

OFFICIAL TRANSCRIPT OF PROCEEDINGS

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

Title: Investigative Interview of:
Richard Calfee
(Closed)

Docket No.

LOCATION: Houston, Texas

DATE: Thursday, December 17, 1992

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1512 K St. N.W., Suite 300

Washington, D.C. 20006

(202) 293-3950

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ADDENDUM/ERRATA SHEET

Page Line Correction and Reason for Correction

Lined area for corrections and reasons.

Page 1 Date 1/10/03 Signature [Handwritten Signature]

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF INVESTIGATIONS

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In the Matter of: :
INVESTIGATIVE INTERVIEW :
Richard Calfee :
(CLOSED) :

- - - - -X

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

Thursday, December 17, 1992

The above-entitled matter commenced at 4:15
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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3 REBECCA D. FULLER, Investigator
4 U.S. Food and Drug Administration

5

6 JAMES KNAUSS, Director, Product Assurance
7 Omnitron International, Inc.

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P R O C E E D I N G S

[4:15 p.m.]

1
2
3 MR. LLOYD: Good afternoon. It is approximately
4 4:15 in the afternoon. My name is Ron Lloyd with the U.S.
5 Nuclear Regulatory Commission, Section Chief for the
6 Incident Investigation Program.

7 What we would like to do is have each individual
8 introduce themselves by name and spell your last name if
9 it's difficult.

10 MR. RICH: My name is Tom Rich and I work for the
11 U.S. Nuclear Regulatory Commission in the Sealed Source
12 Safety Section.

13 THE INTERVIEWEE: I am Richard Calfee, President
14 of Omnitron.

15 MR. KNAUSS: James Knauss, Director of Product
16 Assurance, Omnitron.

17 MS. FULLER: And I am Rebecca Fuller, FDA
18 Investigator.

19 MR. LLOYD: Thank you. Since you have been
20 interviewed before by the IIT team, let me just state that
21 I'm sure you're aware of our transcription process. We'll
22 try to get copies available to you. We'll even address it
23 to you if you misplaced the last one, and you'll have an
24 opportunity to take a look at your transcript and then make
25 any corrections you choose to by an errata sheet.

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1 THE INTERVIEWEE: Okay. I thought you guys last
2 time told me you were going to send that to me and I never
3 received it.

4 MR. LLOYD: Those were sent to Washington, D.C.
5 In fact we just got them I think yesterday.

6 THE INTERVIEWEE: So they're going to send it on
7 down.

8 MR. LLOYD: They'll send it on down.

9 THE INTERVIEWEE: Okay.

10 MR. LLOYD: I have talked to the people there, so
11 they'll send that down here by Federal Express and it will
12 give you a chance to look at it and make any corrections and
13 then mail it back to us.

14 THE INTERVIEWEE: Okay.

15 MR. LLOYD: So I think that's it as far as the
16 intro because you have already heard all this before.

17 Could you restate for the audience that we have
18 now what your current position is and your responsibilities?

19 THE INTERVIEWEE: I am the President of Omnitron.

20 MR. LLOYD: And what is your connection with the
21 Omnitron 2000?

22 THE INTERVIEWEE: It's a product of our company.

23 MR. LLOYD: Did you help develop that product or
24 was it partially developed when you came here?

25 THE INTERVIEWEE: It was partially developed,

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1 mostly developed when I came here.

2 MR. LLOYD: What's your feeling as far as how the
3 machine operates, its limitations, its design
4 specifications?

5 THE INTERVIEWEE: I think it is the best machine
6 on the market by far.

7 MR. LLOYD: How closely are you involved with the
8 actual operation and testing and use?

9 THE INTERVIEWEE: That's a pretty subjective
10 question. It's -- I'm generally aware of the operation and
11 testing of the machine.

12 MR. LLOYD: Have you had any input as far as
13 making design changes or specification changes, material
14 changes?

15 THE INTERVIEWEE: I guess as the President of the
16 company you get a little input on everything but I haven't
17 been intimately technically involved, if that is your
18 question.

19 MR. LLOYD: What is your management process? Do
20 you have daily meetings, weekly meetings with people?

21 THE INTERVIEWEE: We generally have weekly
22 meetings with senior staff members.

23 MR. LLOYD: Do they discuss progress or problems
24 that they are currently having?

25 THE INTERVIEWEE: Each individual area discusses

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1 what is going on in their area, sales, marketing,
2 conventions, engineering -- whatever.

3 MR. LLOYD: Okay. We have some general questions
4 that we've put together. We'd like to go through those.

5 As best you can, give whatever answers you can.

6 THE INTERVIEWEE: Okay.

7 MR. LLOYD. As factually as possible. If you have
8 any questions, please ask questions. If you are not sure,
9 just say that you are not sure and we'll continue and go on.

10 THE INTERVIEWEE: Okay.

11 MR. LLOYD: Tom?

12 MR. RICH: Since the last two source wire breaks
13 in Pennsylvania, has Omnitron hired any additional
14 personnel?

15 THE INTERVIEWEE: I don't believe we've hired any
16 additional full-time personnel.

17 MR. RICH: Have you hired part-time personnel to
18 look at the failure analysis?

19 THE INTERVIEWEE: As you know, we've hired Dr.
20 Massoud Simnad to assist us in that evaluation.

21 MR. RICH: Any additional people he's hired on
22 your contract?

23 THE INTERVIEWEE: I don't know who all he's worked
24 with out at San Diego but of course they've also been
25 working with the NRC's own experts in San Antonio.

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1 MR. RICH: Has anyone received a reprimand from
2 the cause of the wire failures or anything else going on
3 within the company since the wires broke?

4 THE INTERVIEWEE: Not to my knowledge.

5 MR. RICH: Who is the assigned person within
6 Omnitron responsible for the failure analysis on your part?

7 THE INTERVIEWEE: Tony Bradshaw.

8 MR. RICH: Okay. Will he be providing you
9 directly information relating to the root cause of failure?

10 THE INTERVIEWEE: Yes.

11 MR. RICH: Since you've been at the company since
12 the beginning or pretty much the beginning of the
13 afterloader, what is the performance history of the
14 afterloader?

15 THE INTERVIEWEE: I'd say it's been excellent.

16 MR. RICH: Any units that had to be removed from
17 the clinics due to poor operating environment or because of
18 too many failures of parts?

19 THE INTERVIEWEE: None that I recall.

20 MR. RICH: Can you explain in some detail how
21 Omnitron International Incorporated began or started?
22 There's a lot of relationships along the line to the
23 documentation that we really don't understand.

24 THE INTERVIEWEE: Well, in general Omnitron was
25 founded back in 1988 by Dr. Michael Hayman, Dr. Sam Liprie,

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1 who hired an engineering firm to develop the original
2 prototypes, engineering models of the machine.

3 MR. RICH: Was it called Omnitron International
4 at that point?

5 THE INTERVIEWEE: I believe it was.

6 MR. RICH: Okay.

7 THE INTERVIEWEE: And Mr. Chambers, our Chairman,
8 got involved along that time period also and the company
9 they were working with also did consulting work in the oil
10 business so when the oil business for them picked back up,
11 they got disinterested in the project and I believe that Mr.
12 Chambers was instrumental in getting some people out of
13 Georgia Tech -- Tony and Rick -- involved in making this
14 preliminary design more production-worthy.

15 He recruited me to come to the company in the
16 middle of 1990 at which time we moved it all here to Houston
17 and started preparing for our production and marketing of
18 the product.

19 MR. RICH: What was your past history before being
20 signed on to Omnitron?

21 THE INTERVIEWEE: You mean since birth or when?

22 MR. RICH: No -- what was your last job?

23 THE INTERVIEWEE: I was with Intermedics,
24 Incorporated, for about thirteen and a half years where I
25 was an officer of that corporation and responsible for

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1 engineering research and development.

2 MR. RICH: Who finances the company?

3 THE INTERVIEWEE: Its shareholders.

4 MR. RICH: Do you have stock on the open market or
5 is it private stock?

6 THE INTERVIEWEE: It is privately held.

7 MR. RICH: Can you mention who the major
8 shareholders are?

9 THE INTERVIEWEE: The major shareholders are the
10 members of our Board of Directors, which is Mr. Chambers,
11 myself, Dr. Liprie, Dr. Hayman and Wayne Rollins -- Randall
12 Rollins at this point in time.

13 MR. RICH: What is the relationship between RADS,
14 which I understand that Dr. Sam Liprie is President of, and
15 Omnitron?

16 THE INTERVIEWEE: He was previously in the wire
17 building business on his own for a number of years as the
18 company RADS, SL.

19 MR. RICH: There's no other relationships to that
20 company?

21 THE INTERVIEWEE: No.

22 MR. RICH: What about relationship between the
23 Radiological Physics and Engineering Company and Omnitron?

24 THE INTERVIEWEE: Radiological Physics and
25 Engineering Company --

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1 MR. RICH: There was some documentation submitted
2 along with the prototype testing in the Louisiana history
3 file that mentions that company's name as doing the testing
4 or being responsible. What was the relationship and was
5 anybody from that company brought into Omnitron's personnel
6 department or --

7 THE INTERVIEWEE: I think that may be Dr. Wright's
8 physics consulting company.

9 MR. RICH: Were they in charge of the prototype
10 testing, do you know?

11 THE INTERVIEWEE: The prototype testing of what?

12 MR. RICH: Of the nickel titanium wire and the
13 stainless steel wires?

14 THE INTERVIEWEE: I think that before she joined
15 us full-time she may have been hired in a consulting role to
16 do some of the testing on that wire.

17 MR. RICH: What is the relationship between Test,
18 Incorporated and Omnitron?

19 THE INTERVIEWEE: That was the company I mentioned
20 that originally did the engineering work and prototype
21 development back in 1988.

22 MR. RICH: Who were the founders of Test,
23 Incorporated?

24 THE INTERVIEWEE: I do not know.

25 MR. RICH: One more company I guess we're trying

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1 to straighten out here. What is the relationship between
2 Tuttle Engineering Services Team, Incorporated, and
3 Omnitron?

4 THE INTERVIEWEE: I am not familiar with that
5 name.

6 MR. RICH: Did you hire Dr. Wright on after you
7 became President of Omnitron?

8 THE INTERVIEWEE: Eventually, yes.

9 MR. RICH: What education and training does she
10 have?

11 THE INTERVIEWEE: Best ask her that question, but
12 she has a Ph.D. in Physics is my understanding and a lot of
13 clinical experience. She's I think also immediate Past
14 President of the APM and the ACPM, so she's a well-known
15 person.

16 MR. RICH: What training experience has she had
17 with the ISO 2919 prior to her coming to Omnitron?

18 THE INTERVIEWEE: I do not know.

19 MR. RICH: Where was the prototype testing done on
20 nickel titanium? I understand you were one of the people
21 watching the test as well as signing off on the
22 documentation. Where were those tests performed?

23 THE INTERVIEWEE: That particular, the one that I
24 signed off on, let's see. There was some testing that was
25 done here and there was some testing that was done at our

1 lab in Edgerly.

2 MR. RICH: Where is the equipment that the tests
3 were done with?

4 THE INTERVIEWEE: Which tests?

5 MR. RICH: Okay, the temperature test involves an
6 oven. Where is that oven at this time?

7 THE INTERVIEWEE: I would think that that would be
8 at Edgerly.

9 MR. RICH: And there was also a puncture test that
10 involves a 50 gram hammer. Where would that be?

11 THE INTERVIEWEE: That also would be at Edgerly, I
12 believe.

13 MR. RICH: Is there any part of the testing that
14 was done for ISO 2919 equipment-wise that would be located
15 here that we could see?

16 THE INTERVIEWEE: Not that I am aware of but I
17 have to tell you that I don't remember all the specific
18 details of that testing.

19 MR. RICH: Do any of the other Omnitron facilities
20 do any manufacturing besides the Houston facility and Dr.
21 Sam Liprie's lab?

22 THE INTERVIEWEE: No.

23 MR. RICH: Have you thought about starting
24 procedure-wise or a documentation listing different
25 corrective actions that you will be taking as a result of

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1 the failures?

2 THE INTERVIEWEE: Once we finish the analysis, I
3 would think we would if any corrective actions are required.

4 MR. RICH: Is there any procedures or functions
5 that you will change now, not as a result of failures but as
6 a result of investigations?

7 THE INTERVIEWEE: Well, we've discussed changing
8 the error message that would come up when you do an
9 emergency retract. I mentioned that in my last interview to
10 Dr. Paperiello.

11 MR. RICH: Were there any other previous
12 manufacturers besides SMA that you received the raw
13 materials from?

14 THE INTERVIEWEE: I do not know.

15 MR. RICH: Who would be in charge of purchasing
16 that wire?

17 THE INTERVIEWEE: Our purchasing is generally
18 handled by John Edison.

19 MR. RICH: Do you have oversight for all purchase
20 orders?

21 THE INTERVIEWEE: I do initial most if not all
22 purchase orders, yes.

23 MR. RICH: I have no more questions at this time.

24 MR. LLOYD: When do you expect a report on the
25 cause of failure?

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1 THE INTERVIEWEE: Well, when we get the failure
2 analysis complete. The commitment to Dr. Paperiello was to
3 try to have that complete by December 23rd. I still hope to
4 achieve that date. There were some, you know, delays in
5 getting our hands on it, as you know. In fact, the second
6 wire is just now undergoing analysis. The analysis on the
7 first wire is pretty much complete.

8 MR. LLOYD: What are the preliminary findings on
9 the first wire?

10 THE INTERVIEWEE: That it was fractured due to
11 overstress.

12 MR. LLOYD: Tensile failure, tactile, brittle
13 failure, bowments?

14 THE INTERVIEWEE: I am not a metallurgist but my
15 understanding of the situation is it was a ductile failure
16 due to overstress on the material.

17 MR. LLOYD: Was that supposedly when the wire was
18 being pulled out or inserted?

19 THE INTERVIEWEE: We believe it was when it was
20 being pulled out.

21 MR. RICH: Do you plan on sending anybody down to
22 Southwest Research to examine the testing going on on the
23 second wire?

24 THE INTERVIEWEE: That hasn't been determined yet.
25 We were very impressed with the quality of people there at

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1 Southwest and we of course have documentation from what they
2 have done already in our presence during the testing of the
3 first wire and have been assured by them that they are
4 taking the same kind of documentation on the second wire,
5 so, you know, if Tony hadn't had to be here today he
6 probably would have been over there but we have a lot of
7 confidence in those people.

8 MR. RICH: Are you having any difficulties with
9 sharing information between Southwest and your --

10 THE INTERVIEWEE: Not that I know of. I think
11 it's been a very cooperative relationship so far.

12 MR. RICH: That's good to hear.

13 MR. LLOYD: What about other areas? Beyond the
14 break of the wire are there any other changes that you're
15 looking at at Omnitron as far as training, oversight,
16 recordkeeping, quality assurance or QC, testing -- the list
17 kind of goes on and on and on about, you know, possible
18 areas where you could make changes.

19 THE INTERVIEWEE: Obviously you can make changes
20 in all those areas overtime, always. As we review this --
21 I don't know that I can tell you whether there will be or
22 won't be. It's certainly possible.

23 MR. LLOYD: What about oversight at the Atlanta
24 firm that actually drills the hole and ships that to you?

25 THE INTERVIEWEE: I think that that would be a

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1 function of, you know, what we find in this testing. To my
2 knowledge we haven't found anything that would indicate an
3 out of specification condition or process-related material,
4 property, anything like that.

5 MR. LLOYD: Tony mentioned that there were no
6 tensile tests done on the wire with the hole drilled in.
7 You have a wall, a min wall I believe that's approximately
8 three and a half thousandths. It's fairly easy to do a
9 calculation on that that would show how many pounds that the
10 thing would take before it would break and it's a fairly
11 small number.

12 THE INTERVIEWEE: I beg your pardon?

13 MR. LLOYD: It's a fairly small number.

14 THE INTERVIEWEE: Is it? I mean I've --

15 MR. LLOYD: And nobody has ever done those
16 calculations evidently and nobody has ever done a tensile
17 test.

18 THE INTERVIEWEE: I don't know if that's true or
19 not. I know that the testing to my knowledge that was done
20 is the mode of where it's used, where it's the kind of
21 stress it would be subjected to in real life.

22 MR. RICH: No questions.

23 MR. LLOYD: No further questions. Do you have any
24 further questions of us?

25 THE INTERVIEWEE: No. I just -- I would like to

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1 get a copy of that first transcript and a copy of this one
2 when you get it produced.

3 MR. LLOYD: We'll do that.

4 THE INTERVIEWEE: All right.

5 MR. LLOYD: Thank you very much.

6 THE INTERVIEWEE: All right.

7 [Whereupon, at 4:35 o'clock p.m., the taking of
8 the interview was 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:

NAME OF PROCEEDING: Richard Calfee

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.

Wanda Lewis

Official Reporter
Ann Riley & Associates, Ltd.