using?
21 THE INTERVIEWEE: No, I don't. John might. I
22 don't know.
23 MR. RICH: Were they provided to the lab for them
24 to use?
25 THE INTERVIEWEE: I don't know that either.

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1 MR. RICH: Is this documented?

2 THE INTERVIEWEE: No.

3 MR. RICH: Have you looked at one after it's been
4 through the 250 cycles?

5 THE INTERVIEWEE: No.

6 MR. RICH: What damage could be caused to the
7 source wire from the dry rollers or the optical sensors?

8 THE INTERVIEWEE: The optical sensors being the
9 encoder?

10 MR. RICH: The encoder.

11 THE INTERVIEWEE: Well, there's frictional wear
12 from being driven. I don't really classify that as damaged,
13 though.

14 MR. LLOYD: There's no way that those components
15 could dent or nick or bend any portion of the wire to create
16 any kind of a stress concentration factor?

17 THE INTERVIEWEE: No, I don't think so. You have
18 a urethane roller pinching against the steel. So, it's not
19 really like a scissor action at all.

20 MR. LLOYD: How much of the wire do those rollers
21 contact of your 80 or 90 centimeters, or however long the
22 wire might be?

23 THE INTERVIEWEE: Well, the extension is 150
24 centimeters. It takes two different dimensions to get from
25 the proper position outside the machine. So, 20, 30 --

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1 probably 180 centimeters. The wire is 2201 millimeters.
2 They have no contacts at the tips. It's never close to the
3 source. No active sides.

4 MR. LLOYD: Thank you.

5 MR. RICH: Has Omnitron personnel ever examined
6 the catheters in the connection sections of the catheters
7 for wear and done cycling testing on those as well as the
8 source wire?

9 THE INTERVIEWEE: On the quick connects? Which
10 part of the catheters are you referring to?

11 MR. RICH: The needle to the connecting catheter.
12 There's a connection made there. There's also a connection
13 made at the -- assembly. Has anybody checked that process
14 and cycle tested that process?

15 THE INTERVIEWEE: Not as a specific test. We've
16 never noticed during running cycle tests that there was any
17 undue wear at those points.

18 MR. RICH: The actual individual catheters were
19 not checked for wear or the connectors were not checked for
20 wear?

21 THE INTERVIEWEE: No, not formally.

22 MR. RICH: Do you know what the pushing force or
23 the stress that is generated at the stepping mode is at the
24 tip of the wire?

25 THE INTERVIEWEE: At the tip? Well, that's where

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1 we take the force readings. It's nominally about a pound
2 and a half.

3 MR. RICH: Is that what's actually applied to the
4 tip or is that what the gauge reads?

5 THE INTERVIEWEE: That's what the gauge reads.

6 MR. RICH: Has anybody converted that for the
7 actual pressure on the tip of this wire itself?

8 THE INTERVIEWEE: No.

9 MR. RICH: That was a pound and a half?

10 THE INTERVIEWEE: Uh-huh.

11 MR. RICH: What about for the emergency retract
12 motor? What is the retracting force?

13 THE INTERVIEWEE: I think it's typically around
14 2.2, 2.3 pounds. I would have to look at the spec to see.
15 I don't recall specifically.

16 MR. RICH: Do you know what speed the wire travels
17 out and what speed the wire travels in under these emergency
18 conditions?

19 THE INTERVIEWEE: No.

20 MR. RICH: During normal use, how fast does it
21 travel out?

22 THE INTERVIEWEE: I think its 13 centimeters a
23 second.

24 MR. RICH: Okay. During emergency retraction, do
25 you know?

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1 THE INTERVIEWEE: No. But John Edison assisted us
2 for that test. I think he has experience and expertise in
3 that.

4 MR. RICH: Do you know if he is NEE qualified?

5 THE INTERVIEWEE: I don't know.

6 MR. RICH: Do you know what the performance
7 history of all the afterloaders, as a group, is? I mean, do
8 you know how many failures you have per unit or how many
9 failures you have of a certain part, or what your weakness
10 link is in the afterloader?

11 THE INTERVIEWEE: No, I don't.

12 MR. RICH: So there's been no trend analysis done
13 by your engineering group?

14 THE INTERVIEWEE: No.

15 MR. RICH: Going through some of the ECOs that
16 were provided, we saw a reference to a 50/50 blend.
17 However, in looking at the specifications for wire, we never
18 see a 50/50. Can you explain the difference?

19 THE INTERVIEWEE: Yeah, the sample that he sent.
20 He was telling me in general terms at that point that it was
21 50/50. Then later I asked for, you know, specific. We
22 decided after prototyping that wire, that it was what we
23 wanted. I told him I wanted specific specifications on it.
24 So, that's when he provided what you've seen. It has a more
25 detailed breakdown of the blend.

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1 MR. RICH: Okay. You mentioned early on in this
2 interview that you changed manufacture to, I think, SMA.
3 You said it was to improve the turning radius and
4 durability. Do you have a spec sheet for that company? Do
5 they provide you with a specification sheet or a
6 certification?

7 THE INTERVIEWEE: Okay. What SMA --

8 MR. RICH: You said you changed the manufacturing
9 company.

10 THE INTERVIEWEE: The --

11 MR. LLOYD: The supplier.

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15 MR. RICH: They're the ones that drill the hole.
16 Who supplies the raw material?

17 THE INTERVIEWEE: SMA.

18 MR. RICH: Okay, SMA. We received the
19 certification from a Japanese firm. That's what your
20 material is certified to. Can you explain --

21 THE INTERVIEWEE: He handles that material. SMA
22 is --

23 MR. RICH: But he is not your supplier?

24 THE INTERVIEWEE: Yeah, he's the supplier.

25 MR. RICH: But he goes to a Japanese firm. get

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1 the wire used for the afterload besides this one?

2 THE INTERVIEWEE: No.

3 MR. RICH: One of the engineering change orders
4 says, "To clarify and redefine wire specifications." Why
5 were the specifications changed?

6 THE INTERVIEWEE: It's like I was telling you. He
7 gave me a general specification. When we first got the
8 samples, we did development work with. Then when we went to
9 production we had to clarify or actually give them more
10 specification in detail.

11 MR. RICH: Okay. I guess that brings another
12 question in mind. On that same engineering change order,
13 the turnaround time was effective immediately. If it was
14 just a change of a typo, why would that be immediately?

15 THE INTERVIEWEE: Because that material was, in
16 fact, what we had. If you change the spec sheet --

17 MR. RICH: You had no other specifications except
18 the one sheet from Japan, basically, I think, it was 56
19 percent nickel and 40-some percent titanium.

20 THE INTERVIEWEE: Right. That's the alloy we've
21 used.

22 MR. RICH: That's the only alloy you've used
23 besides the stainless steel. Okay.

24 I don't have any more questions.

25 MR. LLOYD: Are you involved in the investigation

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1 to determine the root cause of failure?

2 THE INTERVIEWEE: Yes.

3 MR. LLOYD: Who is helping you?

4 THE INTERVIEWEE: Dr. Simnad, our consultant.

5 Then here, Ken Beuche and Dr. Calfee, Steve Warrenburg.

6 MR. LLOYD: When do you anticipate finishing that
7 report?

8 THE INTERVIEWEE: I don't know for sure. We're
9 getting -- part of this is getting back to Herman to see
10 what he's learned since I last saw him two days ago. We're
11 still looking for different pieces of information. He has a
12 second wire. We have no -- I haven't had chance to view or
13 get any details on the second wire at all, thus far.

14 MR. RICH: Why has Omnitron not chosen to go down
15 there and observe the tests being done at Southwest with the
16 second wire?

17 THE INTERVIEWEE: Because we had to come here and
18 talk to you guys. I got back from California yesterday
19 afternoon from that investigation. We heard I was wanted to
20 be interviewed.

21 MR. RICH: Okay. I didn't know if they had sent
22 some representative down or not because Herman got back
23 Wednesday, is my understanding.

24 THE INTERVIEWEE: Right. He left and I stayed for
25 the test on the dummy wire from the metallography and came

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1 back when that was finished.

2 MR. RICH: In your opinion, were the breaks
3 similar in geometry between the dummy wire and the wire you
4 did examine in San Diego?

5 THE INTERVIEWEE: Geometry? I don't know.

6 MR. RICH: The same type of surface structure, the
7 same type of failure, rear ductal? It looks like it could
8 have been very easily caused by the same process.

9 THE INTERVIEWEE: Yes. That's also listening to
10 the experts, though, you know, their opinions. I mean, when
11 you have got the experts there --

12 MR. RICH: That was their opinion as well?

13 THE INTERVIEWEE: Yeah, they were similarly
14 caused, but there was -- they weren't identical. So that's
15 what -- one of the samples I Fed-Ex'd to Herman was the
16 mouth to the dummy wire we examined so he could take a look
17 at it.

18 MR. RICH: Do you feel that the other wires in the
19 field could fail the same way?

20 THE INTERVIEWEE: I don't know until we identify
21 specifically the root cause.

22 MR. RICH: Okay.

23 MR. LLOYD: What's your best guess as to the
24 cause to date?

25 THE INTERVIEWEE: Well, to date, it looks like it

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1 probably would be a high-load stress on a hard edge, such as
2 the -- coupling or the quick-connect caused by the patient
3 moving the catheter or her moving.

4 MR. LLOYD: Because of the way the hole, the size,
5 the dimensions, the design? You're always going to have a
6 patient moving?

7 THE INTERVIEWEE: No, I'm talking about drastic
8 movement. You know -- that's what we're testing here with
9 these wires that we're looking at today and what it takes to
10 damage one, you know, that the quick -- if you pull the
11 catheter straight down under pressure, which is a natural
12 clinical position, but, you know, I guess anything is
13 possible. That's what we're looking for today, in that
14 situation.

15 MR. LLOYD: There's no suspected gross movement on
16 the part of the Indiana individual, but the breaks are the
17 same.

18 THE INTERVIEWEE: Well, it could be the flexing
19 needle. The obstruction was right at the point where the
20 tip of the wire would be 13 millimeters beyond the base of
21 the hub, which again, is a hard point.

22 There could be some movement because when the
23 afterloader checked that channel with a dummy wire, it went
24 in and out with no problem at all. It treated all four
25 channels. Then there was a obstruction, well, a

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1 constriction, which wasn't there when the dummy checked it.

2 Was anybody monitoring the patient actively at
3 that time with a room monitor?

4 MR. LLOYD: Supposedly.

5 THE INTERVIEWEE: That is where I get -- that
6 assumption is based on the fact that the dummy wire made it
7 in the prior path check. I understand that the physicist or
8 someone at Pittsburgh saw the patient hit the catheter.

9 MR. LLOYD: That's correct.

10 THE INTERVIEWEE: The degree of hitting it is what
11 I've had first-hand information -- how hard did she hit it
12 or it is videotaped or what did he say? I mean, those kind
13 of details --

14 MR. LLOYD: I'm not sure about that. I think the
15 only information we have on that is basically what was put
16 in the preliminary notification which indicated that the
17 individual sneezed or coughed and moved the hand and
18 happened to hit the catheter.

19 THE INTERVIEWEE: What was that?

20 MR. LLOYD: I think sneezed. It was through the
21 nose and down the throat.

22 THE INTERVIEWEE: Uh-huh, right. What was her
23 motion?

24 MR. LLOYD: With the hand, moved it up. Whether
25 or not it hit the catheter or did something to it, I guess

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1 that's still to be determined.

2 THE INTERVIEWEE: I thought -- we were told by the
3 physicist or through somebody that when he walked through
4 the room, the catheter was bent down at a sharp angle and
5 had a kink in it, which is hard to do from doing this.

6 MR. LLOYD: Right.

7 THE INTERVIEWEE: It's a very kink-resistant
8 catheter. So, we're looking now at the hard edges of the
9 back side of the quick-connect, the possibility of that hub
10 in that position. It's very strange that a -- that the
11 construction in Indiana was exactly at the point where that
12 13 millimeter was at that hub.

13 So you have two opportunities for hard edges.
14 Now, you would require motion there. Now, the metallography
15 we've seen so far shows no evidence of any kind of
16 corrosion, external. There is some microscopic interior --
17 what they think might be some corrosion. But there feeling
18 was when I saw Herman -- the other night it was probably not
19 causal. But Herman was going to do some stress analysis
20 test because the scale of it was so small.

21 So, you've got two situations where the transition
22 point could be at the hard edge of a mechanical part. But
23 then it would take patient movement in both cases. From
24 what we're seeing today in trying to break some models, you
25 know, to actually try to reproduce it in force here, it

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1 would take some fairly drastic patient movement, which is
2 possible.

3 MR. LLOYD: Do you intend to test them to failure,
4 do any tinsel tests or moment bending tests on them, other
5 that what you have been doing, just going through catheters?

6 THE INTERVIEWEE: Yeah, we can do that and see
7 where we're getting. But, you know, I'm not, at this point,
8 concerned about what that might yield, based on what we've
9 seen today in these situation tests.

10 MR. LLOYD: Has there been any indication that the
11 drilled holes have not been concentric?

12 THE INTERVIEWEE: Well, yeah, they're -- we know
13 some of them are not concentric. You know, we inspect them
14 by wall size.

15 MR. LLOYD: How do you inspect the wall size?

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THE INTERVIEWEE: Uh-huh.

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1 Or do they just keep them in Atlanta?

2 THE INTERVIEWEE: Well, if there is a gross
3 failure, they guy at the x-ray, you know, just tell the
4 driller, "This is not worth inspecting," so we never see
5 those. Otherwise, they get sent here with the videotape.

6 MR. LLOYD: Who does the x-ray?

7 THE INTERVIEWEE:

8 MR. LLOYD: That's in Atlanta?

9 THE INTERVIEWEE: Uh-huh.

10 MR. LLOYD: What's the accuracy of the x-ray?

11 THE INTERVIEWEE: We ran some tests when I was
12 here earlier. It would be plus or minus one-ten-thousandth.

13 MR. LLOYD: I don't have any more questions.

14 MR. RICH: During the prototype testing, the
15 nickel titanium wire, which standards were compared? I
16 guess, what the standards were in the process of being used
17 for testing?

18 THE INTERVIEWEE: Which --

19 MR. RICH: Did you evaluate any of the standards
20 to see which ones were applicable for testing?

21 THE INTERVIEWEE: Which standards?

22 MR. RICH: ISO standards, ANSI standards. Other
23 standard industry standards.

24 THE INTERVIEWEE: Well, we tested for ANSI
25 standards.

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1 MR. RICH: Okay. One of the recommendations of
2 ANSI is for wires, or basically for needles, is to do
3 additional testing. One is bend test. One is tinsel test.
4 Were they ever considered?

5 THE INTERVIEWEE: We did the bend test. I think
6 those were included with the --

7 MR. RICH: The bend test was. It is unclear
8 whether the stainless steel wire was and the nickel titanium
9 wire, but we do have results of the bend test. But was the
10 tinsel test ever considered at one time?

11 THE INTERVIEWEE: I don't think so, no.

12 MR. RICH: Okay.

13 THE INTERVIEWEE: What's unclear? Whether it was
14 nickel or stainless?

15 MR. RICH: We received the background file from
16 Louisiana.

17 THE INTERVIEWEE: Uh-huh.

18 MR. RICH: We're going through documentation of
19 what tests you submitted. We have the documentation of the
20 bend test, but where it falls in the application is unclear,
21 whether it's in the stainless steel wire or in the nickel
22 titanium wire.

23 THE INTERVIEWEE: Doesn't it say so right on the
24 cover of the report?

25 MR. RICH: I don't have the cover of the report.

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1 THE INTERVIEWEE: I think it is just the nickel
2 titanium source wire.

3 MR. RICH: Okay. We'll check that.

4 MR. LLOYD: I think that is probably all we have.
5 We'll have some requests, probably, for some additional
6 documentation that maybe you don't already have.

7 THE INTERVIEWEE: Yes.

8 MR. LLOYD: We mentioned that a transcript will be
9 made available to you. We will give you an address when we
10 are all finished.

11 THE INTERVIEWEE: All right.

12 MR. LLOYD: You can have a chance to go back
13 through it and read it, if you like. When the report is
14 finally issued, we'll have approximately 45 days from, I
15 believe it's tomorrow or the next day. We'll have that
16 report issued. It comes out in what is called a NUREG
17 format, similar to other IIT reports that have been
18 generated. At that time then you can actually request to
19 have your transcripts, and you can receive a copy of that.

20 Since you're doing any investigation, FDA is also
21 doing things. Is anybody else doing investigations? Is the
22 State of Louisiana doing anything? Is Texas doing anything?

23 THE INTERVIEWEE: I don't know.

24 MR. LLOYD: Is Indiana?

25 THE INTERVIEWEE: They're not down here that i

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1 know of. I've not heard of Indiana being here.

2 MR. LLOYD: Have they requested any information
3 from you?

4 THE INTERVIEWEE: You would have to ask Richard
5 Calfee about that.

6 MR. LLOYD: One of the items that we have to
7 report on is that we'll go through and we'll gather our
8 facts. From that, we'll generate various findings and
9 conclusions and also root causes and failure.

10 Obviously we'd like to have the benefit of any
11 investigatory work that you've done prior to the time that
12 we would issue the report so we could compare some of your
13 findings and conclusions and root causes with ours so that
14 we don't have grossly different opinions as to what the
15 cause of failure was.

16 Following this, there would also be generated by
17 the EDO, which is the Executive Director for Operations with
18 the NRC some follow-up action items which would include
19 making recommendations for inspections, making license
20 changes, specification changes, and things like that.

21 Do you have any recommendations as far as what
22 Omnitron might do differently in the future that could have
23 prevented this incident from taking place in the first
24 place?

25 THE INTERVIEWEE: I can't comment on that until we

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1 know the root cause.

2 MR. LLOYD: That's all I have.

3 MR. RICH: No more questions.

4 MR. LLOYD: Thank you.

5 THE INTERVIEWEE: All right.

6 [Whereupon, at 3:25 p.m., the interview was
7 concluded.]

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in the matter of:

NAME OF PROCEEDING: Anthony J. Bradshaw

DOCKET NUMBER:

PLACE OF PROCEEDING: Houston, Texas

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

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