

OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: Nuclear Regulatory Commission

Title: Quality Assurance Pilot
Program Post Trial Workshop

Docket No.

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NUCLEAR REGULATORY COMMISSION

QUALITY ASSURANCE PILOT PROGRAM
POST TRIAL WORKSHOP

Sheraton International
O'Hare Airport
6810 North Mannheim Road
Rosemont, Illinois

Thursday, August 23, 1990

Whereupon, the above-entitled meeting commenced at
9:05 a.m.

1 WORKSHOP PARTICIPANTS:

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Robert Lawalan, Harrison County Hospital

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Alessandro Ricci, St. Joseph Medical Center

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Robin Schaefer, St. Joseph Medical Center

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Judy Bastian, Freeport Memorial Hospital

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Charles Lee, St. John's Hospital

8

Larry Camper, Nuclear Regulatory Commission

9

Edward Kaplan, Brookhaven National Laboratory

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Anthony Tse, Nuclear Regulatory Commission

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John Telford, Nuclear Regulatory Commission

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Darrel Wiedeman, Nuclear Regulatory Commission

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Ed Kline, BWL

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Ray Wery, Marquette General Hospital

15

Tracy King, Medical Physics Consultants

16

Thomas Stefanakos, Krause, Lubert & Associates

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Pita Duffy, Marian Health Center

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Terry Garner, Mt. Sinai Medical Center

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Richard Clouse, Elkhart General Hospital

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Bill Erickson, Mercy Hospital

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P R O C E E D I N G S

[9:05 a.m.]

MR. TELFORD: Good morning. My name is John Telford. I'm from the Rulemaking Section, Regulation Development Branch, Division of Regulatory Applications at NRC.

We welcome you all. We're glad to see you all today. We're going to have an interesting two days. I'd like to call your attention to the agenda. I have a viewgraph, but it may be a little hard to see. So perhaps you should take out your own copy.

First we will go through the sort of self-introduction of the volunteers, that you may remember from the first workshop. So I'll ask you to remind us -- tell us your name, tell us your institution, hospital or clinic, size of the hospital or clinic, how many beds, its location, and most importantly, your departments that participated in the 60-day trial period; that's teletherapy, brachytherapy, radio-pharmaceutical therapy, or diagnostics. So let's start here.

MR. LAWALAN: My name is Robert Lawalan. I'm with the Harrison County Hospital in Corridan, Indiana. It's a 66-bed hospital, located about 30 miles due east of Louisville, Kentucky. We just have diagnostic nuclear medicine.

1 MR. RICCI: Alessandro Ricci, St. Joseph Medical
2 Center in Juliette, Illinois; about 300-bed hospital;
3 teletherapy program; picks up to a linear accelerator; an
4 active, very active nuclear medicine department.

5 Mary Ann Swan couldn't make it because of surgery.

6 MS. SCHAEFER: Robin Schaefer. I'm from St.
7 Joseph Medical Center in Bloomington, Illinois. We're a
8 180-bed facility and our Nuclear Medicine Diagnostic
9 Department participated.

10 MS. BASTIAN: Judy Bastian from Freeport Memorial
11 Hospital, Freeport, Illinois. It's about 110 miles west of
12 here. Our hospital is about 150 beds, and the participants
13 are diagnostic and radio-pharmaceutical therapy.

14 MR. LEE: I'm Charles Lee from Salina, Kansas, St.
15 John's Hospital. We're about 190 miles west of Kansas City.
16 Both nuclear medicine and radiation therapy, brachytherapy
17 participated.

18 MR. CAMPER: I'm Larry Camper. I'm with the
19 Nuclear Regulatory Commission Headquarters. I'm the Section
20 Leader for the Medical and Academic Section. My department
21 is responsible for regulatory policy, guidance and so forth,
22 as relates to the medical, academic, and biomedical uses of
23 byproduct material.

24 MR. KAPLAN: I'm Ed Kaplan, Brookhaven National
25 Laboratory.

1 MR. TSE: My name is Anthony Tse. I work with the
2 NRC Headquarters. I'm the Program Manager of this project.

3 MR. WIEDEMAN: My name is Darrel Wiedeman. I'm
4 the Technical Assistant to the Director of the Division of
5 Radiation Safety and Safeguards in the NRC Region III
6 Office, Glenn Ellyn, Illinois.

7 MR. KLINE: My name is Ed Kline. I work out of
8 the Region II-Atlanta, Georgia Office. Licensing and
9 Inspection were the members of the pilot program.

10 MR. WERY: My name is Ray Wery. I'm from
11 Marquette, Michigan, Marquette General Hospital. It's a
12 350-bed hospital. We participated in teletherapy, nuclear
13 medicine, and brachytherapy.

14 MS. KING: Tracy King, representing a cardiology
15 clinic in Kalamazoo, Michigan. Our out-patient cardiology
16 program does only cardiac functions.

17 MR. STEFANAKOS: I'm Tom Stefanakos, Krause,
18 Lubert, Beachwood, Ohio. We're about a block-and-a-half
19 east of Cleveland, Ohio. We just have a teletherapy unit in
20 a satellite department.

21 MS. DUFFY: I'm Rita Duffy from Marian Health
22 Center in Sioux City, Iowa. We have a 350-bed institution.
23 We participated in nuclear medicine, diagnostic,
24 therapeutic, and radiation oncology, teletherapy.

25 MR. ERICKSON: I'm Bill Erickson, Mercy Hospital,

1 Muskeegan, Michigan. Muskeegan is located just about
2 direct\ across Lake Michigan from Chicago, a little bit
3 north. It's 138-bed hospital and we participated in the
4 area of nuclear medicine, diagnostic, and limited therapy.

5 MR. TELFORD: We're going to go through a couple
6 more things, and then we'll go through the agenda for the
7 next couple of days; for the next two days, exactly.

8 The next item you see on the agenda is called
9 "Recap and scope of this workshop." You will recall at the
10 first workshop that viewgraph on your left, and it said what
11 you could expect from this.

12 The last two on here I want to call your attention
13 to. This is where we said at the first workshop that at
14 this workshop, we would be listening to you. I predict a
15 half-hour from now you will know what that's all about,
16 because we'll be doing all the discussing. We're here to
17 listen.

18 What we have assembled for you here is -- four out
19 of the five people will be writing the final rule. The
20 Commission has told us to bring the final rule in March of
21 1991. There is only one person missing. It will be the
22 basic staff that will be writing that final rule.

23 We are here to listen to you. We want your
24 suggestions. We're not here to take a vote. We're not here
25 to develop a consensus. If you've got a good suggestion

1 about an objective, if you have a good suggestion, you've
2 got a good rationale for it, I can guarantee that you will
3 be heard.

4 Let's go off the record for a minute and let these
5 people come in.

6 [Discussion off the record.]

7 MR. TELFORD: Back on the record. Say your name.

8 MR. CLOUSE: My name is Richard Clouse. I'm from
9 Elkhart Hospital in Elkhart, Indiana. We have 360 beds.
10 I'm from nuclear medicine, and we do basically diagnostic
11 and I-131 therapy.

12 MR. GARNER: My name is Terry Garner. I'm from
13 Sinai Samaritan Medical Center in Milwaukee. We're
14 approximately 400 to 500 beds. It's fluctuating. All three
15 departments of radiation oncology, which does both
16 teletherapy and brachytherapy, nuclear diagnostic, nuclear
17 medicine, and I represent the nuclear cardiology-only
18 department.

19 MR. TELFORD: We're on the first item on this
20 agenda, which is the welcome, then Item 2. So that's the
21 recap that I wanted to do for you, what we told you during
22 the first workshop.

23 That's the theme of this workshop. We're here to
24 listen to you. If you look at the agenda, we've broken it
25 up into four basic chunks. The promise we made to you at

1 the first workshop is that we would tell you the criteria
2 that we would use to do the program review; the criteria
3 that we would use to do site reviews; and, we would tell you
4 the results. Ed Kline and Darrel Wiedeman are going to do
5 that for you.

6 The next chunk is in the afternoon we'll talk
7 about the eight objectives, each part of those 35.35; the
8 introductory paragraph, as well as the audit. Tomorrow
9 morning we're going to talk about the Regulatory Guide and
10 go through each section and listen to your comments.

11 Tomorrow afternoon we'll talk about the reporting
12 requirements for diagnostics, 35.33; therapy, proposed
13 35.34. We will see that it's repeated here each of those
14 last three parts. We will be asking you do we delete,
15 modify, or retain each of those, one at a time.

16 Groundrules. The groundrules are we're here to
17 listen to you. We have many interested observers, and the
18 observers have been requested to make no comments and ask no
19 questions until the second day, which is at 5:00 the second
20 day.

21 The times on the agenda are flexible. For
22 instance, we just had, in Philadelphia, a workshop last
23 week. I think we were done by 5:00. So we can go through
24 this more quickly, more slowly, it's up to you.

25 I will now turn it over to Darrel Wiedeman. He's

1 going to talk about the criteria for the program and site
2 review.

3 MR. WIEDEMAN: Good morning, everybody. Welcome
4 to the Chicago area. I'm sure this is really downtown
5 Chicago or considered Chicago. This is one of the suburbs.
6 I'm glad to have you all here.

7 This morning I'm going to be talking to you about
8 the background behind the QA Team activities, the evaluation
9 criteria. Now, when I say evaluation criteria, I should
10 probably clarify that.

11 We have, in the NRC, what we call an SRP, Standard
12 Review Plan, and this is a document that is issued to our
13 licensing staff so that they will have consistency in the
14 way that we review a license application.

15 So the QA Team, which was made up of four
16 individuals that have experience in nuclear medicine,
17 brachythera, γ , teletherapy, we sat down and we put together,
18 by using the eight objectives and the Regulatory Guide, and
19 systematically placed them down one after another and tried
20 to set up a way that would be a consistent approach to
21 evaluate a license application.

22 When it comes to the program evaluation, this
23 would be the criteria that an NRC inspector would use as
24 possibly criteria for doing inspection to review the QA
25 Program. I will also discuss this morning the program

1 evaluations on the site visits, our findings for the nuclear
2 medicine and radio-pharmaceutical therapy.

3 Once again, just keep in mind there will be two
4 things I'll be talking about. That is the evaluation
5 criteria and the site visit. Later on we will hand out
6 copies of the document that we used to evaluate your
7 specific program.

8 I will give you some statistics on what we did.
9 We selected 18 licensees randomly from a list. We tried to
10 get a good sampling of the licensees. We used 11 NRC and
11 seven agreement state licensees. There were 15 diagnostic
12 nuclear medicine programs that were evaluated; 12
13 therapeutic and radio-pharmaceutical programs; five
14 brachytherapy; and, of course, eight teletherapy.

15 MR. TELFORD: Darrel?

16 MR. WIEDEMAN: Yes.

17 MR. TELFORD: This is 18 of the 70 volunteers.

18 MR. WIEDEMAN: That's correct. Eighteen out of
19 the 70 volunteers. Now, in the last couple of months, I
20 have, along with the Site Team, gone to some real garden
21 spots in America; San Waukeen Valley, California; of course,
22 over in New York; and Sarasota, Florida made up for the
23 cabbage patch area that we had.

24 Of course, we had Iowa as a participant. We had
25 one over in Indiana, Ohio, and a couple in Michigan. All in