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**OFFICIAL TRANSCRIPT OF PROCEEDINGS
UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION**

**Title: CONFERENCE CALL TO DISCUSS
THE MATTER OF GRAYSTAR, INC.**

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1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION

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4 CONFERENCE CALL TO DISCUSS THE MATTER
5 OF GRAYSTAR, INC.
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9 U.S. NRC
10 11545 Rockville Pike
11 Room T3-B51
12 Rockville, Maryland
13

14 Wednesday, November 8, 2000
15

16 The above-entitled teleconference commenced,
17 pursuant to notice, at 10:00 a.m.
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P R O C E E D I N G S

TELECONFERENCE

[10:00 a.m.]

JUDGE YOUNG: We were going to discuss today, any requests for further proceedings and any other appropriate matters. And I have received GrayStar's request for the proceedings.

And I thought that what might be helpful to do today, is for me to share with you, my thinking to this point, which I have discussed with Judge Murphy. We're pretty much in accord.

Of course, as always, anything that I share with you in terms of what my thinking is at this point, is subject to being changed, if persuaded differently.

And so I'll also share with you, sort of how strong my inclinations are at this point. But before I do that, is there anything that any of you would like to raise before we get into that discussion?

Really, I want to make that be somewhat of a discussion, because I may have some questions that would also give an indication of the types of questions that I might be apt to ask on a more formal basis, depending on how this proceeding goes forward.

Is there anything from either party at this point?

MR. THOMPSON: This is Anthony Thompson, Your

1 Honor. I don't have anything at this point in time. I'm
2 prepared to go forward with the discussion.

3 JUDGE YOUNG: Okay. Mr. Hall?

4 MR. HULL: Yes, I was prepared to address
5 GrayStar's November 2 request, but I'm not sure if you want
6 me to do that now, or wait?

7 JUDGE YOUNG: Well, why don't you go ahead and say
8 what you have to say, and then I'll sort of have that
9 knowledge for when we start our discussion.

10 MR. HULL: Okay. I see it as being really two
11 separate requests: Number one, the request to file a reply
12 brief to the Staff's October 30 filing.

13 In the absence of any formal written questions
14 that you may have, Your Honor, the Staff has no need to
15 reply to GrayStar's October 30 filing, but allowing a
16 GrayStar reply to the Staff's October 30 filing would -- you
17 know, that filing, that GrayStar reply, would undoubtedly
18 make additional arguments which the Staff would necessarily
19 want to respond to.

20 And that just sets up a cycle of filings with no
21 logical end. So the Staff would object to GrayStar's being
22 allowed to file an additional legal filing as they propose.

23 On the second request, which concerns their need
24 or desire to make some sort of oral presentation, they refer
25 here in their November 2 request to presenting a

1 three-dimensional model of the GrayStar irradiator and other
2 issues.

3 The Staff would also object to that proposal. I
4 think you need to look at the provisions of 10 CFR
5 2.1235(a), which GrayStar does not cite in their November 2
6 request.

7 Before allowing any oral presentation -- and let
8 me go to the reg itself to get the exact wording -- the
9 Presiding Officer is supposed to make a determination that
10 it is necessary to create an adequate record for decision.

11 So before allowing any oral presentations in these
12 Subpart L proceedings, the Presiding Officer is required to
13 make that determination.

14 And so I think it's quite premature at this point
15 to even reach that question under the provisions of
16 2.1233(a). The Presiding Officer has discretion to submit
17 written questions to the parties, and you've provided for
18 that. Your Honor, in your August 17 and September 14 orders,
19 although obviously I don't know at this point whether you
20 feel the need to submit any written questions or not.

21 But before we reach the question of whether
22 GrayStar should be allowed to make an oral presentation, I
23 think you first need to determine whether you need to submit
24 any written questions.

25 And it's only after you consider the written

1 presentations and the responses to your written questions,
2 would you reach the question of whether you think further
3 oral presentations are necessary to create an adequate
4 record for a decision.

5 I have some other things, but I think I'll stop
6 there at this point.

7 JUDGE YOUNG: Okay. Before we start into this
8 discussion, which I really see as one means of sort of
9 moving at the head a little bit more efficiently than might
10 otherwise be the case, if we just sort of leave these things
11 for, as you put it, Mr. Hull, a new cycle of response after
12 response after response.

13 Before we get into that discussion, Mr. Thompson
14 and Mr. Lashway, do you have anything that you'd like to
15 say, briefly, in response to Mr. Hull?

16 MR. THOMPSON: Yes. This is Tony Thompson, Your
17 Honor.

18 Yes, we disagree with Mr. Hull. First of all, we
19 think that the Staff's position is evolving, and new
20 standards are created with every document that they file.
21 There are some inaccuracies in the most recent document, and
22 we feel that it's important that we be able to address them,
23 and the fact that they keep changing their position.

24 I don't see there to be any reason for there to be
25 an endless cycle. Your Honor has had simultaneous filings

1 that can be done again.

2 The Staff chose not to put much meat in their
3 first filing and reserved it for the second filing. And so
4 we think that there are things in that filing that we need
5 to address.

6 That's with respect to additional filings, and, of
7 course, all of that could be modified by the discussion that
8 Your Honor has indicated we're going to have.

9 Secondly, we don't object to waiting on an oral
10 presentation, so if Your Honor has questions. written
11 questions to propound, as we have indicated, we're not even
12 sure Subpart L necessarily applies. We don't object to it
13 being used, but Subpart L was supposed to be a flexible kind
14 of procedure.

15 Your Honor indicated that you were looking at this
16 on a de novo basis, and to the extent that visual aids would
17 help you in understanding the proposed unique design for
18 this particular irradiator, then I think that could be
19 useful.

20 Dave, do you have something to add?

21 MR. LASHWAY: I think I would just add that we
22 don't agree with Mr. Hull's representation that 2.1235 oral
23 presentations should only come after the 2.1233 written
24 questions from Your Honor.

25 Nothing in -- we recognize that 2.1235 oral

1 presentations are generally disfavored in the context of a
2 Subpart L hearing, and we have reviewed that case law
3 thoroughly.

4 However, what we're trying to -- as our motion
5 indicates, we'd like the opportunity, Your Honor, to show
6 information that has been presented to the Staff, in visual
7 format, that has not been presented thus far in the hearing.

8 It is additional information that will help build
9 an adequate record for your decision, and we don't think
10 that information necessarily needs to come after
11 questioning, but certainly I think, as Mr. Thompson
12 indicated, we're willing to wait to do that.

13 But as a legal matter, nothing in 2.1235 requires
14 you to wait.

15 JUDGE YOUNG: Okay.

16 MR. HULL: Could I respond to that, Your Honor?

17 JUDGE YOUNG: Yes, just briefly, but I don't want
18 to get into an endless cycle of responses here, either, but
19 go ahead, yes.

20 MR. HULL: Okay, the SOC, the Statement of
21 Considerations, published February 28 of 1989, when Subpart
22 L was established, sheds some light on the provision in
23 2.1235(a) that Mr. Lashway was just talking about.

24 And I'm just going to read a short portion of
25 what's stated in the Statement of Considerations. The cite

1 is 54 Fed Reg at Page 8274, second column: In the event
2 that the written presentations afforded by 2.1233 and the
3 responses to written questions posed by the Presiding
4 Officer prove to be inadequate to resolve the issues raised,
5 the Presiding Officer is given the discretion to allow or
6 require the parties to make oral presentations. So that's
7 where I'm coming from, Your Honor, on my earlier statement
8 that you first need to determine whether you need an oral
9 presentation in order to create an adequate record.

10 JUDGE YOUNG: Okay. We'll get back to that whole
11 issue of whether we need to have an oral presentation or
12 demonstration at a later point. I think that obviously we
13 would not do that unless I found that it was necessary to
14 create an adequate record, or that it would be necessary or
15 helpful to me in making a decision.

16 And my general approach is not to stand on a whole
17 lot of ceremony. And I think that's the general approach of
18 Subpart L, to try to make these proceedings as efficient as
19 possible, while still achieving a complete record that will
20 stand on its own to support whatever decision is made.

21 Now, getting to sort of a discussion of the
22 issues, I think the first main issue that both -- that
23 everything hinges on to some degree, is the proper
24 interpretation of 36.21, and whether it applies in this
25 case.

1 And I want to share with you, that my very strong
2 inclination at this point is that 36.21 does apply. I think
3 that the Staff's argument with regard to that, especially
4 insofar as they refer to the SOC in 58 Fed Reg 7715 and
5 following, those arguments are very persuasive to me.

6 There is a discussion of the rule applying not
7 only to wet sources, or wet-stored sources, but also to
8 Category II panoramic dry source storage irradiators. So,
9 obviously, the wet/dry distinction is not -- I don't find it
10 to be a meaningful one in terms of whether Part 36 applies
11 to dry irradiation devices.

12 In addition, I found persuasive, the reference in
13 the discussion of the application of 36.21 to the
14 manufacturer, and the interaction between 36.21 to 32.210.
15 My reading, from page 7718 under the discussion of Subpart
16 C, my reading of the SOC there is that the reference to if
17 this procedure has been followed, referring to the procedure
18 for applying for registration, for approval, I think the
19 word is used there. If that's been followed, the licensee
20 need only note the manufacturer's name and model of the
21 sources in its license application to demonstrate that the
22 requirement is met.

23 That, to me, incorporates by reference, 32.210 or
24 the standard of that, as well as the process of applying for
25 registration, as the Staff has argued, links the

1 requirements in 36.21 to the registration process, and links
2 the standards of 32.210 relating primarily to knowing that a
3 device is safe, to the specific requirements of 36.21.

4 So, at this point, I am much more persuaded by the
5 Staff's argument with regard to the applicability of Part
6 36, and specifically 36.21, and also to the linking of the
7 registration under 32.210, the licensing under 36.21.

8 Obviously, under the language used here, if the
9 registration were approved under a different standard, then
10 the license applicant would not be able to come in and
11 demonstrate that the requirement is met under Section 36.21,
12 unless the same criteria were used in both cases.

13 Another aspect of this whole issue has to do with
14 whether or not this is a panoramic dry-source storage
15 irradiator or the Category I. And there again I am more
16 persuaded by the Staff's argument that even though the area
17 for the irradiation is not a room, it is an area that would
18 be accessible to personnel, and the time aspect of it, I
19 don't find to be significant enough to shift this back into
20 Category I type of irradiator.

21 The reference in the Category I discussion to
22 human access not being physically possible, pretty much
23 persuades me that the GS-42 -- I think that's the right --
24 the GS-42 would not fall under that category.

25 Now, obviously it has aspects of both, but I am

1 generally more persuaded by the Staff's argument that this
2 would be a panoramic dry-source storage irradiator.

3 I would be interested to hear what GrayStar would
4 like to argue in response to the Staff, but I find the
5 arguments by the Staff with regard to this issue to be
6 pretty persuasive, and you'd have to meet a pretty high
7 standard in my mind at this point to overcome that.

8 Now, I did notice your reference to the NUREG, but
9 also I think it was in the Shoreham case that the Staff
10 cited NUREGs would not have -- the NUREGs would not stand up
11 against the plain language of the Rule and the Statement of
12 Consideration would be given more weight in interpreting the
13 Rule.

14 Now, when I read the Part 36.21(a)(3), I read it
15 as the Staff has argued it, namely that there would be no
16 reason to separate out the phrases, must use radioactive
17 material that is as non-dispersable as practical, and that
18 is as insoluble as practical if the source is used in a
19 wet-source storage or wet-source change irradiator, there
20 would be no reason to add in that that is not as
21 non-dispersable as practical twice, if the last phrase,
22 referring to the wet-source storage or wet-source change
23 irradiators, was intended to modify both non-dispersable and
24 insoluble.

25 In other words, I read the plain meaning of it as

1 the reference to the wet-source storage or change
2 irradiators to modifying the word, insoluble, not the word
3 non-dispersable, which is separated by the and.

4 So, again, you're going to have to meet a pretty
5 high standard to persuade me differently on that issue.
6 Now, I have sort of, in my analysis, divided this up in --
7 after looking at the applicability of 36.21, generally at
8 the sort of subissue of whether the relevance of this being
9 a registration as opposed to a license, and the specific
10 applicability of 36.21(a)(3), I've sort of analyzed those
11 altogether.

12 The next issue for me -- well, the next two
13 general areas for me are the -- what one would have to do or
14 show to justify the exception to the general decision of the
15 NRC, not to approve further use of cesium sources. That
16 would be one issue.

17 And then the final sort of collection of issues is
18 whether GrayStar has done adequate testing and description
19 of the filling procedure and so forth

20 With regard to the justification issue, I guess I
21 find -- at this point, I find the Staff position to be a bit
22 problematic, in that I think I read -- well, at one point in
23 Mr. Hull's response, it's stated that the Commission
24 determined that the safety hazards associated with leaks of
25 dispersable cesium chloride, even though the leaks were

1 infrequent, justified restricting its use.

2 The question that arises in my mind is how would
3 or how could cesium ever be appropriately justified? And it
4 -- another related question that arises in my mind is if the
5 cake or the powder made into a cake form described by
6 GrayStar would ever be justifiable in the -- from the point
7 of view of the Staff.

8 Prior to reading this, and actually reading it
9 twice, I had been associating the issues of adequacy of
10 testing, leak prevention, and so forth, as being related to
11 the justification issue, and I think I read the Staff now as
12 wanting to separate those issues and say that totally apart
13 from the adequacy of the testing and showing how
14 satisfactory the filling procedure is, that even if GrayStar
15 were to show that leaks would be statistically very
16 improbable at -- it's the dispersability of the cesium
17 chloride powder itself that causes the problem, and that
18 would need to be justified independently.

19 And the question again -- I had -- I would have
20 there is, under what circumstances could it ever be
21 justified? And is the Staff saying that the powder form
22 could never be justified? And I guess it would be helpful
23 to me to hear a little bit more with regard to that, and
24 that would likely be the type of thing that I might have
25 additional questions for the Staff on.

1 Now, with regard to the final collection of issues
2 around the testing, I noticed in the Staff's response, that
3 you made reference in several places to GrayStar's bringing
4 up new testing procedures or new descriptions or changes in
5 design at this point.

6 I'm not sure whether that by doing that, you're
7 saying that that's not appropriate to do at this point, or
8 what should be the consequence of that.

9 In the discussion that Judge Murphy and I have had
10 with each other on this case, both of us have had the
11 feeling that it might be very appropriate for the two
12 parties to try to work with each other further on these
13 testing issues.

14 I think that some of the things that the Staff
15 points out with regard to, for example -- I think there was
16 one place where the inner capsule had leaked during one of
17 the tests and its design was not subsequently modified. And
18 then there was another reference to the heat insulation
19 being possibly compromised by virtue of the fact that the
20 inner end cap had contact with the outer end cap.

21 There were things like that. The impression that
22 I have at this point, the inclination I have at this point
23 is that the Staff's approach would appear to be reasonable
24 and that it very well might be appropriate for more
25 interaction to take place and for GrayStar to work with the

1 Staff on doing whatever testing, and also testing of the
2 filling procedure, for example, that would provide further
3 assurance of the safety of the source in actual use.

4 However, I can understand how GrayStar would not
5 be real inclined to engage in that, if, going back to the
6 second issue, if the Staff's position with regards to how
7 the use of cesium would ever be justified and whether the
8 use of the cesium chloride powder made into a cake would
9 ever be justified.

10 And so that's why I separated that out into a
11 separate issue that I think it might be -- benefit everyone
12 to discuss a little bit further, either today or at some
13 other point, and whether that can be done more informally,
14 so as to lead to a quicker and more efficient resolution for
15 all concerned, or whether we need to do that in a more
16 formal, within the informal hearing context of written
17 questions, written responses, and so forth, I think is
18 largely up to the parties, and how well you can communicate
19 with each other.

20 Again, I still see a little bit of talking past
21 each other, and I hope that maybe the discussion that we can
22 have today might facilitate moving a little further in that
23 direction.

24 And let me just say one final thing before I try
25 to get some responses from you both to what I have just gone

1 through, and that is, we, Judge Murphy and I, had both felt
2 that it would be -- I think we asked for a photograph or a
3 better diagram of the actual irradiator and where the source
4 capsules would be located and how it would work and so
5 forth.

6 The description that GrayStar has provided in your
7 written presentation was very helpful in clarifying that a
8 little further for me. But -- and I'm not sure that it
9 would be necessary to see the actual device, but on the
10 other hand, I don't see that that would necessarily present
11 an -- I don't see that that would be necessarily
12 inappropriate, assuming that it looks as though these second
13 and third categories of issues that I have described can
14 somehow be addressed by the parties.

15 So, just to briefly summarize, my inclination at
16 this point is that the Staff's position with regard to the
17 applicability of Part 36, and specifically 36.21, including
18 36.21(a)(3), I find to be quite persuasive.

19 With regard to the testing and filling procedures,
20 I find the Staff's arguments to be fairly persuasive in that
21 I think there needs to be more interaction between the
22 parties, especially on some of these new issues that
23 GrayStar has raised.

24 However, on the issue of how to justify the use of
25 cesium, and specifically the cesium chloride caked powder

1 that GrayStar talks about, I think that I'm having a little
2 bit of difficulty understanding how it could ever be
3 justified, if not with regard -- or by relating it to the
4 design, the use, the value of the use, the testing
5 procedures and so forth.

6 I guess I should add that both Judge Murphy and I
7 -- and correct me if I'm wrong, Judge Murphy -- but we find
8 that some of GrayStar's arguments about the value of having
9 a relatively easily transportable device like this that
10 would not require onsite source change, and that would
11 permit for lower cost and larger amounts of irradiating of
12 or lower cost irradiating of relatively larger amounts of
13 food, we find a lot of those arguments to be appealing.

14 Does that -- Judge Murphy is nodding his head in
15 agreement. So, Judge Murphy, have I left anything out in
16 our discussions that we've had over the last weeks, and
17 mostly the last couple days on this, that it would be good
18 to share with the parties at this point?

19 I think I've more or less gone over -- I had made
20 some notes to myself on some of the very specific issues
21 with regard to the testing of the GS-42, but I'm not sure
22 how helpful it would be to go into those at this point.

23 It might be more helpful to go into a discussion
24 with responses from you to what I have had to say? Judge
25 Murphy?

JUDGE MURPHY: No, I don't think there's anything else at this point.

JUDGE YOUNG: Okay, well, then, let me go to GrayStar first. Just taking the issues that I have gone over, in order, could you summarize for me what -- and for the Staff, what your response to the Staff on the issue of the applicability of 36 and Section 36.21 and 36.21(a)(3) --

MR. HULL: Excuse me, Your Honor. This is John Hull for the Staff. Could I just confer with the people here for a minute on a couple of points before we go further?

JUDGE YOUNG: Sure. Actually, GrayStar -- Tony Thompson and David Lashway may also want to confer, and then maybe we can all come back together in a couple of minutes, and see where we go from here.

MR. HULL: Thank you.

MR. THOMPSON: Thank you, Your Honor.

[Discussion off the record.]

JUDGE YOUNG: We're still waiting for the Staff to come back on. We'll just wait a few more minutes.

[Discussion off the record.]

JUDGE YOUNG: Okay, Mr. Hull, you said you were on?

MR. HULL: Yes.

JUDGE YOUNG: And you have all your people?

1 MR. HULL: Correct. Yes, we're here.

2 JUDGE YOUNG: Okay, and Mr. Schmelling is on with
3 Mr. Lashway also, and Mr. Thompson.

4 MR. LASHWAY: That's correct.

5 JUDGE YOUNG: Okay, and we've got the Court
6 Reporter back?

7 COURT REPORTER: Yes, ma'am.

8 JUDGE YOUNG: Great, okay. I guess the first
9 thing I should say is, do either of you want any
10 clarification from me on any of the things I said?

11 If not, I think the first question I had was
12 whether GrayStar could give me some indication of the types
13 of arguments that you wanted to raise on the issue of the
14 applicability of 36 and 36.21 and 36.21(a)(3).

15 MR. THOMPSON: Your Honor, this is Tony Thompson.
16 Let me just start.

17 One of the things that, based on your laying out
18 your thoughts about some things that comes up is if 36.21(a)
19 is going to be applicable and it's going to be tied in
20 through 32.210, then it seems to me that the standard for
21 demonstrating for registration purposes, the standard for
22 demonstrating that you've satisfied 36.21(a) has to be
23 reasonable assurance of adequate protection of public
24 health.

25 It isn't some extra-substantial justification

1 which the NRC they have created new standards at every
2 turn. For example, in the most recent brief, they talk
3 about complete thermal protection.

4 That's nowhere in the regulations, and so I guess
5 we would say that if you do tie 36.21 in with 32.210, then
6 it seems to me that the standard that is applied to
7 determining whether you've satisfied 36.21(a) is, in fact,
8 the standard in 32.210, reasonable assurance.

9 And also, it's important, I think, as we've noted,
10 to note that in 32.210 with registration, if there isn't
11 anything that absolutely fits perfectly, the Staff is
12 supposed to sit down and work with the licensee to create a
13 standard.

14 And, in fact, in our first telephone conference,
15 you referenced, I guess, a letter or something in the record
16 from Larry Kampfer saying that a collaborative effort
17 between all of the parties, because of the unique design,
18 was going to be the way to go.

19 We thought we were collaborating with the Staff.
20 We thought we were moving forward and addressing issues that
21 they had raised.

22 For example, on leaks, they requested we do the
23 helium test on the leak testing. The helium test is not
24 required. It's much more sensitive. As I understand it,
25 helium atom can actually go through glass.

1 We passed the test. What's the point of all the
2 tests if we can't -- if it's irrelevant, as you suggested,
3 at least in part, by the way NRC's most recent brief is
4 addressing the non-dispersable issue.

5 We thought we were collaborating, and out of the
6 blue comes this denial. And so -- and the Staff's position
7 has changed. We don't agree with your reading of 36.21(a)
8 -- and I'll let Mr. Lashway address that -- but I do want to
9 emphasize that if, in fact, you stand firm with what you've
10 indicated as your current persuasion, then we think that the
11 standard has to be articulated, which is 32.210, and that is
12 reasonable assurance, and, therefore, that the testing and
13 all these other things, won't be meaningless because they
14 are what provide you with the reasonable assurance.

15 In fact, in our first telephone conference, you
16 asked the question, what was the Staff's concern, and Mr.
17 Hickey said leaks.

18 Well, you know, the material is dispersable and
19 there are leaks, then, you know, you have a potential for
20 more of a problem.

21 But if there are no reasonable assurance -- if
22 there are not reasonable possibilities of leaks, then
23 dispersability is not relevant.

24 And so I'm going to let Mr. Lashway address
25 36.21(a) and our reading of it, but we are certainly willing

1 to sit down with the Staff, but somebody on the Staff has
2 pulled the plug on this and taken a very, very sort of an
3 unreasonable position as far as we're concerned on the use
4 of cesium chloride.

5 And so with that, I'll turn it over to Mr.
6 Lashway.

7 MR. LASHWAY: Your Honor, I guess I would add to
8 Mr. Thompson's comments, that with respect to the
9 applicability of 36.21, generally, we're still not
10 necessarily in agreement with the Staff as to its general
11 application here, for the reasons not only laid out in our
12 initial brief, but also in our reply brief.

13 The plain language of the regulation suggests that
14 it doesn't apply. We've looked at the Shoreham case cited
15 by the Staff, and we've reviewed the statement of
16 considerations, of course, prior to filing our initial brief
17 and our response brief, but still those statements of
18 consideration don't overrule the plain meaning of the
19 regulation.

20 And what the regulation says, 36.21(a) is that
21 sealed sources installed after July 1st, 1993, and so we're
22 just not certain at this point, that the Staff is correct.
23 In fact, we take the opposite position about the
24 applicability of 36.21 generally.

25 JUDGE YOUNG: Let me interrupt there for just a

1 second. When you were talking about the plain language, I
2 thought you were referring to the 36.21(a)(3).

3 And my question that I wanted to interject was,
4 how do you explain that as practical and that is as rather
5 than saying just must use radioactivity -- active material
6 that is as non-dispersable and insoluble as practical, if
the source is used in a wet-source storage or a wet-source
8 change irradiator? That would be a question I would want to
9 interject.

10 But then you made a reference to -- what was it?
11 You made a reference to the -- now I've lost it -- what were
12 you referring to when you talked about plain language?

13 MR. LASHWAY: Well, Your Honor, we don't
14 necessarily disagree. I think, as Mr. Thompson points out,
15 as an initial matter, before I get to your question
16 directly, if 32.210, which, of course, is the controlling
17 regulation here, applies, and we believe it does, you need
18 to have a standard upon which you're going to base a review
19 of the sealed sources for the registration.

20 And if you are correct in your interpretation that
21 you look to 36.21 for those standards, I think our position
22 is the same position that we had in our initial brief and
23 all throughout this process with the Staff. And that is
24 that you'll look at the industry standards, and, however, if
25 there are no standards that specifically apply because of

1 the variation of the GrayStar Model 1, and the GS-42 sealed
2 sources, we need to work with the Staff to develop
3 appropriate standards.

4 We, in fact, did that with respect to some issues
5 in this case, and that's how we decided to utilize the
6 helium test, as well as tailor the vibration tests in a
7 specific manner, such that they would adequately reflect the
8 use of the sealed sources in the Model 1.

9 So we went through and we developed more
10 scrupulous testing for those sealed sources, pursuant to
11 discussion with the Staff, to meet the standards in 32.210,
12 but, of course, we were guided by the standards set forth in
13 36.21, not only (a)(1), (2), (3), and (4), but the standards
14 set forth in (5).

15 Now, with respect to 36.21(4), the corrosion, we
16 noted that -- and this is one of the reasons we've asked for
17 another short bite at the apple with respect to filing a
18 reply of ten pages or less -- every time the Staff files a
19 brief, it seems that they either drop an issue that they
20 raised before, or they change their position.

21 For example, 36.21 (a)(4) is the corrosion
22 regulation. We went through -- GrayStar spent a significant
23 amount of time, resources, and energy, developing tests,
24 working with the Staff, and testing the sealed sources for
25 corrosion.

1 The Staff now withdraws their objection on
2 36.21(a)(4), because they say we read the regulation wrong
3 and it no longer applies to dry sources.

4 JUDGE YOUNG: Right.

5 MR. LASHWAY: GrayStar spent a significant amount
6 of time briefing that issue in their first brief and their
7 second brief, only to learn from the Staff, after two full
8 rounds of briefing and over a year and a half of
9 negotiations, that corrosion is no longer an issue because
10 that reg doesn't apply.

11 With respect to 36.21, generally, getting
12 specifically to your question, Your Honor, you cannot read
13 (a)(3) without reading (a) first, and that says 36.21(a)
14 requirements, sealed source: installed after July 1st, 1993,
15 suggesting, of course, that these are performance criteria
16 for sealed sources that are installed.

17 All we're proposing here at this stage is a
18 registration of the GS-42; not the installation, not the use
19 in the Model 1. All we're proposing is the registration of
20 that sealed source.

21 And that brings us to the more difficult issue --
22 JUDGE YOUNG: Wait an let me interject there. I have just
23 remembered what it was that you said that confused me
24 before, and that was the reference to being installed.

25 The SOC talks about that the test use to

1 demonstrate that the criteria under 36.21 can be met, are
2 conducted by the manufacturer and not the irradiator
3 licensee, and then says if the procedure then follows and
4 the licensee need only note the manufacturer's name and so
5 forth, are you -- and that's what I referred to when I said
6 -- when I said that I agreed that 36.21 and 32.210 are sort
7 of linked together.

8 And I'm not -- and I'm not altogether
9 un-persuaded. As a matter of fact, what you argue about the
10 reasonable assurance argument makes sense, but I guess I'm
11 not following the installed after July 1st 1993, the
12 relevance of that.

13 Because if we can agree, at least for argument's
14 sake, that the standards in 36.21, at least (a) (1), (2), and
15 (3), apply here, and that you read those with the 32.210,
16 what's the remaining argument on the installed after July
17 1st, 1993? I'm not following that.

18 MR. LASHWAY: Well, it's a question of timing. I
19 think you put your thumb right on it, Your Honor. The
20 question is, whose burden is it? Is it the manufacturer's
21 burden at the time they manufacture the sealed source? The
22 manufacturer's burden at the time of the installation of the
23 encapsulations in the irradiator itself, or the burden on
24 the registrant of the Model 1, you know, or the person who's
25 going to lease the Model 1 from GrayStar?

1 And it was GrayStar's opinion from the outset that
2 at this point, all they're seeking is the registration of
3 the GS-42. Subsequently, when they wish to install the
4 GS-42 into the Model 1, they will likely seek a license, and
5 then --

6 JUDGE YOUNG: When you say "they," who do you
7 mean?

8 MR. LASHWAY: GrayStar will seek a license for the
9 installation of the sealed sources into the Model 1, and
10 they will -- and GrayStar will seek a license for the Model
11 1.

12 Then GrayStar, intends on leasing the Model 1, the
13 licensed Model 1, to a third party.

14 JUDGE YOUNG: Right.

15 MR. LASHWAY: And that third party will also have
16 to have a byproduct material license from the NRC.

17 JUDGE YOUNG: Right.

18 MR. LASHWAY: And they will go through the
19 licensing process, and, moreover, they will be subjected to
20 the regulations in 36.21, which means they have to have a
21 certificate of registration, and doubly-encapsulated, et
22 cetera.

23 So it's a question of timing, and GrayStar's
24 opinion is that at this point, all they're seeking is the
25 registration, and then when they want to install it in the

1 Model 1, GrayStar will seek a license, and then beyond that,
2 when they go to lease it to a third party, say, USDA, the
3 third party will be required by the Atomic Energy Act, to
4 acquire a license from the NRC as well.

5 JUDGE YOUNG: Let me interrupt you again. I guess
6 I'm still not following you exactly, because even assuming
7 all of these steps take place, you would not want GrayStar
8 when they come forward to license -- to seek a license for
9 the irradiator or the ultimate user, the Department of
10 Agriculture or whoever, to come and then present the
11 registration approval and then have to meet a higher
12 standard at that point under 36.21, you're not arguing that
13 you don't have to meet at this point, the same standards
14 under 36.21(a)(1) through (3), assuming I'm correct that it
15 does apply?

16 You're not arguing that those standards don't
17 apply now but might apply later; are you? Because if you're
18 not, I guess I'm not following the relevance of this
19 step-by-step process. If they apply what the SOC seems to
20 be saying, if they apply that, apply it from the start, and
21 then all the licensee later has to do is to show that
22 they've got the registration, and that's enough to show that
23 they have met the relevant criteria, right?

24 MR. LASHWAY: Correct, Your Honor. I think, you
25 know, as a practical matter, your reading is correct. But

1 in terms of the regulations themselves, I think it sets out
2 this kind of timing sequence, and GrayStar -- I mean, for
3 GrayStar's purposes, it's neither here nor there at this
4 point, because it intends on meeting most of the
5 requirements in 36.21.

6 So, as a practical matter, we're in agreement with
7 you that at this point, if 36.21 applies or at least sets
8 out standards that we need to meet, then we want to meet
9 those standards at this point.

10 JUDGE YOUNG: Okay.

11 MR. LASHWAY: And that brings us to your final two
12 questions, and that is, the applicability first of
13 36.21(a)(3), and then the justification issue.

14 With respect to 36.21(a)(3), GrayStar maintains,
15 continues to maintain that the reading of that regulation,
16 the plain meaning and a reading of that regulation, shows
17 that it's inapplicable here.

18 The background leading up to that regulation, as
19 Chairman Sellins's comments suggested, dealt with concerns
20 over wet-source irradiators.

21 JUDGE YOUNG: But he also said in his comments
22 that it did apply to dry-source irradiators. Now, he also
23 asked -- he indicated that further justification should be
24 discussed in the rulemaking package, and I don't think that
25 the Staff disagrees that that was not specifically done.

1 But still, I think it seems pretty clear in the Statement of
2 Consideration, that it applied to dry-source. I never can
3 get that sequence of words right, but dry-source
4 irradiators.

5 And so then the question becomes whether it's a
6 panoramic irradiator or a Category I irradiator.

7 You were referring to Commissioner Sellins's
8 comments there, and that's why I interrupted you, because he
9 seems to be clear that it does apply to dry-source
10 irradiators, at least the larger panoramic kind.

11 MR. THOMPSON: Excuse me, Your Honor. This is
12 Anthony Thompson. The way I read it was, his comments were
13 addressed at a proposal that didn't have the words,
14 wet-source and so forth, in it. And it seems to me that
15 there is no evidence in the Statement of Consideration, and
16 as far as I'm aware, there's no evidence in the record
17 anywhere -- and if NRC knows about it, then they know more
18 than we do -- of dispersion being a problem with cesium
19 chloride in dry-source irradiators.

20 So, to the extent that the Staff didn't come back
21 and provide that, it suggests that they didn't have any
22 evidence and they couldn't justify it. And if, in fact,
23 though, you say that 36.21 nevertheless still applies, then
24 taking a rigid position on cesium chloride, the way the
25 Staff has in its most brief, is obviously unreasonable,

1 because there is nothing in the record that suggests
2 dispersion in dry-source irradiators is a problem.

3 JUDGE YOUNG: Wasn't there a footnote somewhere in
4 the Staff's brief -- and, Mr. Hull, you might want to help
5 us here, too -- that referred to some evidence of -- I'm
6 thinking that there was a footnote that referred to some
7 evidence of dry-source problems.

8 MR. HULL: Your Honor, this is John Hull for the
9 Staff. You may be referring to the Staff's reference to --
10 in the draft 1990 Part 36 rulemaking. There was a reference
11 in the Statement of Considerations there, to an incident in
12 Italy involving a dry-source storage irradiator where there
13 was an operator fatality

14 MR. THOMPSON: Yes. And this is Anthony Thompson.
15 That didn't have anything to do with dispersion of cesium
16 chloride.

17 The guy crawled up into the irradiator when the
18 source was up.

19 JUDGE YOUNG: Okay, anyway, go ahead with your
20 argument. Was there anything else -- well, let me -- hold
21 on.

22 Mr. Hull, was there any other reference in either
23 of your documents to any dispersion situation with the
24 dry-source?

25 MR. HULL: I'd have to review the document, Your

1 HONOR. I do not have -- did not bring my copy with me.

2 JUDGE YOUNG: All right, go ahead then, Mr.
3 Thompson. Excuse me.

4 MR. THOMPSON: I'll turn it back to Mr. Lashway.

5 MR. LASHWAY: I think, Your Honor, with respect to
6 (a)(3), again, you specifically were focusing on the "that
7 is" language and the repetition about language, and if it
8 does not mean something, why would it be used because it
9 would be superfluous.

10 I think our reading was that a comma would be
11 necessary after the first, "is practical," for the reading
12 that the Staff now proposes.

13 And there is no comma there. Why they used "that
14 is" twice, I mean, if you look at (a)(4), which the Staff
15 now agrees, after a year and a half, is not relevant to the
16 GrayStar GS-42, you know, the language is similar if used
17 for irradiator pools.

18 In (a)(3) it says if the source is used in a
19 wet-source storage or a wet-source change irradiator.
20 They're not that different.

21 But I think that without the comma, you know, the
22 failure to punctuate, to give it that reading, is
23 significant here.

24 And the that brings use -- even assuming,
25 arguendo, that it does apply, that brings us to your final

1 concerns over the justification issue.

2 And, quite frankly, we are as concerned as you
3 are, and I think we still prevail, even the Staff is correct
4 that 36.21 applies, 36.21(a)(3) applies, GrayStar still
5 prevails in that the justification standard that the staff
6 has set out is nowhere to be found in the regulations.

And we are -- GrayStar is most concerned with the
8 Staff's most recent brief, in that they raise this argument,
9 this new argument that you even highlighted, that the
10 radioactive material itself has to be inherently
11 non-dispersable. That reading reads out the as-practical
12 language which the Staff then references later.

13 So they can't have it both ways, and quite
14 frankly, Your Honor, what is the purpose of testing,
15 GrayStar wonders, if the as-practical language is read out?
16 Why would you test at all, if you're just considering the
17 radioactive material at all, you know, solely, and not its
18 encasement in the encapsulation.

19 And as Mr. Thompson pointed out, during our
20 initial telephone conference, the Staff indicated that the
21 issue was leaking, and leaking from the encapsulation. So,
22 therefore, surely the Staff must be concerned about the
23 encapsulation itself, leaking from the encapsulation,
24 testing of the encapsulation, and they recognize that
25 as-practical language refers to the source, the entire

1 source, not just the source term and the source within
2 inside the encapsulation.

3 MR. THOMPSON: This is Anthony Thompson. After
4 all, we are talking about sealed sources. We're talking
5 about the licensing of sealed sources. You can't leave out
6 the encapsulation.

7 I mean, if this thing was a solid steel ball and
8 you could stick it upon the wall with some chewing gum or
9 something, it might not be dispersable, but it sure might
10 not be protected. You have to look at the whole instrument,
11 and you have to look at the sealed source and the
12 encapsulation.

13 I don't see how you can possibly just look at the
14 radioactive material and say that the sealed sources and the
15 encapsulation are irrelevant. And, indeed, GrayStar has --
16 it is not a powder, it is not a granulated form; it is a
17 cake.

18 It is a solid form and as far as we're concerned,
19 that satisfies as-practical in this application.

20 MR. HULL: This is John Hull for the Staff. I
21 think it's described as a caked powder. I don't know how
22 you term that as being a solid.

23 MR. THOMPSON: It's a solid. It's caked. Once
24 you evaporate the water off, and vacuum it off, it is a
25 solid cake.

1 JUDGE YOUNG: I think it's probably not real
2 useful -- I understand at this point, your positions on what
3 it is. I'm not sure that it's that useful to argue over
4 whether it's a solid or not.

5 I would have to say that the arguments about if it
6 got -- if there were a leak, the possibility of air
7 turbulence or an explosion or whatever, it obviously could
8 be dispersed more easily than the metal, cobalt, for
9 example.

10 But I would still like to hear from the Staff on
11 the justification, on the relationship of the justification
12 issue to the testing issue, and you know, how could it be
13 justified, and is the Staff's position that the caked powder
14 is never justifiable?

15 MR. THOMPSON: Your Honor, can I just ask one
16 question. This is Anthony Thompson.

17 Where does this air turbulence and explosion and
18 fire come from? Where is that in the regulations, and what
19 justification do they have for it?

20 I mean, that's just something that somebody made
21 up. All of the dispersion discussion that I'm aware of in
22 the records, as we have indicated, addresses the solubility
23 of cesium chloride, and particularly in water. Where does
24 this explosion come from? Where does air turbulence come
25 from?

1 I mean, they make no attempt to relate it to the
2 sealed source itself, or to the GrayStar. That's just
3 pulled out of the air.

4 JUDGE YOUNG: Okay. Maybe Mr. Hull can address
5 that. I guess one type of thing we would like to raise for
6 GrayStar address to some degree today and that I would want
7 some addressing of in any event at some point would be the
further testing issues assuming -- well --

8 MR. HULL: Your Honor, on that --

9 JUDGE YOUNG: Maybe that's not resolved but
10 through settlement so you don't necessarily have to answer
11 that at this point but if you would like to you may go ahead
12 but it might be logically more sensible to let Mr. Hull to
13 respond to what you said so far and then move on to the
14 testing issues because I see those as sort of separate, more
15 factual type issues as opposed to the first two, which are
16 more legal or interpretation type issues.

17 MR. HULL: Your Honor, let me confer with the
18 Staff for a minute.

19 JUDGE YOUNG: Okay.

20 [Discussion off the record.]

21 JUDGE YOUNG: Yes?

22 MR. HULL: Your Honor, I was a little bit
23 uncertain as to just what question you want the Staff to
24 address at this point.
25

1 JUDGE YOUNG: Well, I wanted to allow you to
2 respond to anything that you wanted to respond to in
3 GrayStar's arguments on 36, although I really don't know
4 that -- well, hold on.

5 Mr. Thompson and Mr. Lashway, are you back?

6 MR. THOMPSON: Yes, Your Honor.

7 MR. LASHWAY: Yes, Your Honor.

8 JUDGE YOUNG: I was going to say I guess I am
9 still not terribly persuaded by anything you have said that
10 any of 36.21 other than (a) (4) would not be applicable.

11 I am still pretty persuaded by the Staff's
12 argument on that but apart from responding to that, Mr.
13 Well, I think it would be helpful if you could either now or
14 at some point and now would be helpful if you could to some
15 degree address this whole issue of how would an Applicant
16 ever justify the use of cesium and specifically in this case
17 the cesium chloride caked powder and the example I was
18 thinking of in my mind was, you know --

19 [Technical interference.]

20 JUDGE YOUNG: Hello?

21 MR. LASHWAY: We're back.

22 JUDGE YOUNG: Does anyone know what that was?

23 MR. LASHWAY: No, there was a just a beeping
24 noise.

25 MR. THOMPSON: And we lost you, Your Honor. This

1 is Tony Thompson.

2 JUDGE YOUNG: Okay, well, we are all back now. I
3 stopped as soon as that started happening but what I was
4 saying, Mr. Hull, I guess the thing that is puzzling me is
5 that from my understanding the Staff has known from the
6 start what material GrayStar intended to use as a source.

7 Now there may have been some change in the
8 description of it as loosely packed as opposed to a cake,
9 caked powder and the example I was going to give that comes
10 to my mind is a woman's compact that has pressed powder as
11 opposed to loose powder. Obviously the loose powder is a
12 lot more dispersable in the air if you just, say, blow on
13 it.

14 Apart from any distinctions like that, the Staff I
15 assume has known what the intended source was from the start
16 and yet engaged in these discussions about the various types
17 of testing that needed to be done and so forth, and yet I
18 sort of read your response brief as saying that the
19 justification for the use of the cesium chloride is a
20 separate issue from whatever testing needs to be done, and
21 that was sort of -- caught my attention.

22 I am not -- to the degree you are not trying to
23 separate that and say that the cesium chloride is just
24 inherently never justifiable, that confused me a bit, and if
25 you are saying that it has to be justified apart from the

1 testing and design and so forth types of issues, I guess I
2 am having a hard time comprehending in what way it could
3 ever be justified, and so that is the main issue that for me
4 was problematic from the point of view of your argument.

5 MR. HULL: Okay. Hold on just a second.

6 [Pause.]

7 MR. HULL: I am going to let Mr. Hickey address
8 your question.

9 JUDGE YOUNG: Okay.

10 MR. HICKEY: Yes, this is John Hickey for the
11 Staff.

12 First of all, it's correct that we are
13 distinguishing between the issue of dispersability in its
14 own right and the likelihood of a leak and I believe
15 GrayStar has said that it opposes use of cesium in wet
16 irradiators, although if you look at its arguments I think
17 the arguments would say that cesium should also be permitted
18 in wet irradiators because the sources could be designed so
19 that they would not leak in the wet irradiators, but in any
20 case we do distinguish between the two.

21 With respect to justification, we of course didn't
22 establish at the time the rule was issued what the adequate
23 justification was. If we had known that, we would have put
24 it in the rule but we have considered that.

25 One case -- some scenarios would be if cobalt,

1 let's say cobalt became unavailable, there was no cobalt to
2 be found. Another case would be if a single, there was a
3 single irradiator, either a new one or an old one that
4 needed replacement sources and perhaps a justification could
5 be developed for a limited case, we believe that the
6 statement of considerations is clear that the Commission did
7 not want this, the particular scenario that is being
8 proposed by GrayStar here which would be a proliferation of
9 a large number of irradiators that contain cesium chloride.

10 We agreed in the first conference call that the
11 use of cesium chloride was not ruled out completely so we
12 are not saying it is impossible to justify. We did raise
13 the issue with GrayStar about using other forms of cesium
14 and they made it clear that they did not feel that that was
15 practical so we were left with whether the cesium chloride
16 itself was justified.

17 JUDGE YOUNG: If I may ask, after you raised the
18 issue of other forms of cesium, I assume by that that you
19 were thinking that a more solid form of cesium or maybe not
20 the chloride salt --

21 MR. HICKEY: Correct. A ceramic type, a glass
22 bead type.

23 JUDGE YOUNG: After you had that discussion or
24 correspondence or interaction with GrayStar, were there
25 still discussions going on about the testing? I guess if

1 there were -- did you ever more or less say to GrayStar,
2 well, we just don't see how -- powder would ever be
3 justifiable unless there was just no other source available?

4 I guess the reason I am asking this, I don't want
5 to sound like I am cross examining you, I guess the reason I
6 am asking this is just to provide some enlightenment in
7 terms of to what degree the testing is relevant.

8 MR. HICKEY: Well, with respect to the first
9 question, I don't believe we said to GrayStar after they
10 came back with their explanation for using cesium chloride,
11 I don't think we informally said to them we are going to
12 deny your application.

13 We just proceeded to deny the application.

14 MR. HULL: Just as a point of clarification, Mr.
15 Hickey, I think you are talking about their responses to the
16 request for additional information --

17 MR. HICKEY: Correct.

18 MR. HULL: -- and also where they had talked in
19 their April '99 application about what testing has been
20 done.

21 MR. HICKEY: Correct.

22 MR. HULL: And then the testing is relevant and I
23 suppose someone could make a proposal that their sources are
24 foolproof and could never leak and that could be accepted as
25 a justification in theory, but as a practical matter I don't

1 think what's happened.

2 Our view is the Commission's concern when they
3 promulgated the rule was that even though the sources were
4 well designed they could leak, and the consequences of those
5 leaks are unacceptable. Therefore, we do not want people
6 using dispersable material unless there's a substantial
7 justification and I know that GrayStar objects to our use of
8 the words "substantial justification" but I think that is
9 the reading of the statement of considerations, that that is
10 what was expected, that the Commission had a strong
11 preference that cobalt be the material of choice.

12 MR. HULL: This is John Hull. Getting back to
13 what Mr. Hickey had earlier said, that the Commission on the
14 other hand did not want to totally rule out Cesium-137 if
15 supplies of Cobalt-60 for any reason became unavailable.

16 That is why the rule was worded as it was.

17 JUDGE YOUNG: Could I interject another question
18 here for Mr. Hull and Mr. Hickey.

19 To what degree, we're being informal here and I
20 can't help wondering about this, that to what degree is a
21 comparison of the dangers of cobalt and, say, source
22 replacement activities and other activities that may be
23 unique to cobalt source irradiators compare to the dangers
24 of probability, I guess I should say, of a cesium chloride
25 leak and then that becoming a burst?

1 MR HULL: It is my impression, Your Honor -- this
2 is John Hull -- that GrayStar covered this in their various
3 filings and the Staff has responded to it.

4 JUDGE YOUNG: And you may need to point me to a
5 place that -- I guess my general recollection of your
6 response at this point was just that that was sort of not
7 relevant and I don't recall, you may have, but I don't
8 recall you actually comparing the probability of danger with
9 cobalt, which may have different types of dangers, with the
10 probability of danger of a leak and dispersion of cesium
11 chloride.

12 MR. HICKEY: Yes. This is John Hickey. You are
13 correct. We did not construct such a comparison. We did
14 not say the issue was irrelevant. What we said was that
15 GrayStar's justification focused on these advantages and
16 it's not complete. It didn't talk about potential
17 disadvantages. It's known that -- it was known and is known
18 that cobalt has a shorter half-life and therefore requires
19 more frequent source changes. We don't think it is adequate
20 to base the justification on that fact because that was
21 known at the time that the Commission promulgated the
22 regulation.

23 JUDGE YOUNG: And I recall the arguments made in
24 the response brief about the generic knowledge that the
25 Commission had and obviously the Commission had generic

1 knowledge about the nature of cesium and cesium chloride for
2 that matter and about cobalt and source changes but they
3 probably did not have knowledge about the specific design
4 that GrayStar is proposing here and so that is not real
5 persuasive to me.

6 I guess I can't help wondering what if the
7 comparison of the probability of danger using cobalt with
8 accident setup could occur with it -- cesium and possible
9 dispersion --

10 [Discussion off the record.]

11 MR. HICKEY: Well, as we pointed out -- this is
12 John Hickey -- we pointed out in one of our filings that if
13 there is a leak, cesium has a longer half-life so if you
14 have to secure the area and wait, which we often do with
15 contaminated facilities, you have to wait a lot longer for
16 the cesium to decay away than you do for cobalt --

17 JUDGE YOUNG: Right.

18 MR. HICKEY: -- but we did not try to do -- our
19 position is GrayStar did not provide a comprehensive
20 evaluation and we did not attempt to do that.

21 MR. HULL: It's GrayStar's burden here to make
22 that argument, not the Staff.

23 JUDGE YOUNG: Okay -- and I recall that argument
24 now that you did make about the longer half-life and am I
25 correct in assuming that the immediate radioactive strength,

1 and I may not be using the right words, but cobalt may be
2 greater but it lasts a shorter time obviously, based on the
3 shorter half-life, is that a correct assumption or not?

4 MR. HICKEY: That is correct in terms of the
5 energy in the gamma rays and therefore the amount of
6 shielding that is required, but in terms of the hazard to a
7 human being exposed to these high levels, they are very
8 dangerous for both cesium or cobalt.

9 MR. HULL: For the record, that was John Hickey.

10 JUDGE YOUNG: Okay, and if I might just to ask one
11 further question to clarify something for myself, I realize
12 that the GrayStar irradiator has a much higher total curie
13 amount, if that is the right term, than the smaller cesium
14 irradiators, but assuming, just to give me some
15 understanding, assuming that one source in the GrayStar
16 irradiator were to leak, does the same comparison that you
17 just made hold or does the comparison that you just made in
18 terms of the high amount of cesium chloride and high curie
19 amount, is that made based on the total amount, a leak of
20 one source capsule?

21 MR. HICKEY: This is John Hickey. I'm sorry. I'm
22 still not sure of the question, because I think the
23 considerations with the leak are different than the energy
24 of the gamma rays.

25 JUDGE YOUNG: I think what you said was that the

1 gamma rays of cobalt was greater but the total curie amount,
2 if I am using the right terminology, of the cesium chloride
3 that is in the GrayStar is very high, so that the difference
4 becomes not as significant, and so what I then asked you was
5 when you said that were you thinking in terms of the total
6 amount of source in one of the GrayStar irradiators and
7 would the same comparison hold if you compared one cobalt
8 irradiator accident with a leak from one source capsule in
9 the GrayStar irradiator, and that is just background
10 information just for my knowledge. I was curious as to
11 whether you had an answer to that.

12 MR. HICKEY: This is John Hickey. You are now
13 talking with respect to a leak?

14 JUDGE YOUNG: Right, exactly.

15 MR. HICKEY: Yes. I think in terms of the amount
16 of radioactive material the hazard would be comparable.

17 The issue would be the potential for dispersion.

18 JUDGE YOUNG: So it would be comparable between
19 the amount of irradiation if somehow the shield on the
20 cobalt or the shield was gone with the cobalt and there was
21 a leak in one of the source capsules in the GrayStar?

22 Did I understand that right?

23 MR. HICKEY: Could you repeat that, please?

24 JUDGE YOUNG: The amount of or the total amount
25 danger of the irradiation from an exposure to the cobalt in

1 one of the cobalt irradiators, which I understand is just
2 one large piece of the metal cobalt, so that if the shield
3 broke down or the shield were not there somehow or there was
4 a source change going on, that you would be exposed to the
5 whole thing and as compared to being exposed to a leak from
6 one of the source capsules in the GrayStar, were you saying
7 that those were equivalent?

8 MR. HICKEY: Are you talking about a leak in both
9 cases?

10 JUDGE YOUNG: As I understand it, with cobalt it
11 would not be a leak, it would somehow a person being exposed
12 to the metal cobalt by virtue of first being changed and
13 somehow the --

14 MR. HICKEY: Oh, okay. I would say that the
15 hazard from the cobalt would be much greater than the
16 material that would leak from the cesium because that would
17 be a relatively small amount. However, the cesium sources
18 would also be present so that would assume that the cesium
19 sources are shielded and that the only exposure is to the
20 leaking material.

21 JUDGE YOUNG: Right. Okay. Well, thank you, and
22 if you want to provide any more clarification on that, you
23 are free to, but I was just trying to get a handle on some
24 of these amount issues because we are talking about
25 obviously a large total amount in the GrayStar but each

1 separate source has a relatively smaller amount because of
2 the number of sources obviously.

3 MR. HULL: Keep in mind that each of GrayStar's
4 proposed sealed sources contain 51,500 curies.

5 JUDGE YOUNG: Which is a lot more than the present
6 smaller cesium irradiators I think, right?

7 MR. HULL: Exactly.

8 JUDGE YOUNG: Okay.

9 MR. HICKEY: This is John Hickey. I could just
10 add that this assumes a small leak as the type postulated by
11 GrayStar. A source can also be severely damaged and that
12 earlier we were talking about the issue of a fire or
13 explosion, so that, you know, if a substantial amount of
14 material is released as a result of a source being severely
15 damaged then the consequences would be greater.

16 MR. HULL: Because due to -- correct me if I'm
17 wrong, Mr. Hickey -- due to the greater dispersability of
18 cesium as compared to cobalt.

19 MR. HICKEY: Yes, but both the amount released and
20 the more dispersion.

21 JUDGE YOUNG: Okay. Well, thank you, and I guess,
22 Mr. Hull and/or Mr. Hickey, you can continue if you like on
23 the issue of the justification or responding to anything
24 else that GrayStar discussed.

25 MR. HULL: We don't see any need to respond to

1 anything that GrayStar's attorneys have said today.

2 JUDGE YOUNG: Okay, then before we end with you,
3 let me just ask you one more question.

4 If I understand you correctly --

5 [TELEPHONE OPERATOR: "Your conference is
6 scheduled to end in 15 minutes."]

7 JUDGE YOUNG: We are going to have to wrap this
8 up.

9 If we need to go longer, we may be able to do
10 that, but let's try to wrap it up.

11 Did I understand you, the Staff's position to be
12 that the only scenarios that came to mind with regard to
13 justifying the use of the cesium chloride in the form that
14 GrayStar is talking about using it would be if cobalt were
15 unavailable or if a single irradiator needed some kind of
16 replacement sources in a limited circumstance, that those
17 were the only ones that came to mind?

18 MR. HULL: I'll speak for Mr. Hickey. I think
19 you're accurate in that those were the two examples he used,
20 and again that was off the top of his head.

21 MR. LASHWAY: Your Honor, if we can just add --
22 this is David Lashway for GrayStar -- I think with respect
23 to this justification issue, Mr. Hickey recognized that the
24 Commission never established what adequate justification
25 would be and he has given a couple of examples here.

1 When GrayStar was in the process of developing its
2 product, it was in constant discussions with the Staff and
3 the Staff never raised any standards such as the ones
4 elaborated on today, so when Mr. Hull raised the fact that
5 GrayStar has the burden we certainly recognize that we have
6 the burden here, but there was no justification standard set
7 out for GrayStar to meet, and we just want to make that
8 clear.

9 MR. THOMPSON: Well -- this is Tony Thompson, Your
10 Honor. I mean Mr. Hull just said it. Mr. Hickey just made
11 those up off the top of his head.

12 I mean what kind of a reasoned decisionmaking
13 process is this? I mean to say that you can't use cesium
14 chloride -- the Commission put those words in there and we
15 assume and we go along and arguendo we agree with you that
16 36.21 applies and then the standards in 32.210, reasonable
17 assurance, would apply, you can't make up stuff now at this
18 juncture. That is post hoc rationalization.

19 It is totally -- it is totally irrelevant and
20 frankly, frankly if the Commission made a decision that you
21 couldn't use cesium in dry source irradiators without any
22 explanation in the preamble it would be totally arbitrary.

23 JUDGE YOUNG: Let me interrupt --

24 MR. THOMPSON: That have no evidence of any
25 problems with it.

1 JUDGE YOUNG: Mr. Thompson, Mr. Hull, at one point
2 you were sort of breaking each other up there and I am going
3 to ask Ms. McCanniff, could you go ask Alex or someone if
4 they could call and see if they could extend our conference
5 another half hour if necessary?

6 I don't want to encourage us to take that
7 half-hour, but I don't want us to be cut off right in the
8 middle of something.

9 I guess just listening to both of you at this
10 point, I think that it would be very appropriate for each of
11 you to conduct further discussions with each other on the
12 justification issue and try to satisfy yourselves first I
13 guess with that, and then if you can get past that issue on
14 some of these testing issues or even on the testing issues
15 on their own, because at this point I am sort of
16 half-inclined to go ahead and issue an order on the
17 applicability of 36 and 36.21 and then leave the remaining
18 issues for a future order that would be issued after further
19 proceedings, assuming the parties cannot reach a settlement
20 in this case.

21 Those further proceedings would probably in my
22 mind consist of some further questions from me, if not a
23 demonstration of a 3-D model at least some further two
24 dimensional diagrams, but I guess I really am somewhat stuck
25 on this justification issue at this point and I probably

1 need to say as well that even assuming we get past the
2 justification issue and I were to find that GrayStar by
3 virtue of the design and so forth and so on had shown
4 justification for using the cesium chloride, I would still
5 have some issues about the testing that has been done to
6 date.

7 [TELEPHONE OPERATOR: "Your conference is
8 scheduled to end in 10 minutes.]

9 JUDGE YOUNG: I would still have some concerns
10 about the testing that has been done to date, so I would
11 like to hear from both of you as to -- not on the merits of
12 the arguments at this point but as to what you would propose
13 in terms of what, how much you think you can communicate
14 with each other and work together, if at all, at this point
15 and how you would prefer that we proceed from here on out,
16 and I encourage you to try to approach that from the
17 standpoint of making a good faith effort to see how we can
18 all try to reach a reasonable, rational and efficient
19 resolution of this as soon as possible.

20 Mr. Hull, do you have any suggestions there or any
21 thoughts in terms of the Staff's -- and you might want to
22 talk with your people -- openness to talking further with
23 GrayStar and GrayStar, the same question --

24 MR. HULL: Your Honor, before I get into that, Mr.
25 Hickey wanted to make an additional comment.

1 JUDGE YOUNG: Okay.

2 MR. HICKEY: I just wanted to make one clarifying
3 point, that during some of the early communications between
4 GrayStar and the Staff the question of whether this
5 irradiator was a panoramic irradiator was also on the table,
6 so the issue of dispersability was not just in a vacuum.

7 There was -- we were also getting more information
8 about whether this was a panoramic irradiator and therefore
9 whether dispersability would be an issue.

10 JUDGE YOUNG: Right. Okay.

11 MR. HULL: Thank you.

12 JUDGE YOUNG: And I appreciate that and at any
13 rate we are at the point we are at now, and so I think to
14 some degree everybody, both of you will need some time to
15 think over some of the things that have come out in this
16 conference, but what can you tell me, each of you, in terms
17 of the possibility of talking further with each other and
18 how you would like to see this proceed from here on out in
19 terms of the process and any further proceedings.

20 MR. HULL: This is John Hull for the Staff.

21 The Staff sees that there are certain legal issues
22 that I think need to be resolved, and I would go back to
23 what I said at the very beginning of the conference today.

24 I think the procedure to follow at this point,
25 Your Honor, is that if you have any additional questions

1 that you have that you think need or needed to create an
2 adequate record for decision that you submit written
3 questions to us that we would then answer and then -- I
4 think that is where we need to go from here, rather than
5 trying to jump into the technical issues.

6 MR. THOMPSON: Your Honor, this is Tony
7 Thompson --

8 JUDGE YOUNG: Let me just clarify something with
9 Mr. Hull first.

10 First, a question, Mr. Hull. Am I correct in
11 reading what you just said to be sort of an implicit
12 statement that you don't think that further communications
13 with GrayStar would be fruitful at this point?

14 MR. HULL: I think we made the decision which was
15 reflected in one of our earlier conferences in this
16 proceeding that -- because you had raised this earlier, I
17 think, about trying to get together with GrayStar to see if
18 we could agree to some sort of settlement and I think the
19 Staff position is the same now as it was then.

20 There are certain legal issues that need to be
21 decided and the Staff position has not changed on that.

22 JUDGE YOUNG: Okay, then let me ask you this, and
23 clarify for you, the types of questions that I would likely
24 have would be all technical kinds of questions, really,
25 relating, apart from possibly on the justifiability, but

1 really mostly on some of the technical questions relating to
2 the design and testing and filling process and so forth.

3 I could very well go ahead and issue an order
4 solely on the legal issue of the applicability of 36.21 and
5 to the degree that GrayStar I thought that you have any
6 further arguments to make on that, you know, I would be open
7 to allowing you a very short deadline, which is I think all
8 you asked for to provide anything further in writing on that
9 before I issue such an order, if that would get us moving
10 along, but in terms of the further proceedings and the
11 questions, those would be on the technical issues, so Mr.
12 Hull, do you have any requests on behalf of the Staff with
13 regard to my issuing an order on the applicability of 36 and
14 36.21 at this point as opposed to later?

15 MR. HULL: I think what is envisioned in this
16 whole Subpart L procedure that has been set up is to try to
17 expedite these cases and reach a decision, and it is within
18 your discretion, Your Honor, as to how much information you
19 feel you need in order to have an adequate record on which
20 to make a decision.

21 I don't know quite where you are going with this,
22 what seems to be a piecemeal approach. I guess the Staff
23 would prefer to have a decision on all of the issues that
24 are pending and take it from there.

25 Obviously if either GrayStar or the Staff were not

1 happy then they would have the right to petition the
2 Commission for review.

3 JUDGE YOUNG: Hold on just a second. I have a
4 question about how we can continue.

5 [Pause.]

6 [TELEPHONE OPERATOR: "Your conference time is
7 over."]

8 [Pause.]

9 JUDGE YOUNG: Okay. Let's go back on the record.
10 Are you there, Mr. Hull and Hickey?

11 MR. HULL: Yes.

12 JUDGE YOUNG: Mr. Lashway and Thompson?

13 MR. THOMPSON: Yes, Your Honor.

14 JUDGE YOUNG: And Ms. Riley?

15 THE REPORTER: Yes, ma'am.

16 JUDGE YOUNG: I was talking with Mr. Hull about
17 the Staff's position or preference on whether to go ahead
18 and issue an order on the legal issue of the applicability
19 of Part 36 and specifically 36.21, and 36 21(a)(1) through
20 (3) and I think (5) perhaps.

21 I had thought and the initial thing that you said,
22 which is that we need a legal resolution, a resolution on a
23 legal issue, that is sort of what you were asking me to do,
24 but then I think you were saying no, that's not what you
25 wanted me to do and then the other alternative would be to

1 hold off on a ruling on that legal issue until I ruled on
2 the whole case, issued an order resolving the whole case,
3 and I was just about to tell you, just to summarize again
4 for you my inclinations at this point would be -- you know
5 what they are on the legal issue of the applicability of
6 Part 36 and so forth.

7 On the justification issue I am still -- sort of
8 have that under consideration.

9 On the factual issues relating to testing and
10 filling processes and so forth, as I said before, I do find
11 that at this point the Staff's concerns about not doing
12 further tests and not having done the testing on the filling
13 procedure yet are fairly persuasive to me, which was one of
14 the reasons why I was encouraging the parties to engage in
15 further interactions, because I frankly don't feel that we
16 are at a point where resolution of those issues would be
17 most efficient at this point, but if neither party is
18 willing to engage in those further proceedings or either
19 party is willing -- if one of the parties is not willing to
20 engage in those further interactions and if both of you want
21 a decision at this point, those are my inclinations at this
22 point.

23 Mr. Hull, did you want to add anything in terms of
24 what to do at this point -- and -- I'm sorry, let me go back
25 for a second.

1 I guess incorporated within what I said earlier I
2 might have some further questions on some of the factual
3 technical issues but apart from that, Mr. Hull, go ahead.

4 MR. HULL: Okay, thank you, Your Honor.

5 I think under the Subpart L regulations the ball
6 is in your court, so to speak, at this point in terms of
7 what additional information, if any, you think is necessary
8 for you to reach a decision.

9 If you don't feel you have the necessary
10 information at this point, the next step would be for you to
11 submit written questions to the parties asking for any
12 additional information.

13 JUDGE YOUNG: Mr. Hull, I actually do understand
14 that.

15 My question to you was whether you would like to
16 have an order at this point resolving solely the legal issue
17 before we move onto that process.

18 MR. HULL: I hate to tread on your discretion,
19 Your Honor.

20 Obviously my preference would be for you to issue
21 a legal ruling which would dispose of this case and then let
22 the parties take it to the Commission if they feel they need
23 to.

24 JUDGE YOUNG: So in other words you are asking me
25 to hold off on ruling on the applicability issue until I

1 rule on the whole case?

2 MR. HULL: I think that's what is envisioned in
3 the Subpart L rules, that there be an initial decision by
4 the presiding officer which encompasses all the necessary
5 issues rather than a bifurcated approach of trying to split
6 up a ruling on legal issues versus a ruling on technical
7 issues.

8 JUDGE YOUNG: Okay. I am not sure that it
9 precludes doing that kind of an order but I understand your
10 position.

11 Did you want to say anything else further before I
12 ask Mr. Lashway and Mr. Thompson to speak to this?

13 MR. HULL: No, I don't have anything further.

14 JUDGE YOUNG: Okay. Mr. Lashway and Mr. Thompson,
15 do you have any preference or anything that you would like
16 to say in terms of the further proceedings and specifically
17 do you wish to provide anything in writing after our
18 discussion today about the applicability of Part 30 and so
19 forth?

20 MR. THOMPSON: This is Tony Thompson, Your Honor.

21 We are perfectly comfortable with your bifurcating
22 the proceedings. We have indicated from our first telephone
23 conference that we are willing to sit down with the Staff to
24 try to resolve issues, if that would make some sense when
25 the issues are narrowed, and we continue to be in that mode.

1 We would like to address in a brief timeframe, in
2 a brief number of pages the 36.21 issue before you make a
3 ruling, and we don't believe that Subpart L proceedings --
4 there's plenty of flexibility and you can bifurcate it if
5 that makes sense.

6 We are perfectly happy to address your questions
7 and other questions on the issues of testing.

8 We have passed every test we have taken so far,
9 and representations to the contrary are inaccurate.

10 We recognize there is work to be done on the
11 filling procedure. We agree with that. We would certainly
12 be willing to discuss that with the Staff.

13 We want to remind Your Honor that the NQA-1
14 procedure is such that we can't --

15 JUDGE YOUNG: Excuse me. What is the NQA-1
16 procedure?

17 MR. THOMPSON: In our brief we have committed to
18 NQA-1, and what is it? -- 70.71, David?

19 MR. LASHWAY: I believe so.

20 MR. THOMPSON: It is a performance commitment that
21 we will meet certain standards so when we say that this
22 sealed source will not contain more than 1 percent moisture
23 we can't -- we would be violating the registration if we
24 come out with it and there are stringent penalties.

25 If you look, there's an attachment to our most

1 recent brief, you can see the NRC approval of our commitment
2 to abide by this, which is -- it's sort of an ISO kind of
3 performance requirement, standards, and we have committed to
4 them, and so we can't -- if a filling procedure doesn't work
5 the way we say, we can't -- the registration won't be valid
6 because we have committed to the NQA-1, and we are perfectly
7 willing to sit down with the Staff and discuss the filling
8 procedure more.

9 We recognize that we are going to have to try to
10 do it at some point but again, as you pointed out earlier, I
11 think, and correctly, that if the Staff is going to take a
12 position now, after all this time, that cesium -- by
13 definition cesium chloride -- is dispersable and that
14 practical doesn't have any meaning, then why would we want
15 to waste our money and our time?

16 Dave, do you have anything else to add?

17 MR. LASHWAY: No. Just to reiterate, I think it
18 is important, Your Honor, that with respect to your testing
19 concerns that as Mr. Thompson pointed out, the GS-42 passed
20 every test, contrary to the Staff's most recent assertion
21 that the inner source capsule leaked.

22 That is incorrect. That did not leak. Some
23 preliminary outer source capsules leaked but no inner source
24 capsules ever leaked and then in the final design of the
25 GS-42 there were no leaks.

1 GrayStar went ahead and did helium testing, which
2 again in cooperation with the Staff, which is not required
3 by the regulations, and passed those tests. It passed
4 vibration tests. It passed stress tests and it even passed
5 corrosion tests, which the Staff now admits are not
6 relevant, so with respect to the testing requirements of
7 36.21 and the industry standards, the GS-42 sealed sources
8 passed all of those tests.

9 If there are additional justifications beyond the
10 testing requirements that the Staff in cooperation with
11 GrayStar developed protocols for and the GS-42 subsequently
12 satisfied, we are not aware of what they are, and so if you
13 have concerns about, factual concerns about the actual
14 testing, we are just not certain what those concerns relate
15 to because we in fact passed the tests.

16 However, we recognize, as Mr. Thompson pointed
17 out, that if you have questions about the filling procedure
18 in the hot cell, that cannot be worked out at this point
19 because you can't fill the cesium sources with the actual
20 hot cesium outside of a hot cell and GrayStar would be
21 required to get a license to do that prior to filling those
22 cesium sources samples for testing purposes, and that has
23 just not been the case under NRC's procedures for any sealed
24 sources to date.

25 That is why they committed to do the NQA-1 program

1 and they are criminally liable if they are wrong and they
2 put products on the market that don't meet those standards
3 in the NQA-1.

4 JUDGE YOUNG: Okay. Let me just see if I can
5 clear up a couple things real quickly.

6 I just turned back to the Staff's response brief
7 and Mr. Hull, you say that the two, the three main concerns
8 that the Staff has with the cesium chloride pattern, which
9 related to the justification issue and then the leak test
10 failures in the vibration tests, so maybe I was wrong in
11 stating that the Staff still has issues relating to the
12 filling procedure.

13 I thought that you had said that at one point but
14 perhaps that is no longer an issue for the Staff and then
15 with regard to -- maybe I should get the answer to that
16 before I go on. Is that right?

17 MR. HULL: Well, the filling process, Your Honor,
18 the problem there relates to a problem of internal
19 corrosion, a possibility of internal corrosion of the source
20 capsule, as opposed to the issue of external corrosion,
21 which would only be present if it is a wet source storage
22 situation.

23 I think the Staff still does have some concerns
24 about the potential of internal corrosion and that would be
25 covered under 10 CFR 32.210. As the Staff pointed out, it

1 did make a citation error in its denial letter in citing
2 36.21(a)(4) on that issue.

3 JUDGE YOUNG: Okay, so the fill issue would be
4 with regard to internal corrosion and assuming by that that
5 Staff's position would be that there would need to be
6 further testing of the filling procedure using the
' non-radioactive cesium, correct?

8 MR. HULL: Hold on.

9 [Discussion off the record.]

10 MR. HULL: Your Honor, you asked about the
11 non-radioactive cesium issue?

12 JUDGE YOUNG: Right, for the filling tests.

13 MR. HULL: Yes, the Staff still have a concern
14 about that, and it is linked to the dispersability issue.

15 JUDGE YOUNG: Okay, and then the leak test
16 failures, to respond to Mr. Lashway about what my concerns
17 were, I guess I am a little confused at this point because I
18 thought there wasn't any dispute, that in an early test
19 there was one failure of an internal, the internal seal or
20 the capsule, and then on the vibration test as I recall the
21 Staff's concern was that it had not been done on the third
22 axis, and as I understand it, the dispute between the
23 parties is whether the test needs to be done on two axes or
24 three axes, and what I am envisioning is that or that
25 GrayStar is viewing this as an oblong or oval shape and that

1 the Staff is saying that it may be oval in one dimension but
2 it is flat on two sides, therefore it needs the three axes
3 tested.

4 So let me just ask Mr. Hull again and the Staff,
5 am I correct in understanding -- I mean what I just said in
6 understanding the issues relating to the leak test failures
7 and the vibration tests?

8 MR. HULL: Yes, I think your description of the
9 vibration test issue is correct, and I think there is still
10 a disagreement between the parties as to the results of the
11 leak tests that Mr. Lashway just mentioned.

12 JUDGE YOUNG: The Staff's position would be that
13 at -- I mean it is correct that one of the internal capsules
14 had a leak test failure early on and there would need to be
15 some modification to address that?

16 Okay. Mr. Lashway, I think that answers your
17 question about what the concerns about those were, and the
18 reason I am going into all this is because I guess I can go
19 ahead and make a ruling on all this after I get your -- I am
20 inclined to allow you a week or so, as you asked, to provide
21 a short document on the applicability issue and then if I
22 have any further questions I can go ahead and ask those in
23 writing and then proceed from there to decide to grant your
24 request for further proceedings and extent and then I'll
25 issue an order on all these issues.

1 Let me just ask you, is GrayStar -- do you have an
2 interest in assuming the Staff is correct on the failure on
3 the inner capsule on doing anything further with regard to
4 that and doing anything further with regard to the vibration
5 tests before you want a final ruling on this from me?

6 MR. THOMPSON: Well, I would -- I guess I don't --
7 I mean my understanding from our client is that the
8 vibration testing was approved by the NRC Staff as
9 conducted, that Mr. Jankovich was aware of it and that he
10 agreed that that was an appropriate way to test it, that
11 tested it in the fashion that was most likely to put the
12 most stress on the thing, on the capsule, and I don't
13 know -- Bill Schnelling, are we still clear that there was
14 no leak in the internal capsulation?

15 MR. SCHNELLING: Yes.

16 MR. THOMPSON: So I mean we can provide some
17 additional information on those and to the record and again
18 we are, as I said, we are always willing to talk with the
19 Staff about resolving these concerns but it doesn't sound
20 like they are much interested in doing that.

21 I don't know. Dave, do you have anything else to
22 add?

23 MR. LASHWAY: Yes. With respect to the leaking
24 inter-encapsulation, Your Honor, we point out in our brief
25 that the inner seal plug of the inner sealed source was

1 tested and a helium test was conducted on that, I believe,
2 and correct me if I am wrong, Bill, but it was an inner
3 sealed source, sealed plug that was tested with respect to
4 the end cap test. It was not the entire encapsulation that
5 leaked.

6 MR. HULL: And Your Honor, this just brings -- let
7 me just say one more thing. This is Tony Thompson.

8 MR. LASHWAY: That was a preliminary design,
9 again.

10 MR. THOMPSON: That obviously I don't think NRC is
11 taking the position that if something didn't work the first
12 time and you made it work thereafter that the fact that you
13 failed the first time is it, it's over, there's no point in
14 going farther. That would be arbitrary in the extreme.

15 But I believe that it would be very useful for you
16 and Judge Murphy to see the capsule -- the Staff has
17 samples -- to see how the plugs fit and what happens when
18 they get torqued off and what this thing looks like
19 because -- and that is one of the reasons we wanted to bring
20 some of these things to you so that you could actually see
21 them, because when I heard okay, we are going to torque this
22 seal off, you know, I couldn't envision the way the seal
23 fits into the capsule and what happens when you torque it
24 off.

25 I think it is important for the Court to see these

1 things and the Staff has them, so it isn't something that
2 they haven't seen either.

3 JUDGE YOUNG: Why don't we make a record on that,
4 I am wondering.

5 MR. THOMPSON: I suppose we could -- it's like a
6 piece of physical evidence.

7 JUDGE YOUNG: Okay. Mr. Hull, anything further
8 from you?

9 MR. HULL: Yes, two points, Your Honor.

10 I wanted to reinforce what I stated upfront about
11 the Staff's objections to allowing GrayStar to make another
12 response brief to the Staff's October 30 filing.

13 I just don't see any logical end to the filings if
14 you allow such a filing because obviously there's going to
15 be new arguments in that filing that the Staff will want to
16 respond to and then GrayStar will want to respond to Staff's
17 filing, et cetera, et cetera.

18 MR. THOMPSON: We have done simultaneous filings
19 so far. Why would we change it?

20 JUDGE YOUNG: Okay. One of the reasons for this
21 discussion today which is helpful to me and I hope it's been
22 helpful to you, was to try to sort some of that process by
23 getting out on the table the positions of the various
24 parties.

25 I am inclined to allow GrayStar a short period of

1 time to file a short response since I think Mr. Hull, your
2 position all along has been that your main -- if you file a
3 brief -- would be a response brief because it was your
4 position that GrayStar had not yet addressed the issues in
5 the Staff's denial, so I am inclined to allow that and I
6 think all you are asking to do is the 36 applicability or
7 was there anything further, Mr. Lashway, Mr. Thompson, that
8 you wanted to address in that part of your further filing?

9 MR. THOMPSON: Just based on your tying 32.210 in,
10 we would make the point again I think that we made here
11 today about the standards to be applied to justification.

12 JUDGE YOUNG: Okay. Could you get that in within
13 a week?

14 MR. THOMPSON: Yes.

15 JUDGE YOUNG: Okay. Mr. Hull, I appreciate your
16 concern about an interminable going back and forth but I
17 think on this I will allow GrayStar one week from today and
18 if you want to respond to that, then you can respond a week
19 after that.

20 Meanwhile, especially after I get the transcript
21 back on this, I will enter an order as soon as possible,
22 possibly ruling on the applicability issue once I have both
23 of your briefs on that, and also submitting further written
24 questions to the degree I have any, and ruling on that
25 later, at the same time on GrayStar's request for further

1 proceedings in the nature of a hearing where the GrayStar
2 model could be demonstrated.

3 MR. HULL: This is John Hull for the Staff.

4 I guess I would request, the Staff would request
5 some sort of -- I mean assuming the Staff does feel the need
6 to file a response in two weeks from now to the reply that
7 GrayStar will be filing in one week, is there going to be
8 any sort of standard as to, you know, whether or not
9 GrayStar will then be allowed to seek to reply to the
10 Staff's filing that is going to be filed in two weeks.

11 JUDGE YOUNG: I don't think so. I think the
12 issues are pretty much laid out at this point.

13 The only reason that I would allow GrayStar to
14 then file would be if you raised a new issue that may not
15 have been raised before, and I think you are right that we
16 do need to bring the argument on these issues and the legal
17 issues to a close and at the same time as you all are doing
18 that I will be formulating any further questions I have on
19 the factual issues and then that will get us in a posture to
20 either hold a further short hearing or to move without that
21 to a final ruling.

22 In the interim I of course encourage you as a
23 separate matter to talk with each other and try to resolve
24 some of these testing issues and if possible the
25 justification for cesium chloride and if you can talk

1 informally or authorize your clients to talk informally with
2 each other, in other words the Staff directly with some of
3 the GrayStar folks, then that's fine. That is up to you.

4 MR. HULL: The other point I had, Your Honor, is
5 just in response to something Mr. Thompson said just
6 recently about the need for you to see various models of the
7 Model 1 irradiator and such, you had requested GrayStar, you
8 had allowed GrayStar back in the September 7th telecon we
9 had, you had stated that -- this is page 80 of the
10 transcript -- "Mr. Thompson, Lashway, Holloway, if you can
11 get a more clear picture and include it with your written
12 presentation, that would be great."

13 Mr. Thompson responded, "We will certainly do
14 that. We want to assure that it is as clear as it can be
15 for you to review it."

16 Now the Staff would have no objection if GrayStar
17 wants to submit some photographs to you which might be
18 clearer than in the documents that the Staff has made part
19 of the hearing file, but the Staff does not see the need at
20 this point for you to allow actually -- having GrayStar
21 actually bring in things for you to look at, again as I
22 think I have stated earlier today, you first need to
23 determine that you do not have an adequate record for
24 decision, and I believe the regulation is 2.12(35)(a).

25 You would need to make that determination before

1 allowing GrayStar to make any sort of an oral presentation
2 to you.

3 JUDGE YOUNG: Okay. I think you have suggested a
4 good idea and actually GrayStar or Mr. Lashway and Mr.
5 Thompson, would you with your filing a week for today
6 include the better photographs, both of the irradiator
7 itself and to whatever degree possible pictures of the
8 capsules themselves.

9 I think that is a good idea because I had asked
10 for those before, so --

11 MR. THOMPSON: Let me ask one question, Your
12 Honor. We also have a videotape that is an animated version
13 of how it works and so forth and so on and the Staff has
14 access to that.

15 JUDGE YOUNG: I don't have any problem with your
16 submitting that along with it as well and if it is the same
17 one the Staff has, then I assume Mr. Hull would not require
18 getting another one?

19 MR. HULL: Your Honor, I haven't seen this
20 particular videotape. I am assuming that somebody at the
21 Staff has it, based on Mr. Thompson's representation, but I
22 would view that as a videotape would have, obviously
23 somebody would be saying something on the videotape and that
24 would be an oral presentation, and there may be statements
25 made in there that the Staff would feel the need to respond

1 to so I would strenuously object to their submitting to you
2 a videotape at this point.

3 JUDGE YOUNG: Well, I am sure you are not saying
4 that you don't want me to understand as much as possible
5 about this in the easiest possible way, so let me suggest
6 this. Why don't you, Mr. Thompson, Mr. Lashway, get the
7 videotape to Mr. Hull today and then send the videotape to
8 me. Mr. Hill can submit objections to my viewing the
9 videotape with his response to your filing next week and I
10 will consider those objections before I consider looking at
11 the videotape.

12 MR. THOMPSON: That's fine, Your Honor. This is
13 Tony Thompson.

14 JUDGE YOUNG: Okay. I will try to get an order
15 out in the next day or so.

16 Just setting these deadlines. To repeat, one week
17 from today GrayStar will file a single reply not to exceed
18 10 pages with respect to the 36, the applicability of Part
19 36 et cetera. You will include with that to me a copy of
20 the videotape. Meanwhile you will go ahead and get that
21 videotape to Mr. Hull unless he already has it through the
22 Staff within the next day, and then Mr. Hull, you can reply
23 to GrayStar's written filing two weeks from today and
24 include with that any objections with regard to the
25 videotape and whether or to what extent I should view that.

1 MR. LASHWAY: Your Honor, just to clarify -- this
2 is Mr. Lashway. With respect to the applicability of Part
3 36, et cetera, are we to address the justification issue,
4 the legal issue tied in with the justification questions
5 that you posed today, or is that for another day?

6 JUDGE YOUNG: You can go ahead and include
7 whatever you want on that as well.

8 I am not going to limit you, as a matter of fact,
9 on -- let's get everything out as soon as possible and then
10 during this same time period I will be considering what
11 further questions I have on the facts.

12 Also, obviously, let's go ahead and do these by
13 e-mail and if you can -- you can go ahead and mail me the
14 videotape or have someone deliver it. I guess it's okay to
15 send videotapes through the mail, but do get that, make sure
16 Mr. Hull has a copy right away so he can go ahead and look
17 at that and start formulating whatever issues he has with
18 regard to that.

19 MR. HULL: Excuse me, Your Honor, about the
20 videotape, I am advised by the Staff that we could not
21 quickly get our hands on it, and there's no telling if it is
22 the very same videotape that Mr. Thompson is referencing, so
23 I will need to see that videotape as soon as possible.

24 JUDGE YOUNG: Okay. Mr. Thompson, Mr. Lashway,
25 could you get that to him by tomorrow?

1 MR. LASHWAY: Yes, Judge. I have two copies that
2 I will put in overnight mail or for hand delivery this
3 afternoon, one to Mr. Hull and one to yourself.

4 JUDGE YOUNG: Okay, well, I don't need it right
5 away because I am not going to look at it till I consider
6 Mr. Hull's objections, but -- all right, then.

7 This has taken a little while but I think we have
8 made some progress and in the meanwhile again, I know it may
9 not get anywhere but in the meanwhile while all this is
10 going on, to whatever degree you all want to talk to each
11 other and try to work out some of these factual testing
12 issues, I think that would be a good idea.

13 That would conclude this proceeding and
14 conference.

15 MR. HULL: Thank you, Your Honor.

16 JUDGE YOUNG: Thank you.

17 MR. THOMPSON: Thank you, Your Honor.

18 MR. LASHWAY: Thank you, Your Honor.

19 JUDGE YOUNG: Thank you and Ms. Riley --

20 THE REPORTER: Yes, ma'am.

21 JUDGE YOUNG: Okay, bye.

22 [Whereupon, at 12:45 p.m., the teleconference was
23 concluded.]

24

25

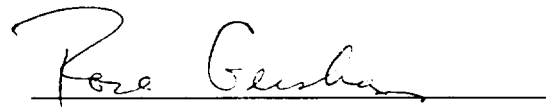
CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission in the matter of:

Name of Proceeding: CONFERENCE CALL TO DISCUSS THE
MATTER OF GRAYSTAR, INC.

Case Number:

Place of Proceeding: Rockville, Maryland
were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission transcribed by me from recorded tapes provided by the Nuclear Regulatory Commission, and that the transcript is a true and accurate record of the foregoing proceedings to the best of my belief and ability.

A handwritten signature in cursive script, reading "Rose Gershon", is written over a horizontal line.

Rose Gershon

Transcriber

Ann Riley & Associates, Ltd.