

1 UNITED STATES OF AMERICA
 2 NUCLEAR REGULATORY COMMISSION
 3 ***
 4 MEETING WITH
 5 ADVISORY COMMITTEE ON MEDICAL USES OF
 6 ISOTOPE (ACMUI)
 7 AND
 8 BRIEFING ON PART 35 QM RULE
 9 ***
 10 PUBLIC MEETING

11
 12 Nuclear Regulatory Commission
 13 One White Flint North
 14 11555 Rockville Pike
 15 Rockville, Maryland
 16 Wednesday, June 17, 1998
 17

18 The Commission met in open session, pursuant to
 19 notice, at 2:06 p.m., the Honorable Shirley A. Jackson,
 20 Chairman, presiding.

- 21 COMMISSIONERS PRESENT:
 22 SHIRLEY A. JACKSON, Chairman of the Commission
 23 GRETA J. DICUS, Member of the Commission
 24 NILS J. DIAZ, Member of the Commission
 25 EDWARD McGAFFIGAN, JR., Member of the Commission

- 1 STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:
 2 JOHN C. HOYLE, Secretary
 3 KAREN D. CYR, General Counsel
 4 L. JOSEPH CALLAN, NRC
 5 CATHERINE HANEY, NRC
 6 DONALD COOL, NRC
 7 MAL KNAPP, NRC
 8 JUDITH STITT, ACMUI
 9 JOHN GRAHAM, ACMUI
 10 NAOMI ALAZARKI, ACMUI
 11 DENNIS SWANSON, ACMUI
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1 P R O C E E D I N G S
 2 [2:06 p.m.]
 3 CHAIRMAN JACKSON: Good afternoon, ladies and
 4 gentlemen. Today the NRC staff and the NRC Advisory
 5 Committee on the Medical Uses of Isotopes, a.k.a. ACMUI,
 6 will provide the Commission with its annual briefing. The
 7 Advisory Committee last met with the Commission in April
 8 1997 and a lot has happened in the ensuing year.
 9 In June 1997, in a June 30th staff requirements
 10 memorandum, the Commission approved the staff's plan for

11 revision of both 10 CFR Part 35 and the Commission's Medical
12 Use Policy Statement. The staff has proceeded in an
13 expedited manner to develop the proposed draft rule language
14 over the last year by establishing a working group and a
15 steering group that included NRC headquarters and regional
16 licensing and inspection staff, and representatives of the
17 Organization of Agreement States and the Conference of
18 Radiation Control Program Directors.

19 The program to revise Part 35 and the associated
20 guidance document has provided more opportunity for input
21 from potentially affected parties than is provided by the
22 typical notice and comment rulemaking process. The staff
23 has held multiple meetings with the public and professional
24 societies and boards, have placed a straw man version of the
25 rule on the Internet for comment, and met extensively with

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1 the ACMUI and members of its subcommittees. I should say,
2 parenthetically, that the Commission itself has had a number
3 of visits from various groups with interests in our revision
4 to the rule.

5 Today the staff will brief the Commission on the
6 results of these activities, focusing on the more
7 significant aspects of the proposed revision of 10 CFR Part
8 35 and the medical use policy statement. The ACMUI's
9 presentation will follow the staff's, since their slides
10 focus on points of agreement and disagreement with the
11 staff's proposal.

12 Now, I understand that copies of the viewgraphs
13 and copies of the two papers are available at the entrances
14 to the meeting, and I welcome Ms. Haney, who we have not had
15 the opportunity to hear from before. So, unless my
16 colleagues have anything to add, Mr. Callan, please.

17 MR. CALLAN: Thank you, Chairman. Good afternoon.
18 Good afternoon, Commissioners.

19 As you pointed out, Chairman, we are taking the
20 unusual step of having the staff to go first to brief you
21 for the reasons that you stated, and then we will be
22 followed -- I am not going to rely on the acronym, I am
23 going to say the Advisory Committee on Medical Uses of
24 Isotopes.

25 [Laughter.]

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1 MR. CALLAN: But we promise we will not leave
2 after our presentation, we will stay and --

3 CHAIRMAN JACKSON: You didn't see the shackles
4 that we --

5 [Laughter.]

6 MR. CALLAN: And we will be ready to come back to
7 the table to respond to any questions you may have after the
8 Advisory Committee's presentation.

9 Ms. Cathy Haney will be our principal presenter.
10 Cathy.

11 CHAIRMAN JACKSON: Please, go ahead.

12 MS. HANEY: Basically, what I would like to do is
13 to tell you -- go over what we will start with. We will
14 discuss the process and the schedule, the approach, a
15 discussion on the medical policy statement, the
16 cross-cutting issues and the net impact on licensees from a
17 burden standpoint.

18 For the process, as you said, we did use a working
19 and steering group approach to develop the rule
20 alternatives. We also used that same approach in developing
21 alternatives for the medical policy statement. This group
22 also developed what we call alternatives for the

23 cross-cutting issues. The cross-cutting issues being things
24 that addressed all areas of the programs, whether we are
25 talking diagnostic or therapy uses, things such as Radiation

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1 Safety Committee Quality Management Program.

2 We held several facilitated public meetings to get
3 input from the stakeholders. It was well attended by
4 professional societies. And, as you said, we placed a straw
5 man on the Internet in January. We received approximately
6 330 comments during this rulemaking process. The majority
7 of them focused on training and experience. The remainder
8 focused on the more technical areas of the rule.

9 With the approach -- as I said, we started out
10 with identifying cross-cutting issues. These were primarily
11 -- and the issues that were noted in the staff requirements
12 memorandum. We have -- or we are proposing a change in
13 licensing philosophy, as we have come to call it, which will
14 reduce the amount of paper work that the licensees will
15 bring to us at the time of amendment or license application.
16 This being that we -- NRC would no longer review the
17 procedures that the licensee has. They will still be
18 required to have those procedures, but the licensing staff
19 would not be reviewing. We estimate that this could impact
20 -- reduce the amount of licensing, the time to review a
21 license application by up to 50 percent, in that area.

22 CHAIRMAN JACKSON: What is a typical time frame
23 for reviewing a license application?

24 MS. HANEY: It varies whether you are talking a
25 broad scope, which is the larger. In that case, the average

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1 may be as high as 70 to 100 hours. In the routine -- I say
2 routine -- specific licensees, your smaller community
3 hospital, maybe in the 10 hour range. Then license
4 amendments, depending upon the complexity of the issue,
5 would be slightly less.

6 We have developed a guidance document. It's
7 following the same format that was used for the consolidated
8 licensing guidance that we have put together before. We
9 have been careful not to include any specific requirements
10 in the guidance documents. This was one of items that the
11 public mentioned that we should not do, if there were any
12 requirements, they should appear in the rule.

13 The last thing that we did from an approach
14 standpoint was to rely on requirements in other portions of
15 Title 10. For example, if there was a requirement in Part
16 20, we did not -- we deleted the requirement from Part 35,
17 figuring that the requirement in Part 20 was adequate.

18 To move right into the medical policy statement,
19 this was an area where we received a large amount of
20 comments from the public, and there were also a wide variety
21 of viewpoints that were expressed by these individuals. The
22 key elements that are the items that the working group felt
23 were key elements in developing a proposed policy statement
24 was that the policy statement should provide for the
25 radiation safety of workers and the public, that we did not

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1 want to intrude into medical judgments, that was at the
2 discretion of the physician and, also, we wanted to focus
3 our regulation on assuring that the use of radionuclides is
4 in accordance with the physician's directions.

5 With those things in mind, the staff is proposing
6 a revision to the medical policy statement. I won't go
7 through line by line, but there are a few items that I want

8 to focus you to. In the first item -- bullet, basically, we
9 are just doing a change in terminology there. There is no
10 change in the scope or intent of the regulations. The
11 current policy statement says medical use of radioisotopes,
12 and we are just changing it to radionuclides to be more
13 accurate.

14 In the second item, we are changing -- proposing a
15 change from "minimize intrusion", which is what is in the
16 current policy statement, to "will not intrude". We made
17 this change at the advice of the ACMUI.

18 In the third item, this is where we bring in the
19 focus that radionuclides are used in accordance with the
20 physician's direction.

21 And in the last item, we have made a change there.
22 The corollary statement in the present policy statement says
23 that we will rely on industry standards. We are proposing
24 that we use the term "will consider industry and
25 professional standards" and we believe that this is more

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1 consistent with identifying key objectives in the rule,
2 putting the requirements for the objective in the rule that
3 the licensee needs to meet and then putting the putting the
4 more prescriptive requirement -- or more prescriptive
5 requirements would fall to the industry standards for
6 implementing the objective.

7 CHAIRMAN JACKSON: Let me ask you a question. I
8 mean you have in this bullet 3, the phrase "where justified
9 by risk" and that seems to indicate somehow perhaps a set
10 point that would justify NRC's intervention or interceding
11 on behalf of a patient. Do you have a qualitative, a
12 quantitative idea of how you would arrive at that judgment?

13 MS. HANEY: What I would offer is that in the low
14 -- the diagnostic uses of medicine are your low risk areas
15 and your therapy area, therapeutic uses, for example, the
16 teletherapy, the use of high dose rate remote after-loaders,
17 those would be the high risk therapy areas, and that --
18 that's really where we would be looking at were justified by
19 the risk.

20 CHAIRMAN JACKSON: And what do you -- do you
21 define what you mean by radiation safety for a patient?

22 MS. HANEY: I think we do in the last statement
23 where we are saying to assure the use of radionuclides is in
24 accordance with the physician's directions. We would not
25 question the physician's judgment. However, once the

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1 physician makes a determination of how much radiation the
2 patient should receive or the treatment, at that point NRC
3 would pick up their regulatory authority and there we would
4 be looking at instrument calibration, things such as that.

5 CHAIRMAN JACKSON: So exposures beyond what the
6 physician would --

7 MS. HANEY: Correct. Or that differ from what the
8 physician said.

9 CHAIRMAN JACKSON: Okay. Thanks.

10 COMMISSIONER MCGAFFIGAN: Could I? I am having a
11 little problem with the "will not intrude" into medical
12 judgments as opposed to "minimize intrusion", which is what
13 the 1979 policy statement says. I am a Commissioner who is
14 going to be reluctant to give up patient notification, and I
15 don't know whether the -- and I believe the medical
16 community will say I am, therefore, intruding medical
17 judgment affected patients. And so, can one be for patient
18 notification and for "will" -- you know, the blanket "will
19 not intrude", as opposed to "minimize intrusion"? The 1979

20 Commission was consistent. They minimized intrusion but
21 they felt patient notification was important.

22 MS. HANEY: I believe you could support patient
23 notification under Statement 3 of the proposed medical
24 policy statement, provided we maintain the clause in the
25 rule that says that if it is the -- at the discretion of the

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1 physician, the patient should not be notified. I felt it
2 could be justified under 3 because you are requiring
3 notification following a medical event, and the medical
4 event would be an example of where the physician's
5 directions were not carried out and, therefore, that would
6 give us the step into being able to notify the patient,
7 justified under this statement. Even with the "not intrude"
8 in Statement 2.

9 COMMISSIONER MCGAFFIGAN: Okay. The 2 statement
10 -- it may be more honest to say "minimize intrusion" rather
11 than "do not intrude". Just, at first -- at first glance --
12 but we don't have to dwell on that. We will probably have a
13 good discussion later.

14 CHAIRMAN JACKSON: And certainly in the Commission
15 process. Thanks. Okay.

16 MS. HANEY: As I said, there were several
17 cross-cutting issues that the group addressed, and I will go
18 briefly through these. We do have some backup slides that
19 go into greater depth if you would like us to go there, but
20 I will just give you a two sentence version on each one.

21 On Radiation Safety Committee, in accordance with
22 the performance-based approach to the rule, we are proposing
23 that the Committee no longer be required. We have
24 identified key elements that the Radiation Safety Committee
25 currently perform and those items we have listed in the rule

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1 and made them the responsibility of the licensee management.

2 COMMISSIONER MCGAFFIGAN: Are your two sentences
3 finished on that?

4 CHAIRMAN JACKSON: Let her finish. Let her
5 finish.

6 [Laughter.]

7 MS. HANEY: Well, my two sentences are finished.
8 That's two sentences. I'm okay.

9 COMMISSIONER MCGAFFIGAN: On that item, I just
10 want to make a -- the Radiation -- the basic rationale for
11 giving up the Radiation Safety Committee is that there are
12 other committees at hospitals that might be able to carry
13 out this function, is that the thought?

14 MS. HANEY: That is one of the reasons. Another
15 reason is that we want the licensee to have flexibility in
16 how they manage their program and, in that, if there are
17 other committees in a hospital forum that would allow them
18 to address this problem. But we are also extending this
19 particular proposed section to cover all licensees, just,
20 again, to make it more explicit that there are some basic
21 things in the Radiation Protection Program that we expect
22 the licensees to do.

23 COMMISSIONER MCGAFFIGAN: But is there a chance
24 that radiation safety gets lost, if there isn't a Radiation
25 Safety Committee, in a big hospital where people have lots

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1 of other things to worry about besides radiation safety?

2 MS. HANEY: It's always a potential for that to
3 happen. I think, given today's structure for the hospital
4 setting with the Joint Commission on Accreditation of Health

5 Care Organizations, JCAHO, they require certain committees
6 in a hospital now, one being a committee to review risk, and
7 that would be an ideal location for radiation safety to fall
8 under. So, yes, there is a potential, but I think in the
9 hospital setting where the risk is the greatest, there are
10 other committees that are in place, required by other
11 organizations, that would address this item.

12 COMMISSIONER DIAZ: If I may follow on that
13 question. I don't think it's the issue of the committee,
14 are the functions that are required for the protection of
15 health and safety that we envision should be carried out,
16 are they going to be addressed by someone that will have
17 accountability on those issues?

18 MS. HANEY: I believe the rule as proposed does
19 that, in the Section 3524 where we --

20 CHAIRMAN JACKSON: Makes it clear that is a
21 fundamental requirement.

22 MS. HANEY: I believe -- I believe so.

23 CHAIRMAN JACKSON: Okay. Why don't you do on.

24 MS. HANEY: Okay. Moving into quality management,
25 again, we took a performance-based approach there. We have

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1 deleted the current requirements as seen for the Quality
2 Management Program. However, we have focused in on
3 confirming patient identify, requiring written directives,
4 and verifying dose. The licensees would still need to be
5 required to have written directives and then they would need
6 to develop procedures, develop, implement and maintain
7 procedures for verifying patient identity and verifying that
8 the correct dose is given to the correct patient.

9 COMMISSIONER DIAZ: Is this risk-informed on a
10 certain way, or are you cutting across all procedures?

11 MS. HANEY: I believe it is risk-informed because
12 the requirements for the written directive are in your
13 therapy area and your high risk procedures. We really did
14 not make any changes, or I should say significant changes to
15 when a written directive is required and the procedures, the
16 requirement for having procedures flow out of if you need a
17 written directive.

18 The third issue is that of reportable events.
19 There are two items that fall under this -- one, it being
20 medical events, which we are proposing to change the term
21 from misadministrtion to medical event, and then the second
22 item being precursor events.

23 We have made some minor changes in the Medical
24 Event Reporting to address two items that were brought to
25 our attention by the public, one being patient intervention,

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1 and the second being wrong treatment site.

2 In the area precursor events, we have included a
3 requirement for reporting precursor events. We have,
4 however, focused the definition for precursor events to
5 events that would have implications beyond that specific
6 licensee's facility.

7 In the case of notification following a medical
8 event, the proposed rule contains the essential requirements
9 as they appear in the current Part 35.

10 Then moving into training and experience, training
11 and experience was one of the big issues of this rulemaking
12 and if you would turn to the next slide, I do have a slide
13 on this one.

14 CHAIRMAN JACKSON: Let me just ask you this
15 question as a generalized comment. On all the cross-cutting
16 issues, you know, obviously I think we are interested in

17 moving to a risk-informed and as appropriate
18 performance-based approach question is the rule enforceable
19 in your opinion?

20 MS. HANEY: Yes.

21 CHAIRMAN JACKSON: Okay.

22 MS. HANEY: Staff is proposing the requirements
23 for training and experience be risk informed and focused on
24 radiation safety. That was really our focus on going into
25 making any proposed changes in the training and experience

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1 criteria. We believe that individuals should complete a
2 structured educational program and that educational programs
3 should consist of a didactic training portion, which is your
4 classroom training in physics and biology, things like that,
5 and then practical experience, which would include
6 experience in ordering, receiving packages and safety
7 precautions, ways to prevent medical events and calibrating
8 dose calibrators and eluting generators.

9 In some cases we have proposed some clinical
10 experience where we believe that there is a greater risk
11 posed by the procedure. An example of that would be in your
12 use of unsealed radiopharmaceuticals for thyroid treatment,
13 for example with your Iodine-131s.

14 We also believe that an exam should be given to
15 assess clinical competency. The idea of an exam grew out of
16 meetings with the professional societies, the facilitated
17 public meetings, and also comment letters. The majority,
18 vast majority of the individuals, did support an exam to
19 assess clinical competency and because of that we are
20 proposing that an item be included in the rule.

21 If you would like I can get into the specific hour
22 requirements, but I think I will stop there.

23 CHAIRMAN JACKSON: Commissioner Diaz and then
24 Commissioner McGaffigan.

25 COMMISSIONER DIAZ: On the issue of Iodine-131,

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1 which is specifically separated -- it is a special
2 category -- is the training then going to be Iodine-131
3 specific or are you still thinking of generic training plus?
4 I mean there is a difference in how much you can provide
5 generic training and how much you can go into a specific
6 radionuclide use.

7 MS. HANEY: The proposed rule would require the
8 didactic training and in that case I think it would be very
9 general and really with the didactic training that is
10 adequate, because you are learning decay formula. You are
11 learning the radiobiological implications, things like that,
12 so that would be very general.

13 In the practical that we are proposing, and in
14 this case we are talking 40 hours of practical experience,
15 we are also looking at five cases and we believe that this
16 practical experience would be more tailored to what that
17 individual is using.

18 For example, if an endocrinologist was coming
19 in -- was wishing to become an authorized user, and for
20 hyperthyroidism treatments or thyroid cancer, there would be
21 a requirement for five cases. Some of that practical
22 experience could be obtained while they were doing those
23 five cases. They would still need to receive a package.
24 They would need to order the material. They would need to
25 assay it -- things like that -- so there is some overlap

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1 there.

2 To answer your question, some would be very
3 general, but I could see some of it being specific to the
4 type of use the individual is doing because we are focusing
5 in on radiation safety.

6 COMMISSIONER DIAZ: Yes. It would seem that as an
7 equity issue that in some specific areas like Iodine-131 you
8 really want to become very specific, not broad.

9 CHAIRMAN JACKSON: Let me make sure -- this is a
10 piggyback to his question -- so then is the point that the
11 didactic part is some baseline knowledge level --

12 MS. HANEY: Right.

13 CHAIRMAN JACKSON: -- that you would expect
14 everyone working with radionuclides to have, and then where
15 the specificity comes is in what you would call the
16 practical training that is tailored to the particular
17 radionuclide or set of radionuclides that are being used or
18 tailored to the risks involved.

19 MS. HANEY: It would be tailored to the risks. I
20 would like to say a flat yes to that, but in the case of the
21 endocrinologist their five cases would be very specific, but
22 if you are looking at a physician that is doing general
23 nuclear medicine, that practical would be a little bit
24 broader.

25 CHAIRMAN JACKSON: Right.

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1 MS. HANEY: So I just wanted to give the full
2 story.

3 CHAIRMAN JACKSON: I appreciate that.
4 Commissioner?

5 COMMISSIONER McGAFFIGAN: I am going to follow on
6 the same line of questioning. There basically are two
7 categories of specialist who are adversely affected by the
8 rule in that their hours of training is going to have to go
9 up, and one of them, I understand, the Strontium-90 eye
10 applicator folks -- we have had all sorts of problems in
11 that area -- and misadministrations and damage to eyes and
12 whatever.

13 The endocrinologists argue that you are trying to
14 fit them in a one-size-fits-all box, that they have had zero
15 problem, that this is straightforward. These are smart
16 people and the 80 hours that are required at the moment is
17 all they need for dealing with basically one radionuclide
18 and one organ. If there were a backfit rule, which there
19 isn't, for materials licensees, this would never pass a
20 backfit test because there is no health and safety benefit
21 that is going to accrue from upping -- in fact, they would
22 argue and have argued that there will be an adverse health
23 and safety benefit because it is a larger entry barrier and
24 people will not bother to get -- to get certified and they
25 will send people off to other specialists and the patient

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1 has to now deal with a more complex medical system and all
2 that.

3 But what is the rationale for increasing the time
4 for the endocrinologists?

5 MS. HANEY: Staff's approach to the rulemaking in
6 the training and experience area was to focus in on the
7 radiation safety and from the comments that we received, the
8 input that we received across the board from diagnostic
9 therapy users, a certain amount of practical experience was
10 needed as part of a training program.

11 To use the example of the endocrinologist, right
12 now they are required to have three cases if they are in the
13 hyperthyroidism area and 10 cases if they are treating the

14 cancer, so there is some practical that they are getting
15 there right now inherent in the fact that they are in the
16 clinic, that they are handling the pharmaceuticals, and
17 treating the patients, and our pulling it out as an hour of
18 a 40-hour practical -- well, it looks like an increase -- in
19 the rule it is an increase.

20 I believe that you could get the clinical -- the
21 practical training and the clinical at the same time, so it
22 may not be as great as an actual net 40 hours that they must
23 be in the clinic.

24 COMMISSIONER MCGAFFIGAN: Why fix something that
25 isn't broken is the question that they will ask, surely, in

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1 the process that you are about to enter?

2 MS. HANEY: All I can offer to that is that we
3 have attempted to focus on radiation safety and this is what
4 we were -- the comments that we received across the board,
5 that this was needed.

6 COMMISSIONER MCGAFFIGAN: Okay.

7 CHAIRMAN JACKSON: Actually, this is probably more
8 directed at Dr. Cool or Dr. Knapp, because it actually lifts
9 it out of, strictly speaking, Part 35 rulemaking.

10 You know, since these training and experience
11 requirements that you are focusing on have to do with
12 radiation safety, do you anticipate any effort to require
13 similar training and examination requirements for,
14 experience requirements for other licensed individuals using
15 the same types of licensed materials and faced with the same
16 radiation safety risks but from a non-strictly medical point
17 of view, industrial or research applications, possibly
18 veterinary, which some people call medical, some say not,
19 but you know -- what can you say about that from a
20 consistency perspective?

21 MR. COOL: That is an extremely good question and
22 one that we have done at least a little bit of thinking
23 about.

24 In fact, the case in Part 35 here is not the first
25 place where we have gone with an examination type of

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1 approach. The radiography arena and the certification of
2 radiographers by independent testing organizations for which
3 there is one test plus several states are doing it, was a
4 stalking horse, if you will, a similar kind of approach.

5 What we learned from this in terms of working in
6 the unsealed arenas and how this scales out I think we ought
7 to use to then look to see whether there are other arenas
8 and other uses as we go back and look at it, to see whether
9 or not it also makes sense.

10 There is an advantage in this arena, I would
11 note -- that we have a number of professional societies and
12 organizations who are in the business of testing and
13 certifying people in terms of these particular fields, so we
14 have that baseline which is not present to varying degrees
15 in some of the other areas.

16 MR. KNAPP: And I would say that obviously we have
17 a diverse set of licensees. In some cases in ways that
18 perhaps we hear from the auto industry, it's better to have
19 an automated breaking system than to train each driver to
20 pump their breaks. In some cases there are other fixes
21 which literally if we have some classes of licensees we can
22 solve a problem with an engineered fix, but the fundament
23 questions you asked, Chairman, I agree entirely with Don.

24 This is something we should consider across the

25 board and to the extent that we have similar risks and

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1 similar needs I think we should take some more steps.

2 CHAIRMAN JACKSON: Okay.

3 MS. HANEY: Now I would like to move into some
4 areas where there is a reduction in the regulatory burden on
5 licensees.

6 In the slide that you see, the deletion of the
7 Radiation Safety Committee and a requirement for the Quality
8 Management Program, this would represent a significant
9 reduction in the burden on licensees.

10 If we look at the diagnostic and the therapy areas
11 as separate areas, some minor changes that we are proposing
12 to the rule and more the technical orientation would also
13 decrease burden. In the diagnostic area and the therapy
14 area we are also proposing that the medical physicist --
15 change in the medical physicist, no longer requiring
16 amendment to the license. This is a similar consistency
17 with how we are doing it with other users in the rule.

18 There are some areas where there is an increase in
19 the regulatory burden on licensees because of the proposed
20 rule change, the first being that the rule now specifies
21 that the licensee develop, maintain, and implement
22 procedures.

23 The vast majority of the procedures that the rule
24 is proposing to be included are already developed by the
25 licensee and this is part of their license application.

24

1 There are however a few procedures that they currently do
2 not have that they would need to develop if they were going
3 to be in compliance with the rule.

4 We have also added the two reporting requirements,
5 one for reporting unintended dose to the embryo fetus, or
6 nursing child, and also for precursor events. While we do
7 believe that there is a small impact here, there is however
8 an impact.

9 Finally we would be requiring an output
10 measurement for all brachytherapy sources, and this would be
11 just to make our regulations more consistent. Right now we
12 require it in the teletherapy area and the high dose rate
13 remote afterloader area, but we are not requiring it in the
14 manual brachytherapy, so here we are looking for
15 consistency.

16 CHAIRMAN JACKSON: Did you get many comments in
17 these three areas?

18 MS. HANEY: Where did we get the most? I'll start
19 at the bottom first again.

20 The medical physics community was very supportive
21 of requiring output measurements on the sources. We did not
22 receive comment on the reporting requirements for the
23 unintended dose to the embryo fetus because the version of
24 the rule that went up on the Internet really had totally
25 different language than what we are proposing now, so we

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1 were talking apples and oranges and therefore I can't say
2 that they -- the public has seen this.

3 I would expect that we will receive a lot of
4 comment in both the area of the embryo fetus and the
5 precursor events.

6 In the area of the procedures, the big comment
7 there was don't put requirements for procedures in the
8 license or in your reg guides. If you want us to have
9 procedures, put it in the rule and state it upfront, which
10 is what we have done.

11 CHAIRMAN JACKSON: Okay. Commissioner?
12 COMMISSIONER McGAFFIGAN: Can you give an example
13 of a procedure that is not currently part of the license
14 application that would be required by the new rule?

15 MS. HANEY: Right. An example would be that we
16 have deleted the prescriptive requirements for labelling of
17 vials and syringe shields and have gone to what we think and
18 believe to be more performance-oriented, which is that the
19 licensee should develop procedures for how they will label
20 and under what conditions they will label.

21 The only other requirement would be falling back
22 to the requirements in the Radiation Safety Committee. How
23 we have resolved that area, we have asked for procedures for
24 the interdepartmental, interdisciplinary communication
25 between departments, and that was one of the things to

26

1 offset the fact that we would no longer require a Radiation
2 Safety Committee.

3 COMMISSIONER McGAFFIGAN: Can I --

4 CHAIRMAN JACKSON: Please.

5 COMMISSIONER McGAFFIGAN: On the Radiation Safety
6 Committee, which wasn't -- isn't it true that most of the
7 written comments that we received from Radiation Safety
8 Officers and the health physics community were against
9 giving up the Committee for fear that it would get lost and
10 other reasons, that the main impetus for doing it came from
11 the hospital administrators.

12 I am not arguing for retaining all the
13 prescriptive elements of the current rule, but that the
14 notion of having a Radiation Safety Committee that doesn't
15 get lost in the hospital infrastructure is something that
16 the people who are in the field working in these hospitals
17 are arguing for. Maybe they are all about to get fired by
18 their hospital administrators, I don't know, but I am a
19 little troubled by the disconnect there.

20 MS. HANEY: It is true that the comments from the
21 Health Physics Society and the American Association of
22 Physicists in Medicine supported retention of the Radiation
23 Safety Committee.

24 We do have a lot of other comments from other
25 organizations, however, that do support the deletion of the

27

1 Committee.

2 Again, I believe the proposed rule would still
3 address the concerns of the Radiation Safety Officer. The
4 authority for the day-to-day running of the program is
5 delegated from licensee management to the Radiation Safety
6 Officer. We are looking for that delegation in writing, so
7 there is a clear path between the licensee, Chief Executive
8 Officer, and the Radiation Safety Officer and because of
9 that I don't think it would get lost.

10 COMMISSIONER DIAZ: If I understand the proposal,
11 it's not to delete the Radiation Safety Officer --

12 MS. HANEY: No.

13 COMMISSIONER DIAZ: -- but the Radiation Safety
14 Committee.

15 MS. HANEY: That's correct, yes. We would still
16 maintain the Radiation Safety Officer.

17 COMMISSIONER DIAZ: For functions and
18 communications that are important to safety should be
19 maintained through the Radiation Safety Officer.

20 MS. HANEY: Yes.

21 CHAIRMAN JACKSON: And to have that specific

22 delegation in writing of which you spoke.
23 MS. HANEY: Right.
24 CHAIRMAN JACKSON: Okay.
25 MS. HANEY: And with that, this concludes our

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1 formal presentation.

2 CHAIRMAN JACKSON: Any comments?

3 I do have one. This is on one of your backup
4 slides having to do with resolution of reportable events.
5 You almost got away.

6 It talks about the situation that meets the above
7 criteria would not be reportable if it was the result of
8 patient intervention in the treatment that could not have
9 been reasonably prevented by the licensee.

10 Now will the final determination of what is
11 reasonable be left to our licensees to make, or will that
12 determination be left to the NRC Office of the General
13 Counsel to judge on a case by case basis? Is this the
14 General Counsel Full Employment Act?

15 [Laughter.]

16 MS. HANEY: There will be some events that the
17 licensee will rule out automatically and say that it was the
18 result of patient intervention, and we would never hear
19 about them unless for example we were out doing an
20 inspection and an inspector identified it by reviewing a
21 dose log and then questioned why wasn't this reported.

22 In that particular case we would -- the inspector
23 would bring it back through the regional office through NMSS
24 and into OGC for determination of whether this falls into
25 that category or not.

29

1 There also will be some cases where a licensee
2 wanting to be on the safe side would call NRC and say in my
3 opinion it was caused by the patient, but I just want to
4 make sure.

5 I would expect too that in these cases where it
6 did come to NRC's attention and that there was some question
7 about what was reasonably prevented that we would also rely
8 heavily on the use of our medical consultants and the ACMUI
9 for whether they believed that it should have been a
10 reportable event.

11 CHAIRMAN JACKSON: Are inspectors going to be
12 directed to review logs from time to time?

13 MS. HANEY: No more so than what they are doing
14 now, as far as going in and looking at doing a sampling of
15 records to make sure that the program is functioning
16 properly.

17 CHAIRMAN JACKSON: All right. Commissioner?

18 COMMISSIONER DIAZ: Yes. Since you were going
19 away too easy --

20 [Laughter.]

21 COMMISSIONER DIAZ: -- I decided there's just a
22 little bit of a problem in here. In the process of
23 developing the new rule, have you come into some additional
24 knowledge of how our particular procedures and regulations,
25 or the absence of, in the area that we do not regulate --

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1 say, accelerators and isotopes made by accelerators -- you
2 know, is there a compatibility or are we so far apart that
3 we don't even want to look at it right now?

4 MS. HANEY: I would say that it was mentioned at
5 some of the meetings about whether NRC would be going into
6 other areas of medicine, but we did not spend a lot of time
7 in that particular area. The Working Group had

8 representatives from an agreement state and from a state
9 that is trying to become an agreement state on the
10 committee, so there were times during the process where they
11 brought to our attention, well, this is the way it's done in
12 x-ray, this is the way that it is done in nuclear medicine.

13 There was nothing that came to our attention that
14 was a gross problem.

15 COMMISSIONER DIAZ: Yes, because I am not
16 concerned whether we do it or not. I am concerned with the
17 compatibility and consistence between processes that are
18 used in this large, growing area, compared to what we do,
19 and I think you have just kind of said that it came in bits
20 and pieces but we really didn't look at it.

21 MS. HANEY: Correct. We didn't focus on that.

22 CHAIRMAN JACKSON: Yes, Commissioner?

23 COMMISSIONER McGAFFIGAN: Not to let them off too
24 easily --

25 CHAIRMAN JACKSON: I'm sorry, Ms. Haney --

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1 [Laughter.]

2 COMMISSIONER McGAFFIGAN: -- the cardiologists
3 whom we may hear about from the next panel, one of the
4 issues that they have raised, aside from training and
5 experience, where they obviously support the proposed --
6 what the Staff is proposing -- is the issue of these
7 treatments for restenosis I think is the right medical term
8 get routinized?

9 At the moment I guess you are going to treat them
10 under 35.900, and there is a requirement that there be a
11 team including a radiation oncologist who participates in
12 the various and sundry experiments underway with various
13 treatment modalities, but when that gets routinized, and
14 they are respectfully suggesting that the radiation
15 oncologist doesn't need to be there and indeed in a real
16 medical setting where it is now a routine practice, getting
17 the cardiologist, the radiation specialist at the hospital,
18 et cetera there, that that is enough and in getting an
19 oncologist who at the moment, when it is an experimental
20 thing, they can all come together and schedule it, but that
21 is not how cardiology is practiced, so how will that,
22 whatever treatment modality wins the horse race and gets the
23 approval of the community and becomes the routine treatment
24 for restenosis or maybe there will be several, how does that
25 then transfer from 900 in your rules to some other place and

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1 do you see a need at that point for a radiation oncologist
2 to be part of the team administering the health care?

3 I know we are in an impossible position as a bunch
4 of nondoctors to basically settle the scrap between the
5 cardiologists and the radiation oncologists, but we probably
6 are going to have to at some point.

7 MS. HANEY: Right now, the current rule is
8 structured with the 35.900 -- what we refer to as "emerging
9 technology" section, that you could license the
10 intervascular use under that and in fact we have had
11 conversations with the oncologists that this would be the
12 ideal place for the intervascular use to come into play.

13 There is a lot of discussion though that the
14 intervascular use that they are proposing does not differ
15 significantly from that of what is being done currently with
16 high dose rate remote afterloaders, so shouldn't it in fact
17 fall under the medical device use.

18 Right now the current framework, as you said, is

19 to have a group with an oncologist involved. As they become
20 more familiar in whichever treatment is going to end up
21 being their preferred route and as Part 35 is finalized next
22 year, I could see us having to make some tough decisions
23 next year about whether it does in fact fall under this
24 emerging technology where we would be looking at some
25 possibly different training requirements for these

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1 individuals or in fact is the use that of a medical device
2 in an HDR unit and therefore it should just be treated as a
3 medical therapy device and the cardiologist should be
4 expected to have the same amount of training as a radiation
5 oncologist if they wanted to become an authorized user.

6 So I think this is an evolving process that we
7 will have to --

8 COMMISSIONER MCGAFFIGAN: I am not sure we are
9 going to have to make the decision in the next year given
10 the rate at which the technology is emerging, but I think it
11 is an issue that we are going to have to deal with at some
12 point and the cardiologists obviously do not believe that it
13 is likely that they are going to need the full training of
14 radiation oncologists to administer whatever, whichever
15 technology wins the day.

16 CHAIRMAN JACKSON: Commissioner?

17 COMMISSIONER DIAZ: Yes. Looking at the detail
18 that we are going to require on precursor events, as you
19 know, root cause analysis is deeply rooted in this
20 Commission and I am not sure if it's the Commission or the
21 entire Staff but I just want to make sure that when we go
22 into this precursor event issue that we have constrained it
23 to things that actually are licensable and can be of use
24 rather than getting into a habit of saying this has a
25 precursor.

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1 What is the, from your viewpoint, what is the
2 dividing line on how you actually get into trying to
3 determine precursors?

4 MS. HANEY: What we are proposing as the dividing
5 line would be an event that would have implications outside
6 that licensee's facility.

7 Let me give you an example. That might be the
8 best way to say it.

9 You have a manufacturer that gives you a procedure
10 for calibrating -- let's use the high dose rate remote
11 afterloader where there is risk involved with use of this
12 procedure. The physicist takes and tries to implement that
13 procedure and realizes that if he does exactly what that
14 procedure says that significant exposure could occur.

15 In that case one would like to think that the
16 physicist would go back to the manufacturer and the
17 manufacturer would correct these procedures, but we also
18 believe that it would be important for NRC to hear about
19 these events so that we could consider generic
20 applicability, possibly issue an information notice, or
21 given the nature of the error, issue an NRC bulletin that
22 would require further action than just an information
23 notice.

24 COMMISSIONER DIAZ: Okay. I don't want to be a
25 broken record, but again this would be a process that would

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1 be fully risk-informed in the sense that you are not going
2 to start looking for --

3 MS. HANEY: Correct. Right.

4 COMMISSIONER DIAZ: Thank you.

5 CHAIRMAN JACKSON: Okay. Well, I think before
6 they ask any more questions, or I, thank you very much.

7 We will now hear from the Advisory Committee on
8 the Medical Uses of Isotopes.

9 Good afternoon.

10 DR. STITT: Good afternoon. Good to be here, I
11 think.

12 My colleagues and I are here today representing
13 the Advisory Committee on Medical Uses. We would like to
14 start with our first viewgraph, the process. We would like
15 to say the NRC staff has been very responsive and forthright
16 in dealing with these issues with the ACMUI, both in areas
17 of agreement, as well as disagreement.

18 The regulated community has had significant
19 opportunities for input and for participation, and Cathy
20 Haney defined the myriad way we have been involved.

21 The web site has been an efficient use of
22 technology to facilitate our communication. This has
23 certainly been a very intensive time and labor process with
24 a lot of demands on the NRC staff, but we appreciate the
25 benefits that it should provide to the community.

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1 In our presentation today, all of my colleagues
2 get the opportunity to speak and we will speak when spoken
3 to by you. John Graham is going to discuss the
4 recommendation for medical policy statement.

5 DR. GRAHAM: Good afternoon. I hope it was
6 serendipity that my name tag was placed at this seat since
7 it seems to be the hot one so far.

8 In its staff requirement memorandum,
9 COM-SECY-96-057, dated March 20, 1997, the Commission stated
10 that it supported continuation of the ongoing medical use
11 regulatory program with improvements, decreased oversight of
12 low risk activities, and continued emphasis on high risk
13 activities. This SRM directed staff to revise 10 CFR Part
14 35 and, if necessary, the Commission's 1979 medical policy
15 statement.

16 This policy statement has been the subject of
17 considerable review and discussion by the ACMUI since it
18 represents the guiding policy for our review and
19 recommendation on proposed regulation governing the medical
20 use of isotopes.

21 As stated in the draft proposed policy statement
22 on the medical use of byproduct material, dated June 4th,
23 1998, certain themes have emerged in ACMUI meetings,
24 public-facilitated work shops and written and electronic
25 comments that have convinced the staff that some revisions

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1 of the medical policy statement are warranted.

2 These themes include insuring that the Nuclear
3 Regulatory Commission will regulate the medical use of
4 byproduct material, as necessary, to provide for the
5 radiation safety of workers and the general public, but it
6 will not intrude in the practice of medicine or with medical
7 judgments affecting patients. It limits its role in
8 regulating the radiation safety of patients to requiring
9 that the physician's directions are followed and that it
10 regulate the radiation safety of patients only where the
11 voluntary standards or compliance with these standards are
12 inadequate.

13 The ACMUI concurs with the staff-proposed revision
14 of the medical policy statement which essentially retains
15 Statement No. 1, that NRC will continue to regulate the use

16 of radionuclides in medicine, as necessary, to provide for
17 the radiation safety of workers and the general public.

18 The ACMUI is gratified by the proposed Revision
19 Statement No. 2 that NRC will not intrude into medical
20 judgments affecting patients except as necessary to provide
21 for the radiation safety of workers and the general public.

22 The ACMUI continues to advocate an alternative to
23 the staff-proposed Statement No. 3, that the NRC will, where
24 justified by risk to patients, regulate the radiation safety
25 of patients primarily to insure -- to assure the use of

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1 radionuclides is in accordance with the physician's
2 directions.

3 The ACMUI recommends that NRC will regulate the
4 radiation safety of patients only where justified by the
5 risk to the patients and only where voluntary standards or
6 compliance with these standards are inadequate. Assessment
7 of the risks justifying such regulations will reference
8 comparable risks and comparable voluntary standards and
9 modes of regulation for other types of medical practice.

10 CHAIRMAN JACKSON: Let me stop you for a second
11 there. You have referenced the Atomic Energy Act in coming
12 up with this statement, because -- this is the lawyer's
13 question. You could have such a statement, is that
14 consistent with what the law requires? As opposed to saying
15 that the NRC will regulate the radiation safety of patients
16 in a manner justified by the risk to patients?

17 MS. CYR: I think -- I don't know that the Atomic
18 Energy Act requires that you -- only where justified by the
19 risk to patients. I mean I did not view this as a
20 jurisdictional statement, I viewed this as sort of a
21 judgment statement about where it was appropriate to --

22 CHAIRMAN JACKSON: Give attention.

23 MS. CYR: Right. To give attention.

24 CHAIRMAN JACKSON: Okay. And then my question to
25 you, Mr. Graham, is there a compendium of risk from medical

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1 treatments that would provide this reference that you are
2 talking about here?

3 DR. GRAHAM: There is certainly not, to my
4 knowledge, having sat on the Advisory Committee for three
5 and a half years now, I believe, any simple document that we
6 could go to that would, in clear black and white, draw those
7 lines of risk. And I think what we are suggesting in the
8 next part of our recommendation gets to the issue of having
9 an ongoing process over the review of those risks and
10 separating them into low risk versus high risk categories.
11 And we speak specifically to the concerns that were raised
12 by General Counsel and some of the background documentation
13 that we received. So maybe it will become clearer in a
14 couple of minutes.

15 COMMISSIONER DIAZ: Okay. Because I have got a
16 little problem with assessment of risk, comparable. It
17 seems like in certain cases when the assessment methodology
18 is sharply defined or it is better defined, that that should
19 be taken not as an additional imposition but as a
20 definition, that when you do risk analysis or you actually
21 establish risk inside a regulation as a goal or as a
22 guidance, we might have better information that are
23 available from voluntary methods or comparable voluntary
24 standards in medicine, and we should not forsake those.

25 Am I making myself clear? In other words, I have

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1 got a problem with this phrase "assessment of the risk

2 justifying" -- "will reference comparable risks and
3 comparable voluntary standards" and you just say that, you
4 know, there is really not a medical compendium, like the
5 Chairman said, that actually will reference risk. Shouldn't
6 we serve better by, in the cases which we have a risk
7 assessment, that it is well defined even it is not
8 comparable to other practice of medicine.

9 My impression is that medicine has so many
10 variations that are based in the practice of medicines, the
11 different biological responses of individuals, et cetera, et
12 cetera, that we might be able to focus more on the use of
13 radioisotopes or radionuclides in medicine and address that,
14 you know, specifically, rather than trying to compare it
15 always to other areas of medicine. I think some comparisons
16 might be valid. I am concerned that you are trying to put
17 this in a context that is very, very broad and I am not sure
18 that that breadth is justified.

19 DR. GRAHAM: Well, I think it was a concern, and I
20 will request clarification from other committee members, as
21 appropriate. But I think it was a concern of the ACMUI
22 that, in particular, it was the threshold of risk and the
23 definition of threshold that needed to be evaluated in the
24 broader context of risk assessment as it would occur in the
25 other practice of medicine.

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1 DR. STITT: I can add to that. If you understand,
2 and you do understand the composition of the committee,
3 basically, clinicians who are working in various parts of
4 medicine, and so radiation medicine and radiation risk is a
5 part of what we do. And so there are some philosophic
6 differences. A patient who is having an anaesthetic to have
7 radioactive isotopes used, a clinician would view several
8 parts of that risk, in addition to, potentially, the
9 antibiotic that might be used.

10 But when you strictly extract out, as you are
11 probably more likely to do, looking at the radiation risk
12 only, I think this helps to explain, at least to you, where
13 we are using this in a broader context than you might be
14 willing to do.

15 CHAIRMAN JACKSON: Okay. Commissioner.

16 COMMISSIONER McGAFFIGAN: I'll ask the question I
17 asked earlier. If a majority of the Commission decides that
18 it wants to retain patient notification, would it be more
19 honest to say, in 2, which is essentially the same -- or at
20 least start's the same as the staff -- or is the same, "will
21 not intrude" go to -- back to the "will minimize intrusion"?
22 I mean every letter that I have seen on patient notification
23 starts off by saying that this is an intrusion into medical
24 judgment.

25 DR. GRAHAM: If I could, I would like to

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1 specifically discuss patient notification as an example of
2 this.

3 COMMISSIONER McGAFFIGAN: We'll get to that.

4 DR. GRAHAM: It's about two paragraphs. I think
5 it will sharpen or focus the discussion. It would help me
6 in answering that question.

7 COMMISSIONER McGAFFIGAN: Okay.

8 DR. GRAHAM: So let me put it in that context.

9 COMMISSIONER McGAFFIGAN: We can come back --

10 DR. GRAHAM: And I will pursue it more
11 specifically after about a minute from now.

12 COMMISSIONER McGAFFIGAN: Okay. The second

13 question, my sense is that the whole medical policy
14 statement stuff, that we told the staff to go do Part 35,
15 and we said, as appropriate, you know, argue about this
16 stuff, because this isn't rules. This is a policy
17 statement. Policy statements don't amount to all that much,
18 to be honest with you, in regulatory space.

19 But I regard -- I look at this and I say, oh, my
20 gosh, this is Institute of Medicine and all that
21 regurgitated. We are back to arguing about whether there is
22 a function for the NRC in this area, and the purpose of your
23 policy statement, as opposed to the staff's policy
24 statement, is to constrain us down into the smallest box you
25 think we can tolerate for what the NRC role is. I mean is

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1 that an honest -- it that a factual assessment?

2 DR. STITT: Commissioner Jackson, I think that as
3 we have worked and worked this, we feel that the medical
4 policy statement is the centerpiece from which regulation
5 emanates. And I think that when you look at our
6 conversations and our minutes and compare them to the
7 proposal, they actually have many areas of inter-digitation
8 and are very close, and I don't feel that the sense of our
9 work has been a reflection of the Institute of Medicine
10 report. We took our direction from you, as well as from the
11 staff, after we had that Institute of Medicine discussion, I
12 believe two years ago. And I really believe that we are
13 looking at some fine points here, and probably different
14 interpretations based on whether you are coming from the
15 regulated community or the regulator community.

16 John, do you want to continue?

17 DR. GRAHAM: In the proposed rule revision of 10
18 CFR Part 35, Medical Use of Byproduct Material, which is
19 dated June 4th, 1998, the Commission directed the
20 restructuring of Part 35 into a risk-informed, more
21 performance-based regulation. The ACMUI recognizes the
22 challenge of defining comparable risk and we look forward to
23 working with the staff of the NRC to achieve the
24 Commissioners' goal of developing risk-informed, more
25 performance-based regulation.

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1 The regulation of patient notification following a
2 medical event, which is slide No. 7 in your packet,
3 represents a concrete example of regulation where there is
4 no clear data documenting risk which justifies such
5 regulation due to risk to the patient. Patient notification
6 is fundamental to the practice of the medicine and there is
7 widespread agreement regarding the need to notify the
8 patient and the patient's attending physician, but the
9 requirement by federal regulation to present the patient
10 with an official written notification which will be sent to
11 the Nuclear Regulatory Commission distorts these lines of
12 communication and can create unwarranted fear and concern on
13 the part of the patient.

14 The ACMUI has a fundamental concern that these
15 medical events, at the threshold defined in the regulation,
16 may not constitute a serious risk to the patient's health.
17 The ACMUI advocates continued discussion with NRC staff to
18 protect the patient's safety and promote the practice of
19 medicine.

20 CHAIRMAN JACKSON: Now, let me make sure, you said
21 something. Is the fundamental issue what the threshold is,
22 or having a requirement at all?

23 DR. GRAHAM: Speaking as one member of the
24 Advisory Committee on the Medical Use of Isotopes, I have

25 sat through hours and hours of meetings discussing how to

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1 define the threshold and how to balance out the public
2 safety, the safety of workers, the legitimate protection of
3 the safety of patients and yet retain the practice of
4 medicine. So, yes, I think it is an issue of the threshold.

5 CHAIRMAN JACKSON: So it is the issue of the
6 threshold.

7 Commissioner McGaffigan.

8 COMMISSIONER MCGAFFIGAN: There are a couple of
9 other issues. You mentioned sending the same notification
10 -- the current rule requires that we pretty much -- the
11 report you submit to us has to be potentially made available
12 to the patient, and, indeed, that probably is the practice
13 out there, you just give them the report you send to us.
14 The report you send to us is written in, presumably,
15 bureaucratic gobbledeygook that we are good at receiving, and
16 the patient may not be. So what if you distinguished the --
17 or you weren't required any longer to provide the report
18 that you give to us, but something that was more
19 patient-friendly in the way of describing what the impact of
20 this medical event might be on the patient? Would that
21 relieve some of the concern?

22 DR. STITT: John is looking at me. John is a
23 hospital administrator so he is not notifying patients.

24 There are some very specific time periods in the
25 rule as to who is notified when and some if it is

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1 notification. Other parts is sending a copy of the report
2 and I think that is one of the issues. It's one thing to
3 send a notice to an individual and it is another thing to
4 send a copy of a report that may engender a lot of anxiety
5 because they simply don't understand what is in it.

6 COMMISSIONER MCGAFFIGAN: Right.

7 COMMISSIONER DIAZ: I'm sorry -- no, go ahead.

8 COMMISSIONER MCGAFFIGAN: This issue of risk
9 levels, I mean I suspect the medical community is not wild
10 about this either, but there's currently passed by the
11 Senate and under consideration in the House a Mammography
12 Standards Act that will authorize the FDA to have patient
13 notification to individuals who receive bad mammograms, and
14 my recollection is mammogram -- you know, I'll refer it to
15 the doctors -- but if we are talking about thresholds, if
16 Congress were to pass that law, what is the judgment they
17 are making about rems to a woman which may have been
18 misapplied, that they now want the patient to be notified
19 on? Is it of comparable magnitude to the numbers that we
20 have in our rule, the 5 rem and 50 rem to an organ and all
21 that?

22 DR. STITT: No. The mammogram quality standards
23 refer to deficiencies in the mammography program so it is a
24 systematic program approach.

25 COMMISSIONER MCGAFFIGAN: You are talking about

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1 the laws that exist today but I am talking about the law
2 that the Senate has passed, the House is considering which
3 goes to individuals.

4 DR. STITT: Are you talking about a particular
5 dose from a mammogram or are you talking -- the mammogram
6 quality standards have several issues.

7 One is the quality of the program, the units that
8 are being used, and also reflect the potential for serious
9 harm from the mammograms.

10 The reporting that we have been talking about in
11 patient notification really is any particular patient, a
12 specific event involving that patient, and my understanding
13 of what we discuss in our Part 35 is quite different from
14 mammography standard requirements.

15 COMMISSIONER MCGAFFIGAN: As they exist today but
16 not as the Senate and the Congress may -- I think
17 Congresswoman Morella and various Senators, Snowe and
18 others, are advocating an amendment to that law that would
19 require something very similar to what we require today, so
20 my question was just laying that aside, if Congress were to
21 pass a law that requires patient notification for --
22 individual patient notification in the case of mammography,
23 would they be essentially endorsing a threshold similar to
24 the threshold that we have today in our rules, if you try to
25 convert it to personrem?

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1 DR. STITT: Mammography is diagnostic. It's a
2 screening. It's a diagnostic test. This is entirely
3 different from the therapeutic, so you are not measuring
4 doses. In a woman's having a mammogram there is no dose
5 that is being measured at that point in time so I think the
6 two are very difficult to compare.

7 Now there is a notification requirement in the
8 mammography standards and that is a notification as to the
9 report -- that is, the report that is generated from that
10 study, and that is one level of reporting and the other
11 level is the program and how that program is carried out in
12 an institution.

13 If there are programs that are poorly monitored
14 with poor equipment, screens, films, et cetera, my
15 understanding is that is where the reporting to the health
16 care provider or the referring physician and the patient
17 comes in.

18 CHAIRMAN JACKSON: Commissioner?

19 COMMISSIONER DIAZ: Yes. Let me go back to
20 something you say -- just trying to refocus on the risk and
21 if I might quote, it says, you know, the medical event might
22 not constitute a serious risk to the patient health, and
23 that may not constitute it becomes an issue.

24 How about if a physician determines that it does
25 constitute a serious risk to the patient health? What will

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1 be your recommendation regarding a patient notification?
2 Just assume you make the determination it is a serious risk.
3 Then what should be done regarding patient notification?

4 DR. STITT: It would be in keeping with what we
5 would do in that circumstance or any other. You talk to the
6 patient about what has transpired, be it a surgical event, a
7 medication event --

8 COMMISSIONER DIAZ: But I mean in relationship to
9 our obligations.

10 DR. STITT: I guess off the top of my head my
11 response would be this is something that needs give and take
12 with the NRC Commissioners and the Staff and the ACMUI.

13 If we are looking at specific thresholds, that
14 would open up an area of discussion for the future.

15 CHAIRMAN JACKSON: Would you go on?

16 DR. STITT: We are going to look at a viewgraph
17 entitled Radiation Protection Program. This brings up some
18 issues that have already been discussed.

19 The entire section has become less prescriptive
20 and the ACMUI concurs with the proposed rule. In
21 particular, we agree that the elimination of the

22 prescriptive requirement for Radiation Safety Committee is
23 one that can be workable throughout the programs in the
24 country.

25 The proposed regulation permits the licensee to be

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1 flexible and to maintain a Radiation Safety Committee
2 consistent with the scope of their operations or to unfold
3 that within the other requirements for the hospital
4 operation.

5 CHAIRMAN JACKSON: Go on.

6 DR. STITT: Viewgraph on Written Directives.
7 Dennis Swanson.

8 MR. SWANSON: Written Directives in COMSECY
9 96-057, the Commission directed NRC Staff to re-evaluate and
10 revise the Quality Management Program requirements to focus
11 on those requirements that are essential for patient safety.
12 For example, requiring written directives confirming patient
13 identity and verifying the correct dose.

14 The proposed rule addresses these concerns of the
15 Commission, minimizes prescriptive requirements, provides
16 for a performance-based approach to the Quality Management
17 Program, and ensures patient safety. Thus, the ACMUI
18 concurs with the proposed ruling which I think it's probably
19 to emphasize however that when you go to a performance-based
20 rule where you are going to have individual institutions
21 developing their own procedures, that is going to definitely
22 a change in how your inspection people take a review of that
23 program.

24 Your inspections can't be as prescriptive either.
25 Your inspectors are not going to have prescriptive guidance,

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1 prescriptive NRC approved procedures by which to evaluate
2 those programs so it's going to require certain changes in
3 how the inspections work. That's important to point out.

4 CHAIRMAN JACKSON: Yes.

5 COMMISSIONER MCGAFFIGAN: How do you violate this
6 rule? Given how it is written, the Chairman asked earlier,
7 is it enforceable, of the Staff, but it is how hard you have
8 to work to violate the rule as it is drafted at the moment.

9 MR. SWANSON: Well, it is a performance-based rule
10 so obviously if you have problems with misadministrations or
11 medical events -- then those problems can derive from
12 different mechanisms.

13 Number one, you may not as an institution have the
14 appropriate set of procedures in place to appropriately
15 provide those protections, okay, so that could be a
16 violation in itself, that you do not have the appropriate
17 procedures in place to address verification of identity,
18 verification of the proper dose, et cetera.

19 Then a second way that medical events could occur
20 is you could have the appropriate procedures in place and
21 the individuals aren't properly following those procedures.
22 In that case, then you have violated the training
23 requirements for the people working at institutions with
24 regard to them following the appropriate procedures and what
25 those procedures are.

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1 CHAIRMAN JACKSON: Go ahead.

2 DR. STITT: Written Directors and Procedures --
3 Dennis?

4 MR. SWANSON: I think we just did that.

5 DR. STITT: I'm sorry, Reportable --

6 MR. SWANSON: Unless you would like me to repeat

7 it?

8 [Laughter.]

9 DR. STITT: I think we got it the first time.
10 Reportable Events.

11 MR. SWANSON: With regard to medical events, the
12 ACMUI concurs in general with the proposed rule as it
13 relates to the definition of medical events and the
14 reporting of medical events to the NRC.

15 It is recognized that medical events associated
16 with patient interventions or exposure of the wrong
17 treatment site are difficult issues to define.

18 The ACMUI has noted that the background section to
19 the proposed rule addresses specifically these gray areas
20 and requests respective public comment. The ACMUI will
21 continue to address these two problem areas in particular.

22 With regard to the proposed regulations addressing
23 the unattended dose to the embryo fetus and nursing child,
24 the ACMUI recognizes the Congressional mandate for the NRC
25 to capture and report abnormal occurrences and that the NRC

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1 has defined the unintentional radiation exposure of an
2 embryo fetus or nursing child to be an abnormal occurrence.

3 The proposed rule appropriate relies on industry
4 standards for the prevention of such exposures. ACMUI
5 recommends a final regulation that avoids a real or de facto
6 requirement for the mandated pregnancy testing of women of
7 childbearing potential.

8 And with regard to precursor events, ACMUI does
9 not feel that it is necessary to have a Part 35 rule
10 addressing the reporting of precursor events, that the
11 reporting of precursor events as defined in the proposed
12 rule is adequately addressed through existing NRC and FDA
13 regulations and voluntary reporting programs.

14 However, should the reporting of precursor events
15 be retained within the Part 35 rule it's imperative that the
16 responsibility of determining what needs to be reported be
17 defined. In other words, the clause "in the opinion of the
18 Radiation Safety Officer" or "authorized user" or a clause
19 which states "in the opinion of the licensee" must be
20 retained in order to prevent second-guessing on the part of
21 NRC inspectors.

22 DR. STITT: Training and experience will be
23 discussed by Dr. Alazarki.

24 COMMISSIONER MCGAFFIGAN: Could I just stop on
25 that one for a second. That is in there at the moment, this

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1 "in the opinion of the Radiation Safety Officer" or
2 "authorized user" -- the precursor events, if they are
3 precursors of the sort that were discussed earlier, is the
4 one day no later than the next calendar day overly
5 burdensome? These are things that were -- that when we get
6 them we are going to do things like put out an information
7 notice or watch, just monitor the process as the
8 manufacturer modifies the device or whatever, but it is not
9 of the urgency that perhaps would require a one-day notice.

10 Is that something you all talked about, the one
11 day in the precursor?

12 MR. SWANSON: No, I don't think we have
13 specifically discussed that specific reporting requirement.
14 My personal opinion on that is if you are going to leave it
15 in the opinion of the Radiation Safety Officer or the
16 opinion of the licensee is it one day from their
17 determination that it is a precursor event? In that case,
18 it is probably not a major burden.

19 If it was within one day of when the event
20 occurred, that would be a burden because it does take some
21 time to evaluate that event.

22 DR. STITT: Go ahead, Dr. Alazarki.

23 DR. ALAZARKI: In formulating ACMUI's
24 recommendations for training and experience requirements and
25 in keeping with Chairman Jackson's opening remarks, ACMUI

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1 did attempt to heed stakeholder input but this has not been
2 easy and in fact it's quite problematic because there are so
3 many diverse views among the stakeholders.

4 Nonetheless, for 35.100 and .200 recognizing low
5 risk of diagnostic procedures, ACMUI supports the proposed
6 significant decreases in training and experience
7 requirements to reflect only competence in radiation safety.
8 ACMUI chose not to define criteria to determine clinical
9 competence, which is in contrast to ACMUI's recommendation
10 about 35.400 and .600 where high risk of the procedures
11 mandated linkage to clinical competence.

12 ACMUI did strongly recommend that the decreased
13 training and experience requirements for 35.100 and .200 be
14 conditioned on physician candidates passing an
15 NRC-administered examination designed to assure competence
16 in radiation sciences and practices.

17 Further, central to its recommendation is that the
18 currently recognized appropriate certifying bodies for
19 radiation medical practice competence continue to be relied
20 upon for assurance of clinical competence of individual
21 physicians. We recommend a clear statement as part of the
22 regulatory language from NRC that licensure does not
23 constitute credentialing for radiation medical practice.

24 ACMUI was split in its voting on the
25 recommendation of training and experience for 35.300 --

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1 35.300 provides training and experience requirements for
2 unsealed source radiation therapies, often using very high
3 doses of Iodine-131, which are certainly high risk
4 procedures to patients and personnel and require special
5 consideration for protecting the general public.

6 As such, there is a definite similarity to 35.400
7 and .600 which ACMUI agreed required linkage to clinical
8 competence upholding the current 500 plus 200 hours, as part
9 of a three year ACGME approved residency program in
10 Radiation Oncology as training and experience requirements.

11 Part of the committee would have favored
12 comparable requirements for unsealed source byproduct
13 radionuclide therapy procedures. As written however, the
14 proposal is not to distinguish between the high dose usage
15 and low dose, low risk diagnostic training and experience
16 requirements.

17 We anticipate that there will be an abundance of
18 spirited comments, hopefully, polite, in response to the
19 Federal Register request for comments. The ACMUI advocates
20 continued involvement with staff in reviewing these comments
21 and formulating modifications, as deemed warranted.

22 As we understand it, the comment period planned is
23 75 days, starting in July, but because of the importance of
24 these issues to so many diverse groups of practitioners and
25 institutions, we urge the comment period to be extended

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1 beyond the summer, when so many people are away on vacation,
2 for 120 days. Thank you.

3 CHAIRMAN JACKSON: Okay.

4 DR. STITT: Shall we go ahead?
5 CHAIRMAN JACKSON: Any further questions?
6 COMMISSIONER MCGAFFIGAN: Well, why don't I try
7 the questions I asked earlier. The endocrinologists, and
8 you just discussed it some degree, but they basically take
9 the point of view that their 80 hours which are in the rules
10 at the moment are adequate and there isn't a risk basis for
11 extending the 80 to 120 and making the other conforming
12 changes, and they are arguing that the staff took a cookie
13 cutter approach to that area.

14 What is your opinion on that?

15 DR. ALAZARKI: Let me first call attention to a
16 few other things and then bring it together on the
17 endocrinologists. There are about, probably in the
18 neighborhood of 15,000 board certified radiologists who use
19 radiation material, radioactive byproduct material in their
20 practices. There are about -- the Society of Nuclear
21 Medicine and the American College of Nuclear Physicians
22 jointly have a membership of about 12- to 14,000, but, of
23 those, probably about 4,000 actively practicing physicians
24 use these materials.

25 As I understand the numbers, there are about 300

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1 NRC licensed endocrinologists using these materials, and
2 --out of about 7,000. So less than half a percent of all of
3 endocrinology, but a very small number compared to the other
4 users. And, further, I believe that most of the
5 endocrinologists who are using radioactive materials are
6 using it to treat hyperthyroidism, not thyroid cancers,
7 although there may be some.

8 The high risk in radionuclide therapy with I-131
9 is the cancer therapies, not the hyperthyroidism. So there
10 may be some compromise that might be -- that might work very
11 well for all concerned in terms of taking out the
12 hyperthyroids and putting them perhaps closer to the
13 diagnostic groups, which would not alter their requirements
14 significantly, I don't think.

15 CHAIRMAN JACKSON: But it would introduce the need
16 to have a restriction.

17 DR. ALAZARKI: Yes. It would change the way in
18 which --

19 CHAIRMAN JACKSON: Right.

20 DR. ALAZARKI: Right. It would.

21 CHAIRMAN JACKSON: And so it would create a
22 bimodal distribution --

23 DR. ALAZARKI: Alternatively --

24 CHAIRMAN JACKSON: -- of endocrinology.

25 DR. ALAZARKI: Alternatively, they are such a

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1 small number participating that, you know, if you don't want
2 to start making exceptions like that, which I think is
3 totally understandable, then that is it, these are the
4 requirements.

5 COMMISSIONER MCGAFFIGAN: But for the physician
6 who is just treating hyperthyroidism, it is an increase and
7 it is an additional entry barrier for somebody who is --

8 DR. ALAZARKI: Only 300 though out of multiple
9 thousands who we are talking about.

10 CHAIRMAN JACKSON: Are there endocrinologists that
11 do both treatments, for hyperthyroidism --

12 DR. ALAZARKI: There may be. Very, very few.

13 CHAIRMAN JACKSON: Very few.

14 DR. ALAZARKI: Very, very few.

15 CHAIRMAN JACKSON: Okay.

16 COMMISSIONER MCGAFFIGAN: Then the brachytherapy
17 -- not the brachytherapy. The Strontium-90 applicators, you
18 would agree that the increase there is warranted given the
19 history --
20 DR. ALAZARKI: Absolutely.
21 COMMISSIONER MCGAFFIGAN: -- that we have had with
22 that?
23 DR. ALAZARKI: Right.
24 COMMISSIONER MCGAFFIGAN: Okay.
25 DR. ALAZARKI: Right.

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1 CHAIRMAN JACKSON: Commissioner? You wanted to
2 make a comment, Mr. Swanson?
3 MR. SWANSON: Yes. With regard to that, from my
4 perspective, probably why the ACMUI was split on the vote on
5 Part 300 deals with, if you are truly taking a risk-informed
6 approach to these regulations, and if you look at the risk
7 of brachytherapy, for example, versus the risk of giving
8 four millicuries or 100 millicuries of I-131, it is hard to
9 argue that, you know, the internal administration of a
10 radioactive drug, I-131, is just as risky, if not more risky
11 than brachytherapy. So how can you justify having 700 hours
12 and three years of training here and 80 hours over here?
13 Okay.
14 So one of the problems with the training and
15 experience requirements, as I see it, is we are going to
16 have to look at uniformity across these sets of
17 requirements. And that's, in fact, what I think led to some
18 of the split vote in looking at the Part 300.
19 Let me also remind you that 40 hours is only week
20 of training, okay. It's not like we are talking a lifetime
21 on behalf of the endocrinologist.
22 CHAIRMAN JACKSON: Thank you. Well, I would like
23 to thank each member of the staff and each of the members of
24 the Advisory Committee on Medical Uses of Isotopes for
25 today's briefing.

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1 COMMISSIONER MCGAFFIGAN: Did they get finished?
2 CHAIRMAN JACKSON: Were you done?
3 COMMISSIONER MCGAFFIGAN: There is one more
4 viewgraph.
5 CHAIRMAN JACKSON: I'm sorry.
6 DR. STITT: One more viewgraph. There is one
7 viewgraph. We had very little to say. I would be glad to
8 -- I'll let you continue.
9 COMMISSIONER MCGAFFIGAN: Well, that's an
10 interesting viewgraph because the word "enforcement" --
11 CHAIRMAN JACKSON: Why don't we talk about that
12 viewgraph.
13 COMMISSIONER MCGAFFIGAN: So I don't want to let
14 them off the hook that easily.
15 CHAIRMAN JACKSON: Thank you.
16 DR. STITT: No, we would like to -- in fact, I was
17 pushed to leave this in. We were thinking about putting
18 this one aside. The ACMUI recognizes the performance-based
19 approach taken by the NRC staff in the development of
20 guidance documents and license submission requirements. The
21 ACMUI looks forward to continuing our work with the NRC
22 staff in these areas. That's pretty simple.
23 COMMISSIONER MCGAFFIGAN: That covers this last
24 viewgraph?
25 DR. STITT: That covers that slide.

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1 COMMISSIONER MCGAFFIGAN: Sorry.
2 COMMISSIONER DIAZ: The last bullet on that --
3 [Laughter.]
4 DR. STITT: No, it's easy to address, because as
5 we were having our pre-sessions, we didn't get into that, so
6 there is -- that is a non-entity right now.
7 CHAIRMAN JACKSON: So you put it on the slide for
8 purposes of stimulation.
9 Well, the Commission, as always, will give serious
10 consideration to the views expressed today as it reviews the
11 staff's proposal for the revision of 10 CFR Part 35, the
12 Medical Policy Statement.
13 It is clear that in many areas the staff and the
14 Advisory Committee are in agreement as to the revisions that
15 are necessary, but as in many things, the areas of
16 disagreement will obviously require more attention by the
17 Commission in its review of the two papers.
18 So let me thank again the staff and the Committee,
19 and I would not that the Commission recognizes that the
20 staff's development of the draft proposed rule, the
21 associated draft guidance and the recommendations for
22 revision of the medical policy statement in the time period
23 provided was no small feat. However, it is now the
24 performance standard.
25 [Laughter.]

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1 CHAIRMAN JACKSON: Therefore, I would like to
2 thank the staff for their diligence over the last year on
3 this expedited rulemaking and let those in the reactor world
4 understand the standard.
5 And if there is nothing more, we are adjourned.
6 [Whereupon, at 3:32 p.m., the meeting was
7 concluded.]
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