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NUCLEAR REGULATORY COMMISSION

Title: Predecisional Enforcement Conference
RE Dr. Bradley Bastow, NRC Licensee

Docket Number: EA-14-116

Location: Lisle, Illinois

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Pages 1-96

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UNITED STATES OF AMERICA

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BEFORE THE NUCLEAR REGULATORY COMMISSION

REGION III

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PREDECISIONAL ENFORCEMENT CONFERENCE

+ + + + +

BRADLEY BASTOW, D.O.

SOUTH HAVEN, MICHIGAN

License No. 21-32316-01

Docket No. EA-14-116

FRIDAY

SEPTEMBER 19, 2014

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2443 WARRENVILLE ROAD, SUITE 210

LISLE, ILLINOIS

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The above-entitled matter commenced
pursuant to notice at 1:00 p.m.

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1 PRESENT:

2 NRC STAFF: (Personal Appearance)

3 Patrick Louden - Director, Division of Nuclear
4 Materials Safety

5 Cynthia Pederson - Regional Administrator,
6 Region III

7 Steven Orth - Enforcement Officer, EICS

8 Andrew Bramnik - Materials Inspector, Materials
9 Inspection Branch, DNMS

10 Patricia Pelke - Chief, Materials Licensing Branch,
11 DNMS

12 Patricia Loughheed - Senior Enforcement Coordinator,
13 EICS

14

15 NRC STAFF: (Telephone Participation)

16 Michelle Burgess - Regional Coordinator, Office of
17 Federal and State Materials and Environmental
18 Management Programs

19 Thomas Marenchin - Enforcement Specialist, Office of
20 Enforcement

21 Christopher Hair - Senior Attorney, Office of
22 General Counsel

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LICENSEE:

Bradley D. Bastow - Licensee

Phillip Troy - Attorney

MEMBERS OF THE PUBLIC:

Rosemary Parker-Reporter, Kalamazoo Gazette

P R O C E E D I N G S

(1:00 p.m.)

1
2
3 MR. LOUDEN: It's 1:00 o'clock, 1:00 p.m.
4 Central Time, so let's get started. My name is Pat
5 Louden, I'm the Director for the Division of Nuclear
6 Materials Safety here in the Region III office. So,
7 we welcome you. We'll be back to our introductions
8 here at the table in a moment.

9 This is a predecisional enforcement
10 conference between the Nuclear Regulatory Commission
11 and Dr. Bradley Bastow, NRC Licensee, to discuss issues
12 associated with the items described in the confirmatory
13 order issued on September 3rd, 2013. This conference
14 is open for public observation. For members of the
15 public who are in attendance or on the phone, be aware
16 that this is a meeting between the NRC and Dr. Bastow.
17 And following the conference, NRC staff will be
18 available to answer questions and receive comments from
19 members of the public concerning matters discussed at
20 this conference.

21 Also, because it's a public meeting, we
22 have feedback forms available here. We look for
23 feedback on our process. We take that to heart and make
24 adjustments accordingly. If you'd like to provide
25 feedback online, you can go to the NRC public website,

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1 select public meetings, go to the meeting details
2 button and then that will take you straight to the form
3 if you wish to provide feedback electronically.

4 And I will also make one other note. As
5 we proceed today, we have microphones in use here. If
6 you do speak, make sure that you press the button on
7 the front here and you'll get a green light, that means
8 your microphone is active. And when you're finished
9 you click it again and it will be red, we won't be able
10 to hear you. Thank you.

11 Okay. So, before we get into the rest of
12 the agenda, I think that we'll start by doing some
13 introductions. We'll go for folks here at the table
14 on both sides, and then I'll coordinate an introduction
15 for those on the phone.

16 Again, my name is Pat Loudon, Director of
17 the Division of Nuclear Materials Safety at Region III.

18 MS. PEDERSON: Good afternoon. I'm Cindy
19 Pederson, Regional Administrator, Region III.

20 MR. ORTH: Good afternoon. I'm Steve
21 Orth, I'm the Region III Enforcement Officer.

22 MS. LOUGHEED: I'm Patty Lougheed, the
23 Chief of the Nuclear Materials Licensing Branch here
24 at Region III.

25 MR. BRAMNIK: And I'm Andrew Bramnik,

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1 Inspector of the Nuclear Materials, Division of Nuclear
2 Materials Safety here.

3 MR. TROY: I'm Phillip Troy. I'm the
4 attorney for Mr. Bastow, or Dr. Bastow. And this is
5 Dr. Bastow.

6 DR. BASTOW: Yes, I'm Brad Bastow, the
7 Licensee.

8 MR. LOUDEN: Thank you. Okay. Now, I'd
9 like to turn to those on the phone. I'll do this
10 through groups. First off, there are other NRC staff
11 on the phone which would like to be identified. Go
12 ahead.

13 MR. MARENCHIN: This is Tom Marenchin,
14 Office of Enforcement.

15 MR. LOUDEN: Okay.

16 MR. HAIR: This is Christopher Hair,
17 Office of General Counsel, Attorney.

18 MR. LOUDEN: Okay.

19 MS. BURGESS: This is Michele Burgess, the
20 headquarters Program Office Enforcement Coordinator.

21 MR. LOUDEN: Anyone else from the NRC?
22 All right. What about local officials or other
23 government officials? Any members of the media on
24 line?

25 MS. PARKER: Rosemary Parker, Kalamazoo

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1 Gazette.

2 MR. LOUDEN: Okay, Rosemary, thank you.
3 Any other members of the public? All right. With
4 that, I would ask the folks on the phone, if you could,
5 if it's possible to place your phones on mute, we'll
6 try it that way. That way it would be easier to control
7 the dialogue. And then if we run into any problems,
8 we'll make adjustments accordingly.

9 Okay. For our agenda this afternoon, I'll
10 first start by going over the purpose of the
11 predecisional enforcement conference. And then Steve
12 Orth will discuss aspects of our enforcement policy and
13 also go over the specific matters that relate to the
14 purpose of the meeting today. And then Cindy Pederson
15 will provide some opening comments. And at that point,
16 we'll turn the meeting over to you for your
17 presentation.

18 And following the presentation, we will
19 take a break for a short caucus to discuss what we've
20 heard and formulate any follow-up questions we may
21 have. When we come back, if we have those questions,
22 we'll ask those questions. And then we'll adjourn this
23 portion of the meeting. Following the end of the
24 formal portion of this meeting, we will be then, we will
25 be available and provide, the meeting will be open for

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1 questions and we will take questions at that time.

2 Any questions or comments regarding our
3 plans?

4 MR. TROY: No, sir.

5 MR. LOUDEN: Okay. All right, so let's
6 get started.

7 The NRC requested this enforcement
8 conference prior to making an enforcement decision on
9 matters surrounding your failure to complete actions
10 as agreed to following an alternative dispute
11 resolution session conducted on July 1st, 2013. These
12 agreed-upon actions were documented in a confirmatory
13 order which was issued on September 3rd, 2013. These
14 issues are of concern to the NRC because these
15 agreed-upon actions, once we have obtained them would
16 have satisfied NRC concerns with your program.

17 As mentioned in our letter provided to you,
18 our preliminary evaluation of these issues, this
19 predecisional enforcement conference provides you with
20 an opportunity to assist the NRC in making an
21 enforcement decision by providing to us any additional
22 information that you may deem important for us to
23 consider. At this time, I'll turn it over to Steve
24 Orth.

25 MR. ORTH: Okay, thank you. The NRC

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1 Enforcement Program is governed by the Commission's
2 enforcement policy. The purposes of policy are to
3 encourage compliance with our requirements and
4 encourage licensees to identify and to take prompt and
5 comprehensive corrective actions. After we identify
6 a potentially safety significant issue, we determine
7 whether or not it involves a violation of NRC
8 requirements.

9 When an apparent violation is identified,
10 the NRC evaluates its actual potential significance in
11 accordance with our enforcement policy. The policy is
12 available on the website. The apparent violation is
13 assigned a preliminary severity level of 1 to 4, with
14 1 being the highest. Severity levels 1, 2 and 3 are
15 considered escalated enforcement.

16 If we identify a violation that appears to
17 warrant escalated enforcement, we hold an internal
18 meeting called an enforcement panel. One of the
19 purposes of this meeting is to ensure that the NRC is
20 consistently applying our enforcement policy. At this
21 meeting, the NRC will make a preliminary determination
22 about the appropriate outcome for the issue and will
23 also discuss whether a civil penalty appears warranted.

24 In cases where we determine that more
25 information is necessary, we request that a licensee

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1 participate in a predecisional enforcement conference.
2 It is important to note that the decision to hold a
3 conference does not mean that the Agency has made a
4 final enforcement decision. The apparent violation we
5 will discuss today is subject to further review and may
6 change prior to any resulting enforcement action, based
7 in part on the information we gather here today.

8 If we determine a violation did occur,
9 there are a number of sanctions available. They
10 include notices of violation, civil penalties, or
11 orders. Normal civil penalty amounts are contained in
12 our enforcement policy; however, we may escalate or
13 mitigate the amount of civil penalties based in part
14 on factors such as identification, corrective action,
15 prior enforcement history, and whether the violation
16 was wilful. The nature and the extent of the
17 enforcement action is intended to reflect the
18 seriousness of the violations.

19 The NRC requested this enforcement
20 conference prior to making an enforcement decision on
21 the apparent violation identified in your facility.
22 As discussed in our inspector report, a predecisional
23 enforcement conference provides you with the
24 opportunity to assist us in making an enforcement
25 decision by providing your understanding of the facts

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1 and circumstances surrounding the violation, whether
2 you agreed or disagreed with our understanding, as
3 provided in the inspector report. We'd also like to
4 get your perspective on the root causes or cause of the
5 few, your view on the safety significance, and
6 certainly a description of the correction actions, both
7 immediate and long term, to resolve the issue.

8 Finally, the conference provides you the
9 opportunity to present any additional information that
10 you believe is important for us to consider before
11 making our enforcement decision. We would like this
12 meeting not to become a debate. The apparent violation
13 discussed at this conference is subject to further
14 review, it may change. It is important to understand
15 that the decision to conduct this conference means that
16 the NRC has not yet determined our final enforcement
17 action. So, the purposes of the conference and our
18 questions is to gain more information so that we can
19 make a high quality judgment of the enforcement action.

20 Before I go into the apparent violation,
21 do you have any questions about our enforcement
22 process?

23 MR. TROY: No, sir.

24 MR. ORTH: Okay, thanks. As Mr. Loudon
25 indicated, we performed an inspection to assess your

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1 compliance with the order and to evaluate your
2 corrective actions for the violations. Based on that
3 inspection, we identified 13 areas of apparent
4 noncompliance with the confirmatory order which were
5 documented as examples of the apparent violation. I'd
6 like to go through those now in kind of a relatively
7 low level of detail, but we can have a further
8 discussion as we go through.

9 Item A-2 of the confirmatory order
10 requires that you will either restore a well counter
11 to service, calibrated and operable, or will provide
12 a license amendment request for alternate
13 instrumentation within 60 days of the issuance of the
14 order. Based on our inspection, we found that you
15 failed to do either within the time frame required by
16 the order.

17 Item B-1, Bravo 1, of the confirmatory
18 order requires that within 90 days of the order, you
19 will complete a medical radiation safety officer
20 refresher training class, approximately eight hours.
21 Although you completed online training courses, you
22 failed to complete those training courses within the
23 time frame required by the order.

24 Item B-2, Bravo 2, of the confirmatory
25 order requires that within 60 days of the completion

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1 of the radiation safety officer training, you will meet
2 with and shadow for at least eight hours another
3 radiation safety officer who oversees a nuclear medical
4 program. We found that you failed to meet with and
5 shadow another radiation safety officer.

6 Item Bravo-3 of the confirmatory order
7 requires that you provide a copy of the reports of your
8 program reviews to the NRC within 60 days of completion
9 of those reviews. We found that you failed to provide
10 a copy of the November 2013 and January 2014 reports
11 to the NRC within the time frame required by the order.

12 Item Bravo-3, B-3 of the confirmatory
13 order requires that you provide written certification
14 in the program reviews that you have reviewed the report
15 and agreed with the results of the review, along with
16 independent observations that you have made of the
17 health of the radiation safety program. We found that
18 you failed to provide an independent observation of the
19 health of the radiation safety program in the November
20 2013 and January 2014 reports.

21 Item C-1, Charlie 1, of the confirmatory
22 order requires that you conspicuously post the safety
23 culture policy or a notice about the policy in your
24 office and at least two locations. Our inspection
25 found that you failed to post the policy or a notice

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1 about the policy in your office.

2 Item C-1, Charlie 1, of the confirmatory
3 order requires that the safety culture policy must
4 iterate that any concerned individual can contact the
5 NRC, provide a number and contact person in the NRC for
6 additional action on nuclear safety issues if
7 necessary. You failed to include that information in
8 your policy.

9 Item C-1 of the confirmatory order
10 requires that you provide a copy of the policy to all
11 persons, staff and contractors performing duties under
12 the NRC license in your facility. You failed to
13 provide a copy of that policy to the technologist, the
14 only person performing duties under the NRC license,
15 until approximately April 21, 2014 which exceeded the
16 time frame required by the order.

17 Item Charlie 2, C-2 of the confirmatory
18 order requires that documentation of the initial
19 training regarding the safety culture and raising
20 safety concerns would be maintained for future
21 inspections including the dates of the training, names
22 of the attendees, and the subjects covered. Based on
23 our inspection, we found that you failed to document
24 and maintain documentation of the training.

25 Item C-3 of the confirmatory order

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1 requires that once a quarter you meet with each person,
2 staff and contractors, performing duties under the
3 license to solicit concerns. Based on our inspection,
4 we found that you failed to meet with each person
5 performing duties under the NRC license to solicit
6 concerns.

7 Item D-1, Delta-1, of the confirmatory
8 order requires that you verify that all required
9 records, including all the records and documents
10 created in support of such records, are onsite and
11 available for inspections. We found that you failed
12 to verify that provisions of the radiation safety
13 program, the maintenance of which is required by 10 CFR
14 Part 20, were onsite and available for inspection. For
15 example, you did not have onsite and available for our
16 inspection your procedures entitled Rules for the Safe
17 Use of Radiopharmaceuticals, or your emergency
18 procedures.

19 Item D-1 of the confirmatory order
20 requires that you ensure all documentation completed
21 following the issuance of the order is complete,
22 accurate, clear and legible. We found that you failed
23 to ensure that the January 2014 audit report or
24 inspection report of your facility was complete and
25 accurate.

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1 Finally, Item Echo of the confirmatory
2 order, Item E, requires that you submit written
3 notification to NRC's Region III Director of Division
4 of Nuclear Materials Safety upon completion of each
5 specific action at six months, one year, and annually
6 thereafter. We found that you failed to submit the
7 six-month written notification twice.

8 In many cases, our inspection found that
9 you did not appear to complete the actions until
10 questioned by our inspector.

11 Now, in addition to the apparent
12 violation, our inspection also identified three
13 severity level 4 violations which concerned the failure
14 to handle radioactive material in accordance with your
15 procedures, the failure to monitor occupational
16 exposure of your staff, and the failure to secure a
17 Cobalt 57 flood source stored in the imaging room as
18 required by 10 CFR Part 20.

19 MS. PEDERSON: Good afternoon. As you
20 recall, last July, we entered into an alternate dispute
21 resolution process. We came into that in a good faith
22 attempt to resolve our enforcement issues and to ensure
23 compliance on the part of the facility. When our
24 inspector came back and did our series of inspections,
25 we found gross noncompliance with our order, as well

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1 as some new violations that Steve also articulated.
2 This is extremely troubling to us, to find a program
3 with this level of noncompliance. This caused us to
4 lose confidence in your ability or your willingness to
5 abide by our requirements and our regulations.

6 So, today's meeting is very important. It
7 is an opportunity for you to inform us into what you
8 will be doing differently and how that will restore
9 compliance and how you will sustain compliance. At
10 this time, Dr. Bastow, we'd like to hear from you.

11 MR. TROY: As in the ADR, I'm going to be
12 speaking for Dr. Bastow. For the record, Cardiology,
13 P.C. is a small cardiology office in South Haven,
14 Michigan. The practice consists of one physician, Dr.
15 Bastow, who is also the radiation safety officer, and
16 one certified nuclear medicine technologist. The
17 office conducts nuclear stress tests generally two days
18 a week, though that can change depending on
19 cancellations and inclement weather. When not
20 conducting nuclear stress tests, our other non-nuclear
21 medical procedures are performed. The nearest office
22 conducting nuclear stress tests is approximately 25
23 miles away, besides Dr. Bastow's office.

24 It's also important to note, during the
25 exit conference call, the Region III inspector and

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1 supervisor were asked if any of the cited violations,
2 13 apparent violations or open items detailed in the
3 inspection report were of safety significance. The
4 question was asked because, to be perfectly honest,
5 they went rather quickly through the list of items and
6 I was not able to copy them down and take notes on all
7 of them, and I was concerned that I might have missed
8 something. So, I asked if there were any safety
9 significant issues. The answer that was given by the
10 supervisor and the inspector was that none of these
11 items were of any safety significance.

12 We're going to go through -- do you want
13 us to address the notice of violation or just the
14 apparent violations or both?

15 MR. LOUDEN: Whatever you'd like to
16 propose, we're open to hear everything you'd like to
17 address relative to the non-compliances that were
18 detailed. So, I would say if you're prepared to
19 address both --

20 MR. TROY: Okay. We're fine, we're
21 prepared to address both.

22 MR. LOUDEN: All right, thank you.

23 MR. TROY: There may be some, we may not
24 have facts that necessarily align directly with the
25 facts that you have in the inspection report. That

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1 doesn't mean that we don't take the matter seriously,
2 and it doesn't mean that we don't understand that there
3 are issues that need to be addressed at the practice
4 and that will be addressed.

5 Dr. Bastow had an event with his camera a
6 few weeks ago and then it was out of service. It could
7 have been repaired relatively quickly. At that time,
8 we decided that it was clear that we needed to take a
9 radical step to address the NRC's concerns. What was
10 done at that point was we entered what in Part 50
11 licensing world we called a standout. And the office
12 has not conducted nuclear activities since that time.

13 We have used that time, because time is the
14 issue here, that we've used that time to address the
15 deficiencies that were identified in the inspection
16 report. And we've made some substantial progress in
17 that area. There are still things that need to be done.
18 And so, it's true, we haven't gotten everything
19 addressed, but we are working on it. And we will
20 address those before we return the office to service,
21 so we think that's a commitment that should give you
22 some assurance of his level of commitment.

23 MR. LOUDEN: Sir, if I may? What was the
24 time frame again when this occurred? When you --

25 DR. BASTOW: Five weeks ago. Or six weeks

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1 ago.

2 MR. TROY: Yes.

3 MS. PEDERSON: When you're discussing
4 these things that you addressed, that they return to
5 compliance, can you please articulate for us what
6 you're going to do to ensure ongoing compliance?

7 MR. TROY: That's in here also.

8 MS. PEDERSON: Because when we went to ADR
9 last year --

10 MR. TROY: Yes.

11 MS. PEDERSON: -- the needed expectation
12 was to return to compliance. And we added in things
13 into the order that should have assured ongoing
14 compliance, and those weren't effective. So, it's
15 important for us to hear what you're going to do
16 differently and that's going to comply and sustain.

17 MR. TROY: We plan on addressing that
18 issue. The way that we set it up in the presentation
19 was that we did the notices of violations first, the
20 three notices of violations. And I think I made it even
21 simpler than you did but summarizing, because I thought
22 we all knew what they were.

23 The first violation was that the certified
24 nuclear medicine technologist did not use a syringe
25 shield during dose preparation. We deny that

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1 violation. We agree that he did not use a dose shield
2 during, or a syringe shield during the dose
3 preparation, but our understanding is that what he did
4 was in fact a commonly used process in the medical
5 industry. And it was developed based upon the use of
6 the ALARA concepts. What he did was he put his
7 operating, or withdrawing the dose from the vial inside
8 the L-Block, he reaches inside and he takes it out or
9 withdraws the dose into the syringe. And I apologize,
10 I'm a lawyer, not a technologist, so I may not have the
11 terminology exactly correct, but the important parts
12 are that when he lifted the, or if he puts the syringe
13 shield on the syringe, it's very difficult for him to
14 see the levels on the syringe, and it frequently results
15 in additional operations inside the L-Block to adjust
16 the syringe to the right level. By not using the
17 syringe shield in that case, he is able to see the
18 syringe, get the dose right in one effort, and that
19 reduces the handling of the nuclear material and the
20 L-Block.

21 We have talked to two different radiation
22 safety officers and two technicians, all of which say
23 that's a common procedure that they've used. It was
24 developed because the idea was to trade off time of
25 exposure versus the shielding. So, our understanding

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1 was, at the time, that we were doing something that
2 complied with ALARA. And so, we don't know, at this
3 point, we're unsure because the inspector suggested an
4 alternative procedure that --

5 MR. ORTH: I think that procedure is bound
6 by your license which is the inspector's
7 recommendation.

8 MR. TROY: No, I'm talking about there was
9 another procedure that he suggested.

10 MR. ORTH: Oh, I'm sorry.

11 MR. TROY: I'm not, I don't know if that
12 was bound by the license.

13 MR. ORTH: Oh, okay. Okay.

14 MR. TROY: He was saying you were supposed
15 to use it during the handling of all aspects, and we're
16 saying if a licensee comes up with a process that lowers
17 dose, the licensee should be free to use that dose as
18 long as it doesn't increase the dose. And if it's a
19 valid attempt to lower dose, no one is intentionally
20 violating regulation, or even believes they're
21 violating a regulation.

22 MS. PEDERSON: But I think what Steve was
23 saying is the procedure you are required to follow per
24 your license requires the use of syringe shields.

25 DR. BASTOW: Even if there is greater

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1 exposure?

2 MS. PEDERSON: It seems to me like that
3 would be a reason why you would want to change your
4 procedure and use the appropriate licensing process to
5 do so.

6 DR. BASTOW: So, there is an ALARA for --

7 MR. TROY: Well, then the issue is that we
8 didn't process a licensing memo for what we were doing,
9 not that we were violating NRC regulations?

10 MR. ORTH: You need to follow your license
11 until such time that you get an approval to have it
12 changed. So, that puts you in violation of the
13 license.

14 DR. BASTOW: Even if they get greater
15 exposure?

16 MR. ORTH: Which would be a valid reason
17 for sending in a license amendment in a timely manner
18 to update the procedure.

19 DR. BASTOW: Okay.

20 MR. TROY: Okay.

21 MS. PEDERSON: Patty, is there anything
22 you, Patty, is there anything you'd like to add?

23 MS. PELKE: Well, I would offer that you
24 seem to be relying on the cumbersomeness of the syringe
25 shield or the visibility of the technologist who is

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1 drawing up the dose to actually use the syringe in
2 combination with the syringe shield. I would say, did
3 you consider providing additional training to that
4 individual so that they could appropriately use the
5 syringe shield? And did you think about getting
6 another vendor that may have syringe shields that may
7 not have had that visibility challenge that it appears
8 to me that you are saying this individual had?

9 MR. TROY: We did not consider another
10 vendor prior to this. We are looking at the issue, and
11 if, well, let me back up. The inspector suggested an
12 alternative procedure in which, I don't know that I can
13 duplicate it because I don't, I'm not that familiar with
14 it. But essentially, in talking to the tech, the
15 alternative procedure required holding your hand a
16 different way and you effectively move the range of the
17 badge outside the stream from the pick or whatever you
18 called it, which to us isn't reducing exposure, it's
19 reducing measured exposure. And that would expose us
20 to another enforcement action for not accurately
21 measuring dose, right?

22 So, our point is, or what we were
23 committing to was that we will evaluate the right of
24 the various processes. We will train the technician
25 on the use of his hands during that process. And if

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1 it turns out that the process that we were supposed to
2 be using or is suggested or whatever, then we will
3 implement that process and we will do that by the end
4 of the year. But we will complete the evaluation and
5 then we will include that during the radiation safety
6 audits, and the materials, I'm sorry, the radiation
7 physicist will conduct the training with the technician
8 on the appropriate procedure.

9 MS. PELKE: I will offer these syringe
10 shields are widely used in the nuclear medicine field
11 for precisely what we're discussing here to ALARA
12 purposes to reduce extremity doses to technologists.

13 MR. TROY: I understand. It apparently,
14 I mean we didn't make this stuff on our own. This
15 wasn't a thing that just happened. It is, apparently
16 it's a fairly widely used process. So, I mean it wasn't
17 that RSO instructed him to do it, it was that's why the
18 tech was doing it. So, it's not that we did it alone.

19 So, we support ALARA, right, and obviously
20 we support reducing dose. And so, we will take the
21 appropriate actions to make sure that's done.

22 MR. LOUDEN: Well, before we move on, what
23 actions will you do in association with what you plan,
24 whatever actions you plan to do, as far as, I mean I
25 recognize the ALARA aspect, but what about reconciling

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1 the differences in your procedures with your license.

2 MR. TROY: Well, obviously if we are doing
3 something that's inconsistent with the license, we
4 would to fix the license.

5 MR. LOUDEN: I just wanted to make that
6 clear, follow it up.

7 MR. TROY: I mean if it turns out that the
8 procedure you all are recommending or suggesting we
9 should use is in fact the better procedure, we will do
10 that and we will comply with the license, because I
11 think you're saying your procedure complies with the
12 license. If it turns out that our procedure or the one
13 that we were using turns out that we have a lower dose,
14 then we would change the license.

15 MS. PEDERSON: I just want to comment on
16 this concept that the inspector suggested a particular
17 procedure, we are not in the role of making suggestions
18 how you should fix your problems and how you restore
19 compliance. You have choices. You need to evaluate
20 what works best for you, what conforms with the
21 requirements. If it requires a license change, it
22 would require a license change. But don't interpret
23 what the inspector said as this is the answer to your
24 problem, that's not his role or her role, and I just
25 want to make that clear. You need to decide what works

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1 for you.

2 MR. TROY: We completely agree.

3 DR. BASTOW: Yes, we're concerned.

4 MR. TROY: And that's, we're not being
5 disrespectful to the inspector, okay.

6 The second level 4 violation was the
7 licensee failed to monitor the nuclear medical
8 technologist's exposure. I believe the word monitor
9 is what our difficulty is here. And on that basis, we
10 deny the violation. Each month, the licensee provided
11 dosimetry, received dosimetry reports and reviewed
12 those reports. Those reports may not have been signed,
13 but that doesn't mean they weren't reviewed.

14 Recently, accurate dose estimates can be
15 prepared without written calculations. Specifically,
16 the number of studies per year is essentially constant.
17 From memory, I believe it was 410 in 2012, and 409 in
18 2013. The dose per study, if you calculate it, it's
19 not constant but it's basically relatively constant.
20 It's stable, right. And in reviewing the way to come
21 up with the best prediction, I believe the best
22 prediction of estimated dose is by the use of dose per
23 study because it's the dose per patient that varies,
24 or it's the patient load that varies from day to day
25 and month to month, not the number of days because he

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1 operates two days a week, you know. So, some days, you
2 know, it might be 25 patients, or some months it might
3 be 25 patients, some months it might be 48, okay.

4 The other issue is that because the dose
5 is about 650 millirem, 690 millirem per month on
6 average. You don't really know you're going to get to
7 the 10 percent limit if there are cancellations on the
8 audit until fairly late in the year. So, that's not
9 an excuse, it's just an observation. So --

10 MR. ORTH: Can I just ask a question?

11 MR. TROY: Yes.

12 MR. ORTH: As you're saying for those
13 months, just for my clarification, for the months when
14 the fingerings failed or you we're getting a process
15 or dose, you were entering then an estimated dose for
16 those months?

17 MR. TROY: No. Not in the --

18 MR. ORTH: You weren't?

19 MR. TROY: There was not a written record
20 and that is absolutely, we are correcting that. What
21 was done was you look at the form and you know about
22 how many studies they do, you know what the average dose
23 per month is and you can make a reasonable evaluation
24 based upon that experience that the nuclear medical
25 technologist was not going to exceed the annual limit,

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1 right, and that his dose was relatively predictable.
2 It averages, as our inspector said, in the 650 dose,
3 690 millirem per month range.

4 So, there was a safety evaluation. There
5 was not, the deficiency is that there was not a dose
6 estimate recorded and a dose estimate was not reported
7 to RDC, okay.

8 DR. BASTOW: Right, yes.

9 MR. TROY: Not that it wasn't monitored.
10 So, we're quibbling over the word or the violation
11 terminology, not that there was not something wrong.

12 DR. BASTOW: The dose is pretty easy by the
13 number of patients and it's very consistent.

14 MR. TROY: Do you understand?

15 MR. ORTH: No. But you're saying that you
16 basically limited his activities such that he wouldn't
17 exceed an NRC limit, but during the course of the year
18 you weren't really estimating the missing exposure nor
19 quantifying it nor recording it, but you had a high
20 level understanding that he wouldn't exceed the NRC
21 limits?

22 MR. TROY: It depends on --

23 MR. ORTH: I guess I'm trying to
24 understand because I can't.

25 MR. TROY: Not to refer to a past political

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1 issue, but it depends on what the definition of
2 monitoring is, okay. And what we're saying is we
3 monitored the dose, okay. We provided dosimetry, we
4 measured, or we sent the dosimetry off for process and
5 we got the reports. And we looked at the dose reports
6 and could come to the conclusion that he was not going
7 to exceed a safety or the annual limit, right? We
8 considered that monitoring.

9 Where we failed was we did not record the
10 estimate on the dose form and we did not incorporate
11 that into his annual dose limit, or dose accumulation.
12 And that, did I say it right?

13 DR. BASTOW: Yes.

14 MR. TROY: And so, those two things we are
15 correcting. Our corrective actions are focused on
16 that. We are now reviewing the monthly doses. Well,
17 we've gone back and we've calculated all the missing
18 doses, right, estimated them. We have recorded them
19 on the dose sheets and we have informed the RDC to
20 incorporate those into his lifetime exposure
21 calculations. Okay, so we are addressing the concern
22 as we see it.

23 And we are also contracting with a new
24 dosimeter provider because we believe that the
25 dosimeters were failing abnormally. We are at

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1 abnormally high failure rate and we have identified a
2 new vendor and we're in the process of preparing a
3 contract with them.

4 We also have alerted the radiation
5 physicist to include this as a specific category that
6 he looks at to make sure that we are in compliance when
7 he does his audits.

8 MS. PEDERSON: Maybe this is a good time
9 to ask this question, or you can address it later. How
10 come it wasn't identified by your audits? Yours or
11 your external person.

12 MR. TROY: There is an issue here where we
13 had one medical physicist providing the service, and
14 in late 2013, we transitioned from that physicist and
15 that company providing audits to a different physicist
16 and a different company who does the audits. That was
17 not a smooth transition. It took a lot longer to make
18 happen than we thought it would. And it is true that
19 we did not do a particularly good job of communicating
20 to him the weaknesses that we knew about. We gave him
21 the order, we talked about it, but it didn't work.

22 And so, we now have spent a great deal of
23 time working with the physicist to make sure he
24 understands that he can't just come in and do the
25 standard, you know, whatever it is, audit he does. He

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1 needs to look at the order and the subsequent inspector
2 report and check those categories, not only in the
3 specifics of what were identified but in the general
4 nature of what was identified in his future audits.

5 MS. PEDERSON: This one wasn't really an
6 order issue, if you will. This was compliance with
7 Part 20. You know, dose monitoring and dose reporting
8 is a basic fundamental of any license program. So, I'm
9 trying to understand how that was missed.

10 MR. TROY: Can you give us one second?

11 MS. PEDERSON: I can.

12 (Mr. Troy and Dr. Bastow
13 confer.)

14 MR. TROY: I think I would call it an RSO
15 training issue in that he understood he was supposed
16 to be looking at the legal limit, but he had not, in
17 previous incarnations of techs working there, the techs
18 had taken care of recording the dose and reporting it.
19 And so, it was not something he was in the habit of doing
20 beyond looking at the total dose and were we safe
21 relative to annual limits. And so, he didn't pick up
22 on the fact that he should have been doing that when
23 we got the new tech, so it's a training bug.

24 MS. PEDERSON: And I, okay, I understand
25 you're saying that, but your medical physicist that was

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1 coming in to audit your program didn't identify this
2 either, correct?

3 MR. TROY: Well, no, I don't know that he
4 did or didn't personally.

5 DR. BASTOW: He didn't.

6 MS. PEDERSON: Well, if he did identify it
7 but didn't get it fixed before inspection.

8 DR. BASTOW: He didn't do it, that's
9 right.

10 MS. PEDERSON: So, I'll just, I was making
11 an assumption that he didn't identify it.

12 MR. TROY: I think that's reasonable.

13 DR. BASTOW: Yes.

14 MS. PEDERSON: Okay. Why not?

15 MR. TROY: I think that, well, I certainly
16 wouldn't pretend to try to tell or say how the NRC
17 conducts inspections. But most oversight
18 organizations do it on a kind of random sampling basis.
19 And he, you know, whether he looked at it or not, I do
20 know that he, if you look at the forms, they have --
21 hold on for a second.

22 MS. PEDERSON: We don't need to belabor
23 this point. We've got a lot of other things to talk
24 about.

25 MR. TROY: Okay. If you look at the --

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1 MS. PEDERSON: But I guess the question
2 I'm asking is about the quality of the audits that were
3 done --

4 MR. TROY: The physicist understands that
5 he didn't look at it and that he was confused by the
6 form. It was not the form, at least I think he said
7 it was not the format that he was used to seeing, and
8 so he didn't recognize that the blank space was
9 significant, okay.

10 DR. BASTOW: Yes. In my understanding.

11 MR. TROY: He now knows. The tech, the
12 RSO and the medical physicist all understand how they
13 didn't see this and how it wasn't processed. So, we've
14 learned the lesson.

15 DR. BASTOW: That's true.

16 MR. TROY: The unsecured flood source.
17 This one is even trickier. We accept the violation but
18 we disagree with the severity level, and that is the
19 source, there was a source, a flood source that was on
20 the camera. The doors to the room were open and
21 essentially control of the source was theoretically
22 lost for a short period of time. We agree to that.

23 What we are trying to say is that the source
24 has a nominal date of I think 9 March, 9 April, something
25 like that, 9 May of 2009. It's gone through 6.7

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1 something half lives. It's, the current activity
2 level, instead of being 10 microcuries is less than 0.1
3 microcurie. So, instead of being able to put the
4 source on the camera and complete the test within, you
5 know, a nominal period of time of 15, 30 minutes or an
6 hour, the source has to remain on the camera overnight.

7 That really, if you can understand, is the
8 root cause of this because what happened was the process
9 that's followed at the site is they put the source on
10 the camera. To get the required counts, it takes about
11 12 hours, so it stays overnight. They lock the room,
12 they secure the facility and everybody goes home. The
13 next day, what happened we believe, and this is not
14 exactly clear and this is where we're not exactly sure
15 we understand the inspection report, the doctor
16 believes that he went in to the, or he was notified the
17 next morning that the inspector was there, that he went
18 into the room and unlocked the doors and turned on the
19 lights, not the staff, as the inspector said.

20 Now, we're not certain, okay, because to
21 be perfectly honest, other than Jeff and the RSO,
22 everybody else in this facility knows nothing about
23 nuclear medicine. They are totally office staff and
24 ultrasound techs. I mean they're smart people, but
25 when you go to the office manager and say there's a spill

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1 in the nuclear room, that means about like a code to
2 her. She has no concept of what that is, okay.

3 So, because the source had to be left
4 overnight, it was on the camera when he opened the room.
5 The inspector came in the room, and I'm not sure how
6 long a period of time transpired, but at that point he
7 called the doctor and said that there was, pointed out
8 the source. The RSO, the doctor saw the source,
9 immediately moved it from the camera to the storage in
10 the locker, the hot lab, locked hot lab where it
11 belongs.

12 MR. ORTH: So, when the source is normally
13 in place, aside from that, it's normally locked? It's
14 posted on the --

15 DR. BASTOW: Yes.

16 MR. TROY: Yes.

17 DR. BASTOW: Right.

18 MR. ORTH: This seems to be an anomaly is
19 what I'm hearing?

20 DR. BASTOW: No, I went and opened the
21 doors for the inspector.

22 MR. ORTH: Right, that's what I thought.

23 DR. BASTOW: I normally wouldn't go
24 through there but they said the inspector was here, so
25 I went and opened the door and then the flood source

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1 was there.

2 MR. TROY: So, the other, we're quibbling
3 on maybe minor points because we basically accept the
4 violation but the severity level. The imaging room is,
5 just so you understand the layout, the imaging room is
6 where we had the ADR. The camera is right behind it.

7 MS. PEDERSON: I remember.

8 MR. TROY: The door that you were facing
9 that was behind us at that time is the door that leads
10 to the hallway.

11 MS. PEDERSON: Yes.

12 MR. TROY: And that hallway runs from the
13 back of the building to the patient waiting area, but
14 it's not a patient waiting area, right. And it used
15 to be used frequently when people would come from the
16 hospital in the backdoor and go to the pharmacy that
17 was in the front building. The pharmacy is no longer
18 there, so the traffic in that area is substantially
19 reduced. The primary use of that floor is when people
20 come from the patient waiting area in the front of the
21 building to the ladies room, right, and they generally
22 don't go by there.

23 So, we don't believe anybody went into the
24 imaging room. The inspector didn't report anybody
25 going into the imaging room. So, we don't believe that

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1 anybody would have been exposed to radiation or has been
2 exposed to radiation. And if they were, it's at a
3 meter, using the curie meter thumb rule, it would have
4 been about 0.1 millirem per hour which, I'm not blowing
5 off 0.1 millirem per hour but it's not a big number,
6 right, so it certainly didn't endanger anybody or put
7 anybody in reach in kind of legal limit dose.

8 So, and then the other thing was that there
9 is also no mention that the source was actually removed
10 from the room at any time. It just remained on the
11 camera. So, what we're saying is that there was no
12 actual loss of control, although it was, there was
13 access --

14 MR. LOUDEN: Access.

15 MR. TROY: Right. And that, you know,
16 there was no safety significance to the event. So, the
17 RSO immediately stored the source. We've talked to the
18 CMT about reminding him to inform the RSO when
19 conducting overnight tests. And we're looking at
20 buying a new source that can complete testing overnight
21 so that we don't have a situation where we set somebody
22 up to do this again. Those are our, we'll turn now to
23 the apparent violations.

24 MR. ORTH: Right. And we understand that
25 you've documented your response to the severity level

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1 4 violations so that we can have that entered as well?

2 MR. TROY: The copy, a copy today was put
3 in the mail today to the document control desk in
4 Washington. And I hand-delivered a copy which I
5 believe was forwarded to yo before the meeting.

6 MS. PEDERSON: I haven't looked in my
7 inbox in the last few hours so I'm not sure.

8 MR. TROY: If you don't have one, we can
9 give you another.

10 MS. PEDERSON: Has anybody seen it?

11 MS. LOUGHEED: Yes, it was given to your
12 inbox.

13 MS. PEDERSON: Thank you.

14 MR. ORTH: So, we have that?

15 MS. PEDERSON: We have it.

16 MR. TROY: Yes, so we complied with the
17 requirement being timely to do it today, okay.

18 MR. ORTH: No, I appreciate that. Just
19 wanted to make sure we have that full documentation so
20 that we can review it --

21 MR. TROY: We're trying to turn over a new
22 leaf on timeliness here.

23 MR. ORTH: Okay.

24 MR. TROY: We understand that timeliness
25 is a big issue and it needs to be addressed, so that's

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1 an underlying issue to all of us.

2 Under the apparent violations, there was
3 one for restoring compliance, there was four for RSO
4 responsibilities and involvement, five for safety
5 culture, two for accuracy and completeness of records,
6 and one for notification of completion of activities.
7 The first one is restoring compliance and that is the
8 well counter. And we all understand that the well
9 counter was not through an employer for 60 days. We
10 admit that.

11 The issue is we, at the ADR, we accepted
12 a schedule that was probably overly ambitious for us.
13 And by that, that is not the NRC's fault and we're not
14 suggesting it is, it's entirely our fault. The problem
15 is that the facility works two days a week. 60 days
16 means that they work, that's basically seven and-a-half
17 weeks, so they work 14 days. And the rest of the time,
18 the doctor, the RSO is off doing other things, so it's
19 not like this is his only job, you know -- major hospital
20 facility.

21 He realized he was running late and
22 ultimately bought a well counter online, and was
23 provided assurances, oh, it will work for technician
24 99, and when the new radiation physicist came in, or
25 he came in and said I'm not sure that this will work,

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1 and so we then initiated investigation to try and find
2 the documentation supporting the fact that it would.
3 We can't even find the manufacturer. So, the company
4 still exists by name but it has many subdivisions and
5 nobody knows where this thing came from.

6 So, at this point, we've lost faith that
7 the well counter that we have is sufficient. And based
8 upon that, we're going to replace the well counter
9 before we start back up or start conducting -- we will
10 submit a license amendment as was originally required,
11 but until we can find one, you know, they're not
12 necessarily readily available, then we'll make it a
13 condition upon the startup, okay.

14 The other restoring compliance, I've
15 already summarized that page.

16 MS. PEDERSON: Maybe just a comment on the
17 schedule issue. Orders do allow for requests for
18 changes in schedules if you get somewhere near the end
19 of the order. Did it ever cross your mind that you
20 needed relief on the schedule before?

21 DR. BASTOW: It did, yes.

22 MS. PEDERSON: You should have come in
23 with a request to amend the order?

24 DR. BASTOW: Yes. And a lot of it is not
25 even to do with my practice. My fiancé had breast

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1 cancer and ended up going through the mastectomy and
2 the double chemo therapy and then radiation everyday,
3 just finished it. And you know, they gave her, you
4 know, not a very good prognosis. And it did require,
5 I didn't know at the time we met, and during that
6 process, I talked to Phil and he notified, I said I need
7 to tell somebody that I'm running behind on all these
8 things. I had signed up, I think I sent everybody the
9 conferences, I had signed up for two or three different
10 courses and conferences and just lost the money by not
11 going to them because of my commitment to her. And
12 that's really put my timetable behind.

13 But I found out, I did make a mistake, I
14 didn't send it in writing, it was only verbal and that
15 was a mistake.

16 MS. PEDERSON: I'm sorry you had to deal
17 with that, those difficulties. But I would have hoped
18 that, I mean you could have helped in this area, that
19 you follow the process, the regulatory process that's
20 still --

21 DR. BASTOW: Right.

22 MR. TROY: The additional, the piece of
23 information you're asking about is did we notify
24 anybody at the NRC, and the answer is yes. I talked
25 to Ms. Loughheed and we discussed the matter. What the

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1 wrong decision was, was we didn't follow it up in
2 writing and we should have.

3 DR. BASTOW: Yes.

4 MR. TROY: And so, we were somewhat
5 surprised, but in retrospect should not have been, that
6 when the inspection report came out, that there were
7 so many issues with what was done because of schedule
8 in that area, right. There are other areas or schedule
9 areas that this doesn't affect, but in that area it was
10 surprising because we had talked to the NRC. But it
11 wasn't in writing, so I understand you're not taking
12 notice on it.

13 Under RSO responsibilities and
14 involvement, there were four violations. One, the RSO
15 did not complete training by 12/12, and that's related
16 to what we just talked about. The second one was that
17 the shadowed individual was an authorized user, not an
18 RSO. And we believe that that is incorrect, or let me
19 put it in another way. We were under the reasonable
20 belief that the person that was shadowed was an RSO,
21 and we believe so today. We believe, and we're not
22 certain about this, that what occurred was he was in
23 practice with another doctor and they had a split up,
24 and the license, we haven't tracked this down, okay,
25 completely, but we asked him if he was an RSO and he

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1 says, yes, I'm an RSO. So, and we asked him again
2 within the last three days, was he an RSO, and he said
3 yes, I'm an RSO.

4 We believe collectively, not proven, that
5 what happened was when they split up before, the doctor
6 that left was the RSO and he was an authorized user on
7 that license. We believe he subsequently, once again
8 this has not been verified, that he subsequently got
9 a new license for his facility and he is the RSO and
10 that the license that was cited in the inspection report
11 is not the correct one. We certainly don't want this
12 to be another missing meter number kind of fight, okay.
13 And so, you know, if you would like us to investigate
14 that and report back to you, we certainly will. Or your
15 inspector can do it, we don't really care, but we would
16 like to get to the bottom of it.

17 MR. LOUDEN: The intent, the intent of the
18 requirement was to shadow a technically qualified and
19 active RSO and then have the documentation to support
20 that said activity was completed. So, I know that was
21 the basis for a number of the comments. So, what is
22 it exactly that you're proposing now with regard to the
23 difference between the authorized user and the --

24 MR. TROY: Well, if he was an RSO, then he
25 completed the shadow.

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1 DR. BASTOW: I picked him because he was
2 a solo cardiologist in a similar practice, would have
3 the similar issues and similar operations, and it made
4 the most amount of sense. And I knew his partner had
5 left and he had a new license since the beginning of
6 the year and fresh and new, I thought it would be the
7 best exposure.

8 MR. TROY: So, we know --

9 DR. BASTOW: And I called him yesterday
10 and he said yes, I'm the RSO at my facility.

11 MR. LOUDEN: And what did you provide the
12 inspector at that time when he was looking to verify
13 this?

14 DR. BASTOW: We gave him his information
15 to call and talk to the doctor.

16 MR. TROY: We're working on correcting
17 this, but there is a documentation philosophical issue
18 here, and that is a doctor doesn't necessarily document
19 everything that is other than he completed the training
20 and he knew he completed the training. So, he wasn't
21 concerned about that. He did not have a form or a
22 letter or whatever that specified the dates. So, he
23 asked the doctor the dates, he didn't recall them, the
24 other doctor didn't recall them, but that doesn't mean
25 that it didn't happen. That just means that they don't

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1 recall the dates, okay.

2 Philosophically, as a nuclear person and
3 as a nuclear attorney, yes, I live with the
4 understanding of a piece of paper signed and whatever.
5 That's just not his world. So, that's the cultural
6 problem.

7 MR. ORTH: I think we just, we need some
8 documentation or some indication that the individual
9 was responsible as an RSO at a facility to, because as
10 Mr. Louden indicated, the purpose was that you could
11 share from his day-to-day RSO type responsibilities and
12 we want to ensure that it certainly wasn't just as an
13 authorized user because the roles are different.

14 MR. TROY: We understand, we absolutely
15 understand.

16 DR. BASTOW: So, a letter from him would
17 satisfy that?

18 MR. ORTH: To show us what license he was
19 --

20 MR. TROY: Yes, to show what license and
21 to say he completed two days of training with Dr.
22 Bastow.

23 MR. ORTH: Yes.

24 MR. LOUDEN: Yes.

25 DR. BASTOW: Okedoke.

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1 MS. PELKE: I think it's the other way
2 around, that Dr. Bastow completed two days of training
3 with the individual that's designated as an RSO,
4 correct?

5 MR. TROY: Whichever way you look at it.

6 DR. BASTOW: Yes.

7 MS. PELKE: Well, also, I'm just trying to
8 better understand that this was an issue that came out
9 of your ADR discussion about a year ago. So, I would
10 have thought at that time that we were clearer in our
11 expectations on what you needed to do to go forward.
12 So, if you agreed to shadow an RSO from a similar sized
13 program, there are a number of ways that you could have
14 contacted us to follow up on confirming that an
15 individual that you were considering spending two days
16 of your time with to fulfill this training was listed
17 on a valid NRC license as an RSO. I mean you could have
18 called us to verify that.

19 MR. TROY: We could have.

20 DR. BASTOW: I guess it didn't cross my
21 mind that he would lie. Yes, I guess I should have
22 checked.

23 MR. TROY: That thought never entered our
24 mind.

25 DR. BASTOW: It honestly didn't.

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1 MR. TROY: I mean I understand your point.

2 DR. BASTOW: I would have checked. I
3 would have checked if I thought that was --

4 MR. TROY: It just never entered our mind
5 that when he said he was an RSO, that he might not have
6 been. I mean it's the equivalent of somebody has a,
7 you know, says that they're a doctor and they have
8 forged their license. You know, that's the realm that
9 that would be in our minds. I'm not disagreeing with
10 you and I'm not saying that what you were saying is not
11 appropriate. It's just we didn't think of it.

12 MS. PEDERSON: I wanted to expand just
13 briefly what the documentation requirement is in the
14 order. The licensee will retain documentation showing
15 the name of the RSO to be shadowed, contact information,
16 approximate hours, and insights gained. So, that
17 needs to be included, not just it happened, but I think
18 the insights gained is an important piece of the
19 required documentation.

20 DR. BASTOW: Okay.

21 MR. LOUDEN: So, I think just to reiterate
22 what Cindy just said, and that is whatever you provided
23 to us, to go back to the order, verify all the various
24 facets that might have been stated in the order to do
25 that so that each of those items are addressed when you

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1 do provide them.

2 MR. TROY: We agree with that. The
3 quarterly audits were not submitted within the 60-day
4 period as required. Timeliness just runs all through
5 this. There was one audit, and I'm not sure, do you
6 remember which one that was late? We didn't get it in
7 time.

8 DR. BASTOW: I think it was the March one,
9 I think.

10 MR. TROY: But there's also multiple
11 examples so we're not quibbling with that, okay. This
12 is another one of those philosophical things at the
13 bottom. When the RSO reviewed the audits, he did not
14 provide independent observations to argue the health
15 of the radiation safety program. In other words, he
16 didn't write no comment or the plan is fine. He assumed
17 that if he didn't have any negative comments, he didn't
18 have to provide a comment. We will correct that.

19 DR. BASTOW: We're already doing that.

20 MR. TROY: He's already doing it.

21 MR. ORTH: And I understand the no comment
22 aspect. I think perhaps it doesn't come through the
23 words of the order, but we're looking for some, again,
24 insights other than, I understand there are certain
25 periods of time there may be no comment. But it makes

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1 us kind of wonder --

2 MR. TROY: Well, especially in light of
3 what happened before in the history, what you're asking
4 for is not unreasonable, okay. The next one --

5 MS. PEDERSON: Again, I'll just focus you
6 back on the words of the order. Not reading it all but
7 agrees with the results of the order along with
8 independent observations that he has made to the health
9 of the radiation safety program. The licensee will
10 also implement actions recommended in the report or
11 document justifications for not implementing the
12 recommended actions.

13 MR. TROY: I'm sorry, I didn't hear the
14 last sentence.

15 MS. PEDERSON: Also, the licensee will
16 also implement actions recommended in the report or
17 document justifications for not implementing the
18 recommended actions.

19 MR. TROY: Right.

20 MS. PEDERSON: So, it's more than just a
21 signature that the document has been read. There's
22 independent observations, there's actions to be taken
23 upon findings or issues in the report assuming there
24 are some. It sounds like based on the inspections,
25 there should have been at least some observed.

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1 MR. TROY: Yes. Restoring, the other
2 comment is the RSO, we did not appreciate the
3 administrative burden created by the schedule agreed
4 to in the order, and that's back to the two days a week,
5 right. You know, he's got other physician patient
6 safety, you know, other things going on. And even in
7 the days where he's doing different stress tests, that
8 afternoon he's off doing something else. So, it's not
9 intended as an excuse but just to describe the situation
10 as it is that, you know, it wasn't like he had enormous
11 amounts of time to focus on these issues. He should
12 asked for more time, and that's our problem not yours.

13 MS. PEDERSON: This just prompts me to
14 comment at this point. Our regulatory structure is to
15 ensure safe use of radioactive material. How an
16 individual chooses to organize their business and
17 chooses how to spend their time, totally up to people
18 other than us.

19 MR. TROY: Exactly.

20 MS. PEDERSON: Our only interest is that
21 you follow the rules which is our assurance that people
22 and the environment are going to be safe. Now, you need
23 to figure out how you're going to do that, how you're
24 going to spend your time. But it's imperative to us
25 that things get dealt with in a timely way. And working

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1 40 percent on nuclear issues versus 60 percent others,
2 we're not going to give you an extra 60 percent time
3 in order to resolve this stuff. You have material, you
4 use it on an ongoing basis, it needs to be dealt with
5 in a timely way.

6 MR. TROY: We understand. And that
7 really is what prompted the stand-down was that once
8 the, you know, the camera drove being shut down for a
9 period of time. But then we realized, wait, this is
10 an opportunity to buy time to fix these things, and
11 that's what we're doing. So, okay, we don't get full
12 credit because we didn't decide to do the stand-down
13 first, right, but maybe we get the credit because we
14 ultimately got there and realized that this was an
15 opportunity to fix all the things that we hadn't had
16 the time to address, and so we're doing that. And it's,
17 I mean, and I know money isn't your thing but it's at
18 significant cost.

19 Finding and scheduling shadowing was
20 difficult. We talked about the family issues and that
21 the individual appears to be an RSO. Finding an RSO
22 who would agree to it was not the easiest thing. It
23 took some protracted time.

24 And then there's the thing about the no
25 comments which we now have your direction.

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1 The corrective action, the RSO is
2 evaluating hiring a medical physicist to assume RSO
3 responsibilities, that's one possibility. There are
4 other possibilities that are being considered. If he
5 can't do this, then we'll figure out some way to do it.
6 And we're also focusing on timeliness.

7 MS. PEDERSON: Could you elaborate a
8 little bit on your first bullet there about looking
9 possibly for someone to assume RSO responsibilities?

10 MR. TROY: He has always been interested
11 and felt that because it was his office he should retain
12 that responsibility and be responsible for what goes
13 on there, right. It may be that he needs someone who
14 is more able to focus on nuclear activities --

15 DR. BASTOW: It's a matter of time. You
16 know, we used to put more time into it, I had to actually
17 do that, even though you feel you're losing control and
18 you don't want something to happen, you may not be aware
19 of it. It's a little uncomfortable but there's only
20 so much time I have, so somebody may have to do some
21 of that stuff to make sure it gets done, whether I can
22 just do it right.

23 MR. TROY: So, because there are a number
24 of options under consideration, we don't want to make
25 a commitment to any specific option at the present time.

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1 But that is one of the kind of things that we're looking
2 at to address your concerns because I believe that would
3 give you a big boost in confidence that things are going
4 to be handled correctly. So, in other words, we do take
5 the issue seriously.

6 Apparent violations that were for our
7 safety culture, there were five, having to do with not
8 posting the policy in time, not providing the language
9 that he could contact the NRC for additional action and
10 safety issues, not providing policy to the CMT,
11 documentation of the initial training on the policy was
12 not maintained, documentation of the RSO's quarterly
13 meeting with thee CMT was not retained for inspection.

14 All those deficiencies have been
15 corrected. A new revised policy incorporated the
16 language that was identified in the inspection report
17 has been posted in three locations in the office. The
18 RSO and the certified nuclear medical technologist
19 attended our safety culture training. I provided that
20 training. I have experience working with safety
21 conscious working environment with Part 50 licensees
22 and auditing those programs. We prepared a lesson
23 plan, the lesson plan has been annotated with the date
24 that was given, the attendees, and that I gave the
25 training.

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1 MS. PEDERSON: Was any of this identified
2 or done before the inspector's observations?

3 MR. TROY: No. Well, the procedure,
4 there was a revision in the procedure but I don't know,
5 I can't say that it incorporated precisely the language
6 the inspector raised.

7 MS. PEDERSON: How did it address safety
8 culture?

9 MR. TROY: The policy?

10 MS. PEDERSON: Yes.

11 MR. TROY: The original policy was an
12 excellent policy. It just didn't technically have
13 those --

14 DR. BASTOW: I've seen --

15 MR. TROY: It's more than I've used in many
16 places.

17 MS. PEDERSON: But was the tech trained?

18 MR. TROY: Yes. That was, I mean if --

19 MS. PEDERSON: Is this an issue of trained
20 but not documented?

21 MR. TROY: Yes. The telephone call
22 that's mentioned in there is, the purpose of that call
23 was to ensure that the tech understood what a safety
24 conscious work environment was and what his rights and
25 responsibilities were under Section 2-11 were under the

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1 NRC Form 3 and all of that, right. That's why I called.
2 I didn't call to conduct training that day. So, when
3 the inspector asked me did I have records, the answer
4 was no. I didn't understand that, I mean it was not
5 my understanding that I was conducting initial training
6 at that point, and it wasn't conducted as initial
7 training. It was an interview to make sure that he
8 understood what a safety conscious work environment was
9 and that he needed to report safety concerns either
10 there or to you. He did.

11 And so, the frustrating part for me was the
12 inspector didn't ask that question, right. He focused
13 on the missing documentation which, you know, okay,
14 it's on the wall, it's there, but I don't think it
15 changed his understanding of it at all. So, and he has
16 been provided a copy with the new. But that's just me.

17 The one thing I will say is, and this is
18 probably something for all of us, is that we, people
19 that, you know, we don't look at bulletin boards and
20 we read bulletin boards and that's where we get things
21 like phone numbers and whatnot, right? Anybody, Jeff,
22 the tech is, I don't know, maybe what, 28? 30?

23 DR. BASTOW: Yes.

24 MR. TROY: If he isn't on iPad, he isn't
25 going to see it. So, just a wave of the future is coming

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1 and it's changing what people look at and read. We all
2 don't pay attention to it.

3 And also, the documentation of the RSO's
4 quarterly meeting has been, he conducted a quarterly
5 meeting and that documentation has been retained also.

6 MS. LOUGHEED: Mr. Troy, can I ask a
7 question? When was this --

8 MS. PEDERSON: Can you use the microphone?

9 MS. LOUGHEED: When was the safety, this
10 is Patricia Lougheed, when was the safety policy first
11 put into effect?

12 MR. TROY: I don't recall specifically,
13 but it was put up, or it was sent to Dr. Bastow --

14 DR. BASTOW: Late fall?

15 MR. TROY: Yes, like --

16 DR. BASTOW: Late fall.

17 MR. TROY: Not very long after the order.

18 DR. BASTOW: Yes.

19 MR. TROY: And it was not posted
20 apparently, or if it was posted it fell off, I don't
21 know. I don't know when it went on the wall if that's
22 what you're asking.

23 MS. LOUGHEED: So, late fall you believe,
24 Dr. Bastow?

25 DR. BASTOW: Yes. We probably have

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1 documentation, you know, when you sent it.

2 MR. TROY: I mean I sent the e-mail, I just
3 can't tell you when it was on the wall.

4 MS. LOUGHEED: Was it just created at that
5 time?

6 DR. BASTOW: Yes, it was printed and put.

7 MR. TROY: Well, now, Jeff says he never
8 got a copy of it, so we'll stick with Jeff. We're not
9 going to get into a disagreement over that.

10 MS. LOUGHEED: Thank you.

11 MR. TROY: As far as the missing language,
12 we should have recognized that. It was in the order,
13 right.

14 MR. ORTH: And thank you for mentioning
15 that, because when I read just your picture of your
16 slide here, it reminded me of our discussion on the
17 syringe shield and it said the inspector suggested
18 items. And I hope we're on the same page --

19 MR. TROY: No, this is --

20 MR. ORTH: -- firmly documented on your --

21 MR. TROY: Right.

22 DR. BASTOW: Right.

23 MR. TROY: There's no question.

24 MR. ORTH: Okay.

25 DR. BASTOW: Yes.

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1 MR. TROY: The next set of apparent
2 violations are two for accuracy and completeness of
3 records. The first one is the radiation safety
4 document procedures, such procedures were not onsite
5 and available for inspection. And the January 16th,
6 2014 order, I mean audit was not complete, accurate or
7 clear.

8 He cited two specific procedures, once was
9 Rules for the Safe Use of Radiopharmaceuticals, and
10 Emergency Procedures. And they were not posted, or
11 they were -- here is what we believe. We didn't check
12 them the day that the inspection occurred, and so we
13 can't say that they were on the wall. But they are on
14 the wall and they've been on the wall, and to our
15 knowledge they were on the wall, but they were in the
16 hot lab. They are not stored with the rest of the
17 procedures.

18 And our suspicion is he didn't go into the
19 hot lab and see them in the hot lab. And that's why
20 he thought those procedures weren't there. So, can we
21 prove that? No. But we think that. And we don't
22 know, the doctor didn't post them subsequent to the
23 inspection. The physicist didn't post them subsequent
24 to the inspection. And we don't believe Jeff the tech
25 posted them subsequent to it either.

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1 DR. BASTOW: The physicist is the one that
2 told us they're in there.

3 MR. TROY: He told us they were in there.

4 DR. BASTOW: He's the one that says what's
5 this issue about? They're in the hot lab. He was
6 aware of it.

7 MR. TROY: So, that may explain what
8 happened and why he didn't find them, I don't know.

9 MS. PEDERSON: But he wasn't, presumably
10 during the exit this wasn't discussed?

11 MR. TROY: We didn't know. During the
12 exit, well, it wasn't discussed in detail. He kind of,
13 I'm not complaining and I'm not trying to
14 mischaracterize anything, they went through it rather,
15 it's a lot, it was a lot to go through.

16 MS. PEDERSON: Right.

17 MR. TROY: So, they were going through it
18 rather quickly. And I don't know that we asked and I
19 don't know that we even knew it was or wasn't there at
20 that moment during the exit interview at all, okay.
21 So, we weren't able to tell them during the exit where
22 it was, right. So, we're not, I mean we understand
23 we're partially responsible for that.

24 MS. PEDERSON: I'm just trying to
25 understand the sequence there, so okay.

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1 MR. TROY: Yes. So, it's not, and there
2 were a couple of days or at least one day that he was
3 in the office conducting his inspection and Jeff wasn't
4 there, so he was in there by himself. And that may be
5 the day that he looked, I mean we can see this making
6 sense of why he didn't see it, right. And if he didn't
7 go back and look again, then, if it didn't come up again,
8 then we wouldn't have commented on it or Jeff would have
9 known it was there.

10 MR. LOUDEN: So, you're maintaining that
11 these two procedures were in your facility at that time?

12 MR. TROY: We're not quite going that far
13 because we're not comfortable saying that we know they
14 were there the day he did the inspection because we
15 didn't see them that day, do you understand? Okay. I
16 would never make an assertion that something was there
17 if I didn't see it or he didn't see it. So, what we're
18 saying is it's our belief they were there. They were
19 there since then and we don't recall anybody putting
20 them up or posting them in there, so we're making the
21 leap of faith that they were there. But you know, don't
22 hold me to a, you know, perjury statement that they were
23 there, I'm not saying that, okay.

24 Okay. And finally, all of the
25 documentation deficiencies identified in the

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1 inspection report, or the audit report of 1/16/2014
2 have been corrected and the documentation is clear and
3 legible. So, that long list of documents on the page
4 in the addendum portion by Mr. Louden's left hand is
5 there and corrected.

6 Finally, the final apparent violation is
7 the identification of completion of activities. The
8 six-month notification of activity completion was not
9 provided by March 12th as required. We agree. The
10 licensee has implemented a stand-down to correct
11 administrative deficiencies that we discussed.
12 Timeliness was a major focus of that. And this will
13 be the kind of thing that we're trying to fix so it
14 doesn't happen again.

15 And today's presentation basically
16 provides the current status of all actions under the
17 order and the inspection report.

18 MR. ORTH: I think I understand the
19 actions that were taken or discussed to fix the things
20 that we identified or to correct. I'm not sure I got
21 a good understanding of what's going to prevent
22 recurrence.

23 MR. TROY: Hopefully the next page will
24 help you.

25 MR. ORTH: Okay, I'm sorry.

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1 MR. TROY: No, that's okay.

2 MR. ORTH: Jumped ahead of you.

3 MR. TROY: In conclusion, we believe the
4 RSO shadowing was completed and we will provide you with
5 documentation that you asked for to demonstrate that.
6 With the documentation and safety conscious work
7 environment deficiencies that were, I think, you know,
8 Section A was the completion of the well counter, B was,
9 was it B? A? B? Whichever it was, the one on safety
10 conscious work environment, all of that has been
11 corrected. And the one on the documentation of
12 completeness and accuracy of information, those have
13 all been corrected.

14 The transition to the new medical
15 physicist and focusing on correcting the deficiencies,
16 excuse me, identified in the inspection report have
17 served as a tool to address the issues of concern to
18 everybody. And so, the medical physicist just
19 completed an audit. Hopefully, when you review that
20 audit, once we get the copy back and mail it to you,
21 you will see a better focus on activities and less
22 deficiencies on the audit, okay.

23 MR. ORTH: So, this new medical physicist,
24 this is the audit-orientated issue?

25 DR. BASTOW: Yes.

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1 MR. TROY: Yes. We were relying perhaps
2 too much on the audit in the early stages, and we still
3 do rely on the audit because that's the independent
4 check to make sure. You know, the old thing about,
5 there's going to be human error so it will be, you know,
6 a person is going to make an error one percent of the
7 time. If you have two people, you know, two-person
8 check, then you have an error one-tenth of one percent
9 of the time, or a hundredth of one percent, whatever
10 the number is. I'm a lawyer, not a mathematician.

11 So, we were depending on the audit process
12 and I probably over-depended on it because we weren't
13 getting the performance from it that we needed or
14 wanted. And I think we've worked with the physicist,
15 I did, I spent a lot of time on the phone with him about
16 what we need and what we want. Hopefully, we're going
17 to get better performance out of the physicist in this
18 area and help us identify problems and obviously to be
19 more comprehensive than fill in the blanks of, you know,
20 that he shows up, he's there for a couple of hours, fills
21 in the blanks or whatever.

22 Speaking of which, one of the deficiencies
23 was that we did some sort of test on January the 16th
24 by a cal check method, and the actual dates that it was
25 performed was like January 20th through February

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1 something, that's one of the deficiencies. What
2 happened was he wrote the date in on his book, it's not
3 a falsification, so I'm trying to tell you he wrote the
4 date into the book, or his audit, and then he found out
5 that the office had not ordered a, what do you call it?
6 A dose?

7 DR. BASTOW: Dose.

8 MR. TROY: Right, for him to do the test
9 with. So, they changed and decided, no, we want to do
10 the cal check method, bail me out if I say this
11 incorrectly, they didn't use the cal check method, they
12 used the decay method, right. And so, it was done over
13 a period of time. And what he did was he had written
14 in the audit January 16th, but then he had taken the
15 documentation on the test and attached it to the back
16 of the audit and clearly it was done at a later date.

17 DR. BASTOW: The physicist.

18 MR. TROY: The physicist, right. So,
19 even though the audit was the 16th that was appended
20 to, even though it had happened a few days later, it
21 was appended to the back. So, that's how that
22 occurred.

23 MS. PEDERSON: Can I just ask the
24 question? This bullet, you talk about transitioning
25 to a new medical physicist. Is that the medical

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1 physicist that you hired at the beginning of this
2 calendar year?

3 MR. TROY: Yes.

4 MS. PEDERSON: So, it's the physicist that
5 started after whomever you had last year in 2013?

6 MR. TROY: Right.

7 DR. BASTOW: Yes.

8 MS. PEDERSON: Failed you somehow?

9 MR. TROY: I wouldn't say he failed us
10 somehow. We were in the unique position that we
11 required more attention in the audit than just the
12 standard audit, I believe, more detail. And he was
13 doing audits that met the standard requirement but not
14 to the level of detail that we needed. For instance,
15 checking did we complete the requirements of the order,
16 not the inspection report, and he wasn't really looking
17 at that, okay. And we kind of thought he was, he
18 wasn't. You know, whether it was us that didn't tell
19 him or he didn't understand, it really doesn't matter.
20 We as a team didn't do what needed to be done.

21 So, no, I would not put that on the
22 physicist and say he failed us. We failed as a group.

23 MS. PEDERSON: I just want to understand.
24 This is the physicist you've had in place since January
25 of 2014, correct?

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1 MR. TROY: November of 2013.

2 MS. PEDERSON: This is your new medical
3 physicist?

4 MR. TROY: Yes, this is the new medical
5 physicist.

6 MS. PEDERSON: Okay.

7 DR. BASTOW: Yes, that's right.

8 MR. TROY: But what we're saying, what I'm
9 --

10 MS. PEDERSON: That's all I needed, thank
11 you. You answered my question.

12 MR. TROY: But what that bullet means is
13 that the transition is becoming more effective as we
14 work together more.

15 And then we're trying to strengthen the
16 administrative programs to ensure future timeliness as
17 part of, you know, corrective actions. And frankly,
18 we don't have all the answers yes, all right. We don't,
19 obviously we need some sort of tickler system, some sort
20 of better record keeping system. And we're working on
21 it.

22 You know, I don't know what will make you
23 or convince you that we're making a good faith effort
24 to do that, but we're looking at it. We're trying to
25 come up with a better system to make sure this doesn't

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1 happen, including QA audits with the medical physicist,
2 you know, the quarterly audits, right. So, I know I'm
3 not giving you the warm fuzzy you wanted here, okay,
4 but it is a focus, we recognize the problem, and we're
5 trying to come up with something. We just don't have
6 the magic bullet yet, right.

7 So, can I say we will resolve that and
8 report back to you prior to restarting the facility?
9 I'd be willing to do that if that would make you more
10 comfortable. We just don't have all the answers is all
11 I can say.

12 The final issue -- I lost the page.

13 MS. PEDERSON: I think it's before your
14 conclusion page.

15 MR. TROY: It is. I'm sorry, I skipped by
16 that page. If we can backtrack for a moment. The
17 notification -- no, that's not it.

18 MS. PEDERSON: Open items?

19 MR. TROY: Oh, the open items, that's what
20 I'm looking for. There were two open items. One was
21 that survey records from the April 23rd, 2014 were not
22 complete and accurate in material respects. The
23 second is the certified medical nuclear technician did
24 not appear to report the spill to the RSO, and as a
25 result, the RSO did not supervise the cleanup of the

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1 spill and a radioactive spill report and a radioactive
2 spill contamination survey were not completed.

3 My general reaction is to say that there
4 is currently an OI investigation ongoing, OI
5 investigation about that issue, and therefore, we don't
6 want to make any comments about it.

7 MS. PEDERSON: Yes, we're not asking that
8 you respond to those today.

9 MR. TROY: Okay. Other than that, we can
10 answer any other questions for you.

11 MR. LOUDEN: Okay. I think we don't have
12 anything at this point. So, at this point of our
13 agenda, as I mentioned earlier, thank you for your
14 presentation, we will now take a short break for a
15 caucus where we'll meet separately. And then we'll get
16 back to you for any follow-up questions or
17 clarifications we may have.

18 MR. TROY: Do we have the opportunity to
19 talk to you outside the --

20 MS. PEDERSON: Not on the subject matter
21 as it pertains to this meeting. This needs to be an
22 open discussion. Unless there is some reason that
23 there is proprietary or security information or some
24 other kind of protected information.

25 MR. TROY: No.

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1 MR. LOUDEN: So, at this time, we'll take
2 a break for our caucus.

3 (Off the record.)

4 MR. LOUDEN: We're back. We have a few
5 follow up things we'd like to comment on, ask some
6 questions, do some follow up, so I'll turn it over to
7 Steve first to kick that up.

8 MR. ORTH: Okay, thanks. As we got
9 together, we developed a few more questions, just
10 making sure we're understanding the position on a few
11 of the items. One of the conditions in the order was
12 to have quarterly meetings with the technologists or
13 the staff. And I'm not sure that we heard what you were
14 doing with respect to that or what your position was
15 on that issue.

16 DR. BASTOW: Actually, well, because we
17 meet so infrequently, on Monday morning, usually I ask
18 Jeff about, you know, any concerns or safety issues kind
19 of stuff. And then I say make sure you report to me
20 before you leave on Tuesday because that's usually the
21 two days we worked. And that's every week.

22 MR. ORTH: So, what I'm gaining from that
23 is that throughout this, that's been your
24 communications with them as, you know, as part of this
25 quarterly but perhaps it's --

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1 DR. BASTOW: And then the only thing I
2 think I added --

3 MR. ORTH: -- issue that we're talking
4 about --

5 DR. BASTOW: Yes, and the only thing we
6 added was, because there's only the two of us, part of
7 the recommendation was that the NRC is the other person
8 you can call at any time for any kind of issue if you
9 don't want to deal with me about this stuff. And that
10 was the only other thing we added to that.

11 MR. TROY: Now, Jeff, if you read the
12 inspection order, supposedly Jeff said that there was
13 no formal meeting.

14 MR. ORTH: Right.

15 MR. TROY: And that's true, there was no
16 formal meeting where we sat down and --

17 DR. BASTOW: When two of us did sit down
18 for half an hour and discuss anything, it was just
19 checking on Monday and checking on Tuesday.

20 MR. TROY: It's kind of a small office, and
21 so things are unfortunately, well, relatively informal
22 compared to what you're saying. But yes, there is now
23 between them on that subject on a periodic --

24 DR. BASTOW: Every week.

25 MR. TROY: Every week.

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1 MR. ORTH: And I guess what I'm taking from
2 that is there has been --

3 MR. TROY: Ongoing.

4 MR. ORTH: Ongoing. We talked about
5 earlier the shadowing of the RSO of your organization.

6 MR. TROY: Yes, sir.

7 MR. ORTH: Can we get documentation to
8 help us resolve that issue from you folks within, say
9 a week?

10 DR. BASTOW: I asked him last night to text
11 me, the license number to me, you know. And I texted
12 him this morning, he was just in the cath lab and that
13 was last notice, I haven't gotten anything back from
14 him yet, so I expect him to.

15 MR. TROY: Let me answer it this way. We
16 will try and do it in a week. If we can't do it in a
17 week, we will notify you.

18 MR. ORTH: Fair enough. We talked about
19 the well counter, certainly that's an area that I know
20 we've been dealing with for quite some time now.

21 DR. BASTOW: Yes.

22 MR. ORTH: Going back to the original
23 inspection, well before we got into the ADR. Can you
24 give us a better idea of where you're going with that
25 in terms of the time line, what you're doing, when will

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1 we get this resolved?

2 MR. TROY: I think what we said was that
3 we were trying to procure a new well counter. It's
4 difficult to necessarily find one today, that we will
5 get a new well counter prior to restarting operations
6 at the facility, or we will submit a license amendment
7 to do that. So, the facility will not operate without
8 a well counter, an adequate well counter. Is that
9 acceptable?

10 MR. ORTH: I think we wanted to follow up
11 a little bit more on your, you know, your stand-down,
12 and it sounds very voluntary, very, it lacks some
13 formality. Is that something that you might provide
14 to us as a letter indicating that your standing down,
15 you're going to put your license into a standby mode
16 until you satisfy --

17 MR. TROY: Does that change the status of
18 the license such that we have to report back to you?
19 Or is that just a letter notifying you of what we're
20 doing? I'm interested in the license implications of
21 what you're asking.

22 MR. LOUDEN: It would, if you submitted a
23 request to place your license in standby, you would then
24 be required to notify us of or actually you would have
25 to submit a request to put your license back to an active

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1 status.

2 MR. TROY: Would there be a review program
3 involved in that? Or would it be just a question of
4 a letter and another letter?

5 MR. LOUDEN: I'll turn to Patty for that
6 question.

7 MS. PELKE: No, there would be a review
8 based on the circumstances on why you're putting your
9 license in the standby, and then commitments on what
10 you've put in place and your preparedness to stand your
11 program back up and not only chief compliance but also
12 a sustained compliance going forward.

13 DR. BASTOW: If formality matters, then we
14 could do that because that's essentially what we're
15 doing.

16 MR. ORTH: And I raised it because a lot
17 of things that we're discussing, they really hinge on
18 that.

19 DR. BASTOW: Yes, certainly.

20 MR. TROY: I understand that. The
21 hesitance isn't to do that, right, because --

22 DR. BASTOW: Because we are doing that,
23 yes.

24 MR. TROY: We're basically doing it and we
25 will do it. We have no problem with that part. The

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1 issue for us is that, I know once again we all aren't
2 concerned about money, but if we got into a long
3 protracted, you know, if you all got busy with some
4 other plan, whatever it was, and we got to the back of
5 the line and we went off for weeks, that would mean that
6 he couldn't operate, it's that part of the commitment
7 that we're kind of balking at a little bit. It's not
8 the fact that we don't want to tell you or have you
9 involved, in fact we welcome your involvement and we
10 welcome telling you. So, that's our only reservation
11 with that.

12 MR. LOUDEN: Okay --

13 MR. TROY: We are more than willing to come
14 back and talk to you periodically. We're willing to
15 talk to you before we start up. We'll do anything like
16 that.

17 MS. PEDERSON: I think part of our concern
18 here is the lack of effectiveness of the actions that
19 have been taken before.

20 MR. TROY: I understand.

21 MS. PEDERSON: And we decided to ensure
22 that this time corrective actions are in place and that
23 they're going to be effective. And we're looking for
24 a process that gives us that added assurance that it's
25 going to be effective this time. And the license, and

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1 because you talked about a number of things that you
2 were going to do prior to resumption of operation, and
3 so we are trying to think about within our regulatory
4 toolbox what would be a mechanism that we could work
5 with that. But I recognize what your concern is
6 because you don't have control of that final step.

7 MR. TROY: Right.

8 MS. PEDERSON: If a licensing action is
9 taken to put your license in standby, you would then
10 request the resumption and then the action is back in
11 our court to approve that and to issue your follow-on
12 amendment that would reauthorize. So, what I would
13 like to do is I'd like to take a few minutes with my
14 team on that aspect before we give you an answer.

15 MR. TROY: Okay. We're not being
16 resistant.

17 MS. PEDERSON: I understand. I
18 understand your concern.

19 DR. BASTOW: It seems more is getting done
20 just by the fact we've had the time to be able, you know,
21 not doing any studies and we've been putting all that
22 towards getting this accomplished and at great expense.

23 MR. TROY: We could, you know, we could
24 conceivably, I don't, I'm not saying this is going to
25 happen, we've gotten so much done in a very short period

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1 of time that if we get a well counter, for instance,
2 and we can figure out how to solve this administrative
3 issue problem effectively, that in essence, the whole
4 of, not that we can't find a way to solve it, we're
5 trying to find something that we know is going to be
6 effective. We could do that in a fairly short period
7 of time. So, then we don't want to get into another
8 couple of months of, you know, you all have time to do
9 that and so, whatever.

10 MS. PEDERSON: Yes, I understand.

11 MR. TROY: Right.

12 MS. PEDERSON: Just a quick question. Is
13 your camera currently fixed?

14 DR. BASTOW: Yes.

15 MS. PEDERSON: Okay. So, these
16 compliance --

17 DR. BASTOW: It was just one-day fix thing
18 but, you know, it just looked like a good opportunity
19 at that point.

20 MS. PEDERSON: Let's ask the rest of our
21 questions and then we're going to take another, a second
22 short caucus on that issue.

23 MR. TROY: We would prefer to do it in a
24 voluntary way, right, to agree to whatever it is you
25 want than necessarily to get an order about it if we

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1 had that option. Okay, we will do whatever you want,
2 we just --

3 MS. PEDERSON: I understand. We'll take
4 that back and have a short caucus, but let's finish with
5 the other questions and then we'll --

6 MR. TROY: Okay.

7 MR. ORTH: I know one of the aspects for,
8 you know, continued compliance or long-term compliance
9 is the proposition for perhaps a new RSO. But if that's
10 not your position that you go down, I'm not sure I heard
11 what would be your alternative pathway. Is that
12 something you can discuss with us today?

13 (Mr. Troy confers with Dr.
14 Bastow.)

15 MR. TROY: I guess there are other
16 alternatives that are commercially oriented and
17 discussing those in public might affect the outcome of
18 the commercial negotiations. So, I'm hesitant to talk
19 about that. But for instance, you know, getting
20 another RSO isn't necessarily going to happen. There
21 may not be anybody available who'll do it, but we're
22 looking for somebody.

23 Another option that we considered was
24 bringing in like an outside vendor to perform the, like,
25 you know, like CT, or something like that. But there's

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1 nobody who does that. So, we're looking at a wide range
2 of possibilities of what might happen that isn't just
3 limited to getting an RSO. And if we can't get an RSO,
4 then you have to look at what are the other alternatives
5 available to us. I mean the least favorable but
6 possibly effective would be, okay, we'll have the
7 physicist here on a much more regular basis, right,
8 rather than quarterly, let's say monthly or bimonthly
9 or whatever is reasonable, right?

10 We're entertaining those kinds of things
11 but, I'd be more than happy to talk to you outside the
12 room about commercial things, but I'm not necessarily,
13 I don't want to do that inside the room.

14 MS. PEDERSON: Right. And we understand
15 for financial and proprietary type information, that
16 is a reason to close a public meeting. And so, if
17 that's necessary in order to have a complete
18 conversation, at the end of the public meeting, we can
19 have a closed session to talk about that.

20 MR. TROY: We'd be more than welcome to do
21 that.

22 MS. PEDERSON: I think the thing that
23 you're hearing from us in this regard is, and you've
24 brought it up multiple times, is the ability of Dr.
25 Bastow to devote adequate time to oversee the program.

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1 And I'm not trying to put words in your mouth but that's
2 what I've taken from this conversation. And if you
3 don't get an RSO to provide that oversight function,
4 what is going to be different such that Dr. Bastow can
5 provide that oversight function?

6 DR. BASTOW: Well, I had provided, it had
7 been done well for 20 years. It's some personal issues
8 that made that a little different than usual. I
9 suspect if we had this the way, when we get these things
10 fixed and operating the way it is, the time that was
11 there before and in time we'll be there again.
12 Shortcomings of something, that's very unusual and
13 rare and a family crisis like that, that occurs, that's
14 the time that I think you jump in and say, you know,
15 hey, I need somebody else, to hire somebody to do these
16 duties until time does become available. But I think
17 that was more the exception than the rule.

18 MS. PEDERSON: But when we met at ADR, I
19 don't believe, at least it was communicated that you
20 were having issues during that previous time.

21 DR. BASTOW: No, that was really, that was
22 a transition from the new contractor that was doing
23 those services that should have, the way we had been
24 running before very smoothly and very well, and the
25 bumps in the road came with the new contractor which

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1 where the problem I think came about which ultimately
2 was my responsibility. But that's where the thing
3 needed to be fixed.

4 MR. TROY: By before, he's talking about
5 2002 and earlier, okay.

6 MR. ORTH: I don't have any other
7 questions on my list.

8 MS. PEDERSON: Okay. Pat, do you have
9 some more things before we caucus?

10 MR. LOUDEN: I think we'll caucus first
11 because I would like to hear what where we are with that.

12 MS. PEDERSON: Yes.

13 MR. LOUDEN: So that we can follow up on
14 that directly right now.

15 MS. PEDERSON: Yes.

16 MR. LOUDEN: This will be shorter.

17 MS. PEDERSON: This will be shorter, yes.

18 MR. TROY: Okay.

19 (Off the record.)

20 MR. LOUDEN: We have a couple of items to
21 follow up, mainly with respect to the discussion about,
22 in association with the various corrective measures
23 that we talked about, you know, the possibility of
24 submitting a request to place your license in standby.
25 And I wanted to clear it up, your response. You made

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1 reference to not being -- you're willing to do whatever.
2 What I wanted to, you know, you can clarify that or
3 provide us a little more that piece, but our interest
4 would be if you submit a request to place it in standby,
5 what we took from it was you had a concern about, hey,
6 if I'm ready to turn into operational status, there
7 could be some delay on that.

8 And while we're, we've discussed our
9 process and with a three-week notice ahead of time of
10 your desire to restart, if you were in that state, we
11 could take the licensing action on that piece of it and
12 certainly we would want to conduct an inspection at that
13 time. So, that's our position right now relative to
14 that. So, I'll let you comment on that.

15 MR. TROY: The issue is that I'm not sure,
16 the discomfort from our side is that the process, we
17 understand the process, it's the same process you use
18 all the time. But that three weeks is a significant
19 amount of revenue lost. So, you know, let's say we
20 could conceivably be ready in a week or two weeks, it
21 doesn't really matter, right? Well, we could
22 conceivably be ready in three weeks but I can't tell
23 you today that we are going to be ready in a week. That
24 makes it a month, if you understand.

25 So, it's that three-week delay that we're

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1 balking at, not the idea that we have to talk to you.
2 But the regulatory process by its very nature is not
3 prompt, right. We understand that, at the same time
4 that, you know, put ourselves in this box and,
5 therefore, we got to kind of live with it, right?

6 So, just understand, that's what our
7 problem is. It's not what you want, or it's not that
8 you want approval, it's just we're trying to figure out
9 a way to do it without incurring such as a significant
10 delay. Three weeks to a Part 50 licensee is not that
11 big a deal. Three weeks to us is a huge problem.

12 So, is there any flexibility there? Or if
13 you telling us there's no flexibility, we'll do what
14 you're asking.

15 MR. LOUDEN: I think that would be our
16 preferred course right now, three weeks on that.

17 MR. TROY: We'll live with it.

18 MS. PEDERSON: Now, you know, this
19 three-week period --

20 MR. TROY: It's from the day you get the
21 letter.

22 MS. PEDERSON: No. The letter would be to
23 put it into the standby mode.

24 MR. TROY: No, that's the first letter.

25 MS. PEDERSON: Right. And then, if you

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1 can project out when you're going to be ready, we need
2 three weeks notice in order to get our inspector out.
3 And so, it's not you're done, then there's three more
4 weeks.

5 DR. BASTOW: That is when the clock
6 starts, I got you. Well, that's good.

7 MS. PEDERSON: We need to, in order to use
8 our person power, we need to be able to plan for it.

9 DR. BASTOW: That makes sense.

10 MS. PEDERSON: And so, if you can say I
11 know by October, you know, 31st, everything is going
12 to be ready, that and notify us three weeks in advance
13 of that date, we then can get our people, a person or
14 persons organized such that we can get them out during
15 that time frame.

16 MR. TROY: We can do that. That's
17 reasonable.

18 DR. BASTOW: Yes, that's reasonable.

19 MS. PEDERSON: But it's got to be
20 developed enough such that our inspector can actually
21 inspect.

22 DR. BASTOW: Yes. Right.

23 MR. TROY: Right.

24 MS. PEDERSON: That the actions are
25 effective.

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1 DR. BASTOW: The well counter is there,
2 everything is there, yes.

3 MS. PEDERSON: Yes. Does that --

4 MR. LOUDEN: Everything is in place.

5 MS. PEDERSON: Is that --

6 DR. BASTOW: That's fair.

7 MR. LOUDEN: That's exactly, thank you for
8 the clarification.

9 MS. PEDERSON: Is that a healthy
10 understanding of the --

11 MR. TROY: Yes. It made it a lot I
12 understandable that way.

13 MS. PEDERSON: Okay, okay.

14 MR. TROY: That's fine, we can do that.
15 So, the letter putting the license in standby. And
16 then a letter, three weeks notice that we're ready to
17 come out of this.

18 MR. LOUDEN: Note --

19 DR. BASTOW: Does the standby start when
20 I started it or --

21 MS. PEDERSON: The duration of the standby
22 doesn't really make a difference.

23 DR. BASTOW: Doesn't matter what date it
24 is? Okay.

25 MS. PEDERSON: So, we would like you to

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1 come in timely though such that we can take the
2 licensing action and put it in standby.

3 DR. BASTOW: No, I meant I started standby
4 four weeks ago. Is that --

5 MS. PEDERSON: Correct. That's okay,
6 that's not a problem.

7 DR. BASTOW: Okay.

8 MS. PEDERSON: The letter just is now a
9 request to have an action with your license.

10 DR. BASTOW: A formal, got you.

11 MS. PEDERSON: A formal action that will
12 change the condition on your license.

13 DR. BASTOW: Okay.

14 MR. TROY: Does it, I already know the
15 answer to this question and I don't. Does standby mean
16 that he cannot, for instance, continue to calibrate
17 equipment and receive nuclear material on site?

18 MS. PEDERSON: We better let Patty --

19 MS. PELKE: It means that you can't use
20 radioactive material.

21 MR. TROY: Period?

22 MS. PELKE: Yes.

23 MR. TROY: Not for patients but period?

24 MS. PELKE: Now, if you want to put a
25 contingency into the standby that you would not use

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1 material with the exception of material you need to
2 calibrate instruments such as the well counter that
3 you're going to purchase.

4 DR. BASTOW: The well counter, we're going
5 to need that then, okay. Yes, we're going to need that.

6 MS. PEDERSON: So, that would need to be
7 articulated in the letter, correct?

8 DR. BASTOW: Got you.

9 MS. PEDERSON: So, anything you think you
10 need to use in order to be compliant or regain
11 compliance such as on the well counter would need to
12 be specified in the letter.

13 DR. BASTOW: Or by the flood source,
14 right.

15 MS. PEDERSON: Correct.

16 MR. ORTH: Any use.

17 MS. PEDERSON: Any use of radioactive
18 material you think you must do must be articulated in
19 the letter. Is that right?

20 MS. PELKE: Yes.

21 MR. ORTH: It sounds like you could have
22 kind of a generic statement of use of material for the
23 purpose of instrument calibration and quality
24 assurance.

25 DR. BASTOW: Okay.

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1 MR. TROY: Okay. That's acceptable to
2 us.

3 MS. PEDERSON: Okay.

4 MR. LOUDEN: All right. We don't have any
5 other questions that have to be answered. Did I miss
6 anything? I think that was it?

7 MR. ORTH: I think that was it.

8 DR. BASTOW: Thank you.

9 MR. LOUDEN: All right. Steve?

10 MR. ORTH: I think for the enforcement
11 wrap
12 up --

13 MR. TROY: Do you want to talk about the
14 commercial issues?

15 MS. PEDERSON: We can still do that after
16 we finish this part. Yes.

17 MR. TROY: Okay. I mean if we're
18 interested, we'll tell you.

19 MS. PEDERSON: Yes, I think that would be
20 helpful to understand.

21 MR. TROY: Okay.

22 MR. LOUDEN: Go ahead, Steve.

23 MR. ORTH: Okay. For the enforcement
24 aspect, just to, you know, again we'll talk about a
25 number of items today. In terms of the beginning of

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1 our discussion, we talked about the severity level 4
2 notice of violation. We plan to handle that separately
3 than the escalated case we're discussing as our primary
4 purpose today. You've provided us your response, your
5 issues, your position regarding those. And we'll
6 evaluate those and determine the outcome of that.

7 Now, in terms of the apparent violation,
8 my understanding is through our discussion of a number
9 of examples, there are probably three examples that you
10 may take issue with. And that is the shadowing another
11 RSO, in terms of that individual being an RSO, you're
12 going to provide us some clarifying information so that
13 we can come to a conclusion on that. I certainly
14 understand that the documentation of that hasn't
15 existed to date but you are going to put some additional
16 information together.

17 Soliciting concerns from the
18 technologist, I understand that you're indicating you
19 meet with him every week and that should constitute at
20 least a quarterly if not more on meeting with the
21 individual.

22 And then, finally, with the availability
23 of records, in terms of those procedures, they exist
24 now and it's your position that very likely they existed
25 at the time that our inspector was out there.

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1 MR. TROY: We think so.

2 MR. ORTH: All right. No, I captured
3 that. Otherwise, I think you agree with the other
4 issues that we discussed?

5 MR. TROY: We agreed with them, although
6 what we were looking for was they weren't licensee
7 identified, right? So, that, we can't chew more there,
8 right, and obviously the corrective action came after
9 it was identified by the NRC inspector, but on the other
10 hand the corrective action we've taken is substantial.
11 And if we've, you know, shut down the practice, not the
12 entire practice, the nuclear portion of the practice,
13 right?

14 MR. ORTH: The nuclear portion.

15 MR. TROY: Which is, you know, a fairly
16 significant commitment for a small medical practice,
17 so we were looking for maybe some acknowledgment or
18 notation of that.

19 MR. ORTH: I think we got a good discussion
20 of the corrective actions, both the shutdown and some
21 other, a number of other activities.

22 Okay. So, as we stated earlier, the
23 nature of this conference, we have not made a decision.
24 Statements or opinions made by the NRC staff during the
25 conference, or silence, should not be taken as our

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1 position or acceptance of your views. We'll take into
2 consideration all the information you've provided us
3 today, the additional information that you're going to
4 provide us within the next week, and the information
5 we gained through the inspection. Following the
6 conference, the staff in region will get together with
7 our counterparts in headquarters, they're the people
8 that were on the phone today, and we will review that
9 information and reach a final enforcement decision.

10 We expect this process should be somewhere
11 in the neighborhood of four to six weeks, maybe a little
12 bit longer, depending upon the information. And then
13 we will notify you prior to issuing our final action.
14 As I mentioned before, we have four basic options: no
15 enforcement action, notice of violation, notice of
16 violation with a civil penalty, or an order.

17 If a civil penalty is proposed, there will
18 be a subsequent press release. If there is a civil
19 penalty, you may pay the civil penalty or you may
20 protest the civil penalty all or in part. If you
21 protest it, we will review the case and determine if
22 we agree with your response. If we disagree, we may
23 issue an order imposing the civil penalty. At that
24 point, you may pay the civil penalty or request a
25 hearing if the civil penalty comes into play here.

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1 So, we'll get together, determine our
2 final action, notify you, and then issue that action
3 roughly in that four to six-week period. Do you have
4 any questions?

5 MR. TROY: No. Standard rules on that?

6 MR. ORTH: Standard rules, yes, thank you.

7 MR. LOUDEN: Okay, thank you, Steve.

8 With that, we've reached now to the close so I'll turn
9 it over to Cindy.

10 MS. PEDERSON: Thank you. Just a few
11 comments here as we close. I find it very
12 disappointing that we had to find ourselves here. As
13 I mentioned in the opening, a year or so we entered into
14 an ADR session to try to resolve issues and ensure
15 improved performance. And that didn't happen.

16 This is not an ADR session, so it is a
17 different process. And as Steve explained, we will
18 make an enforcement decision, taking into effect all
19 of the information that we've talked about. But I just
20 want to reiterate that corrective actions were
21 required. These corrective actions were mandatory
22 that you had to fix your problems and you had to restore
23 compliance.

24 Coming into compliance should not be
25 viewed as, oh, we've met the threshold. The

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1 enforcement process will hold you accountable for your
2 past performance. And so, I don't want you to confuse
3 past performance with current compliance and ongoing
4 compliance, because that, too, is required. You are
5 required to continue to be compliant, whether it's
6 requirements in our 10 CFR or in your license or in the
7 order, none of those are optional. They all have to
8 be complied with.

9 And it's your responsibility as the
10 licensee to ensure that compliance. Whatever time it
11 takes, whatever resources it takes, that is your
12 obligation as a licensee. And those obligations are
13 there to protect people.

14 We had a conversation early on, I believe
15 it was stated in your opening that these issues were
16 not safety significant. You need to think about how
17 you're defining safety significance. Was somebody in
18 immediate danger? No. If that was the case, we would
19 have promptly shut you down.

20 Safety significance here underlies
21 everything that we're doing though. And the role of
22 the radiation safety officer is exceedingly important.
23 We don't allow people to operate without a radiation
24 safety officer. And if you don't have the ability to
25 have an adequate and a fully functioning radiation

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1 safety officer, we need to think about whether or not
2 the basis for the license is there.

3 So, it's imperative that the radiation
4 safety function is adequate. We only require
5 adequacy. We like all licensees to go beyond that, but
6 we do require adequacy.

7 So, you've given us things that we need to
8 assess, so we're not making an enforcement decision
9 today. We will be timely in our decision and we do
10 appreciate your willingness to take a licensing action
11 to help bolster your corrective actions. And at this
12 point, I think that's a very appropriate item, I think
13 it's very appropriate that until you get your program
14 in order you're not using radioactive material. And
15 so, I think that was a good thing that came out of the
16 conversation today.

17 So, at this point, I would like to close
18 this portion of the meeting. We will make ourselves
19 available if there is anybody on the phone, is there
20 anyone on the phone, a member of the public or media,
21 that would like to have a question or answer session
22 with the NRC?

23 (No response.)

24 MS. PEDERSON: Okay. Hearing none, we
25 will close the predecisional enforcement conference

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1 and we will go into a closed session to talk about some
2 protected information. Thank you very much.

3 (Whereupon the meeting was
4 adjourned at 3:36 p.m.)

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