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1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION

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4 MEETING

5 ADVISORY COMMITTEE FOR THE MEDICAL USES OF ISOTOPES
6 (ACMUI)

7 + + + + +

8 FRIDAY,

9 NOVEMBER 18, 1994

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11 ROCKVILLE, MARYLAND

12 + + + + +

13 The Advisory Committee met at the Nuclear
14 Regulatory Commission, Two White Flint North, Room T2B3,
15 11545 Rockville Pike at 8:00 a.m., Dr. Barry A. Siegel,
16 Chairman, presiding.

17
18 COMMITTEE MEMBERS:

19 DR. BARRY A. SIEGEL	Chairman
20 JUDITH I. BROWN	Member
21 DR. DANIEL F. FLYNN	Member
22 DR. WIL B. NELP	Member

23
24
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1 ACMUI STAFF PRESENT:

2 Robert M. Quillin

3 Dr. Judith Anne Stitt

4 Dennis P. Swanson

5 Dr. Louis Wagner

6 Dr. David Woodbury

7

8 ALSO PRESENT:

9 Bob Ayers

10 E. William Brach

11 Larry Camper

12 Kitty Dragonette

13 Dr. John E. Glenn

14 Cathy Haney

15 Dr. Patricia Holahan

16 Florence Kaltovich

17 Stephen A. McGuire

18 Sally Merchant

19 Dr. Bill Morris

20 Dr. Carl Paperiello

21 Dr. Myron Pollyco :

22 Robert J. Prato

23 Dr. Pat Rathbun

24 Janet Schlueter

25 Stewart Schneider

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1 ALSO PRESENT (Continued):

2 Katherine Seifert

3 Torre Taylor

4 John Telford

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P R O C E E D I N G S

(8:01 a.m.)

CHAIRMAN SIEGEL: Why don't we get this show on the road? Judy Brown and John Graham are still not here yet, but from the interest of, as John says, beating the hurricane so we all get out of here today and having once gotten trapped by a northeaster for too long extra days on the East Coast, I'd just as soon get out of here today. I think we should begin the day's business.

We're going to take a brief, very brief, probably 10 minutes at most, diversion from the agenda to revisit the issue on brachytherapy that we talked about last night to talk a little bit about the definition of the treatment site.

We had some materials that we passed out last night from ICRU, document that Larry gave us. But, in addition, Trish has a suggestion, -- right? -- which she's going to share with us.

DR. HOLAHAN: I took this out of the document that you were all handed yesterday on the definition of irradiated volume. And we sort of hashed over yesterday what's wrong treatment site and what is right treatment site.

I guess the question that we're posing to the ACMUI is the irradiated volume here -- and they define it

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1 as "the volume that exceeds an absorbed dose, which is
2 significant in relation to tissue tolerance," and they have
3 used as an example 50 percent isodose line, but I don't
4 think that's hard and fast. They said as an example in the
5 document you've received of the specified target absorbed
6 dose.

7 Could the wrong treatment site be considered
8 what was outside the irradiated volume so that you could
9 still have a misadministration? If it was within the
10 irradiated volume, it would only be a misadministration if
11 it exceeded the threshold specified in the
12 misadministration requirements for that point?

13 So if it's at the 50 percent isodose, it would
14 have to exceed 20 percent greater than the 50 percent
15 isodose line. And if that is a reasonable approach for the
16 irradiated volume, would you have any recommendations as to
17 what this percentage line should be?

18 CHAIRMAN SIEGEL: I'll defer to --

19 MEMBER FLYNN: One problem is that --

20 CHAIRMAN SIEGEL: -- Dan and Judy.

21 MEMBER FLYNN: -- when I was in a working group
22 when we were working on the quality management program as
23 advisers to the NRC, there were several radiation
24 oncologists and about four radiotherapy physicists. This
25 is just for radiation oncology.

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1 The problem that came up is that we felt that
2 as some centers may define their dose to a point, some
3 centers may define their dose to a treatment volume and
4 some centers may still use milligram hours, that we didn't
5 want to force them into a situation to do something that
6 they're not currently doing in clinical practice.

7 DR. HOLAHAN: So if they prescribed in
8 milligram hours, they would not have a treatment plan
9 identifying the isodose?

10 MEMBER FLYNN: And after several days of
11 arguing and debate, we couldn't come to a single
12 definition. And so what happened in those days was that we
13 suggested to the NRC and the NRC accepted that the dose as
14 far as brachytherapy is concerned could be defined as
15 source, strength, and time, which is milligram hours, or
16 dose, absorbed dose, to a target absorbed dose without
17 specifying where the dose was defined to.

18 Wherever the licensee does define the dose to
19 as part of their practice in treating the patients, because
20 of the wide discrepancy of how radiotherapy licensees
21 prescribe their doses in brachytherapy, low-dose
22 brachytherapy, it was decided to keep it as less of a
23 prescriptive type of a definition because then you would
24 end up forcing licensees to change their practice and the
25 way they are defining their dose because they're following

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1 patients along, whether we agree with how they do it or
2 not, to see what kinds of complications they might get as
3 part of routine radiotherapy and what kind of local control
4 of disease they get. And they're monitoring that based on
5 the way they always have been prescribing "the dose."

6 But maybe since Dr. Stitt is on the ASTRO
7 Physics committee, maybe this is something that they will
8 have to re-debate and reargue. I don't think you can come
9 up with a simple solution.

10 DR. STITT: I'm guessing. Is this right,
11 Trish, that the irradiated volume would be something that
12 NRC would be particularly interested in for the
13 interstitial sorts of things where you've got radium seeds
14 because that's about the only occasion when radiation
15 oncologists use that terminology?

16 DR. HOLAHAN: You mean irradiated volume?

17 DR. STITT: Yes. Dan's right. If you're
18 talking about -- essentially all of the gyn implants are
19 either milligram hours -- I'm on the newest Cervix Patterns
20 of Care that's just getting geared up. And we're geared up
21 to the point where we're just now looking at how we're
22 going to collect data and in what forms.

23 You can't use milligram hours for high-dose
24 rate because it simply is not done that way. But it is
25 most commonly done as a dose to a point. Again, you can

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1 use all of that for misadministration percentages. This
2 could be useable for the circumstances when you're talking
3 about volume implants because, obviously, it is talking
4 about a volume. So for volume implants, which is basically
5 all of the interstitial work, in some places you're using
6 several points as a descriptor or an isodose line that
7 encompasses a certain volume.

8 I think this is something that maybe at this
9 point ought to be put out on the table. Let folks think
10 about it. Take it to the brachytherapy group specifically
11 because they do a lot of interstitial work, the members of
12 the ABS. And see if this maybe needs to be made a part of
13 how we're defining things.

14 DR. HOLAHAN: All right. So you're saying for
15 the intracavitary, it would not necessarily apply because
16 it would not have the --

17 DR. STITT: That is right. That would not work
18 for intracavitary because almost all of that is to a point.
19 Now, the volume is really what you're interested in, but we
20 sort of interpolate by prescribing to a variety of points.

21 CHAIRMAN SIEGEL: Don't you have isodose data,
22 though, --

23 DR. STITT: Yes.

24 CHAIRMAN SIEGEL: -- from your treatment plan,
25 --

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1 DR. STITT: Yes.

2 CHAIRMAN SIEGEL: -- even if you prescribe it
3 that way?

4 DR. HOLAHAN: So you have the isodose.

5 DR. STITT: But what we certainly don't want to
6 do is start getting people in a double bind. I mean, if
7 you want to give 3,000 centigray at Point A and your volume
8 distribution will have -- actually, it will be based on
9 where you prescribe some points.

10 And then your volume, your isodoses sort of lay
11 around that, but there could be some circumstances wherein
12 you're going to actually get yourself backed into a corner
13 by trying to use both. So it is possible.

14 CHAIRMAN SIEGEL: That's why in a way I'm
15 actually kind of attracted to this very preliminary
16 proposal that the physicists have already come up with,
17 which is kind of ignoring, not defining a treatment site,
18 but worrying more about when one should be reporting and
19 fretting about when something else got treated that you
20 didn't expect to get treated.

21 And by tieing it to some percentage above or
22 below the expected dose if the treatment had gone as
23 planned and also adding a threshold so that you don't
24 report trivial doses, you kind of get around the problem.
25 Then you're not forced to defining what is the treatment

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1 site, which is kind of a difficult problem, as we've
2 already figured out.

3 And you still capture the data that is of
4 importance to you in terms of finding out whether a
5 systematic problem is going on, and you still protect
6 people who might be having misapplications of the
7 technology.

8 MEMBER FLYNN: Several years ago ICRU came out
9 with a report, Number 38, written by clinicians and
10 physicists, primarily physicists, in an effort to define
11 for low-dose rate implants, instead of getting away from
12 paracentral dose that the Patterns of Care study uses or
13 Point A, a treatment volume.

14 Unfortunately, most people have chosen not to
15 adopt ICRU Report Number 38. And so it becomes a problem
16 if you become too prescriptive. I don't know a way around
17 it myself.

18 DR. STITT: Yes. ICRU 38 is really used in
19 Europe and essentially not at all in this country, just
20 never caught on.

21 CHAIRMAN SIEGEL: It seems to me that this is a
22 sufficiently complex topic that this is the kind of things
23 that a variety of workshops are going to be very useful to
24 help you focus what the community is doing and what the
25 community can live with that makes sense from the point of

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1 view of the way they actually practice.

2 I mean, we've seen in the past that workshops
3 are pretty effective at getting some of these rules in
4 their formulative stages. And I think I would encourage
5 you to do that and also to pick the therapy physicists for
6 this committee quickly so that that person can participate
7 in that activity from the beginning.

8 DR. HOLAHAN: This is, yes, one of the things
9 we're going out with the workshops to try and start
10 flushing out.

11 CHAIRMAN SIEGEL: Right.

12 DR. HOLAHAN: Okay.

13 CHAIRMAN SIEGEL: Good. Thanks.

14 DR. HOLAHAN: Thank you.

15 RELEASE OF PATIENTS CONTAINING RADIOPHARMACEUTICALS
16 OR PERMANENT IMPLANTS, 35.75

17 CHAIRMAN SIEGEL: All right. Let us move on,
18 then, to the real agenda, to "Release of Patients
19 Containing Radiopharmaceuticals or Permanent Implants,
20 35.75."

21 Kitty Dragonette is going to tell us where this
22 activity stands. And, Kitty, before you do, let me give a
23 little bit of background information. As you all know,
24 this is something we've discussed at at least one and,
25 actually, probably a couple previous meetings.

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1 There's obviously a proposed rule on the
2 street. And at the October 20th Commission briefing, on
3 that day following that meeting, three members of this
4 Committee, myself Bob Quillin and Lou Wagner, sat down with
5 some folks from the medical program and some folks from
6 research just to talk about the response letters, to talk
7 about what problems the NRC saw given the response letters
8 that had come from members of the public, and to put forth
9 some potential ideas for solution.

10 We did not attempt to reach any sort of
11 consensus for the Committee because we were not an
12 officially convened portion of the ACMUI or even a
13 subcommittee. It was just a working discussion. But we
14 did come up with some ideas.

15 I'd like to just tell the Committee very
16 briefly the kinds of ideas that we came forth with. And
17 then we can see how Kitty and the other folks in research
18 have reacted to those ideas.

19 One is that the argument for moving from the
20 100-millirem Part 20 limit to the 500-millirem exemption,
21 if you will, was one that needed to be made primarily on a
22 cost/benefit basis.

23 Two was that the activities that were going to
24 be tied to this whole issue should be activities that are
25 currently tied to a written directive and that this concept

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1 should remain largely silent with respect to those
2 activities that don't currently require a written directive
3 so that you wouldn't want to get into this patient release
4 criteria discussion with respect to diagnostic imaging
5 doses used in nuclear medicine.

6 And the particular problem for that relates to
7 the fact that breast-feeding had the potential to be
8 brought in under the umbrella of this overall patient
9 release criteria, viewing the infant, then, as a member of
10 the general public.

11 And it then became potentially very complicated
12 and potentially could involve a substantial amount of
13 resources to cause licensees to really have to do a lot of
14 recordkeeping, investigation, documentation that all women
15 of the right age group who are coming in for nuclear
16 medicine examinations could prove that they weren't
17 breast-feeding and have to have some record for that.

18 So what we were sort of thinking is that it
19 might be better to tie the breast-feeding part of this to
20 an entirely separate rule related to breast-feeding in
21 pregnancy, which we know is something that has been talked
22 about for some time here.

23 I think those were the principal issues that we
24 talked about.

25 MEMBER BROWN: So to remain silent on

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1 breast-feeding is to avoid the necessity for recordkeeping
2 for the doctors?

3 CHAIRMAN SIEGEL: Let's go through it, Judy.
4 It's not to avoid the necessity for recordkeeping so much
5 as it is to avoid the potential to completely disrupt the
6 practice, the day to day practice, of nuclear medicine
7 because of the need that you --

8 MEMBER BROWN: Completely disrupt the day to
9 day practice of nuclear medicine?

10 CHAIRMAN SIEGEL: Yes, yes.

11 MEMBER BROWN: You don't think that's a bit of
12 an overstatement?

13 CHAIRMAN SIEGEL: I actually don't. Let's work
14 through this, and we'll see. So, Kitty, go ahead. Maybe a
15 little bit.

16 (Slide)

17 MS. DRAGONETTE: Well, you already know what
18 this agenda topic is.

19 (Slide)

20 MS. DRAGONETTE: I'm here on behalf of Don
21 Cool, who is still out recovering from a pretty nasty
22 infection, sinus infection. Stewart Schneider, who is the
23 technical lead, is in the room and is going to help bail me
24 out when I need it. And so is Stephen McGuire, who talked
25 to you yesterday about wrong patient.

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(Slide)

MS. DRAGONETTE: Well, as Dr. Siegel mentioned, there's a proposed rule out on the street. It was published in June. Comment period expired August 29th, although some comments on some of the related documents are still coming in. The draft regulatory guide was published essentially in parallel, as was the regulatory analysis.

In response to that notice, we've gotten 56 comment letters, over 80 percent from the medical community, 4 from states and 4 from others; on the draft regulatory guide, 6 comment letters, although things get combined and whatever; and then one comment letter addressing specifically the regulatory analysis.

(Slide)

MS. DRAGONETTE: As Dr. Siegel mentioned, you considered this matter before, but there are some new members on the Committee. So just to recalibrate us and make sure we all remember what the proposed rule provisions were, I was just going to review them very quickly.

The proposed rule would modify Part 20 to explicitly exclude the dose contributions from patients released in accordance with the proposed provisions of Part 35, the annual dose limit of 500 millirem. It was proposing to change the Part 35 criteria from the dose rate and 30-millicurie activity numbers to the 500-millirem a

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1 year annual dose limit.

2 (Slide)

3 MS. DRAGONETTE: It also had some accompanying
4 implementation features that when the dose to the person
5 most likely to receive the highest exposure exceeded 100
6 millirem, the licensee was to provide written instructions
7 and to keep a record.

8 (Slide)

9 MS. DRAGONETTE: The major issues raised by the
10 commenters and that have come out of discussions among the
11 NRC staff and with some of you individually are basically
12 in three areas: the recordkeeping burden and requirement
13 at the 100-millirem threshold providing written
14 instructions being prescriptive that they must be written,
15 as opposed to just provide instructions; and then the
16 breast-feeding child issue.

17 (Slide)

18 MS. DRAGONETTE: The strongest opposition to
19 the provisions of the rule had to do with the recordkeeping
20 burden at the 100-millirem threshold.

21 (Slide)

22 MS. DRAGONETTE: I just want to make sure I
23 highlighted the things I had planned to highlight ahead of
24 time.

25 The commenters argued that it would involve a

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1 lot of time, effort, and dollars to keep those records for
2 every patient where your estimated dose is greater than
3 100. And, consequently, the commenters felt that we
4 underestimated the burden.

5 Now, what are some of the options that we're
6 considering to try to address this problem? Two basic
7 options. The first one, probably the leading one, but
8 still both under discussion, is to just eliminate the
9 requirement for recordkeeping and leave it up to each
10 individual licensee what sort of documentation they might
11 want to kept to show an inspector that they were abiding by
12 the rule, but provide guidance in the regulatory guide that
13 would say "Here's at least one acceptable way" or "Here are
14 some ideas that you might want to use" and in the guidance
15 cover the potential for multiple exposures within the year.

16 Part of what was driving the recordkeeping
17 threshold at 100 was so that there was a record so you
18 could go back and look if the patient had gotten an iodine
19 administration 3 months earlier, you could take both of
20 those into account to determine that you had met the annual
21 dose limit. We were worried about the per administration.

22 So if you eliminate all the recordkeeping, then
23 you would in the regulatory guidance say it's a
24 performance-based rule. So you have flexibility on how you
25 meet it, but you should still address the fact that it's an

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1 annual dose limit, provide the guidance.

2 There is concern among the staff about if you
3 do case by case calculations. In the regulatory guide that
4 was published for comment, it had three basic components.
5 It had a table of by radiopharmaceutical, of the activities
6 and dose rates at the 100 and the 500 levels. It was a
7 cookbook way of complying with the rule that if your
8 patient had this much activity or this was the dose rate,
9 you met the 100 or you met the 500.

10 So it gave you that cookbook way of complying.
11 It also gave guidance on the instructions to give to the
12 patients. And it had a third provision, which was to do
13 case by case calculations if you felt that you had an
14 unusual circumstance where you could justify release at
15 levels higher than those table values.

16 And there is still concern among the staff
17 about the more or less unbounded provision of that and some
18 concern that perhaps records on what assumptions you used
19 to justify those releases at levels higher than in a table
20 should be kept. So that's still under discussion.

21 Does the Committee have thoughts on that,
22 whether just the case by case calculations? If you had to
23 keep a record on that but not any of the others, would that
24 be a significant burden?

25 DR. GLENN: I'd like to just make one comment

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1 so that the Committee is aware. Barry referred to the fact
2 that if you think of this in terms of the context of the
3 written directive, that there is, in fact, already a
4 recordkeeping requirement for the written directive for the
5 procedures most likely to result in the larger exposures.
6 So it's not that there would be no recordkeeping at all
7 under that first open.

8 MS. DRAGONETTE: If you put a requirement in,
9 then you would have to put something, --

10 DR. GLENN: Right.

11 MS. DRAGONETTE: -- some kind of annotation, in
12 that written directive. But yes, it wouldn't be a new
13 record other than it's a new entry on it or something.

14 DR. GLENN: But for the most significant
15 administrations, there would be a record of the
16 administration, not of the dose evaluation. So it could be
17 done retrospectively.

18 DR. WAGNER: What you're talking about, are you
19 talking about only for procedures that require written
20 directive or are you still talking about all procedures?

21 MS. DRAGONETTE: That would be any procedure
22 where you exceeded the cookbook table values where we have
23 calculated the activity or dose rate. So if the table
24 entry for iodine for the 500 was 33 millicuries, I think,
25 if you wanted to release for the 100 millicuries, then you

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1 would need to do a case by case analysis or have something
2 that has different assumptions than we had in the simple
3 version that we used to put the table together to justify
4 that hundred and show that it's still likely that the doses
5 from the patient would still not exceed 500 millirem.

6 DR. WAGNER: I guess one of my major concerns
7 is that issue about guidance to cover issues such as
8 potential for multiple administrations. Would we still be
9 able to use a table for any patient who had multiple
10 diagnostic administrations during a year or would we have
11 to consider the fact that a diagnostic patient might have
12 multiple administrations which would occur at different
13 hospitals?

14 MS. DRAGONETTE: In the diagnostic arena,
15 you're probably not going to get into trouble with many of
16 the procedures other than -- and we'll get to the
17 breast-feeding infant in a little bit and some of the whole
18 body iodine scans. Multiple diagnostics, the diagnostics
19 were pretty much below the 100 millirem. And it's unlikely
20 that you exceed the five.

21 The major concern in the multiple would be the
22 therapies. And there again you would have a written
23 directive. And hopefully if you are prescribing therapy
24 again or these major scans, you would want to know that
25 information about your patient.

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1 And if you had the flexibility to how you found
2 out whether you asked the patient or the referring
3 physician, if you had complete flexibility on how you
4 considered that, used whatever was annotated on the written
5 directive, that --

6 CHAIRMAN SIEGEL: I guess in a way the real
7 question, though -- maybe I'm not focused yet this morning.
8 The real question is whether you need anything at all in
9 the gap between 100 millirems and 500 millirems.

10 That really becomes the fundamental question or
11 whether one is willing to accept that for the unique
12 circumstances of medical administrations, that exposures
13 which for the most part or for nearly the entire part will
14 be to the selected population that comprises members of the
15 family which some professional groups have considered to be
16 a special irradiated population that's distinct from the
17 general public and distinct from occupational workers, that
18 there needs to be any recordkeeping whatsoever related to
19 that 400-millirem gap or whether it suffices to say "Let's
20 divide tables that say 'If you're in this range, you're out
21 the door. If you're going to go above this range, then you
22 need to develop special information to show what
23 assumptions you're using to prove that exposures will be
24 below that 500-millirem unit, what special instructions
25 you've taken to keep exposures below that limit.'"

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1 That I think really is the key question. And
2 eliminating that record keeping between 100 and 500 millirem
3 gets rid of the vast majority of the problem.

4 MEMBER BROWN: I need a little background. Who
5 in their wisdom decided that 100 millirem was the threshold
6 anyway? I mean, is it just an historical thing that you
7 all live with?

8 CHAIRMAN SIEGEL: That's the limit in Part 20
9 --

10 MEMBER BROWN: Right.

11 CHAIRMAN SIEGEL: -- for exposure to the
12 general public.

13 MEMBER BROWN: And has that all been considered
14 ridiculous by the profession that that's just too low? And
15 why?

16 CHAIRMAN SIEGEL: Well, is it too low? Yes,
17 it's too low. It's --

18 MEMBER BROWN: Because I don't have any
19 judgments to make any differential between 100 and 500.

20 CHAIRMAN SIEGEL: If one does what is generally
21 done in the radiation protection community, right or wrong,
22 and that is to use a predominantly linear hypothesis for
23 determination of the risks of radiation.

24 And then when you think in terms of a
25 population, not in terms of individual human beings, but in

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1 terms of a population and you sit down and make the
2 calculations, you say "Let us conservatively draw the dose
3 limit at 100 millirems of exposure from these activities
4 because that way we can avoid any substantial risk to the
5 population."

6 MEMBER BROWN: Erring on the side of caution,
7 but now in the --

8 CHAIRMAN SIEGEL: Unequivocally. When you look
9 at individual patients, the 100-millirem limit starts to
10 become significant. It suggests, for example, that we should
11 evacuate Denver. It suggests, for example, -- and Carol
12 has got this wonderful idea -- that TWA --

13 MEMBER BROWN: Nobody can fly across country
14 that --

15 CHAIRMAN SIEGEL: -- should be forced to keep a
16 record of my mileage and each year when I reach 100,000
17 miles, they should send me a note, say "You've exceed your
18 100-millirem limit for the year because of the extra
19 radiation exposure from flying." I shouldn't get an award.
20 I should get a warning.

21 So when you start thinking in terms of
22 individual people, 100 millirems become unmeasurable in
23 terms of proving that there's a risk to that individual
24 purpose.

25 So the 100-millirem limit is a conservative

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1 population-based limit that says "We would not like to
2 tomorrow add 100 millirems per year of annual exposure to
3 every human being in the United States because if we did
4 that, then we might begin to start seeing a measurable
5 increase in effects as a result of that."

6 Lou, you're the radiobiologist.

7 DR. WAGNER: Well, I was just going to state
8 that to put it in perspective, everybody in this room,
9 everybody on this continent is going to get about 300
10 millirem every year just from natural background radiation.
11 So the 100 millirem is a small fraction of that.

12 If you take it in Denver, they're going to get
13 what we get here. It really is quite trivial. A very
14 important point is it is a population-based recommendation.
15 So when you go to the 500 millirem, that's for individuals.
16 And what that does is basically give you one to two years'
17 background radiation equivalent.

18 MEMBER BROWN: Right.

19 DR. WAGNER: So you're living in those kinds of
20 numbers.

21 MEMBER BROWN: Per treatment? That's not
22 multiple treatments?

23 DR. WAGNER: Well, that would be for whatever
24 it is. That's where you've got to draw the line, --

25 MEMBER BROWN: Right.

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1 DR. WAGNER: -- if it's multiple treatments or
2 not. And you'd be looking --

3 CHAIRMAN SIEGEL: But annually.

4 DR. WAGNER: -- at the individual members, who
5 would basically be the family. That's what you would be
6 looking at.

7 MEMBER BROWN: I have a question also. Are you
8 going to go back to looking at the comments at all or can I
9 bring that up now? You said there were 56 comments and 80
10 percent were from the medical community, 4 from the states,
11 and 4 from others. What bothers me is that there's no
12 consumer-based group, health research group, women's health
13 network.

14 There's nobody with enough familiarity with the
15 subject that's so arcane to develop any thoughtful
16 comments. So hearing only from the medical community, who
17 has the patients' interest at heart, of course, but the
18 cost/benefit very much on their mind, doesn't help me. And
19 I'm wondering who the four others were that commented.

20 MS. DRAGONETTE: Stewart?

21 CHAIRMAN SIEGEL: One of the others was an NRC
22 lawyer who commented as a member of the general public.
23 There were --

24 MEMBER BROWN: What was his name? Is that the
25 --

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1 CHAIRMAN SIEGEL: I didn't actually bring my
2 stack of letters with me, but Peter Crane, I believe, yes.

3 MEMBER BROWN: Okay. I'm familiar with him.

4 CHAIRMAN SIEGEL: Someone who has previously
5 had I 131 therapy.

6 MEMBER BROWN: Right. And, actually, I read
7 something that he had written previously in talking about
8 his experience about being released and going and picking
9 out tomatoes at the supermarket and no one telling him not
10 to, that kind of thing, and then feeling horrible about --

11 CHAIRMAN SIEGEL: That's his hang-up, Judy. I
12 mean, the truth of the matter is if you make careful
13 measurements in the houses of people who have been treated
14 with I 131 and then you do thyroid bioassays in the family
15 measures, you do not find doses that are worrisome in any
16 way, shape, or form.

17 You've got to base this on what's practical.
18 We can't reduce these risks to zero.

19 MEMBER BROWN: See, but what bothers me, Barry,
20 is that your saying "That's his hang-up" doesn't help me.
21 I'm just hearing from the same side of the issue
22 constantly. And when we have kind of a renegade, an NRC
23 lawyer, someone who has had the treatment, whoever he is,
24 who says that this is a different comment, a different
25 opinion and for you to dismiss him and say "That's his

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1 hang-up," that doesn't help me.

2 I'm the only one here who is supposed to look
3 at it from a really, really different perspective.

4 CHAIRMAN SIEGEL: I understand that.

5 MEMBER BROWN: So I'm looking for some help
6 here. I really don't want to just rubber stamp --

7 DR. WAGNER: What would you like to know,
8 Judith?

9 MEMBER BROWN: I'd like to know what other
10 people who are not in the medical community that have those
11 cost considerations primary in their mind think. That's
12 what I'd like to know.

13 CHAIRMAN SIEGEL: Could I make a --

14 MEMBER FLYNN: Well, as someone from radiation
15 oncology who doesn't have the nuclear medicine cost
16 considerations in mind, I agree that I think the NCRP
17 report, I think the dose may be close to 350 millirem a
18 year if you count radon, almost one millirem a day that we
19 all get, almost a millirem a day we all get.

20 If we live in Denver, I think, as opposed to
21 Boston, Boston being at sea level, I think it's close to 20
22 millirem a year in Denver or thereabout, something like
23 chest Xrays a year more.

24 DR. WAGNER: It's more like 100 millirem a year
25 more.

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1 MEMBER FLYNN: In Denver?

2 DR. WAGNER: Yes.

3 MEMBER FLYNN: Okay. And a trans-Atlantic
4 flight, I think, is five millirem. So it's like saying
5 "Should we worry about this or should we worry about
6 individuals making 20 trans-Atlantic flights and should we
7 have warnings to get on airlines because these doses are
8 getting into the noise levels of what we're getting every
9 day and what the public gets every day depending on what
10 geographic region of the country they live in?"

11 Some places of the world they're getting 10 and
12 20 times that dose because of the natural background in
13 that part of the world. So we're really in the noise
14 level, I think.

15 So I would agree with Barry in this issue
16 completely.

17 MEMBER BROWN: I guess also there's a minor
18 distinction to be made between things that you undertake,
19 you choose to live in Denver, you choose to get on a plane,
20 versus things that are done to you.

21 And if the consequence of something done to you
22 has an effect on your family, that may not be communicated
23 to you adequately because you're not listening, because the
24 person is not communicating very well, even though they
25 think they are, the health provider, because you don't

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1 speak English but you're pretending that you do. So you
2 smile and you nod. I'm worried about that kind of thing
3 about a procedure being done to you.

4 CHAIRMAN SIEGEL: But there have to be
5 consequences.

6 MEMBER FLYNN: There's no risk.

7 MEMBER BROWN: I'm sorry?

8 MEMBER FLYNN: I don't think there's any risk.

9 CHAIRMAN SIEGEL: There have to be
10 consequences.

11 MEMBER BROWN: You're saying there have to be
12 consequences.

13 CHAIRMAN SIEGEL: Yes.

14 MEMBER BROWN: And you're saying there's no
15 risk.

16 CHAIRMAN SIEGEL: That's what we're saying. I
17 mean, we're saying worrying about the risk between 100 and
18 500 millirems to members of the general public, and
19 particularly to family members, is something we shouldn't
20 be worrying about.

21 MEMBER BROWN: Barry, are you saying "Trust
22 me"?

23 CHAIRMAN SIEGEL: No, I'm not saying trust me.
24 I'm saying trust a large accumulated body of scientific
25 knowledge, none of which I participated in generating. I'm

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1 also saying we've got to be able to take care of patients
2 in an expeditious way.

3 I couldn't care less about the cost. It
4 doesn't cost me a lot of money to create the record. What
5 it does, though, is it creates a high anxiety level in the
6 people who are working. It creates a high anxiety level in
7 the patient to start getting instructions about risks that
8 don't exist. That's important.

9 And I think people should be instructed. I
10 think people should understand what's going on. I don't
11 think people should be made crazy by the process of being
12 released with radioactive material on board when they don't
13 pose a hazard to the members of the general public.

14 MEMBER BROWN: So they should go home and hug
15 their kid or not?

16 CHAIRMAN SIEGEL: Sure, sure. But, I mean,
17 Judy, what I tell people is I say "I'm letting you out of
18 the hospital. You just got treated with I 131. You should
19 not stop taking care of your child. However, here's what
20 you should do. If normally you would watch ER with your
21 child," which I did, by the way, last night -- thank you
22 for the recommendation.

23 MEMBER BROWN: We'll have that discussion
24 later.

25 CHAIRMAN SIEGEL: -- "with your child sitting

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1 on your lap for the hour, for about the next week or two
2 weeks, what you ought to do is just have your child sit on
3 the other side of the room. It's prudent thing you can do.
4 It will lower an already low dose and make it less. Don't
5 disrupt your life. Don't do things that are crazy."

6 Let's see. David Woodbury first and then Dr.
7 Pollycove.

8 DR. WOODBURY: There are studies, Judy, that
9 look into this. I don't have the reference, but there's a
10 Dr. Jacobson in the School of Public Health, University of
11 Michigan, who has done just that for patients who have been
12 treated for thyroid things, I 131 for hyperthyroid, I 131.
13 He went into the homes and took measurements and saw and
14 found the exposure to family and so on was negligible.

15 And so I think that data is available. I don't
16 have the precise reference, but it could be gotten.

17 CHAIRMAN SIEGEL: Myron?

18 DR. POLLYCOVE: It would be useful to know that
19 throughout the world, and particularly in Denver since we
20 mentioned that, but other places that are high altitude,
21 where the background level is 50 to 100 MR per year, some
22 places even higher, and people have lived there in other
23 parts of the world for many generations and in Denver their
24 lifetime, that all of these places have demonstrated a
25 lowering of incidence of cancer and leukemia and a lowered

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1 mortality rate so that all of the epidemiologic surveys
2 that have been made in these areas have all demonstrated
3 not only no effect, but a positive effect.

4 Now, you say "Well, why, then, these scientific
5 bodies, are they so conservative and come out with these?"
6 Because it's the political legacy of decades. I mean,
7 that's the scientific data.

8 MEMBER BROWN: So it's just historical reasons?

9 DR. POLLYCOVE: Not historical. Scientific
10 data. Historical is the linear no threshold hypothesis,
11 which is being increasingly under attack. We had an entire
12 all-day meeting at the American Nuclear Society showing
13 current data which shows either zero effect or beneficial
14 effects if there's enough radiation.

15 For example, in the Canadian fluoroscopy study
16 that was published in the "New England Journal," it was
17 shown that women who received 15 rad to their breasts when
18 they were in TB sanatoria had two-thirds of the breast
19 cancer mortality of the controlled group, who had no
20 radiation.

21 Now, 15 rad is 15,000 millirem. And we're
22 talking about 100. Now, if women knew that a third of them
23 would not have breast cancer if they were exposed to this,
24 I think that would do more good than mammograms.

25 MR. SCHNEIDER: Just for the record, four

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1 comments. Number 15 was from the Ohio Citizens for
2 Responsible Energy. Number 25, Peter Crane --

3 MEMBER BROWN: Ohio Citizens for Responsible
4 Energy. That sounds like a front for a something group,
5 for an industry group.

6 MR. SCHNEIDER: Number 25 is from Peter Crane.

7 MEMBER BROWN: Does anybody know anything about
8 that?

9 CHAIRMAN SIEGEL: About what?

10 MEMBER BROWN: Ohio Citizens for Responsible
11 Energy.

12 CHAIRMAN SIEGEL: Not a word. Bob does?

13 MR. QUILLIN: The Ohio Citizens for Responsible
14 Energy is a group in northeastern Ohio who's primarily
15 interested in the Perry Nuclear Power Plant.

16 MEMBER BROWN: Okay.

17 MR. SCHNEIDER: Number 42 is from the Clean
18 Water Fund of North Carolina. And Number 48 was from the
19 Nuclear Energy Institute.

20 MEMBER BROWN: Thank you.

21 DR. PAPERIELLO: This is Carl Paperiello.
22 Could I make an observation?

23 CHAIRMAN SIEGEL: Go ahead.

24 DR. PAPERIELLO: The NRC would not be
25 considering this at all if there were not, shall we say,

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1 international and national groups which have established
2 the standards that we essentially work into a regulation.

3 That's our problem, trying to take what has
4 been established by the scientific community using the
5 linear dose hypothesis, the maximum risk, BEIR V, the whole
6 nine yards, and trying to make a regulation out of a
7 recommendation. That's my problem, trying to move
8 something from, shall we say, a scientific recommendation
9 into a legally binding requirement. And that's where what
10 is nice -- you start taking gray and making it black and
11 white.

12 Basically what is said by ICRP in publication
13 60, which is their latest set of standards, -- that's the
14 International Commission on Radiological Protection -- the
15 NCRP, I think, 116, but one of the latest ones, as well as
16 the IAEA and World Health Organization, -- there are about
17 six different organizations that support the international
18 radiation protection standards -- is this: one, the public
19 dose should be limited to 100 millirem a year. And they
20 mean that as you design your program if you're using
21 radioactive material that members of the general public --
22 you don't know who they are, anybody -- is 100 millirem a
23 year.

24 However, they all state that in the case of
25 exposure of patients, the nonoccupational voluntary

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1 care-givers of patients, their exposure is considered
2 medical exposure. And it should be constrained to 500
3 millirem a year. That's IAEA.

4 ICRP basically uses very, very similar words.
5 The National Council on Radiological Protection and
6 Measurement says that for an occasional individual to get
7 500 millirem on occasion is acceptable. I'm paraphrasing.
8 I don't know the exact words. The idea is we don't want
9 one individual to get 500 millirem year in and year out.

10 It's not very likely that you are going to be
11 involved in a situation where you have in this case a
12 family member getting radioactive material that you are
13 going to get 500 millirem every year for your entire life.
14 It's just an episode that happens a couple of times at most
15 likely in your lifetime.

16 Those concepts that are in those publications
17 using the linear dose hypothesis arguably -- maybe it is
18 ultra conservative. Maybe it is unjustified, but it's
19 certainly been the hypothesis or the theory that has been
20 supported by the BIER Committee of the National Academy of
21 Sciences, the EPA, and similar organizations. Using even
22 that theory, they're establishing 500 millirem as a
23 constant level for occasional circumstances.

24 That's what we're dealing with right now. How
25 do I take those recommendations and work them into a

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1 regulation where I understand the recommendations, but
2 they're gray? And now the minute I move them into a
3 regulatory area, everything has to be black and white.
4 That's just what law does to you.

5 So the NRC is not making this up out of the
6 air. We're doing it because it is consistent with the
7 international recommendations. And I had my closest
8 counterpart in England over here in May. And I asked them
9 what they do. They basically do what we're proposing to do
10 here.

11 So we are not an outlier in the international
12 community. That's all I could --

13 CHAIRMAN SIEGEL: And, Judy, just to add one
14 more bit of historical perspective that's important,
15 remember that the reason we're having this discussion from
16 the beginning is that when new Part 20 went into effect,
17 this slipped through the cracks as a gap that the new Part
18 20 failed to address explicitly so that it appeared that
19 current practice was now being outlawed because current
20 practice, current 35.75 that says you can release patients
21 from the hospital when their body burden is below 30
22 millicuries and when their dose rate is less than 5
23 millirems per hour at a meter was predicated on
24 longstanding NCRP guidance to limit exposure to a member of
25 the general public to less than 500 millirems in a year.

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1 That was the idea behind existing 35.75. Part 20 appeared
2 to create a conflict.

3 What we're trying to do by way of this
4 rulemaking, what the NRC is trying to do in response to the
5 petitions is to get back to current practice, which has
6 been in place for years and years and years and which no
7 one considers to be unsafe. In the process the NRC created
8 something that turns out to be more complicated than it
9 needs to be to protect the public and to allow patient care
10 to go forward.

11 MEMBER BROWN: Okay. So the only sticking
12 point, then, should be the breast-feeding.

13 CHAIRMAN SIEGEL: Well, no. The sticking point
14 is whether you really need to do anything in the gap
15 between 100 millirems and 500 millirems and what the paper
16 trail has to be involved in the process, that and then the
17 potential impact on the breast-feeding become the major
18 sticking points. And we'll keep working through those.

19 Now, let's see. Dennis or Buzz had a comment,
20 too.

21 MEMBER NELP: Well, I was going to comment on
22 the problem, the question regarding how you're going to
23 solve the problem. I don't want to comment any further on
24 the question. I think that's --

25 CHAIRMAN SIEGEL: Okay. Dennis?

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1 MP. SWANSON: Just to remind you. In the
2 proposed rule, there was a requirement that you document --
3 the release criteria was 500 millirem, below 500 millirem,
4 but there's a requirement that you document anybody between
5 100 and 500 so that you could look for if they had multiple
6 exposures that they didn't exceed the 500 millirem per
7 year.

8 I don't really have any problems with
9 documenting a single release criteria that the patient fell
10 below 500 millirems per year. Where the problem comes in
11 is trying to keep this running total if they got multiple
12 administrators. The problem is to do that assumes that the
13 patient is going to get all of their radiation therapy at
14 the same site, Point Number 1, which is not reality. Okay?

15 Point Number 2. Let's assume that a patient
16 got an iodine 131 thyroid treatment. We released them at
17 the limit, 500 millirems per year. And for some reason
18 that patient needed another therapy.

19 Are we going to say or refuse that therapy
20 because that patient would receive an excess? Well, no.
21 We can give the therapy. We'd have to keep them in the
22 hospital -- okay? -- and not release them, but then the
23 cost increase and, in fact, patient's insurance provider
24 may not cover that increased cost of requiring to keep them
25 in a hospital.

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1 So those are some of the issues that you get
2 into. And it basically deals with keeping track of the
3 running total, what you have a problem with.

4 One other comment here. I see this
5 performance-based rule. And after our discussion
6 yesterday, an alarm goes off in my head whenever I see the
7 terminology "performance-based rule." I don't know if you
8 were here yesterday, but you might want to go back and
9 review the minutes on that.

10 DR. WAGNER: I'd like to point out that if you
11 do release someone at the 500-millirem level, okay. Fine.
12 They come back for another treatment. You've got a big
13 problem now because you released them at the 500-millirem
14 level the first time. You can't give any more above the
15 500-millirem level, period.

16 What are you going to do, keep them in the
17 hospital for the rest of the year? You've got a problem
18 there.

19 CHAIRMAN SIEGEL: That's actually not true. I
20 mean, the numbers that are in the current tables, one of
21 the problems with them is that they're really fairly
22 conservative numbers. They do not consider attenuation.
23 Correct, Stewart?

24 MR. SCHNEIDER: Right.

25 CHAIRMAN SIEGEL: So they ignore attenuation.

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1 They have assumptions about occupancy factors, the 25
2 percent tandem human being that may not be realistic for a
3 substantial fraction of human beings that we are going to
4 be taking care of.

5 So one of the things we discussed at the
6 meeting in October, the discussions in October, was that
7 creating a much larger series of tables that address a
8 variety of these other issues, such as what the real uptake
9 factors and excretion rates, -- because excretion is being
10 ignored in the first 24 hours in these tables as well --
11 excretion rates, bioclearance rates, attenuation.

12 If we start getting into tables that more
13 realistically reflect the truth, you can start calculating
14 these numbers down to give you much, much wider latitude
15 and still be doing something that's perfectly safe.

16 This is not playing with the numbers. These
17 numbers are conservative by at least a factor of four or
18 five that are in these tables when you start adding in most
19 of the other considerations, the real factors.

20 DR. WAGNER: And it's very important, though,
21 that that get corrected because if we don't get that
22 corrected, then there's going to be a lot of problems with
23 regard to that kind of level.

24 CHAIRMAN SIEGEL: So the concept kind of was
25 "Fine. Create a table that says this is -- ignore the

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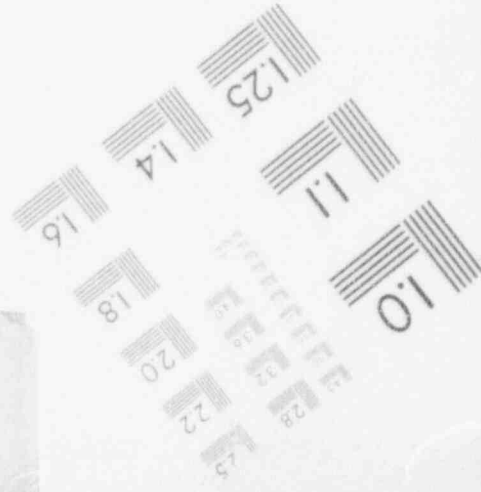
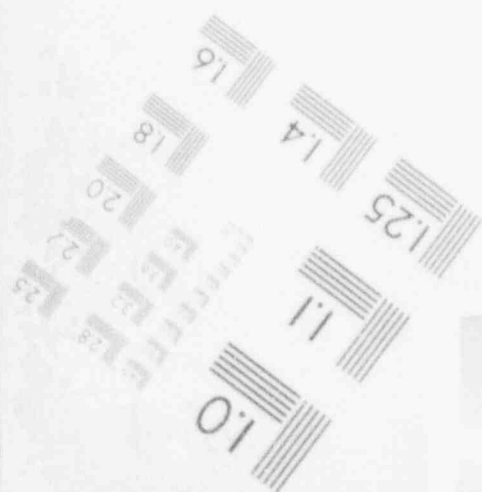
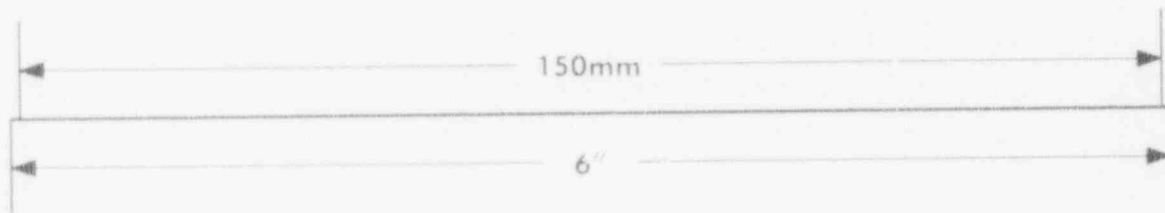
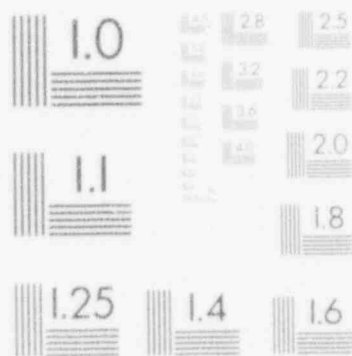
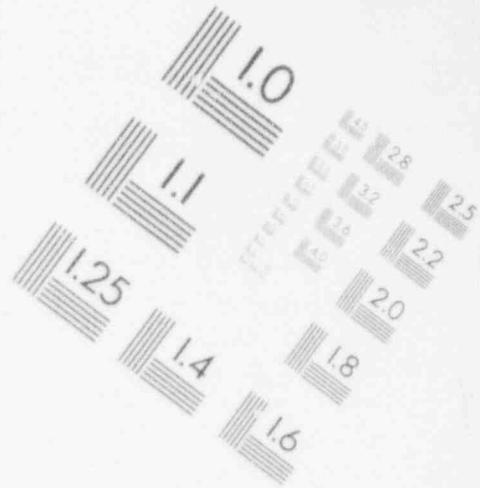
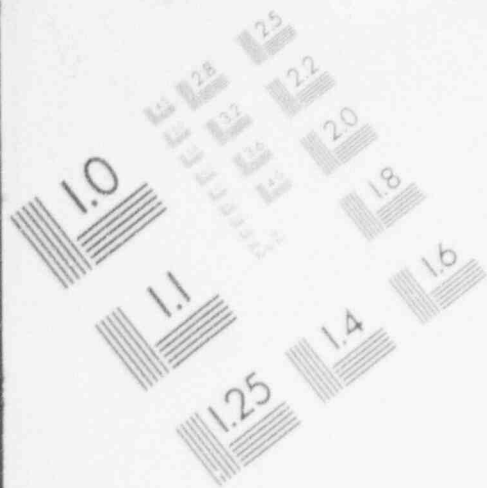
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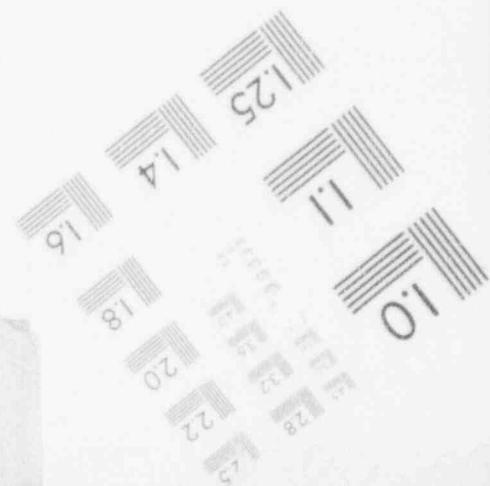
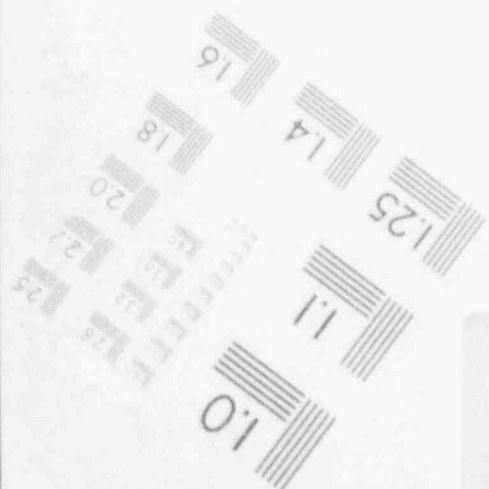
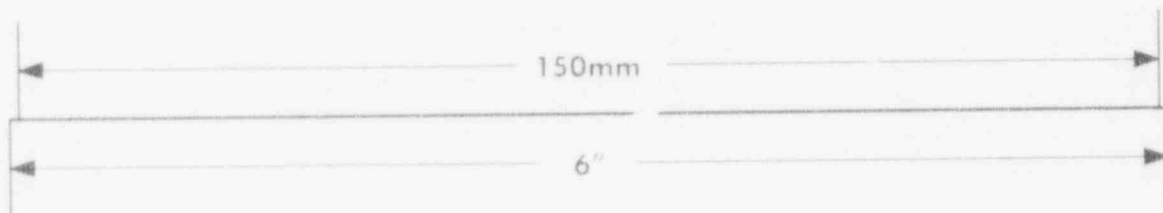
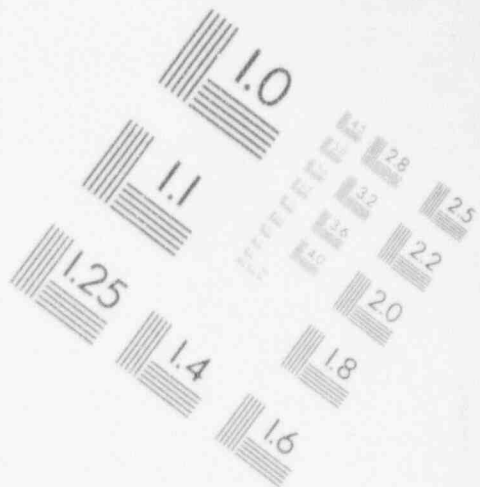
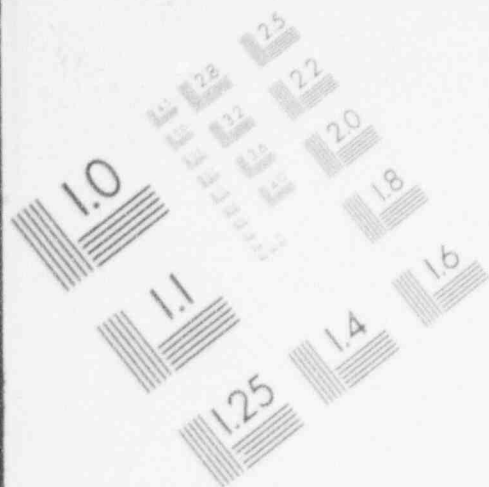
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IMAGE EVALUATION TEST TARGET (MT-3)



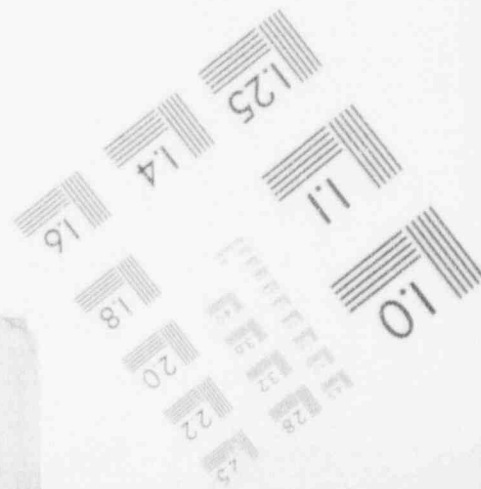
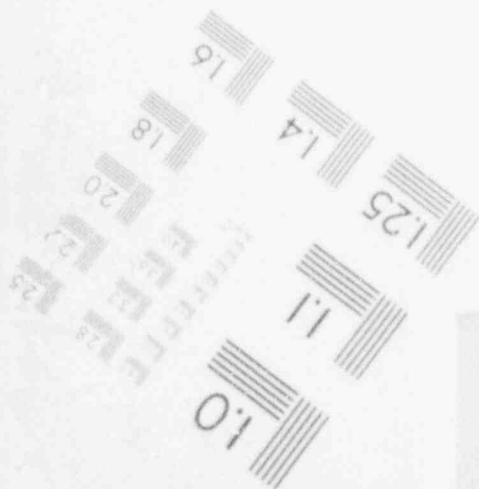
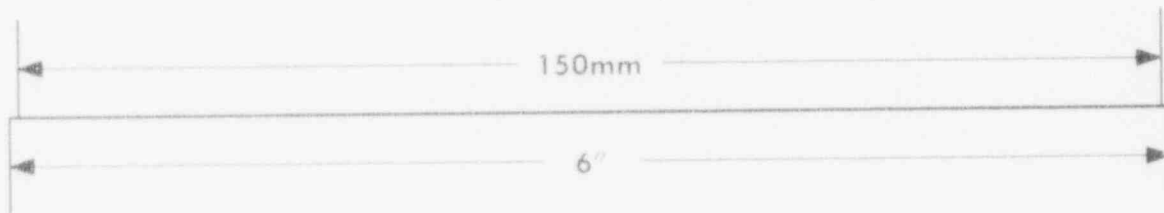
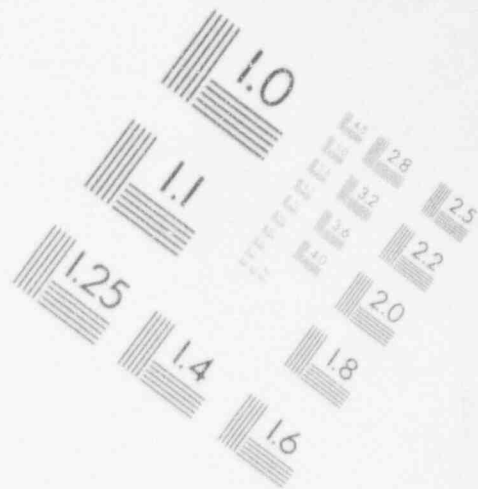
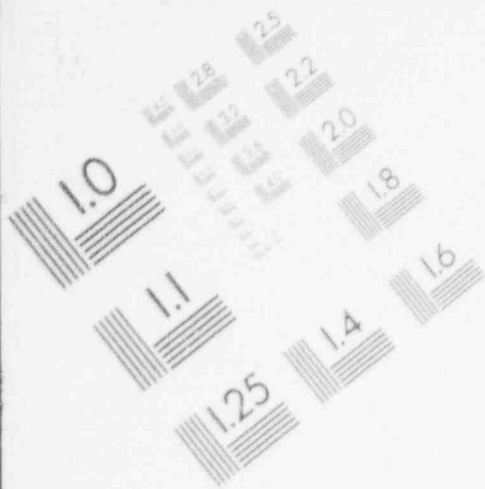
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IMAGE EVALUATION TEST TARGET (MT-3)



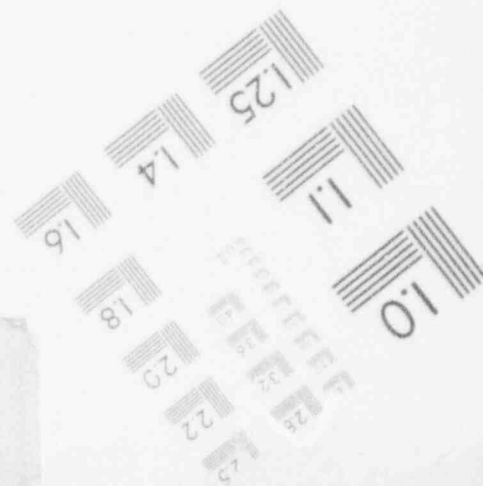
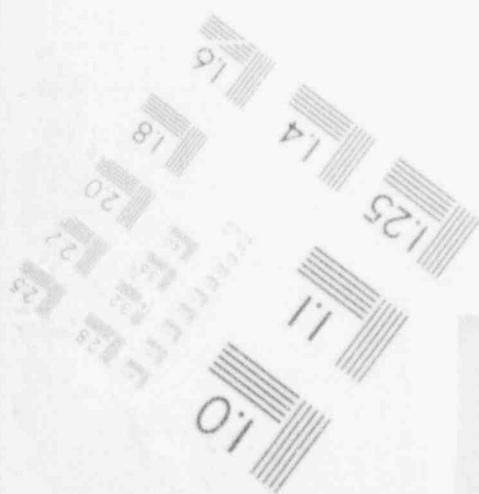
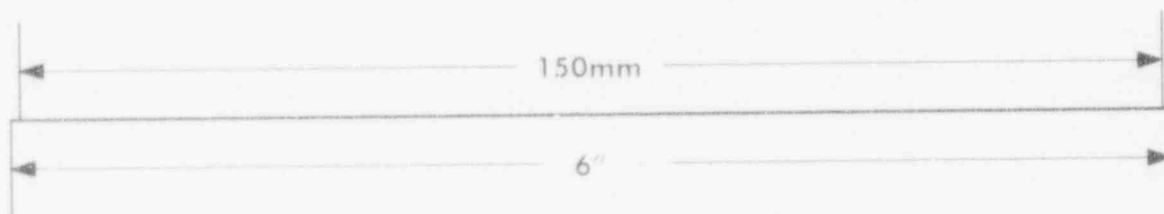
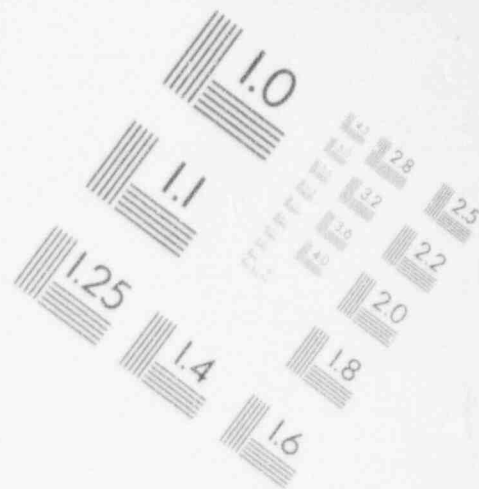
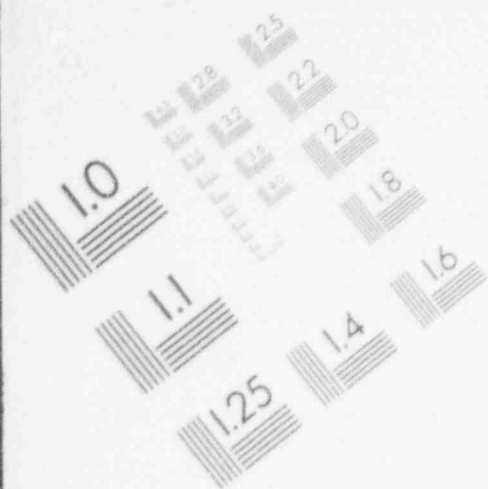
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IMAGE EVALUATION TEST TARGET (MT-3)



1

IMAGE EVALUATION TEST TARGET (MT-3)



1 regulatory space between 100 and 500 millirems because
2 you're ignoring it now. There's no reason in the world to
3 worry about that regulatory space."

4 And that was the concept where a cost/benefit
5 analysis would show that the extra work required in
6 fretting about that 400-millirem gap wasn't worth the
7 effort in terms of the public health and safety. Then
8 create a comprehensive set of tables that let licensees
9 know where those 500-millirem limits are.

10 And then when people have to come back and be
11 re-treated if they're at the margins, that's the point at
12 which the licensee has the responsibility to gather as much
13 data as he or she humanly can about what else has been done
14 during the course of the last 12 months to this patient and
15 then really look at the factors in that person's
16 environment to try to decide what kinds of doses were
17 actually laid out to members of the public.

18 It also turns out that the number of multiple
19 administrations is relatively small. And certainly the
20 number that would likely take you over the 500-millirem
21 limit -- for some reason, I'm having trouble finding my
22 data. Stewart, do you have my note, by any chance?

23 MR. SCHNEIDER: Not with me.

24 CHAIRMAN SIEGEL: You don't have it with you?
25 At Stewart's request, -- I must not have put it in my

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1 package -- I gathered the data from our 2 hospitals for a
2 12-month period and looked at all of the patients who
3 received radiopharmaceutical therapy or I 131 for thyroid
4 cancer imaging, so written directive doses of
5 radiopharmaceutical, and looked at the number who had had
6 multiple things done during the year. And it turned out to
7 be a very small fraction of the total. It was well under
8 10 percent, wasn't it?

9 So that when you reduce the recordkeeping
10 burden to worrying about that fraction of the patient
11 population, it becomes a much more practical rule to work
12 with and much closer to what is currently in place, which
13 makes sense and has worked for 20-plus, 30-plus years.

14 Buzz?

15 MEMBER NELL: I presume we're talking
16 exclusively about I 131 therapy at the present time. I
17 mean, there's no other therapy that we give that exposes
18 the public that I'm aware of. Isn't that correct?

19 CHAIRMAN SIEGEL: At that present time, that is
20 correct. I mean, there is --

21 MEMBER NELL: I mean, there's no other approved
22 use of a radiopharmaceutical for therapy that does this
23 except soluble I 131 for thyroid therapy. I think that's
24 correct.

25 CHAIRMAN SIEGEL: At the present time, that's

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1 correct as long as you control access to a patient's urine
2 after a strontium 89 therapy.

3 MEMBER NELP: Yes. And I don't know the number
4 of people that are treated each year in the United States,
5 but it's a very small number overall compared to the
6 population.

7 CHAIRMAN SIEGEL: Carol always used to spout
8 those numbers. There are about 100,000 I 131 therapies.

9 MEMBER NELP: No, no. It has to be much -- no.
10 It's quite low.

11 CHAIRMAN SIEGEL: For hyperthyroidism?

12 MEMBER NELP: I would bet for a population -- I
13 don't know the number, but it's relatively small.

14 CHAIRMAN SIEGEL: It's a few thousand for
15 thyroid carcinoma and 50 to 60 thousand for
16 hyperthyroidism.

17 MEMBER NELP: There's no problem with treating
18 hyperthyroidism, but for treating thyroid carcinoma with
19 larger doses, I don't know the number, but it's very small.

20 CHAIRMAN SIEGEL: Right. We have the numbers
21 here.

22 MEMBER NELP: And you have subsets of the
23 population that you identify all the time that get
24 different types of radiation exposure. For instance, the
25 occupational workers are a subset, and they come under

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1 special guidelines. And they're a subset of people who are
2 going to be exposed to these patients. And that's going to
3 be a very small portion of the population.

4 Is there any way looking at it from that point
5 of view and saying "The average patient doesn't really
6 expose the population at all," it's average patient may
7 expose 5 or 6 people or 10 people, -- you inferred you had
8 some numbers on that -- and say "Look, this really is not a
9 population problem. This is a medical problem, which is a
10 subset of medicine," and try to avoid the --

11 CHAIRMAN SIEGEL: That's effectively what's
12 being done.

13 MEMBER NELP: -- try to avoid this complicated
14 general public impression?

15 CHAIRMAN SIEGEL: That's effectively what's
16 being done is that an exemption to the hundred is already
17 in existence and now needs to be patched into place --

18 MEMBER NELP: Well, but look at the occupation.
19 The occupational worker --

20 CHAIRMAN SIEGEL: Well, Buzz, I agree with you
21 completely.

22 MEMBER NELP: -- theoretically can get 100 mr
23 per week. Isn't that correct? I mean, that's not --

24 CHAIRMAN SIEGEL: Correct.

25 MEMBER NELP: That's for your information. I

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1 can receive 5,000 mr per year for my working lifetime. I
2 wouldn't, but it's permissible. Anyway, I just wanted to
3 interject that concept, and you've probably already thought
4 about it.

5 CHAIRMAN SIEGEL: That's really what the
6 concept is. The concept is that this is a special case
7 that involves exposures to small numbers of individuals,
8 many of whom have a stake in the patient's welfare.

9 And, consequently, that warrants the exemption
10 to the general population limit. That's the whole
11 philosophical basis to having this in place in the first
12 place.

13 MEMBER NELP: I would like to say one other
14 thing. I understand what you're saying, and I agree, but
15 if it is true that you've put into some sort of format for
16 others to view the projected exposures to a person's body
17 or from a person's body and they're four to five times over
18 what they should be, I think those should really be
19 calculated and put down into reality because that will save
20 a lot of time and trouble if that's true because if you put
21 those tables out, they're going to be referred to.

22 CHAIRMAN SIEGEL: Absolutely.

23 MEMBER NELP: And I think if they're a factor
24 of four off, they should really be trimmed down. That will
25 save a lot of time and effort for those people who have to

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1 get involved in it.

2 MR. CAMPER: One comment on your comments, Dr.
3 Nelp.

4 MEMBER NELP: Maybe you've already thought
5 about these.

6 MR. CAMPER: Historically the 35.75 release
7 criteria has had an implied limit of 500 millirem. The
8 language in the proposed rule makes the 500-millirem limit
9 absolute. This is for medical procedures.

10 So, in fact, this is embodying the very thing
11 that you're saying for medical procedures. The dilemma
12 comes when we start to deal with the issue that Carl
13 raised. And that's the fact that we have this 100-millirem
14 limit to an individual member of the public.

15 And that's what we're wrestling with. What
16 should we do, if anything, between the 100 and the 500?

17 MR. McGUIRE: Could I make a comment, too, on
18 this issue of the conservative factors that are built into
19 the table of releases in the regulatory guide?

20 A guide is not a regulation. It's not a
21 requirement. It's just listed as an acceptable way of
22 doing things, but it also says that it is acceptable base
23 of release on a case-specific calculation. So that there
24 is the option in a performance-based rule to do something
25 that's a little different than the table if you can justify

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1 it in your particular situation.

2 CHAIRMAN SIEGEL: Nonetheless, I think when we
3 discussed this a few weeks ago, we thought that letting the
4 NRC do a little bit of the homework and come up with a
5 complete set of tables that incorporated various different
6 assumptions that one might pick and choose from would be a
7 great service to the community at large and probably would
8 minimize the frequency of errors in calculation.

9 DR. WAGNER: One of the difficulties with just
10 leaving things in a guide, too, is the fact that if you do
11 the calculations and an inspector disagrees with what your
12 assumptions were, you've got a problem now

13 Now you've got to work things out. And that's
14 always a source of disagreement. We really need more very
15 specific guidance.

16 CHAIRMAN SIEGEL: It might be.

17 Kitty, continue.

18 MS. DRAGONETTE: That's a little bit of damned
19 if you do and damned if you don't.

20 (Slide)

21 MS. DRAGONETTE: The second issue, which was
22 not as big a deal but is related also to this zone between
23 100 and 400 was the proposed rule had a requirement to give
24 written instructions to the patients when you were
25 releasing them if the estimated doses would be greater than

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1 100 millirem.

2 And there were comments that we got that we
3 should not specify that they should be written, that they
4 should have the option of doing written or oral. There was
5 support for requiring the written directions. And there
6 was concern expressed about the fact that patients don't
7 always do what their doctors tell them to.

8 (Slide)

9 MS. DRAGONETTE: On this issue, the options --
10 and at this point we're still debating them -- are leave it
11 so it's just instructions so that oral would be sufficient,
12 go ahead with the proposed requirement to require the
13 written instructions, but emphasize and explain again and
14 in more detail in the regulatory guide that explaining
15 things and walking a patient through the directions and the
16 assumptions on the behavior that you factor into
17 demonstrating that you meet the dose limits, that if you do
18 those things, that's a reasonable way of meeting it. You
19 aren't responsible.

20 I mean, we've talked about this before, but the
21 physician would not be responsible if the patient
22 intentionally did not follow the directions and
23 suggestions. So those are the options being considered on
24 that one.

25 MEMBER BROWN: Do you want feedback on that or

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1 do you just --

2 MS. DRAGONETTE: Yes.

3 MEMBER BROWN: Just from my opinion, there
4 would be no way I could be argued out of the position that
5 written instructions should be given. So don't try.

6 MS. DRAGONETTE: Certainly from my own personal
7 perspective, when I've been a patient getting some
8 procedures or something, having something written to refer
9 back to is helpful.

10 CHAIRMAN SIEGEL: Right. But let me go a step
11 further.

12 MEMBER BROWN: Are you going to try?

13 CHAIRMAN SIEGEL: No. I'm not going to try to
14 talk you out of it. I'm going to try to tell you that
15 seeing written instructions is insufficient.

16 MEMBER BROWN: Oh, yes, sir.

17 CHAIRMAN SIEGEL: Okay. And, actually, at the
18 meeting in October, we suggested the concept that what
19 proposed 35.75(b)(1) should say is it should say "provide
20 the patient with instructions, including written
21 instructions, on how to maintain doses to other individuals
22 as low as reasonably achievable" lest the licensee's
23 responsibility is perceived to be "Here. Read this."

24 MEMBER BROWN: Right. I assumed that verbal
25 was a given.

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1 CHAIRMAN SIEGEL: The way it reads here --

2 MEMBER BROWN: So I think you do have to spell
3 that out.

4 CHAIRMAN SIEGEL: The way it reads here --

5 MEMBER BROWN: I appreciate the addition.

6 CHAIRMAN SIEGEL: Do the rest of you agree with
7 that? I mean, this really is something that you shouldn't
8 just give them a pamphlet and say "Go home." This really
9 is something that talking to them is more important than
10 the written instructions.

11 The written instruction sort of is a backup
12 when they get home to say "Now, what were those 300 things
13 that Dr. Siegel told me about?"

14 DR. WOODBURY: We try to abide by written
15 instruction in the "Federal Register" and have trouble.

16 CHAIRMAN SIEGEL: We've noticed.

17 DR. GLENN: I wonder if I could pose a question
18 to you. Is that for all procedures? Are you saying that
19 you would say require instructions only for those
20 procedures that require a written directive? What is the
21 Committee' sense on that?

22 CHAIRMAN SIEGEL: My personal preference
23 depending on how we get into the breast-feeding part of
24 this would be to literally tie this whole thing to those
25 procedures that involve written directives and not to get

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1 involved with this for diagnostic imaging, the kind of
2 diagnostic imaging that does not currently require a
3 written directive.

4 I mean, again, this goes back to the whole
5 series of discussions we had at great length with respect
6 to the quality management rule. What you want to do is you
7 really want to focus people's attention on those things
8 that create a risk.

9 And if you get them spending all of their time
10 working on things that are not a risk, then you divert
11 their attention from the important ones, and then mistakes
12 get made with the important ones.

13 What you want to do is make sure that people
14 who -- in the case of radiopharmaceuticals, you want to
15 make sure the people who are getting I 131 who not only
16 pose a external radiation hazard to the world at large, but
17 also our leaky sources understand what's going on.

18 You, on the other hand, don't particularly need
19 to get carried away explaining to someone who had a bone
20 scan what they need to do for the next 24 hours. That's a
21 waste of time. And if you spend your technologists' time
22 and your time doing that with bone scans, you'll end up
23 doing a less good job where it's important because you
24 won't have enough time. That's resource allocation.

25 MS. DRAGONETTE: Okay. The other sticky is:

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1 How should the breast-fed infant be addressed in this
2 scheme and then worrying about the 100 and the 500-millirem
3 dose limit?

4 Dr. Siegel has mentioned if at the 500-millirem
5 limit per se breast-feeding is not interrupted or
6 discontinued, you could pick up some of the diagnostic
7 patients. It's the radiopharmaceuticals where it doesn't
8 localize in a specific site things that generally circulate
9 like pertechnetate or the iodine 131.

10 As far as the comments go, a few, the two major
11 points, one was that the individual likely to receive the
12 highest exposure should not include the breast-feeding
13 infant. And the other one was that that should be a
14 patient-physician decision.

15 (Slide)

16 MS. DRAGONETTE: This issue is somewhat a
17 generic issue of how to approach the breast-feeding infant.
18 It represents unique circumstances. There are basically
19 two points of view, I believe, in thinking about it: the
20 radiation people, such as myself and Carl and the staff
21 here at NRC, who are worried about that infant or child as
22 an individual and consistently applying our radiation
23 protection equitably; and the other is the
24 patient-physician standpoint, where they want maximum
25 flexibility to make the best decisions for the situation at

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1 hand.

2 So our problem is to try to reconcile or
3 balance those two or figure out ways to accommodate them.

4 (Slide)

5 MS. DRAGONETTE: I'd like to go over a little
6 bit of the perspective from the radiation protection
7 because this is the direction we on the staff are leaning,
8 our rationale and what's behind our view that the infant
9 should be considered.

10 First of all, the infant is physically
11 separated. The situation is different from the
12 embryo/fetus. Clearly the child is separate and can
13 survive and there are alternatives.

14 And the child is not receiving any direct
15 benefit from the radiation. The woman is, but the infant
16 isn't. The benefit the child is getting is from the milk,
17 the biological benefit, but not any benefit from the
18 radiation exposure. And that's one of the basic tenets of
19 radiation protection, you know, that --

20 CHAIRMAN SIEGEL: So you're saying that a
21 healthy mother is not of benefit to the infant?

22 MS. DRAGONETTE: A direct benefit. Obviously
23 --

24 MEMBER BROWN: Excuse me?

25 MEMBER FLYNN: It was a direct benefit in my

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1 case.

2 MEMBER BROWN: How did you get that?

3 MS. DRAGONETTE: Obviously the mother's health
4 is important to the child.

5 MEMBER BROWN: I think you're reaching.

6 CHAIRMAN SIEGEL: No, I'm not reaching. Judy,
7 don't misunderstand me. You know from many past
8 discussions that I don't consider it good practice to
9 irradiate infants with milk.

10 But, on the other hand, there are circumstances
11 in which I would allow an infant to be irradiated when it
12 was in the best interests of both there infant and the
13 mother and the medical care of the mother.

14 They're few and far between. They're not many.
15 But I don't want to make myself crazy with paper trails to
16 achieve something that occurs, first of all, very
17 infrequently and might conceivably interfere with medical
18 care.

19 But let's keep working through this.

20 MS. DRAGONETTE: Another consideration that we
21 have is that all infants and children don't breast-feed.
22 So you would have one level of protection for the -- you
23 could have same-age children or infants or twins and one
24 breast-fed and one didn't. One you would have to evaluate
25 and protect to the 500 per year. The other one there would

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1 be no limit. So intellectually that is very difficult for
2 us.

3 And, in fact, my sister had twins. One was
4 allergic to milk, and the other one wasn't. It's not an
5 abstract situation to have same children in the same
6 household.

7 Another point is that if after birth the child
8 is not considered an individual to be protected, then if
9 you're going to base it on when they stop nursing, that
10 varies. I mean, they can nurse for weeks, months, years.
11 So that's another logic problem we had.

12 A fundamental tenet of radiation protection is
13 to optimize things so that you get the benefit of the well
14 mother at the least dose or the least reasonable dose to
15 others.

16 A practical consideration is related to that
17 the child is separated. And quoting virtually verbatim out
18 of the statements and recommendations of the American
19 Academy of Pediatrics, before you do a nuclear medicine
20 study or particularly one of these therapies, at least for
21 certain diagnostics, if we get into the diagnostics base,
22 the mother could pump the milk and store it in the freezer
23 and feed the infant her own milk during an interrupted
24 nursing.

25 Now, with the directives and the therapy, it's

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1 very difficult to resume nursing with the iodine 131. But
2 for other --

3 CHAIRMAN SIEGEL: It's impossible.

4 MS. DRAGONETTE: Or impossible. But that is a
5 consideration on this issue. I mentioned the American
6 Academy of pediatrics, but in other things we've looked at:
7 the American College of Radiology recommendations; the
8 Society of Nuclear Medicine, who essentially puts the
9 burden in the direction on the patient about interrupting
10 nursing; the U.S. Pharmacopoeia; FDA guidance; and we've
11 also already mentioned ICRP and NCRP. So there are many
12 groups that address the nursing infants.

13 Many of these medical groups are failing the
14 100 as a recommended level for what acceptable doses are
15 for when you could resume nursing. In our formulation, the
16 level is 500, but we in radiation protection are not out
17 there all by ourselves on this one either. The medical
18 community also recommends this is good practice and that
19 should minimize the impact. But philosophically is what
20 I'm talking about here.

21 (Slide)

22 MR. SWANSON: Excuse me. The rest of the
23 medical group considers it also good practice to not give a
24 lot of drugs, including chemotherapy agents, et cetera, to
25 breast-feeding mothers. But the difference, I think, here

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1 is that you don't have to have the documentation trail of
2 that. Again, it's good medical practice.

3 MS. DRAGONETTE: On that previous slide I did
4 mention, but I didn't say that these principles apply to
5 other drugs they give the nursing person.

6 Some of the problems have already come up
7 today. One is that including the breast-fed infant or
8 child in this patient release rule doesn't get at the best
9 time to take these considerations into account.

10 Before you administer the material, finding out
11 that the patient is nursing so that you can decide whether
12 you need to test now, whether you could use iodine 123,
13 instead of 131, or if you have some options, that's the
14 best time to consider it. So that's one problem with it in
15 this rule.

16 Difficulty in calculating doses. There again
17 I'll get to what some of the solutions are, but that's a
18 developing state of the art for both occupational, where we
19 have already imposed the embryo/fetus dose. And the
20 methods of complying with that are evolving. So the
21 nursing infant is another issue and could limit the
22 decisions, as Dr. Siegel has said.

23 And there is the potential depending on how all
24 of this plays out that you might get into the diagnostic
25 space and there theoretically might need to be confinement

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1 for additional patients.

2 (Slide)

3 MS. DRAGONETTE: Now, how to address the
4 problems that we just listed and we've been talking about,
5 what is the current thinking, at least in research,
6 although the staff is still talking and discussing? I said
7 we were leaning toward protection of the nursing infants.

8 So the strategy at this point would be not to
9 change the rule with respect to that. The proposed rule
10 did not have language saying "individual includes nursing
11 infant." We wouldn't add language that says it doesn't.
12 We philosophically have a very difficult time saying that.
13 So the rule would stay the same.

14 Then a discussion of the preventative measures
15 to ask, to plan so that you can do whatever mitigation you
16 might want to do, put that in the guidance in the
17 introductory part of the regulatory guide, but not make it
18 a requirement.

19 Focus on those. Focus and identify those
20 radionuclides that you've got to worry about. If you're
21 into diagnostic space, there's only a handful. The
22 guidance would list those and identify those. Then the
23 others, it would say for the others, you wouldn't have to.
24 So we could focus it on a select few.

25 And then provide a table of acceptable times to

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1 resume nursing. That concept's in several of the medical
2 recommendations. Sometimes it's six hours. Sometimes it's
3 24. And we could come up with some tables on interruption
4 times for those where you would need it in a diagnostic
5 arena.

6 And then again address the problem of
7 compliance with instructions and say that the instructions
8 you give, you can assume that that's what's going to happen
9 and that that's acceptable, to emphasize that again.

10 (Slide)

11 MS. DRAGONETTE: The end. That's our current
12 schedule commitment to the Commission in the summer.
13 Obviously with all of these tables and these calculations
14 and with many of these decisions still being debated,
15 that's --

16 CHAIRMAN SIEGEL: I guess I'm still a little
17 bit confused about what you plan to do with the space
18 between 100 and 500 millirems, what you think you'd like to
19 do.

20 MS. DRAGONETTE: Requiring ALARA, instructions
21 to address ALARA, and leave it to the physician to
22 determine whether the multiple administrations will get you
23 above the 500 per year space but not have any recordkeeping
24 or --

25 CHAIRMAN SIEGEL: So if we look at proposed

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1 35.75 -- do you have a copy there? Most of you should have
2 this. I don't know if it was distributed. It's actually
3 not in the book.

4 So if I understand what you're saying, 35.75,
5 proposed 35.75(a) would stay the same.

6 MS. DRAGONETTE: Yes.

7 CHAIRMAN SIEGEL: It would read "A licensee may
8 authorize release from licensee control any
9 patient-administered radiopharmaceuticals or permanent
10 implants containing the radioactive material. The total
11 effective dose equivalent to an individual from exposure to
12 the released patient is not likely to exceed five
13 milliseverts in any one year." That would stay the same?
14 That's correct?

15 MS. DRAGONETTE: Right.

16 CHAIRMAN SIEGEL: Now, what would happen to
17 (b)? (b) should disappear.

18 MS. DRAGONETTE: Depending on what we decide
19 about the written instructions and depending on whether we
20 decide you need to maintain a record for the case by case
21 calculations. I don't think we've worked out the exact
22 language, but those are the two options that are still on
23 the table that might still be in (b).

24 MR. CAMPER: What do you mean by "case by case
25 calculations" in view of the 100-millirem threshold? What

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1 are you referring to by "case by case calculations"?

2 MS. DRAGONETTE: Case by case calculations to
3 demonstrate compliance with the 500 per year would be the
4 new construct. If you're not using the cookbook tables
5 that are provided in the guides and you're using your own
6 assumptions on metabolism, excretion, all of those things,
7 if you're doing your own calculations --

8 MR. CAMPER: I was asking the question in the
9 context of (b) (1) or (b) (2), which is what Barry was
10 getting at.

11 MS. DRAGONETTE: Maintaining that record, (2)
12 would go unless we wanted to put some provision tied back
13 to the 500 for keeping records on the case by case
14 calculations so people may be releasing patients with 400
15 millicuries in them, for example. And we'd like to take a
16 look at what the basis for that was.

17 MR. CAMPER: I understand.

18 MS. DRAGONETTE: Is that your understanding?
19 Bill, do you want to say anything on that?

20 CHAIRMAN SIEGEL: What's wrong with the concept
21 of tying 35.75 to written directives and addressing
22 pregnancy and breast-feeding separately for things that
23 don't deal with written directives?

24 MS. DRAGONETTE: I don't know if we've thought
25 about how to word it connected to the written directive.

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1 We're still trying to decide the course of action. And
2 then where to put the language will come later. So I don't
3 know that we've thought about the exact language that would
4 tie it to the written direction.

5 As far as not addressing the breast-feeding
6 infant in this rule, the problem we have is that now that
7 we have said in the proposed rule, now that the issue is on
8 the table that you should evaluate the exposures to the
9 breast-fed infant and they should meet this dose limit that
10 we have justified exceeding the normal public dose limit
11 and going up to the acceptable upper bound of 500, coming
12 out and saying that we do not want to afford that level of
13 protection for the infant is difficult. And deferring to
14 another rule, the embryo/fetus rule, that may or may not
15 come about is also difficult for us from a philosophical
16 point of view, radiation protection point of view, because
17 we don't know when that rule may go and what it may say and
18 what the requirements are.

19 And we're concerned now with the disparity,
20 what we see would be disparate treatment.

21 MR. CAMPER: Kitty, I understand the reason
22 that you just expressed in terms of not doing it in another
23 rule, although, arguably, one could defend why we didn't
24 deal with it in this rule, clarifying that we would deal
25 with it under a separate rulemaking, because many of the

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1 issues associated with the nursing infant are very
2 complicated and I think rise to a level of specific
3 consideration through the public comment scenario.

4 Now, having said that, though, what I'm
5 probably most troubled about is that the proposed rule, as
6 you have indicated, really didn't talk about the nursing
7 infant within this scenario. And then the question arises,
8 well, if we proceed and publish the rule and that becomes
9 incorporated without a republishing and consideration of
10 public comment on the issue, I'm concerned that we might be
11 subjected to criticism for that.

12 MS. DRAGONETTE: Well, I beg to differ that we
13 didn't raise it. It was explicitly. And I'll read the
14 paragraph in the proposed rule preamble, "In most cases the
15 dose received by an individual exposed to the patient will
16 be from external exposure. However, in the case of a
17 breast-feeding mother, the infant could be exposed
18 following ingestion of breast milk. In this case the
19 five-millisevert limit applies to the infant as the
20 individual likely to receive the highest exposure."

21 And then the companion draft regulatory guide
22 -- you know, explicitly I could read the words -- also
23 elaborated on it even more fully that they would be
24 considered and outlined some of the options they could
25 have.

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1 For example, if they're going to be
2 administered it said the cookbook tables don't apply to
3 persons who are breast-feeding because of the infant
4 problem. And then it said if they are breast-feeding,
5 there are alternatives available, "Licensee may determine
6 that the quantity and type administered would not likely
7 result in more than the five milliseverts."

8 A second alternative would be to stop for some
9 period of time or to postpone the administration if it were
10 medically acceptable.

11 So it was aired in both the proposed rule and
12 the regulatory guide. So we have a sufficient legal basis
13 to include this and to do this while we consider the other
14 separate rulemaking.

15 Now, when the other rulemaking is developed and
16 on the street and we're trying to work how to reconcile the
17 two, then I would think then we might be in a position to
18 do some adjustments. But to defer totally to that
19 uncertainty of maybe someday --

20 MR. CAMPER: Well, then your comment earlier
21 that this wasn't addressed was strictly related to the
22 100-millirem issue, then? I get the impression from the
23 comments you made a few minutes ago that this had not been
24 addressed as clearly as it might have been in the proposed
25 rule.

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1 Now, I guess from what you just read, I assume
2 you're referring to the 100-millirem issue, then, that you
3 just alluded to? Everything you said was about the 500.
4 So I guess your comment, then, was about --

5 MS. DRAGONETTE: The table had both numbers.
6 Complying with the 500, do you consider the infant in
7 meeting that limit?

8 MR. CAMPER: The 500?

9 MS. DRAGONETTE: The 500.

10 MR. CAMPER: Yes.

11 MS. DRAGONETTE: Yes. Maybe we didn't focus on
12 it as much as you would have liked.

13 MR. CAMPER: I think the fundamental --

14 MS. DRAGONETTE: But it was out there on the
15 table.

16 MR. CAMPER: Well, I think the fundamental
17 question becomes one of: What happens in 100 millirem and
18 between 100 millirem and 500 millirem? The idea is that
19 range captures nursing infants, which is the point that you
20 made at the outset.

21 I guess in the final analysis, what we end up
22 doing between 100 and 500 gets at my concern of whether or
23 not we have made it as clear as we might have to the public
24 in terms of the implications for nursing infants in that
25 range.

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1 Now, it's a function of what we end up doing at
2 100 and above.

3 MS. DRAGONETTE: Which at this point we're
4 considering doing very little instructions.

5 CHAIRMAN SIEGEL: And dropping (b)(2)?

6 MS. DRAGONETTE: Yes.

7 CHAIRMAN SIEGEL: That works effectively. I
8 think that's correct. Dennis, are you with that? Do you
9 have a copy of the rule in front of you?

10 MR. SWANSON: Yes.

11 CHAIRMAN SIEGEL: So if I'm reading you
12 correctly, it says you can release people if the dose to a
13 member of the public is not likely to exceed 500 millirems
14 and then if the total dose will exceed 100 millirems, you
15 provide instructions. Including written instructions is
16 the language I would suggest you include.

17 MS. DRAGONETTE: I think that's a --

18 CHAIRMAN SIEGEL: Tell them how you kept the
19 dose ALARA and drop the recordkeeping, drop the Paragraph
20 (2).

21 MS. DRAGONETTE: Right. That's the leading
22 proposal with the one caveat that there's still some
23 concern about documenting your case by case assumptions
24 when you use something --

25 MR. SWANSON: If you release them other than by

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1 a table?

2 MS. DRAGONETTE: Yes.

3 MR. SWANSON: Okay. But then we still have the
4 breast-feeding issue; right?

5 CHAIRMAN SIEGEL: Well, the actual sum
6 recordkeeping if you go outside of tabular limits was
7 actually implicit anyway because you can't comply with the
8 rule. Even if you dropped that second paragraph, you can't
9 comply with the rule without knowing that the dose will be
10 less than 500 millirems.

11 How can you know that the dose is less than 500
12 millirems? You'd know it by common knowledge. And common
13 knowledge is I went to a table and the table says if I do
14 this, I achieve the intended effect or you do a
15 calculation. If you do a calculation, then you've created
16 a record.

17 Now, I guess the issue is: Are you required to
18 keep the record or can you do it on a paper towel and then
19 throw it away? So probably we may need to build something
20 in that if it's not done in accordance with, then you would
21 have to have a record.

22 That's complicated because I know you don't
23 like to tie anything in the rule to the regulatory guide
24 because the regulatory guide doesn't have the legal status
25 and is subject to change.

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1 MS. DRAGONETTE: Right. So that's something we
2 have to think about, how to do that.

3 CHAIRMAN SIEGEL: Yes. I know. We certainly
4 don't want to put the tables in Part 35.

5 MS. DRAGONETTE: No. It would have to be
6 through a rulemaking.

7 CHAIRMAN SIEGEL: That would make it pretty
8 ponderous.

9 MS. DRAGONETTE: Doing the tables for the
10 nursing infants will give you the cookbook direct way of
11 dealing with that issue. That would be our intent,
12 assuming we go ahead down that path, that they would --

13 CHAIRMAN SIEGEL: I would just encourage you,
14 -- I think I said this in October as well -- encourage you
15 as you work more on the regulatory guide that you also
16 consider putting in some guidance that is not generally
17 known in much of the community. And that is that you also
18 consider in the case of I 131 when breast-feeding should be
19 stopped before the I 131 administration because it isn't an
20 hour before you give the I 131.

21 It probably should be two to three weeks before
22 it because the dose to the breast starts to become a
23 significant concern, especially with the large doses of
24 I 131. And, I mean, we may as well educate the community
25 while we're at it.

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1 MS. DRAGONETTE: In that guidance, dealing with
2 the preventative mentioned that as well.

3 MR. SWANSON: This whole breast-feeding issue,
4 the major concern, it seems to me, is that making sure that
5 the mother, who is also the patient here, is adequately
6 informed of the risk to the breast-feeding infant and
7 adequately informed that she will have to or should
8 discontinue breast-feeding and for what period of time
9 because, in reality, it's going to be the mother. I mean,
10 the infant can't consent to this procedure himself or
11 herself. So the mother is making the determination of
12 benefit and risk for the infant, basically. Okay?

13 And so does the issue come down, the true
14 concern come down to making sure that women in general that
15 are treated with iodine 131 are informed of the risk to a
16 breast-feeding infant and what might go along with that?

17 MEMBER NELP: Did you ever put yourself in the
18 position to say -- this is asking about rules and
19 regulations -- "If you receive I 131, mother should not
20 breast-feed," period, and not make it an issue of exposure,
21 make it a point of fact? Did you ever get to that point?

22 DR. GLENN: We do, in fact, have a rulemaking
23 under development for a proposed rule that would talk about
24 how to avoid unintended exposure, certainly, of the
25 embryo/fetus. And also, I think, the Commission originally

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1 directed us to consider the breast-feeding infant. So it
2 would be probably a rule directed at unintended exposures.

3 MEMBER NELP: The real life world is if I have
4 a woman who is breast-feeding and I'm going to treat her
5 for thyroid cancer, which is really the only situation I
6 think that we're talking about --

7 CHAIRMAN SIEGEL: No. Hyperthyroidism also,
8 Buzz, and, frankly --

9 MEMBER NELP: Or hyperthyroidism. I'm sorry.

10 CHAIRMAN SIEGEL: -- a diagnostic uptake dose
11 of I 131 you shouldn't breast-feed.

12 MEMBER NELP: But if you do those things, we
13 usually say "We're going to do this procedure, and you
14 really should discontinue. You have to discontinue
15 breast-feeding or we won't do it under this," period.
16 That's the real world.

17 Yes, there are some diagnostic considerations.
18 And we always say "If you're going to have this test, you
19 stop breast-feeding for 24 hours" or whatever the
20 requirement is.

21 But if it's a high-dose therapy, which is
22 largely what we're talking about, in the real world you say
23 "You have to plan to stop breast-feeding before we do this.
24 It's going to interfere with your treatment, lest we can't
25 treat you."

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1 MEMBER BROWN: Is it enough of a medical hazard
2 that you would consider prescribing -- is it perganol?
3 What's the drug? I know it's under --

4 MEMBER NEMP: Ordinarily for some if they're
5 permanently going to stop, it will stop themselves in
6 plenty of time. And you don't treat these people
7 overnight. You have a --

8 MEMBER BROWN: Well, if what Barry is saying is
9 that you want to stop breast-feeding not only for the
10 infant but because the dose to the breast, you have to
11 permanently stop because it's not like you can stop and
12 start and stop and start --

13 CHAIRMAN SIEGEL: The bottom line --

14 MEMBER BROWN: -- if you're expressing milk,
15 you're still going to be --

16 CHAIRMAN SIEGEL: -- is if you're going to give
17 I 131 iodide to a patient, even a five-microcurie dose for
18 a thyroid uptake, the patient has to stop breast-feeding,
19 period.

20 MEMBER BROWN: Forever.

21 CHAIRMAN SIEGEL: Now, for a five-microcurie
22 dose, I wouldn't stop two weeks in advance because the dose
23 to the breast would be trivial, although the dose to the
24 infant's thyroid would be higher than I would be happy
25 with.

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1 For a five-millicurie dose for hyperthyroidism
2 therapy, I tell patients to stop breast-feeding two weeks
3 before they come for their treatment. And for thyroid
4 carcinoma, same thing.

5 MEMBER BROWN: And never resume?

6 CHAIRMAN SIEGEL: And never ever ever ever
7 resume in that infant.

8 MEMBER BROWN: Because I think it's very
9 misleading when you read all of this stuff about expressing
10 the milk. And it seems like a kind of a temporary --

11 CHAIRMAN SIEGEL: No. That's with a bone scan
12 or pertechnetate.

13 MEMBER NELP: Twenty-four hours.

14 MEMBER BROWN: Okay. So we're not talking
15 about the temporary discontinuation?

16 CHAIRMAN SIEGEL: There are a few
17 radiopharmaceuticals for which permanent cessation of
18 breast-feeding is the medical recommendation. I 131 is one
19 of them. Most people think gallium imaging is another one.

20 MEMBER BROWN: And how does the medical
21 community handle that, do you think? I mean good doctors
22 and bad.

23 MEMBER NELP: Probably very much like we
24 discussed. I don't think, number one, it's too --

25 MEMBER BROWN: Does NRC have any indication

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1 that that isn't happening, that they're worried about that?

2 CHAIRMAN SIEGEL: One event; correct? Two
3 events. Okay.

4 MEMBER NELP: It's only done by people who have
5 particular experience in this area, and it's a very
6 infrequent occurrence. It's taken very seriously.

7 MR. SWANSON: How we address, actually, all of
8 these issues at our institution is we have an informed
9 consent form where basically we require the patient's
10 informed consent to participate in the procedure, which the
11 informed consent form addresses the issues of pregnancy,
12 addresses the issue of breast-feeding. It addresses the
13 instructions to the patient post the procedure. It also
14 addresses that the patient has read the consent form and
15 understands what they've read and any questions they have
16 --

17 MEMBER BROWN: So it says "I am not pregnant.
18 I am not breast-feeding. And if I am, I will stop and not
19 resume"?

20 MR. SWANSON: Correct.

21 MEMBER FLYNN: My question is -- help me with
22 this -- how many of the patients -- you said 60,000
23 procedures a year. How many procedures are done with
24 iodine 131 would be done in the woman in breast-feeding?

25 CHAIRMAN SIEGEL: A small number.

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1 MEMBER NELP: Very.

2 MEMBER FLYNN: One-tenth of one percent?

3 CHAIRMAN SIEGEL: With both therapy of
4 hyperthyroidism and imaging of thyroid carcinoma and
5 treatment of thyroid carcinoma, I probably encounter --
6 it's a total patient group of 250 or so patients a year I
7 think was the number. Stewart, is that the total, 250-300
8 patients in that list I gave you that I lost?

9 One or two a year that this comes up. So it
10 occurs infrequently, but when it occurs, it's something I
11 take very seriously.

12 MEMBER FLYNN: Nationwide, though, it's
13 probably a few hundred a year?

14 MEMBER NELP: Oh, yes.

15 MEMBER FLYNN: Five hundred a year?

16 CHAIRMAN SIEGEL: Probably not much higher than
17 that, but it's, nonetheless, important.

18 MEMBER FLYNN: Oh, yes.

19 MEMBER NELP: But it happens and --

20 MR. SWANSON: My guess would be that strontium
21 89 might also be a problem, although I've not seen any data
22 on what's excreted in breast milk. But since it is a
23 calcium analog --

24 CHAIRMAN SIEGEL: Very, very few patients with
25 metastatic breast cancer being treated with strontium 89

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1 are also breast-feeding. And no patients with prostate
2 cancer are breast-feeding. I think we can say that as an
3 absolute fact. There are few absolutes, but that's one of
4 them. If they are, we have to talk about that in a
5 different kind of vein.

6 Bill, did you have a comment?

7 DR. MORRIS: I just wanted to focus again on
8 the issue of the written directive and the fact that there
9 are certain administrations, as I understand it, that would
10 not be covered by a written directive that would have a
11 potential for causing rather large doses -- well, I don't
12 want to use that word -- doses up in the 500 and above
13 range for a nursing infant.

14 And so the game plan that we have in mind right
15 now is to pick out and specify in the regulatory guide
16 those isotopes which we are saying if you provide
17 instructions for those isotopes to a potentially nursing
18 mother, that that will be a sufficient way to deal with
19 meeting the criterion of likely to exceed 500 millirem.
20 And then included with that would be the dosage and dose
21 relationship that we believe is involved in the specific
22 set of isotopes.

23 Understand it's a fairly limited number. So
24 this would be a short list that's over and above the
25 written directive category that wouldn't otherwise require

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1 a written directive or anything else be done.

2 And then for that set, there would be some kind
3 of an information about when that nursing could resume.

4 And I gather you're saying that for certain isotopes, the
5 words there would be never. But the iodine 131 is probably
6 not -- well, I guess it would be in that list, too.

7 CHAIRMAN SIEGEL: It's critically on that list.

8 DR. MORRIS: Okay. So I want to make sure that
9 it was understood what our idea is right now so that if you
10 have any comments on that particular strategy, we could
11 gather those now.

12 CHAIRMAN SIEGEL: Yes. I do have one comment,
13 and that is as you sit down to start working on that table,
14 that you let one or more of us try to help you with it,
15 either as a formally convened subcommittee to come in and
16 do a working session with you or at least run it by us so
17 that we can react to it and tell you whether we think
18 you're on the right track and whether your science --
19 because this breast-feeding stuff, as I know you all know
20 from having looked at the literature, is not easy to
21 unravel. It's very complicated. It does involve a
22 moderate number of assumptions because the database is
23 fairly limited.

24 There's a relatively small number of patients
25 in which measurements of breast milk activity have been

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1 often enough to come up with decent dose recommendations.
2 And then there are other issues about how much the infant
3 absorbs across the gastrointestinal tract, and it goes on
4 and on in terms of the complexity.

5 As it turns out, most of the other
6 radiopharmaceuticals for which breast-feeding should either
7 be stopped for a very long period of time or permanently
8 ceased are not in your regulatory space. It's gallium,
9 thallium, some Indian radiopharmaceuticals that are
10 non-byproduct. And the vast majority of the other
11 technician things turn out to be things that with rare
12 exception you can handle with a maximum of 24 hours of
13 cessation of breast-feeding.

14 And for some technician radiopharmaceuticals,
15 there's no need to stop at all, like technetium DTPA. The
16 average dose for renal imaging, the standard literature
17 recommendation is not to worry if the dose is too small to
18 fret about.

19 MR. SWANSON: Where it gets complicated is it's
20 not isotope-dependent. It's radiopharmaceutical-dependent.

21 CHAIRMAN SIEGEL: Right. Good. Any other
22 comments? Judy? Buzz?

23 MEMBER NELP: David, does the FDA label,
24 package insert label, say you should not breast-feed or
25 does it say this is excreted in breast milk?

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1 DR. WOODBURY: In most of the regulations I've
2 seen, they've put limits on it, a person should not
3 breast-feed for a certain time limit after administration
4 of the dose. I've not seen a regulation where it says
5 "should not breast-feed ever." Usually, say, with
6 technetium, it's 48 hours or something of that nature with
7 that and weeks, months out.

8 CHAIRMAN SIEGEL: Does the Committee generally
9 agree that the space between 100 millirems and 500
10 millirems should be handled the way we've discussed it,
11 basically that it's an area in which instruction should be
12 provided but that the recordkeeping requirement should be
13 essentially eliminated or only required when extraordinary
14 calculations are used to justify the release? Is there a
15 general consensus on that?

16 MEMBER BROWN: And those instructions are
17 written and verbal, clearly?

18 CHAIRMAN SIEGEL: Correct, yes.

19 MEMBER NELL: Do you have a problem saying you
20 should give written instructions without saying what those
21 instructions should include? I could give a set of
22 terrible written instructions or I could give a very good
23 set of written instructions. Do you require written
24 instructions in any other regulations?

25 It's sort of a new concept to me, but if I were

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1 going to say "Joe, I want you to give this person written
2 instructions. And here's what I want those instructions to
3 include" or do I leave it up to the wisdom of the person
4 preparing the written instructions?

5 MS. DRAGONETTE: The way the rule is
6 formulated, even the proposed rule was formulated, it left
7 the exact content of the instructions up to the physician
8 to be tailored to the procedure and the patient.

9 And guidance was in the draft regulatory guide
10 on topics that should be addressed and why you're
11 addressing them. And the Society of Nuclear Medicine
12 brochure for iodine therapy was mentioned as one that hit
13 the right points.

14 CHAIRMAN SIEGEL: I think in general it would
15 be better to defer --

16 MS. DRAGONETTE: So the scheme would still be
17 in guidance --

18 CHAIRMAN SIEGEL: -- to defer to the regulatory
19 guide that gives examples of what sorts of instructions you
20 might provide and then acknowledges that there are already
21 things out there that you can tap into as ready-made.

22 I mean, the SNM pamphlet has been out for 20
23 years. And you can use that as your instructions. And
24 there are places where you can fill in the blanks about how
25 many hours or days you should avoid Activity A, B, C, or D

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1 that are tailored to that specific patient and their
2 lifestyle and the way they are.

3 I don't think we'd want to have the detailed
4 specific instructions built into Part 35 because they'd end
5 up not being right. And, in fact, then that would start
6 really interfering with medical judgment about what's right
7 for that patient.

8 MEMBER NELP: I was just questioning. Is this
9 a new concept to require written instructions to a patient?

10 CHAIRMAN SIEGEL: Not at all.

11 MEMBER NELP: That's something that --

12 DR. GLENN: It currently exists in the
13 regulations. If you hospitalized and you're going to
14 release them, you do have to already provide instructions
15 to keep the household --

16 MEMBER NELP: Written. No. Written
17 instructions.

18 DR. GLENN: Oh, written instructions? No.

19 MS. DRAGONETTE: You're talking about 35.315
20 and 415 and --

21 MEMBER NELP: See, I think it's an interesting
22 area. If you require written instructions, that's okay,
23 but that doesn't mean it's going to be any good.

24 CHAIRMAN SIEGEL: But neither would the
25 instructions non-written necessarily be any good.

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1 MEMBER NELP: Exactly. That's the whole point.
2 Requiring them to write them doesn't mean that you're
3 providing a quality set of instructions.

4 MEMBER BROWN: Yes, but if you have a bad
5 doctor that's giving you bad instructions anyway, I mean,
6 you can't like police the quality, it seems.

7 CHAIRMAN SIEGEL: I mean, let's say the NRC
8 generates a set of instructions that I am then required to
9 hand out to the patient and I give it to the patient and
10 say "The NRC made me give you these. I don't agree with
11 anything in here.

12 MEMBER NELP: Well, I say "The NRC makes me put
13 you in the hospital for this treatment. I think I could
14 take care of you at home with less cost."

15 CHAIRMAN SIEGEL: Well, you may be able to
16 under this rule.

17 MEMBER NELP: Yes. There may be --

18 CHAIRMAN SIEGEL: I think the content of
19 written instructions is something that should be left to
20 individual physician judgment guided by the activities of
21 professional societies with the NRC tapping into that
22 information for its regulatory guides.

23 And there is good data out there about what to
24 tell patients. It's in ICRP documents, NCRP documents, and
25 it's in SNM brochures that you can buy for 10 cents each

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1 and give to a patient, whatever they cost. They're not
2 very expensive.

3 So the way I heard this overwhelming consensus
4 we generated is that we're basically recommending that you
5 drop proposed 35.75(b)(2) or work it into something that's
6 tied to an extraordinary circumstance. But otherwise we're
7 saying we can work with that rule the way it is.

8 Okay. Thanks, Kitty.

9 We're a little bit ahead of schedule, but it's
10 probably right to take a break. So let's take a 15-minute
11 break.

12 (Whereupon, the foregoing matter went off the
13 record at 9:49 a.m. and went back on the record
14 at 10:07 a.m.)

15 CHAIRMAN SIEGEL: Moving right along, Judy, I'm
16 going to tell you how nuclear medicine practice would be
17 disrupted by this rule because I remembered.

18 MEMBER BROWN: You have to tell me how it is
19 going to be completely disrupted.

20 CHAIRMAN SIEGEL: Well, could it be just
21 partially disruptive?

22 MEMBER BROWN: No. You said completely.
23 That's why I asked: Wasn't it an overstatement?

24 CHAIRMAN SIEGEL: Okay. Let me explain it.
25 Follow my logic. Let me see if I can walk you through

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1 this. If the rule requires that -- not everybody is here.
2 Probably can't start yet.

3 MEMBER BROWN: You know what? I'm okay with
4 this if you don't want to get into it.

5 CHAIRMAN SIEGEL: No. I do because it's
6 actually not for you that I'm doing this. It's for the NRC
7 that we need to work this through because this was
8 something that came up three weeks ago. And because I'm
9 getting old, I didn't remember. I'm not ready to admit
10 what Ronald Reagan admitted yet, but I lost it.

11 Here's the problem. If the rule says that you
12 can't authorize from release people who have -- if someone
13 is likely to be exposed to more than 500 millirems but also
14 says that you have to provide written instructions if
15 anyone will get more than 100 millirems and if that
16 component is not specifically tied to written directives,
17 then in order for a licensee to prove that they're
18 complying with the rule, they will have to have some
19 verification that every woman who was of breast-feeding
20 potential was evaluated and got the written instructions if
21 there was a chance that they were breast-feeding.

22 So in a sense to prove compliance, it almost
23 meant that every woman would end up having to probably sign
24 a statement that says "I'm not breast-feeding."

25 MEMBER BROWN: Well, think of all the paperwork

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1 involved in keeping them in the hospital. I mean, that
2 doesn't sound --

3 CHAIRMAN SIEGEL: You wouldn't have to keep
4 them in the hospital. I'm talking about people who are
5 having bone scans now.

6 MEMBER BROWN: Okay.

7 CHAIRMAN SIEGEL: See, the problem is right now
8 if someone comes for a bone scan, let's say a thyroid scan
9 with technetium pertechnetate, that goes to the infant from
10 that, that might end up being 150 millirems. It's below
11 500.

12 Well, we wouldn't have to keep them in the
13 hospital. We wouldn't have to force them to stop
14 breast-feeding. But we might have to give them written
15 instructions in order to validate that we've caught every
16 woman who needed those written instructions. We'd probably
17 have to ask every woman who could potentially be
18 breast-feeding and may need to document it. And so that's
19 where --

20 MEMBER BROWN: That doesn't sound like such a
21 big deal to me.

22 CHAIRMAN SIEGEL: It's a big deal. It's
23 keeping track of another 10,000 -- okay. I do in my place
24 12,000 patients a year. Half of them are women. Let's say
25 half again of those are of breast-feeding potential.

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1 That's another 3,000 records I have to hold onto. That's a
2 big deal to find the four who might be breast-feeding whom
3 I probably would have found anyway.

4 MEMBER BROWN: But you being a diligent person
5 are going to go through the process to find them anyhow.

6 CHAIRMAN SIEGEL: No. I go through the process
7 by having brochures in my waiting room, having signs that
8 say "If you're breast-feeding, do this," have my
9 technologist ask, but I don't keep a record of it. And
10 that's the part that is of concern. I act on it once I
11 discover it, but I don't keep a record of it.

12 There are a lot of things I do in the day to
13 day practice that I get a piece of information, I act on
14 it, and I don't make a record of it. Not every single
15 thing we do gets written down and kept in inspectable form.
16 So that's the problem.

17 MEMBER BROWN: What about what Dennis was
18 saying about the informed consent? I mean, that --

19 CHAIRMAN SIEGEL: Informed consent is for
20 therapy or for five-millicurie doses of I 131. We don't
21 get informed consent for bone scans.

22 MR. SWANSON: In other words, we're tying the
23 informed consent back to those agents for which we have a
24 written directive.

25 CHAIRMAN SIEGEL: Written directive. So that,

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1 in part, was my rationale three weeks ago for suggesting
2 that fretting about this in relation to the written
3 directive made sense; whereas, addressing breast-feeding
4 generically by an alternative rule made sense.

5 And so I guess if anyone from Research is still
6 here and wants to -- do you all want to say what you think
7 about that potential problem?

8 MR. McGUIRE: The problem you're concerned
9 about is recordkeeping for breast or potentially child --

10 CHAIRMAN SIEGEL: Well, how you would expect
11 that someone could demonstrate compliance in the space
12 between 100 and 500 millirems with respect to whether or
13 not written instructions were provided to a potential
14 breast-fed infant.

15 MR. McGUIRE: I can't see any likelihood that
16 the regulation would specify records for that. I think it
17 would be basically you saying to an inspector that that's
18 your policy and perhaps having some sort of for the written
19 instructions a typical set of instructions that you would
20 give out in a particular situation where it's appropriate.
21 But that's not something that has been developed, a staff
22 consensus on.

23 CHAIRMAN SIEGEL: Okay, I guess.

24 MR. CAMPER: Well, Dr. Glenn and I were just
25 conferring on this very quickly. I mean, if you really

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1 look at it, this ends up being an inspection phenomenon.
2 And it would appear that either it's something that would
3 not be inspected or there would be a record, which could be
4 inspected. And that's an inspection guidance call.

5 DR. GLENN: It could be inspected in general
6 that there is a policy in checking and people have been
7 instructed in that policy, but if there's not a
8 recordkeeping requirement, you would not be able to verify
9 your case by case.

10 CHAIRMAN SIEGEL: But in a way, the direction
11 where we were headed with the pregnancy and breast-feeding
12 rule in the past actually was much more explicit. And it
13 actually provided more assurance that the job was being
14 done properly than this rule does.

15 This rule sort of seems to leave kind of a wide
16 open gap where even though people might be doing a very
17 good job, it's less clear from the language here that the
18 licensee would have to be as proactive in terms of trying
19 to capture those breast-feeding mothers and making sure
20 they get the instructions than the kind of direction we
21 were heading in where there might be requirements for
22 having signs and having brochures or giving a pamphlet to a
23 woman of breast-feeding potential.

24 Comment? John? Steve? Kitty?

25 MS. DRAGONETTE: As I understand your concern

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1 with the diagnostics and if you couple that with the
2 approach, as Morris summarized it before the break, where
3 we would identify just certain radiopharmaceuticals, only
4 certain chemical/physical forms of certain nuclides where
5 this was an issue, that you would have that group of
6 procedures for which you would have to worry about this
7 issue. If the potential if they don't stop nursing is that
8 the infant could get more than 100, then they would have to
9 give the instructions. What does that mean and how do you
10 deal with that?

11 I think that the comments on having a procedure
12 or if we list these, assuming we list these, in the
13 regulatory guide, you'd say "For these procedures, we give
14 the brochure. We give the instruction," but based on our
15 informal discussion, too, you were pointing out that you
16 would need a column in those tables at the 100 and at the
17 500.

18 It would need to trigger the potential for five
19 -- it would need to deal with the two dose limits in giving
20 the instructions. So those tables should include a 100
21 threshold for giving the instructions.

22 CHAIRMAN SIEGEL: Yes. Well, it's another
23 potential problem that I just think needs to be thought
24 about in terms of the way you're going to address ensuring
25 compliance because if it involves having additional

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1 documentation that it's been dealt with, it's more
2 difficult.

3 In that case --

4 MS. DRAGONETTE: John?

5 CHAIRMAN SIEGEL: John, do you have a comment?

6 MR. TELFORD: John Telford, Research.

7 Just let me see if I understand the scope of
8 this problem.. Let's say that there are approximately 2.2
9 million potential breast-feeding patients out of 10
10 million. I think we've done this calculation before.
11 That's approximately correct.

12 But let's reduce that population by those
13 patients who are going to receive radiopharmaceuticals of
14 interest; in other words, the ones we want to watch out
15 for. So now we're down to a smaller subset. I don't know
16 the size of that, but it's pretty small.

17 Then you could reduce that by those patients
18 for which you're going to deviate; that is, not use the
19 cookbook tables in the reg guide. In other words, this
20 departure is for individual calculations. So now we're
21 down to a much smaller subset.

22 So maybe your question is: How do you prove
23 that for all of those patients you did the right thing?
24 And maybe you're asking: Are we expecting the licensee to
25 either document that for each of those patients, however

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1 small, you really gave the instructions or are you asking
2 us if we're going to expect the licensee will show us the
3 typical set of written instructions that were issued to
4 those kinds of patients? Is that the problem?

5 CHAIRMAN SIEGEL: That's part of the problem.
6 I mean, if the answer is we have a procedure in place that
7 says when we do a pertechnetate thyroid scan we ask the
8 patient if they're breast-feeding and if the answer is
9 "Yes," we instruct them about cessation of breast-feeding,
10 if that does the job, then that's fine.

11 On the other hand, if the question is any time
12 we do a study on a woman between 15 and 50 years of age we
13 obtain a signature from them on a form that says "I assert
14 that I am not breast-feeding," that's where it gets -- the
15 latter would be a lot more complicated.

16 MR. TELFORD: I think not.

17 CHAIRMAN SIEGEL: Okay. All right. Let us
18 move on. Janet, the ANPR for Part 35. That ought to be an
19 interesting job.

20 ADVANCE NOTICE OF PROPOSED RULEMAKING FOR PART 35

21 MS. SCHLUETER: My name is Janet Schlueter, and
22 I'm a member of the Medical and Academic Section. I'm
23 going to take just a few minutes to describe to you the
24 staff effort to issue an advance notice of proposed
25 rulemaking for a major revision to Part 35. We commonly

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1 refer to this as an ANPR.

2 (Slide)

3 MS. SCHLUETER: For those of you who are new to
4 the Committee and maybe members of the audience, all of the
5 issues that you have seen laid out before you today and
6 yesterday are all part of a master plan. There is some
7 method to the madness here, and it's called a five-year
8 management plan for the medical use regulatory program. We
9 commonly refer to it as the medical management plan.

10 It has 90 action items, which are spread across
11 9 different program areas and includes such things as
12 licensing guidance, inspection guidance, rulemaking,
13 enforcement issues, misadministrations, patient follow-up,
14 and other program areas. So some of the things that you've
15 heard discussed or, actually, all of the things that you've
16 heard discussed thus far are part of the five-year
17 management plan, with the finale being the major revision
18 to Part 35.

19 (Slide)

20 CHAIRMAN SIEGEL: The finale.

21 MS. SCHLUETER: Yes, of course. Obviously
22 there are many reasons that have prompted the need to
23 revise Part 35. And they have begun as early as after
24 issuance of the 1987 version. We have discovered that
25 there are issues which need to be either clarified or

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1 revised for one reason or another. And these issues have
2 become apparent through inspection effort and also simply
3 implementation of the rule now for seven years.

4 (Slide)

5 MS. SCHLUETER: Also, if you remember back,
6 back in September of 1992, we came to the Committee with
7 what we called a medical issues paper, which did identify
8 some of the major issues at that time --

9 (Slide)

10 MS. SCHLUETER: -- that we believed warranted a
11 re-review of the medical use program. So this is not a new
12 effort, but, rather, a very long-term one, which has been
13 somewhat altered by subsequent events and concerns over the
14 consequences and root causes of those events.

15 Also, as we know from our discussions yesterday
16 in the brachytherapy arena and other areas, there are
17 emerging technologies, which are currently not addressed in
18 the rule, which need to be incorporated.

19 (Slide)

20 MS. SCHLUETER: And then the National Academy
21 of Science study and the subsequent Commission direction as
22 a result of those findings certainly do have an impact on
23 the issuance of the ANPR and the major revision to Part 35
24 in general. And we'll discuss a little bit more about that
25 in detail in just a moment.

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1 (Slide)

2 MS. SCHLUETER: There are milestones,
3 naturally, associated with this project. And the medical
4 management plan calls for the issuance of the ANPR in March
5 of 1995. Obviously that's not very long from now, and
6 there is lots of work to do in this area.

7 The ANPR will not try to suggest a proposed
8 direction for the major revision to Part 35, but, rather,
9 identify major key areas for discussion and issues which
10 need to be brought to the table for open discussion with
11 many different representatives of the medical community and
12 other interested parties.

13 In order to do that, we will be conducting
14 workshops. And, naturally, with the timing of this project
15 being in the 1995 to 1997-98 time frame, the workshops
16 would take place following the ANPR since the ANPR would be
17 the vehicle for discussions at these workshops. So the
18 workshops would be carried out in the Summer and Fall of
19 1995, perhaps into early '96, then with the staff going
20 back and developing some proposed rule language for a
21 proposed rule published in late 1996, obviously issued for
22 comment, and then a final rule late '97-'98.

23 (Slide)

24 MS. SCHLUETER: The list here of workshops
25 doesn't represent individual workshops, but it represents

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1 the parties which we want to come to the table to
2 participate. We would foresee two or three workshops
3 probably would be the expected number. And representatives
4 from these areas we would expect to be at those workshops.

5 There may be workshops which would be keyed to
6 certain subject areas, such as brachytherapy or training
7 and experience perhaps. And obviously parties who had
8 interest in those matters would be invited to attend. But,
9 naturally, the agreement states would be involved. They
10 have already had a briefing similar to this that Larry
11 Camper did at the all agreement states meeting in October.

12 Larry, you might have noticed I changed your
13 order of your slides here while driving in this morning and
14 taking in another last minute look trying to tune out my
15 two-year-old, who was screaming in the rear seat. I
16 switched the order. So if you're trying to follow along,
17 you're going to have to remove the staple.

18 (Slide)

19 MS. SCHLUETER: Also professional societies
20 that we'd like to see attend, obviously there are many in
21 the health physics, medical physics, nuclear medicine,
22 radiation oncology, and so forth. The list goes on and on
23 as to interested parties, cardiologists, endocrinologists
24 and so forth.

25 "All constituencies" sort of refers to the fact

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1 that we need to have representatives from outside of the
2 medical community, obviously. And that includes patients'
3 rights and care advocates, public interest groups, perhaps
4 even insurance company representatives, individuals who
5 certainly have an interest in the impact of a final rule
6 but not necessarily the technical background or interest in
7 the issues.

8 Obviously we also need to have vendors,
9 manufacturers, device manufacturers and suppliers and so
10 forth that would have an interest, particularly in our
11 authorized types of use and radiation safety requirements
12 and perhaps might even have an interest in the training and
13 experience area.

14 (Slide)

15 MS. SCHLUETER: Speaking of training and
16 experience, I guess Dennis needs to hold onto his seat here
17 because the "p" word is at the end of this slide, and I
18 don't mean prescriptive.

19 Training and experience criteria, as we have
20 discussed before, is a very, very big, big issue. I need
21 to also comment here that it's not limited to just
22 physician training and experience. There will be an effort
23 to evaluate the current training and experience for
24 radiation safety officers and physicists and, as we have
25 discussed previously, the medical physicist category versus

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1 brachytherapy/teletherapy physicists, also the need to
2 determine whether or not training and experience criteria
3 are needed for other allied health personnel, not limiting
4 it to the user RSO and physicists, but perhaps
5 dosimetrists, technologists, and other individuals who are
6 directly involved in the administration of byproduct
7 material.

8 I think Larry mentioned briefly yesterday one
9 of our more near-term efforts to address the T&E issue, and
10 that is to issue a "Federal Register" notice which would
11 solicit interested parties, --

12 (Slide)

13 MS. SCHLUETER: -- meaning those parties which
14 conduct the 200 didactic training programs, to solicit
15 their program name and be subject to a review by NRC staff
16 as to the adequacy of that training program, "Does the
17 training program meet the requirements as so stated now in
18 35.920(b)?" and also to take a snapshot of residency
19 training programs also to determine their adequacy.

20 But this is a very near-term and short-term
21 effort. The bigger effort is to gather the parties, as we
22 mentioned yesterday, and to try to identify what are the
23 minimum radiation safety training and experience
24 requirements that we believe are necessary to be authorized
25 to use byproduct material. And that's a much more

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1 long-term, much more difficult process, I believe, but it
2 is all part of this major revision to Part 35.

3 Again, the new and emerging technologies that
4 need to be incorporated into the rule, we currently have
5 efforts now to provide licensing guidance, but that is in
6 the guidance space. It's not in the rule. We do need
7 requirements in Part 35 that address those issues, QA, QC
8 on these devices, who can use them, and minimum radiation
9 safety requirements.

10 (Slide)

11 MS. SCHLUETER: We discussed yesterday and
12 obviously continued on to this morning about brachytherapy.
13 That's a world unto itself here as far as the number of
14 issues that are involved in resolving all of those
15 questions.

16 We'd like to adopt industry standards, wherever
17 possible, or at least provide the licensee with an
18 opportunity to describe an analogous procedure when it
19 comes to quality controls, let's say, perhaps on a dose
20 calibrator or some other aspect of the radiation safety
21 program, and performance-based. And that's simply up there
22 to recognize that the staff will consider whether there is
23 any component of Part 35 that should or should not be
24 performance-based versus prescriptive. It will be part of
25 the process. We're certainly open to whatever the end

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1 result may be.

2 (Slide)

3 MS. SCHLUETER: Now the NAS study. You may say
4 "Okay. You're marching along here. You've got the medical
5 management plan. You're supposed to issue an ANPR. And in
6 the middle of all of this you're going to get back the
7 final report from NAS." Yes, that's correct. We will.

8 The impact on the timing is that the final
9 report, as you know, from NAS is due back in January of
10 1996. And obviously those findings would be of use to us
11 during the conduct of workshops and also soliciting
12 information from interested parties when we do revise Part
13 35.

14 So there is some consideration by the staff
15 that, rather than issuing the ANPR as scheduled in March of
16 1995, that we would perhaps delay this effort until receipt
17 and review of the final NAS report and receipt of any
18 Commission direction that would be provided to the staff as
19 a result of this report.

20 That's being considered. We have not made a
21 final decision on whether or not the timing will be
22 modified. But the most important message, I think, to send
23 is that the process will be a very interesting one in the
24 sense that we do plan on using --

25 (Slide)

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1 MS. SCHLUETER: -- the ANPR as a vehicle for
2 our discussions at public meetings and workshops. We want
3 to lay the issues out on the table, have a very open and
4 frank discussion of various elements of the existing Part
5 35, including the quality management rule. And also
6 through that is then to develop a proposed rule, obviously,
7 and go through the public comment and final rule normal
8 process.

9 I believe that's all that I have on this
10 subject.

11 MR. CAMPER: That's very good. One comment
12 with regards to timing that Janet is alluding to. If we
13 delay the publishing of the ANPR until the NAS study is
14 available to us, bear in mind that we will get the NAS
15 study, the Commission will have to review it, will react to
16 it, staff will analyze it to determine what is in there
17 that needs to be considered in the public arena, in
18 workshops, and so forth, which would mean, then, that
19 workshops would probably not be conducted until certainly
20 late '96.

21 The net result of that is that the revision to
22 Part 35 would then probably be delayed from December of
23 1997 to most likely 1999, perhaps even 2000, depending upon
24 how the workshops and the feedback go.

25 MS. SCHLUETER: That's true.

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1 CHAIRMAN SIEGEL: All right. Any other
2 comments, questions on that? It should be pretty
3 entertaining. You don't think you could reduce this to
4 just like one set of instructions like --

5 MS. SCHLUETER: "Go forth and be good."

6 CHAIRMAN SIEGEL: -- "Maintain doses as low as
7 reasonably achievable"? That would be the ultimate
8 performance-based rule, --

9 MS. SCHLUETER: True.

10 CHAIRMAN SIEGEL: -- like the ultimate 1040
11 form, which is "How much did you earn? Send it in," --

12 (Laughter.)

13 CHAIRMAN SIEGEL: -- something along those
14 lines. Okay. Good. Any other questions?

15 (No response.)

16 CHAIRMAN SIEGEL: Thanks, Janet.

17 All right. Now you're on, Larry. Larry and
18 Cathy are going to tell us about some misadministrations,
19 patient follow-up, notification of responsible relatives,
20 whatever those are, and use of NRC consultants.

21 MISADMINISTRATIONS, PATIENT FOLLOW-UP, NOTIFICATION OF

22 RESPONSIBLE RELATIVES, AND USE OF NRC CONSULTANTS

23 MR. CAMPER: Well, continuing in our tradition
24 of noncontroversial topics, we thought we'd talk with you a
25 little bit more about patient notification and

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1 misadministrations. I'm going to cover first where we
2 stand on the patient notification issue, and then Cathy is
3 going to talk more about misadministrations and some
4 consultant-related kinds of issues.

5 (Slide)

6 MR. CAMPER: You might recall that we have
7 discussed this issue with you previously.

8 Now, this patient notification process, as a
9 way of background for some of the newer members and perhaps
10 the public as well, --

11 (Slide)

12 MR. CAMPER: -- grew out of an effort by the
13 staff in early 1993, where we went back and took a look at
14 therapeutic misadministrations that had occurred between
15 1990 and 1992. There were 72 of those. Well, in asking
16 the regions to conduct a follow-up analysis of how the
17 patient notification process went, we learned some things
18 that didn't make us particularly happy. There were large
19 percentages of the time in which the patient was not
20 notified verbally and even larger percentages of the time
21 of those 72 -- and I realize with percentages, you're
22 always in the low end when you talk with small numbers.

23 But still disturbing percentages of them had
24 not, in fact, been provided the written notification, as
25 required currently in 35.33. Therefore, in May of 1993 we

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1 published Information Notice 93-36 to bring to the
2 attention of the license community this need to conduct all
3 of the patient notification requirements in 35.33.

4 After that information notice was published,
5 the staff then took upon an analysis to take a look at the
6 reporting requirements in 35.33 given the current
7 heightened concern about patient notification. And the
8 purpose of the analysis was to look at the reporting
9 requirements and say "Do they cover everything that we
10 believe is expected in today's medical care arena with
11 regards to notifying patients?"

12 (Slide)

13 MR. CAMPER: We found some weaknesses or some
14 things about the current reporting requirements in 35.33
15 that we felt warranted attention and consideration by the
16 Office of General Counsel. We then put together a
17 memorandum to the general counsel, Office of General
18 Counsel, to explore these issues. And, in fact, we ended
19 up with the exchange of two or three memoranda about things
20 regarding patient notification.

21 The bottom line was that OGC on all the issues
22 that we raised about patient notification concerns, the
23 response really was that "It is covered. All the things
24 the staff has raised are, in fact, covered within the
25 current reporting requirements of 35.33," to which we said

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1 "Hmmm. Okay. If that's the case, then we need to go back
2 out to the regulated community and make them very aware,
3 clearly aware, of all of these various nuances with regards
4 to patient notification issues that might not be readily
5 clear to someone reading 35.33."

6 (Slide)

7 MR. CAMPER: With that, then, we developed
8 another information notice, which we shared with the ACMUI
9 during your meeting in May. And we discussed that
10 information notice at great length.

11 You told us several very important things. You
12 said the issue is closely associated with the practiced of
13 medicine; that clarification provided in the information
14 notice did, in fact, go beyond what licensees had
15 previously interpreted; if it was harmful to tell the
16 patient but you wanted to tell someone, then you ought to
17 make it very clear in your regulations that's your
18 expectation; that the term "responsible relative" was not a
19 clear term and perhaps we should use the term "relative"
20 because who is the responsible relative; -- and Dr. Siegel
21 raised some crucial points on that particular issue --

22 (Slide)

23 MR. CAMPER: -- and that notifying a
24 responsible relative may, in fact, lead to the patient
25 knowing anyway because odds are most of the time that

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1 responsible relative is going to be the spouse. And the
2 spouse would naturally in conversations with the patient
3 make them aware of the misadministration.

4 So we went back, then, after that meeting and
5 looked at the ACMUI's concerns. And we said, "Well, what
6 can we do to make this issue as clear as possible to the
7 regulated community and to give proper and due
8 consideration to the significant concerns that this
9 Committee had raised?"

10 As a result of that process, we made a decision
11 during a management counterpart meeting the second half of
12 May, just a few weeks after this, the meeting I was
13 referring to, --

14 (Slide)

15 MR. CAMPER: -- that we should develop a
16 generic letter, rather than an information notice. And we
17 would do that for two reasons. One is because the generic
18 letter could require the licensees to do certain things,
19 that being to go back, look at any misadministration events
20 that had occurred, make sure that proper notification had
21 taken place, and if they found anything in the course of
22 that process, to inform the agency.

23 Secondly and more importantly, because we felt
24 that this issue was a policy question and, therefore, it
25 would be appropriate to get the Commission's policy

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1 perspective on this issue at this point in time.

2 Therefore, we abandoned the idea of developing an
3 information notice, and we moved to develop the generic
4 letter.

5 You do have a copy of the generic letter in
6 your briefing books.

7 (Slide)

8 MR. CAMPER: Now, in preparing the generic
9 letter, we, of course, have to develop a vehicle for
10 submitting it to the Commission. And that's our Commission
11 paper. Now, the Commission paper explains two of the six
12 issues and the generic letter in some detail, that being
13 the notifying of the responsible relative and the question
14 of clarifying what is a prescribing physician and a
15 referring physician.

16 For the other issues of the six, the remaining
17 four, we referred the Commission to the GL itself. If you
18 look at the generic letter, the GL, --

19 (Slide)

20 MR. CAMPER: -- you'll find that there is an
21 ample discussion of each of those issues.

22 Now, the Commission paper involves
23 consideration of the generic letter, obviously. It also
24 talks about information notices and perhaps rulemaking.

25 Now, you do not have a copy of the Commission

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1 paper because it's still under development. But the
2 essence of the Commission paper is to discuss the two
3 issues I just mentioned, to refer them to the generic
4 letter, --

5 (Slide)

6 MR. CAMPER: -- some background as to why this
7 is being done and so forth, and then to offer to the
8 Commission four possible options.

9 (Slide)

10 MR. CAMPER: Option Number 1 would be to
11 promulgate the proposed generic letter that you have a copy
12 of.

13 MR. CAMPER: This would reaffirm the
14 Commission's intent regarding patient notification. In
15 other words, all of the things that we talked about at
16 great length last time that were currently contained within
17 the information notice and now in the GL would be the
18 Commission's policy on patient notification and that the
19 notification criteria and so forth and so on, as set forth
20 in 35.33, embodies, encompasses, and is clear on these
21 issues.

22 (Slide)

23 MR. CAMPER: Option Number 2 would be to
24 publish an information notice that addresses Issues 2
25 through 6 of the --

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1 (Slide)

2 MR. CAMPER: -- GL to revise 35.33 --

3 (Slide)

4 MR. CAMPER: -- in a fashion that would make it
5 clear that in the case of a competent adult, if the
6 referring physician determines that it would be harmful to
7 inform the patient, the competent adult, that no further
8 notification is required. The notification process would
9 stop at that point.

10 (Slide)

11 MR. CAMPER: Option Number 3 would again
12 publish an information notice on Issues 2 through 6. There
13 would be a rulemaking to revise 35.33, which would clarify
14 and narrow the language to make it clear that in the case
15 of a competent adult, if the referring physician determines
16 that it's harmful to notify that competent adult that an
17 individual; that is, someone, would be notified.

18 (Slide)

19 CHAIRMAN SIEGEL: "The Washington Post"?

20 MR. CAMPER: No, not "The Washington Post," but
21 the idea is that we would have to come up with some clear
22 --

23 MEMBER BROWN: "The Cleveland Plain Dealer."

24 MR. CAMPER: Right. "The Cleveland Plain
25 Dealer." Good suggestion.

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1 No. We would have to come up with some
2 language to make it clear that a notification is going to
3 occur. Someone would be notified. It would not
4 necessarily have to be the responsible relative because of
5 the problems we've already talked about, but someone is
6 going to be notified. In other words, it doesn't just stop
7 with the patient.

8 MEMBER BROWN: Whether you like it or not.

9 MR. CAMPER: Whether you like it or not.
10 That's right.

11 CHAIRMAN SIEGEL: That's right. Turn to Option
12 4.

13 (Slide)

14 MR. CAMPER: And Option Number 4 would be to
15 publish an IN again with Issues 2 through 6, a rulemaking
16 to revise 35.33 that would say that you always notify the
17 patient or a guardian in the case of a minor, regardless of
18 harm. Harm is not a consideration.

19 (Slide)

20 MR. CAMPER: In such a case there would be no
21 other notification. The notification process would stop at
22 that point. And referring physicians would not need to
23 evaluate whether informing the patient was harmful or not.
24 They would be required to inform.

25 Now, that's clearly problematic, I suspect, in

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1 the practice of medicine, but that is the way the option
2 would be structured.

3 CHAIRMAN SIEGEL: Would you structure that one
4 so that it would also include immunity from breach of
5 confidentiality?

6 MR. CAMPER: I think we would have to do that.
7 That was a suggestion by the ACR attorney during the last
8 meeting. And, yes, it would have to embody that.

9 The option that the staff is recommending is
10 the first one, that the Commission would publish the
11 generic letter.

12 (Slide)

13 CHAIRMAN SIEGEL: Can I suggest an Option 5, --

14 MR. CAMPER: Sure.

15 CHAIRMAN SIEGEL: -- which is that you revise
16 35.33 to go back to the original 1976 concept, which is
17 that you notify the patient when there's a likelihood of
18 harm, because that actually then solves another whole batch
19 of problems related to your information-gathering needs
20 that are tied to the administration rule?

21 It means you can set your thresholds for
22 gathering information about things that go wrong at a lower
23 level than actually cause patient harm without raising the
24 whole emotional specter that doctors have been screaming
25 about for the last 15 years about this "You're forcing us

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1 to tell patients that something happened when nobody
2 benefits from that in any way, shape, or form," that
3 there's no point in me sending a patient a complicated
4 letter that I had the lawyer look at because I needed to do
5 that just to cover myself that says "You've got a one-rem
6 exposure to your thigh because the source was dislodged for
7 a minute."

8 There's nothing wrong with doing it. I don't
9 object to doing it because it necessarily is a wrong thing.
10 It just seems it just struck physicians over and over again
11 that that is a ridiculous, illogical intrusion into the way
12 we relate to our patients.

13 On the other hand, I think we all agree that if
14 patients have been harmed or there's a potential for harm
15 as a result of medical misadventure or error or whatever,
16 that the patient has a right to know that concealment is
17 not the standard of care.

18 And it's the fact that both you've tied the
19 general responsibility to let the public know what
20 happened, which is part of the whole structure of the
21 Atomic Energy Act, to your information-gathering needs.
22 That's the thing that I would suggest you disconnect. It's
23 the connection that's created the problem.

24 DR. STITT: Let me speak to Option Number 5.
25 I'm sitting here trying to decide whether to take these two

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1 Advil or get the other two out. Every time we start
2 talking about not notifying patients and finding somebody
3 else, it just drives me crazy, but that's not the point I
4 wanted to speak to.

5 If you look at misadministrations, I think all
6 of us who have been involved in it, the staff and
7 consultants alike, see the vast majority have essentially
8 no medical consequence and certainly no harm. Those are in
9 many cases technical misadministrations. We've heard lots
10 of examples. So I won't go through them.

11 If you look at a whole variety again that we
12 know well here where there are significant problems, there
13 are medical consequences. If in the situation of the man
14 who had the prostate implant with the sources that were of
15 excess activity -- I mean, we're not talking about letters.

16 The letter is not important. What's important
17 is the doctor was obligated to go to the patient ASAP to
18 say "There's a major problem. Here's what's happened. We
19 have to do another step because we've got trouble on our
20 hands." I mean, that patient had to be informed.

21 How about the patient we heard about yesterday
22 who had the 50-centimeter extra length of high-dose-rate
23 tubing so that the knee got treated and the area that
24 needed to be treated got zero dose? Those patients had to
25 be told because it medically was important. They all went

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1 back and had another go-around of treatment because they
2 had to get the area treated.

3 So I think we need to focus on what the
4 important thing is here. It's certainly apparent to me
5 that somebody's irked because they think the M.D.'s are
6 being sneaky and not telling their patients what happened.
7 So then we've got a bunch of regulations with different
8 options and different numbers of bullets about how we're
9 going to get around making doctors 'fess up to some things.

10 When it involves medical care, if the IV dose
11 was wrong, the medication dose, the radiation dose, you
12 have to involve the patient and the family because you have
13 to make medical decisions and carry out medical treatment.
14 I think that's where the issue belongs.

15 And I'd like to see some versions. I like 5
16 better than 1 through 4, which are more paper trails than
17 anything. They don't have to do with how to take care of
18 these patients.

19 I think the harm business that the doctors are
20 using has to do with medical consequences harm, but also
21 emotional harm. The source got stuck in the tube as it was
22 coming out. It had to be reported because it was a wrong
23 site, but that doesn't have any medical consequence. It
24 doesn't have medical harm. It does have emotional harm.
25 And so I think the docs are using that as a method of

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1 saying "This is harmful to the patient. So I prefer not to
2 tell them."

3 But if we focus on medical consequences, maybe
4 we can get out of that area. I know we haven't been able
5 to use that for defining misadministrations, but this is a
6 different issue.

7 I'll just take two Advil, and I'll let you know
8 how it's going.

9 MEMBER BROWN: I'm wondering how the
10 characterization of people thinking the doctors are sneaky
11 and not informing their patients jibes with NRC's saying
12 that it was a problem when they looked at these
13 misadministrations. Did I get that wrong? I mean, it
14 didn't come out of nowhere, I think.

15 DR. STITT: Well, if patients weren't being
16 informed, I'm just making guesses the doc said "This
17 happened," let's say. How about the computer discrepancy
18 that occurred months to even years after patients had been
19 treated. Is that important? Is that going to cause
20 harm/lack of harm if you're go send a patient a letter a
21 year and a half later on something that had no particular
22 consequence?

23 So it's my personal statement when they see
24 that all of these things are not reported, that they were
25 making an interpretation and we have to make the docs

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1 conform to this particular rule.

2 MEMBER BROWN: I guess I need to know: Was
3 there a value judgment put on whether these patients should
4 have been informed? Was there a harm element there?

5 DR. STITT: And how would the NRC be able to
6 make that judgment because those are medical judgments?

7 MEMBER BROWN: Right. But you all have medical
8 consultants who are looking at misadministrations; right?

9 MR. CAMPER: Of the 72 cases that I have
10 mentioned that we looked at, something like 25 to 30
11 percent of them were not given the verbal notification that
12 they should have been given. Something like 50 percent or
13 so were not provided with the written follow-up
14 notification.

15 Now, the analysis demonstrated many reasons why
16 this didn't occur. In some cases, particularly with
17 regards to the written follow-up, which was the bigger
18 problem of the two, there was probably some lack of
19 familiarity or a thorough understanding of the regulatory
20 requirement.

21 CHAIRMAN SIEGEL: Right.

22 MR. CAMPER: In some cases there was just an
23 administrative error in that the written notification
24 wasn't provided for reasons that one might expect: it just
25 slipped through the cracks, someone else thought someone

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1 else had done it, things like that.

2 There were a few cases, though, where the
3 reason given was inconsistent with the regulatory
4 requirement in the sense that there were cases where the
5 physician said "This was of no consequence. It did not
6 have a deleterious effect. And, therefore, I don't think
7 it's necessary to inform the patient."

8 In those cases, we did go back to the regions
9 and then follow up with those instances and make it clear
10 that that reason, while the physician may genuinely believe
11 that, was not consistent with the regulatory language and
12 was not, therefore, acceptable that notification would have
13 to take place.

14 CHAIRMAN SIEGEL: But, on the other hand, it's
15 the intrinsically logical one.

16 MR. CAMPER: It is the intrinsically logical
17 one. It's the same problem that we've had discussions
18 yesterday, some of the perceptions or feelings about
19 misadministrations in general in the sense that remember
20 again that few of them are really in the range of
21 consequence. Many of them, in fact, result in exposure
22 that in some cases would still have been within an
23 acceptable range of treatment.

24 (Slide)

25 MR. CAMPER: Again, I would say that the

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1 criterion is one that's designed to capture errors of the
2 delivery process. It's a fairly tight criteria. And, as a
3 result of that, in most cases, in some cases not true, but
4 in most cases there is not harm.

5 Therefore, some physicians believe that the
6 reporting requirement is unnecessary. It's trite or
7 picayune. And, therefore, they don't necessarily care to
8 subscribe to it.

9 But, be that as it may, we were compelled in
10 those few cases where that happened to go back and say
11 "Well, that's not consistent with the regulatory
12 requirement, and it's unacceptable."

13 MEMBER FLYNN: May I make a comment? I mean,
14 I've looked at as an NRC consultant about 20
15 misadministrations in the last year, year and a half, year
16 to year and a half.

17 And there were many instances why the patient
18 wasn't informed. A lot of times it was confusion.
19 Sometimes there were several instances that I had whereby
20 the radiation oncologist notified the referring physician
21 and the referring physician said "Well, notifying the
22 patient is just going to cause anxiety. This will not
23 benefit the patient."

24 And then the radiation oncologist, rightly or
25 wrongly, decided not to notify the patient because the

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1 radiation oncologist had dealt with the referring
2 physician, who did not want to notify the patient. And the
3 referring physician is not regulated by the NRC.

4 MR. CAMPEL: Correct.

5 MEMBER FLYNN: And the referring physician
6 expressed the opinion to radiation oncologists that
7 notifying the patient would just cause the patient anxiety
8 and would be of no benefit to the patient and then puts the
9 radiation oncologists in an awkward position that the
10 referring physician is giving a strong opinion. And so in
11 some cases the radiation oncologist didn't notify the
12 patient because of that reason. There were other reasons,
13 too, but what about a --

14 MEMBER BROWN: And what did you think? Did you
15 think the patient should have been notified?

16 MEMBER FLYNN: Only in one case, and they did.
17 They did notify the patient once they understood the
18 regulation. Some have gone back and re-looked at the
19 regulation and notified the patient anyway in some cases.

20 MEMBER NELP: With any of these 20 instances,
21 did any of the misadministrations harm the patients in any
22 substantial way?

23 MEMBER FLYNN: I would say 90 percent no harm,
24 and then there was a couple with possible harm. There was
25 one with a painful ulcer, a few like that, but the patient

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1 was notified in that case.

2 What about another option? What about Barry's
3 suggestion that if the patient's notified by the authorized
4 user, if the authorized user judges that there's a risk of
5 harm? So that's an option, but you could have whereby the
6 authorized user notifies the referring physician.

7 I think what I'm hearing from Judy is that
8 she's worried that some other person, other than the person
9 who administered the radiation, who may be following the
10 patient should be aware, even in the unlikely event where
11 no harm was expected, something is noticed by the referring
12 physician who was also following that patient.

13 MR. CAMPER: Well, currently it's incumbent
14 upon the licensee unless the referring physician informs
15 the licensee that they will either inform them or they're
16 in their medical judgment informing them that it would be
17 harmful.

18 MEMBER FLYNN: One thing is the authorized user
19 informs the referring physician, --

20 MR. CAMPER: Right.

21 MEMBER FLYNN: -- does not inform the patient
22 directly unless the authorized user believes that harm
23 might come to that pati nt. And then in that case he not
24 only contacts the referring physician, but he also contacts
25 the patient.

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1 I think that's what Barry was saying except I
2 added the --

3 CHAIRMAN SIEGEL: There's actually another way
4 around that that removes the authorized user from the
5 potential conflict of interest scenario, although there's
6 an issue of timeliness that is of concern. And that is
7 that the standard operating procedure for
8 misadministrations these days is that they involve a
9 medical consultant.

10 The medical consultant could actually be the
11 one who independently makes the judgment of whether or not
12 there is the potential for harm working as a consultant to
13 the NRC, not involved with the care of that patient
14 directly or indirectly in any way, shape, or form, and that
15 could become the criterion for whether the patient has to
16 be --

17 MR. CAMPER: That's a good point. I was going
18 to ask you that because if we go the harm route, which
19 obviously there's a lot of logic to it, the question is:
20 What does that do to the timing of notifying the patient?

21 CHAIRMAN SIEGEL: Right.

22 MR. CAMPER: Who ultimately has responsibility
23 for making that call? And then how does that process
24 unfold?

25 CHAIRMAN SIEGEL: Right. And the problem I was

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1 going to address with timeliness is right now the
2 conception of this rule, as I understand it, is that that
3 24-hour notification is so that that patient can say "Oh,
4 my God." These are terrible doctors. I've got to get out
5 of here and go to another hospital and get someone who's
6 competent to take care of me."

7 The 15-day notification is sort of the legal
8 information you've got in hand so you can go visit your
9 lawyer and say "Okay. Let's see what we can really do to
10 fix these doctors."

11 And the only problem with letting a medical
12 consultant participate in the judgment is that it might
13 interfere with the 24-hour notification concept. But I
14 think --

15 MR. CAMPER: Well, I think it can --

16 CHAIRMAN SIEGEL: -- in serious
17 misadministrations, you're getting medical consultants in
18 the loop. I mean, I've been called within an hour or two
19 of the time that the region has been notified of an event.
20 And so I'm there to make a judgment pretty quickly.

21 And some things are obvious. I mean, you know,
22 if someone who has an intact thyroid gland gets 50
23 millicuries of I 131 and they weren't supposed to get it,
24 it's pretty obvious that they're going to develop
25 hypothyroidism and that they need to know that and they

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1 need to get medical follow-up.

2 On the other hand, one that I was involved
3 with, a patient who was getting imaging for thyroid
4 carcinoma and got three millicuries of I 131, instead of 2,
5 because there was an error in the dose when, in fact, the
6 rest of the country typically uses between 5 and 10, that
7 patient wasn't going to be harmed by that at all. That
8 kind of error and that thyroid was already gone. So that
9 was inconsequential.

10 MR. SWANSON: I don't even think you have a
11 huge timing problem in that if you still had it in your
12 regulations that you would notify the patient in the event
13 of potential harm within 24 hours, you're going to have a
14 timing problem with those events where they weren't
15 notified if the medical consultant felt they should have
16 been notified. So it's going to be only a limited number
17 or limited subset.

18 CHAIRMAN SIEGEL: It is. It is a small
19 fraction.

20 MEMBER FLYNN: That somewhat compromises the
21 harm concept, though. You're only going to notify them
22 when harm is the criterion, as opposed to alarming them
23 when it's not necessary.

24 MR. CAMPER: Potential problem.

25 MEMBER FLYNN: Yes, I understand. But even

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1 there --

2 DR. STITT: I think "harm" is a word that's
3 very hard to put any definition to.

4 MEMBER FLYNN: It is.

5 DR. STITT: Let's be specific about what we're
6 talking about. One thing that this concept does, there are
7 going to be some overt circumstances. And I gave the two
8 that are really clear and classic: the massive iodine
9 implant and then those women who actually didn't get any
10 treatment.

11 In order to get good medical care, part of your
12 next step is saying "We had a problem. This was not done
13 in proper fashion. Now we have to talk about where we're
14 going to go."

15 So those wouldn't ever be put in that pool. I
16 mean, they will be seen by a medical consultant, certainly,
17 but not for the question "Does this patient need to be
18 informed?" They obviously have to. And some of the
19 thyroid circumstances are going to e out of that pool
20 because they have to have immediate information given to
21 them.

22 But the large gray area where I think -- I
23 don't think -- I know that most of these misadministrations
24 that we review end up in could be well-served if we don't
25 use the word "harm," but let's find a word that's specific.

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1 Let's find a word that talks about what we're really
2 looking at, the medical consequences, long-term issues. I
3 mean, let's define what it is because "harm" is also used
4 by lawyers. And every time you get real close to that, it
5 makes us nervous.

6 CHAIRMAN SIEGEL: And, unfortunately, we have
7 explored this a bit in the past. And then you get into the
8 quandary about I think we all know what to do with
9 deterministic effects, where the thresholds are reasonably
10 well-defined. We get confused about what to do with
11 stochastic effects. Where do you decide to draw the line
12 for the subsequent genetic risks or for the risk of
13 radiation-induced carcinoma?

14 And we've traveled that road before. It is
15 complicated, but, nonetheless, it seems to me that trying
16 to readdress this issue of what really warrants patient
17 notification and have it somehow disconnected from your
18 need to gather data about events that occurred out there
19 would be of benefit to both the NRC and to the world at
20 large.

21 Judy, wait a second. Myron has been chomping
22 at the bit for 10 minutes there. So --

23 DR. POLLYCOVE: Because I'm trying to answer
24 your question, Judy, because I don't think anybody has
25 addressed it directly. I think Judy's question was: Well,

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1 this is all very well to say that you don't have to notify
2 them unless you think there are significant medical
3 consequences, but what does the record show?

4 This didn't come out of nowhere. It seems that
5 the concern of the NRC to a large extent is based upon the
6 fact that there have been instances in which there have
7 been medical consequences which the physician knew about
8 and did not notify the patient.

9 Well, I've been personally involved in an
10 investigation of Sacred Heart Hospital here in Maryland
11 looking into what happened to 37 patients, only a few of
12 which were notified. And there was a significant overdose
13 given as a result of the computer being programmed
14 incorrectly, as Barry stated.

15 Well, we had our own consultant go out and look
16 over all 37 instances. There was one of the 37 in which he
17 thought that it may have probably or it may not probably --
18 there may have been a contributing factor. These patients
19 had metastatic cancer of the brain, were treated. He
20 thought there was one in which possibly the survival might
21 have been shortened. And that was the very careful post
22 facto analysis of what went on.

23 So, although there may be rare instances in
24 which the physician knows that there's been significant
25 harm and in which it was concealed, I don't know of any in

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1 which it's been documented.

2 So it must happen, but it's very rare. And
3 where we've looked into these things, where the physician
4 knew about it, where there was a serious consequence, they
5 were notified. And where subsequent review demonstrated
6 there were no significant consequences, they weren't
7 notified.

8 CHAIRMAN SIEGEL: Judy?

9 MEMBER NELP: I will comment. The
10 misadministration's part of this, I believe, is in giving
11 wrong dose or the dose to the wrong individual, which
12 happens as a human error in a diagnostic setting where the
13 doses are very low. But those people automatically have to
14 be informed on the spot, say "I'm sorry. We have a
15 problem. We can't do the study requested today on you
16 because you've received inadvertently the wrong diagnostic
17 agent. You'll have to schedule another time to come back."

18 CHAIRMAN SIEGEL: Most of those are actually
19 not misadministrations any longer.

20 MR. CAMPER: Right. They are not.

21 CHAIRMAN SIEGEL: Not any longer.

22 Judy, there's an issue. And I know where
23 you're coming from, which is this right of
24 self-determination and the right to know everything that's
25 going on in your space as a human being. And I believe in

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1 that right, but one also has to understand that asking for
2 all of that information and demanding all of that
3 information has a cost that comes with it. And I'll give
4 you an example or come up with an example.

5 Let's say that one clearly has a circumstance
6 where a small alteration in the radiation dose occurs with
7 the patient and clearly in the physician's judgment, this
8 is inconsequential. Explaining the fact that it is
9 inconsequential to the vast majority of patients,
10 nonetheless, takes a lot of time. And going through the
11 additional paper trail and everything associated with the
12 NRC notification, crafting the letter carefully takes a lot
13 of time. That's time that's actually quite unreimbursed.

14 And so before you get upset about this --

15 MEMBER BROWN: No. I'm getting upset about
16 something else.

17 CHAIRMAN SIEGEL: Okay. When a physician makes
18 a decision not to tell a patient about something because
19 it's of no consequence, part of what the physician is
20 protecting is the amount of effort that might be involved
21 to explain it in great length to the patient, for which
22 there will be no reimbursement. There is no CPT code for
23 completion of an NRC notification. There's no way to bill
24 the Health Care Financing Administration for that. There's
25 no way to bill Blue Cross for that.

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1 Let's say you're confused about something legal
2 and you go to see your lawyer and your lawyer gives you a
3 five-minute explanation and you say "That's not enough
4 information for me. I want the hour explanation." The
5 meter is running, and you're going to pay for that.

6 When you go to a physician and you say "I'm not
7 satisfied with the five-minute information," the meter is
8 off. All the physician can charge you for is the base
9 procedure that he's getting reimbursed for or the base
10 consultation. And so physicians in an effort to keep
11 themselves efficient make these judgments.

12 It's not concealment. I know you may interpret
13 it as concealment. It's not. It's the practical decisions
14 that we make about how we're going to get through the day
15 and do the most good for the most people with the time that
16 we have available to us.

17 MEMBER BROWN: I have a different concern, and
18 the concern is that people more and more are trying to be
19 informed patients. They're also just trying to be informed
20 consumers. And I think your bringing up the lawyer may
21 make a good analogy.

22 When you go to a lawyer and you're not sure
23 about their recommendation or something, you could go to
24 someone else. You could go the same and get a second
25 opinion with the doctor.

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1 However, in your specialty, it's so arcane, I
2 guess, for lack of a better word, that nobody is ever going
3 to know that a mistake was made in the calculation of some
4 dose because it was some computer thing. I mean, these are
5 hidden errors. It's not like going to a regular doctor,
6 where I could go home and I could ask my husband, I could
7 go look into it, "Was that right?" kind of thing.

8 I mean, I can be as informed as I could
9 possibly be as a lay person, and I'm never going to get
10 into your area. I think that imposes on you a greater
11 obligation to tell when something screws up because even if
12 something has not harmed me, I've been going to your
13 laboratory for a year now and I've been getting a certain
14 kind of treatment every month or something. And it turns
15 out that I didn't know it, but with no harm to me, you had
16 some dosimetrist or someone who has been screwing up on a
17 regular basis. I want to know that, even though there's no
18 harm to me.

19 I have no judgment to say "I don't think I
20 should be going to these guys. Even though there's no
21 harm, I don't like the way they operate." See, I can make
22 those judgments about a lawyer, about another doctor.
23 There are other people to ask.

24 CHAIRMAN SIEGEL: Do you really think you can
25 make those judgments about another doctor?

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1 MEMBER BROWN: Yes because I have --

2 CHAIRMAN SIEGEL: Do you think you understand
3 the --

4 MEMBER BROWN: -- resources if I have a problem
5 with the --

6 CHAIRMAN SIEGEL: Why do you think you don't
7 have the resources here? That's --

8 MEMBER BROWN: I don't have resources because
9 --

10 MEMBER NEMP: Do you know if I read your
11 electrocardiogram properly?

12 MEMBER BROWN: I guess --

13 MEMBER NEMP: You don't check up on that if I
14 --

15 MEMBER BROWN: Yes. I guess I do. If I don't
16 think you have, I can send it to someone else if I were.
17 But what you gave me in a certain dose and it was
18 calibrated wrong or something is totally hidden, totally
19 hidden from me, unless someone tells me.

20 CHAIRMAN SIEGEL: I apologize, but this is the
21 illogical disconnect between radiation risks and other risk
22 assessment in our society. That's what you're saying
23 without really realizing you're saying it. It's because --

24 MEMBER BROWN: But doesn't it indicate a
25 quality control problem?

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1 CHAIRMAN SIEGEL: -- people don't understand
2 radiation risks, somehow people who use radiation at low
3 risk levels have an obligation to do more than people who
4 use other risky things. And that's ludicrous. We have an
5 obligation to do just the risk amount and no more.

6 MEMBER BROWN: I don't think so. I think you
7 have an obligation if there's a procedure that's totally
8 invisible to the patient. If you have a --

9 CHAIRMAN SIEGEL: Judy, Judy, here, magnetic
10 resonance imaging, you have no risk, none whatsoever, but
11 you have no way of knowing that I'm using the wrong pulse
12 sequences that are incapable of getting the diagnostic
13 information that the examination is intended to provide.
14 And if you think what we're talking about is arcane, you
15 ought to talk about the pulse sequences on magnetic
16 resonance imaging.

17 MEMBER BROWN: Yes. But I send you whatever
18 your product is from the imaging to another doctor, and
19 they say "Hey, they didn't do this right"; right?

20 CHAIRMAN SIEGEL: They might be able to say
21 that.

22 MEMBER BROWN: Well, they might. There's
23 somebody out there. But if you have given me the wrong
24 treatment, --

25 CHAIRMAN SIEGEL: Yes.

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1 MEMBER BROWN: -- it's absolutely invisible.
2 Nobody is ever going to know that. Nobody is even going to
3 know -- I mean, the patient isn't even going to know you
4 messed up.

5 MEMBER NELP: Could you be more specific?
6 Could you give me an example of what's going on in your
7 mind, --

8 MEMBER BROWN: Well, to be real --

9 MEMBER NELP: -- of how you could be harmed
10 from your --

11 MEMBER BROWN: Well, I'll just use the example
12 I gave, and maybe I'll elaborate a little on that. I'm
13 going to your facility, and I've been going at regular
14 intervals. And apparently I have been mistreated, there's
15 been a misadministration perhaps every time I go.

16 MEMBER NELP: You've been treated a number of
17 times.

18 MEMBER BROWN: Okay. And say every time I go
19 --

20 MEMBER NELP: But, you see, that's not the real
21 world. Ordinarily you go in and you get a treatment for a
22 condition, and that treatment encompasses a short period of
23 time, very high-dose short therapy or one single
24 administration. It doesn't happen repetitively. The
25 mistake isn't repeated, repeated, repeated.

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1 MR. CAMPER: I would add that I would
2 understand why you would say that as a nuclear medicine
3 physician, but I'm --

4 MEMBER NELP: Well, I'm trying to get into the
5 real world.

6 MR. CAMPER: Well, but the real world is --

7 CHAIRMAN SIEGEL: But it may not be in
8 oncology.

9 MR. CAMPER: -- in therapy, there are many,
10 many procedures which are fractionated procedures in
11 teletherapy. I'm saying most misadministrations and
12 therapy involve HDRs, manual brachytherapy, and
13 teletherapy. Very few misadministrations involve
14 radiopharmaceutical therapy. I'm just trying to make that
15 point clear, although I would see why you would say that
16 coming from the nuclear medicine perspective.

17 DR. STITT: But we've taken --

18 MEMBER NELP: Well, high-dose radiotherapy is
19 commonly how many --

20 MEMBER FLYNN: It's unlimited.

21 DR. STITT: Say that again.

22 MEMBER FLYNN: Two to five.

23 DR. STITT: How many fractions?

24 MEMBER NELP: Yes.

25 DR. STITT: Two to six.

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1 MEMBER BROWN: Even if it's just to make a
2 determination that I'm not going to go back to that place
3 or I'm not going to recommend it to somebody else --

4 CHAIRMAN SIEGEL: Judy, I agree with you
5 completely except for one thing. Then make it uniform
6 across medicine. Make there be a federal law that says
7 every time a nurse gives you the wrong pill, your referring
8 physician has to be notified and you have to be notified
9 within 24 hours orally and 15 days later by a letter.

10 MEMBER BROWN: So we get back to the --

11 CHAIRMAN SIEGEL: And don't say that we have to
12 be held to a higher standard than the rest of society.
13 That's what you're saying, and it's ludicrous.

14 MEMBER BROWN: We get back to the basic
15 discussion that we generally deteriorate into, which is I
16 vote for that, Barry, and --

17 CHAIRMAN SIEGEL: Then fine.

18 MEMBER BROWN: I think that your --

19 CHAIRMAN SIEGEL: Call your congressman.

20 MEMBER BROWN: Not in this Congress.

21 CHAIRMAN SIEGEL: Alert the media.

22 MEMBER BROWN: Yes, but your profession is
23 unique and I think wonderful in its recordkeeping. I think
24 it's a standard other professions should look to.

25 CHAIRMAN SIEGEL: We're being flailed by the

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1 NRC to do things, --

2 MEMBER BROWN: Yes, but look at your track
3 record.

4 CHAIRMAN SIEGEL: -- some of which we would not
5 do on our own. And sure, yes, you can argue that we've got
6 a great track record --

7 MEMBER BROWN: You've got a great track record.

8 CHAIRMAN SIEGEL: -- because the NRC has beaten
9 us to death. And that may be right, but then get Congress
10 to change all those other laws:

11 MEMBER BROWN: Well, one's doable. One we're
12 talking about at this table.

13 CHAIRMAN SIEGEL: Right. And that's --

14 MEMBER BROWN: And one's for Congress to change
15 all of the laws.

16 CHAIRMAN SIEGEL: So now what you're doing is
17 exactly what we have said the NRC does, "It's my act, right
18 or wrong." That's Atomic Energy Act tunnel vision. And
19 that's because "We've got this Act, and it allows us to
20 impose these ridiculous restrictions on physicians. Let's
21 do it. Unfortunately, we don't have an act that allows us
22 to do it for all the rest of medicine. So let's not worry
23 about it."

24 That doesn't make sense. It's not fair.

25 MEMBER BROWN: Wait. Hold it.

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1 CHAIRMAN SIEGEL: Carl has a comment.

2 MEMBER BROWN: Wait a minute. You're saying
3 that this act allows you to impose all of these ridiculous
4 restrictions on physicians. Yet, you're hearing from
5 someone who is supposed to be looking at this from a
6 patient point of view.

7 CHAIRMAN SIEGEL: Right.

8 MEMBER BROWN: Now, where does that fit in? I
9 mean, isn't that also important?

10 CHAIRMAN SIEGEL: Sure, that's important. But
11 don't just take the Atomic Energy Act as an out and use
12 that as the basis for doing all the --

13 MEMBER BROWN: It's not an out. It's an
14 opportunity to really get the patient to get some --

15 CHAIRMAN SIEGEL: Well, I guess. That's just
16 illogical. I apologize.

17 DR. PAPERIELLO: Yes. I want to --

18 CHAIRMAN SIEGEL: Carl?

19 DR. PAPERIELLO: Patient notification, however
20 we got there, is in Part 35. And it was a Commission
21 decision before my time. I mean, that's given. If people
22 want to revisit it, there are petition rights. Congress
23 can change the law. The National Academy could say "You're
24 all wet." And the Commission could make some decisions.
25 They may require legislation.

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1 I don't know that. I mean, I'm dealing with
2 practical issues. My job is to enforce the Commission
3 decision. And I'm trying to do it as efficiently as I can,
4 and that's how we're into this.

5 We require when you don't notify the patient to
6 notify a responsible relative. Now, that's where we have
7 some real practical problems that have occurred.

8 We have cases. Face it. You're dealing in
9 most cases with cancer therapy, elderly patients, and you
10 may run into people who have no immediate family. So it's
11 usually pretty easy if there's a spouse or a child or a
12 parent to somehow cook up a response to a relative. And
13 I'm not trying to use any loaded words. I'm just saying
14 most of us know what that means.

15 I don't know. We now get into a problem when
16 there is no somebody like that. And it wouldn't be unusual
17 for an elderly patient with no children, perhaps to have
18 their spouse dead or no spouse at all. Their parents
19 clearly would be dead. And you may be talking about
20 somebody quite some distance away. And, secondly, we have
21 had physicians object that the individual was a competent
22 adult and the like.

23 OGC has made a finding on this, on how
24 compliance with the regulations are to occur. Now, that's
25 their responsibility to do that. By putting this

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1 information out as a generic letter, that raises the
2 visibility within the agency I work. Okay? An information
3 notice I can sign out and almost have nobody else take a
4 look at it. The generic letter requires a number of
5 concurrences.

6 We're going to offer the Commission an
7 opportunity to reaffirm this is what they meant,
8 recognizing that it's not the same group of people on the
9 Commission, but the United States Congress does the same
10 thing, too, in the original rule.

11 That's basically where we are. We're dealing
12 with a very limited issue. We are not revisiting the issue
13 of patient notification that is in the rule. We are
14 talking about a situation in which I have patients where it
15 is not obvious, you don't have immediate family to be
16 notified.

17 And does the Commission really want the
18 physicians to turn around and look for the second cousin
19 twice removed or something like that to be notified? And
20 if the Commission says "Ye . That's what we're going to
21 do," which is, of course, what we're being told that by our
22 Office of General Counsel needs to be done, then it's my
23 obligation to enforce that thing. I'm giving the
24 Commission in the sense a chance to say "Well, we think
25 maybe we didn't really mean that." That's really where we

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1 are.

2 Now, are there other ways to accomplish the
3 same thing? Of course, obviously if you have a rulemaking,
4 that gives the Commission a chance to revisit a decision
5 they already made.

6 And that's kind of where I'm at right now. And
7 I appreciate all of the other issues because they've been
8 debated in the past. And I think the National Academy
9 study may give us a chance to revisit the whole thing.

10 CHAIRMAN SIEGEL: So what you're saying is
11 you're not willing to introduce Option 5, which is change
12 the rule and tie notification to harm?

13 DR. PAPERIELLO: No. I'm afraid right now I
14 think changing the rule is going to await the results of
15 the National Academy study. Then that may be on the table.
16 I mean, that would be the time frame in which it is
17 something like that.

18 I think right now I don't think I would ever
19 get concurrence in the agency right now to change that
20 rule.

21 MEMBER BROWN: So did we spend all the time
22 discussing it when it wasn't even a possibility?

23 MR. SWANSON: Weren't some of your other --

24 DR. PAPERIELLO: Right now?

25 MEMBER BROWN: Yes.

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1 DR. PAPERIELLO: Yes. That's why I tried to --

2 MEMBER BROWN: Sorry.

3 DR. PAPERIELLO: No, no. Please don't. No.

4 The issues are there, are important.

5 CHAIRMAN SIEGEL: And it's not going to go

6 away.

7 DR. PAPERIELLO: There's this unrest to be
8 resolved. I look on this Committee to be of immense value
9 to bring these issues to the table.

10 MR. SWANSON: Some of your other options,
11 though, didn't they involve revising the rule?

12 MR. CAMPER: Yes, they do.

13 DR. PAPERIELLO: It would be involved in
14 developing rule language, which you would clarify the
15 interpretation by changing the rule and expanding, defining
16 in the rule what the responsible relative is.

17 MR. SWANSON: So why can't we consider Barry's
18 option in the same light?

19 DR. PAPERIELLO: In principle you could. I'm
20 dealing with it on a practical thing. The Commission would
21 not want to, and I don't think the EDO would go along with
22 it.

23 CHAIRMAN SIEGEL: Three of the options --

24 DR. STITT: Options 2, 3, and 4 all involve
25 rulemaking.

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1 CHAIRMAN SIEGEL: Three actions do involve
2 rulemaking.

3 DR. STITT: Maybe they were set up so that the
4 only one possible is Option 1, which is what he suggested
5 we go with anyway.

6 MR. CAMPER: No. They are provided as genuine
7 options. The staff is recommending the first option for
8 the reasons that Carl is touching upon right now. We think
9 that the probability of success with the other options at
10 this point in time is minimal until such time as the NAS
11 study is developed and so forth.

12 But, be that as it may, the other options are
13 viable options. I think at this point what we should do is
14 go back and take a look at what you've said today with
15 regards to a fifth option, analyze your comments in the
16 transcript, talk this over with management and so forth,
17 and see if adding the fifth option is a viable possibility.

18 If we were to do that, I think then what would
19 be appropriate would be to distribute that option and the
20 supporting information that Judith Stitt was getting at
21 with regards to trying to define or describe not
22 necessarily harm but consequence and run that by the
23 Committee to see if the language makes sense if we were to
24 include the fifth option.

25 CHAIRMAN SIEGEL: I would submit one other

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1 minor consideration, even though I know OGC would disagree
2 with this. I actually think that the current rule if you
3 read the language agrees with Option 2. And it's only if
4 you dig deep into the preambles of various rulemakings
5 along the way that you find out that somewhere along the
6 way Option 2 was -- that it was meant to be that you always
7 informed somebody unless you could prove that both the
8 patient and a responsible relative would be harmed because
9 obviously the next logical question is: Well, one
10 responsible relative is harmed, surely there must be
11 another one who wouldn't be harmed.

12 And ideally that means you have to go and find
13 every potential relative living in the United States or
14 otherwise who could be informed about this, which seems a
15 little silly.

16 MR. CAMPER: You're saying the responsible
17 relative has taken many additional twists and turns --

18 CHAIRMAN SIEGEL: Yes. I agree with this.

19 MR. CAMPER: -- beyond the immediate and the
20 obvious.

21 CHAIRMAN SIEGEL: I mean, maybe I don't read
22 legal English, but I read 35.33. And to me those "ors" are
23 pretty clear there. And the fact that if the patient would
24 be harmed, you still have to tell the responsible relative
25 unless the responsible relative would be harmed just

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1 doesn't come to me by reading 35.33.

2 It comes to me as I read the last information
3 notice in what you're proposing in the generic letter. I
4 think I understand where it came from if I go back to some
5 of the preambles back to '76, but it's not clear from the
6 language of 35.33, which is why I previously suggested if
7 that's really what you mean, then just say "Inform them.
8 And damn the torpedoes. And don't worry about whether you
9 harm the patient or not. Just tell them."

10 MEMBER FLYNN: The compromised position would
11 be in 35.33 to notify the referring physician because
12 presumably notifying the referring physician will not bring
13 harm to the referring physician. And if that's a medical
14 professional who can take an objective stance, a trained
15 licensed medical professional who also has the best
16 interests of the patient at heart and will be seeing that
17 patient in follow-up, the long-term care for various
18 things.

19 And then when we notify the patient of a
20 responsible relative, if you think that there's a risk, a
21 significant risk or a possible risk, of medical
22 consequence, adverse medical consequence, to the patient,
23 then you also notify the patient directly. But if you
24 don't think there's going to be an adverse medical
25 consequence, you can make the judgment not to notify the

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1 patient, but to notify the referring physician within a --

2 MR. CAMPER: That's actually a variation of
3 Option Number 5.

4 MEMBER FLYNN: Yes.

5 MR. CAMPER: And consequence is the determining
6 factor.

7 CHAIRMAN SIEGEL: All right. Well, we have
8 explored this issue.

9 MR. SWANSON: Ad nauseam.

10 MR. CAMPER: Thank you.

11 CHAIRMAN SIEGEL: Good. Cathy?

12 MS. HANEY: Good morning. My name is Cathy
13 Haney. I'm in the Operations Branch in the Division of
14 Industrial Medical Nuclear Safety. What I want to spend a
15 couple of minutes this morning talking to you about is
16 NRC's follow-up of patients who have received a
17 misadministration.

18 In July of 1994 NRC issued an internal
19 management directive. It was titled "NRC Medical Event
20 Assessment Program." Many of the people who have acted as
21 medical consultants have already received copies of this
22 document.

23 (Slide)

24 MS. HANEY: Up on the screen right now you see
25 what the objectives of this directive were. Basically it's

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1 just to set forth the policy for NRC's follow-up and
2 investigation into medical events as it pertains to this
3 Committee, primarily misadministration events. That really
4 covers the first two billets on the screen. The last one
5 is to ensure licensees have complied with the notification
6 requirements of Part 35.

7 As a result of two recent misadministration
8 events, we have gone back and we have looked at this
9 management directive and focused on two particular items in
10 the management directive --

11 (Slide)

12 MS. HANEY: -- regarding patient follow-up.
13 The first one is that NRC will follow up on patients until
14 the deterministic effects of the event have been determined
15 by the medical consultant.

16 The next one really goes into the area of
17 follow-up, but if the medical consultant feels that the
18 patient should be followed beyond that initial review, they
19 would recommend it to us. And NRC management would
20 determine if the follow-up is necessary.

21 As I say, we're re-looking at these two issues
22 and what they mean. And because of that we've come up with
23 a couple of questions that we would like to pose to the
24 Committee and get your feeling and input on these
25 questions. And they'll be factored in, too, if we need to

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1 make any changes to the management directive or how we
2 follow up on events in the future.

3 (Slide)

4 MS. HANEY: The first question is: What is the
5 appropriate role of the NRC and the medical consultant and
6 long-term patient follow-up in the case where the
7 consultant has recommended that long-term follow-up would
8 be necessary?

9 CHAIRMAN SIEGEL: We have addressed this
10 question in the past. I'm trying to remember what we told
11 you.

12 MEMBER NELP: Do you have a specific patient or
13 incident in mind?

14 MS. HANEY: There were two incidents. They're
15 described in your briefing books. The main one that
16 prompted this was the recent incident with the patient with
17 the prostate implants, the Iodine 125 implants.

18 (Slide)

19 CHAIRMAN SIEGEL: The long-term follow-up has
20 two concerns associated with it generically. One is the
21 issue to get the point of wanting to gather information
22 about consequences of the events and understand them and
23 using that as part of a scientific database.

24 I think we've kind of acknowledged in past
25 discussions that the frequency of events is sufficiently

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1 low that they're not adding much to the scientific
2 literature in terms of learning more about thresholds and
3 deterministic effects than we already know.

4 The other issue is what the NRC's role is in
5 making sure that the patient gets whatever medical care is
6 necessary. I'm having trouble remembering what we told
7 you. We didn't think that that necessarily was something
8 the NRC needed to be involved with because once the patient
9 was informed, it was likely to happen most of the time,
10 most of the time, not necessarily all of the time. And I'd
11 be curious to hear what others might think.

12 MEMBER FLYNN: At least in the 20
13 misadministrations I looked at, I always made a point to
14 call the referring physician also. And I would ask the
15 referring physician if he understood the misadministration
16 and also if that referring physician had planned to follow
17 the patient along because one of the questions the NRC
18 asked the medical consultant is "Do you feel that the
19 patient will receive adequate follow-up?" And so it's back
20 to the care-givers of the patient.

21 CHAIRMAN SIEGEL: Right, but --

22 MEMBER FLYNN: The referring physician is
23 following the patient, and the radiation oncologist is
24 following --

25 CHAIRMAN SIEGEL: One of the problems --

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1 MS. HANEY: I think what we're keying in on is
2 in the case where you as a medical consultant came back to
3 us and said "No. We don't think that the referring
4 physician/licensee, whomever, is adequate." What do we do
5 at that point?

6 CHAIRMAN SIEGEL: Well, what can you do? I
7 mean, the problem then is that we're not allowed to
8 participate in the case as medical practitioners. We're
9 consultants to the NRC. If we express an opinion that the
10 patient is not getting adequate care, as individual
11 physicians we have no way of intervening in that process
12 and may, in fact, be viewed as practicing medicine without
13 a license in whatever state it happens to be that this is
14 going on.

15 It's also not clear what in current NRC rules
16 would allow the NRC to compel the referring physician or
17 the licensee to do something for further follow-up.

18 For example, I mean, the patient at this point
19 may have completely left licensee control. In fact, the
20 patient may have fled to somewhere else for their therapy
21 appropriately. Now the patient is being taken care of by
22 another physician.

23 And I don't see how the NRC could write a
24 letter that says "You know, by the way, this patient isn't
25 getting adequate medical care. And you'd better do

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1 something about it." That would be the NRC practicing
2 medicine without a license.

3 DR. STITT: Are you saying that you're getting
4 medical consultant opinions back that are saying the
5 patient's not being appropriately followed or they can't
6 get --

7 MS. HANEY: No. We're looking ahead to if that
8 situation came about, what is our next step because that
9 would be a real time and we couldn't sit around and think
10 at that point about making a decision that might take a few
11 weeks? We would like to have some --

12 MEMBER NELP: What is the NRC's projected
13 interest in this information? I mean, the person who had
14 this misadministration with the implants and the prostatic
15 cancer, it's pretty obvious what the damage was
16 immediately. What is your projected interested in this
17 patient five years from now or two years from now? Is that
18 what I'm hearing?

19 DR. GLENN: Let me make a little comment on
20 that. I think it's more immediate than that. In this case
21 there was ongoing radiation exposure that could potentially
22 be mitigated. And the advice we were receiving was certain
23 things should be done to mitigate the consequences of this
24 exposure. Then what role should we be playing with the
25 licensee and the referring physician to try to see that

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1 that happens? That's the real question we're asking.

2 MEMBER NELP: Well, that seems to be different
3 than what you were talking about.

4 MS. HANEY: I think maybe we'd better --

5 DR. GLENN: Well, okay.

6 MS. HANEY: I think we have both cases. We
7 have the immediate situation where there's a real life
8 situation.

9 MEMBER NELP: I wouldn't describe that as
10 long-term follow-up. That's acute intervention, I think.

11 MS. HANEY: Right. There are actually two
12 questions that are involved in this. One is the short
13 term, which is what John is talking about. I'm looking
14 more at this question at this point as asking more about
15 the long-term after the initial determination is made.

16 MEMBER NELP: Perhaps you could answer the
17 question: And if I tell you what's the status of this
18 patient five years from now or three years from now or
19 whatever long term is, -- to me that's long term -- what
20 would you wish to do or how would you wish to use that
21 information knowing that you're going to have 10-20 bits of
22 this information per annum or whatever the number is? Why
23 do you wish to have the information? And what do you
24 propose to do with it?

25 MS. HANEY: I think our primary concern -- and,

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1 John, you can help me if you want -- is just that the
2 patient would be getting adequate medical care. True
3 statement?

4 DR. WOODBURY: Are you going to legislate
5 adequate medical care?

6 MS. HANEY: Maybe I shouldn't have used
7 "adequate."

8 MEMBER NELS: And what is long term? Long term
9 in our business means a year or two years at intervals or
10 six-month intervals, et cetera, et cetera. That's rather
11 short term.

12 DR. GLENN: My sense is that when we in the
13 staff have talked about long term, it's actually been
14 shorter than that as a rule. It may be six months to a
15 year where there may be some -- you're going to have to
16 wait a while in order to see what complications develop.

17 And then perhaps the NRC should reevaluate any
18 need for involvement. But I can't envisage what --

19 DR. WOODBURY: You're not suggesting that the
20 attending will care less for the patient than NRC will,
21 that follow-up?

22 DR. GLENN: There does come a question about
23 whether the attending physicians are the ones who have the
24 right expertise. In other words, again, this is based on
25 --

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1 DR. WOODBURY: For follow-up?

2 DR. GLENN: -- recommendations of our medical
3 consultants about need for follow-up.

4 MEMBER NEMP: Well, he's probably saying "I
5 can't clearly tell if this has any consequence, but I might
6 be able to tell a year or two down the pike." I would
7 imagine that's what he's telling you.

8 In the case of the person who had the immediate
9 consequence that required immediate medical attention, you
10 know exactly what happened to that patient. Is that
11 correct?

12 I'm simply trying to get you to tell me how you
13 wish to use the information. I don't think you can use the
14 information to direct a patient's medical care.

15 DR. STITT: It sounds like both questions are
16 NRC wants to practice medicine. And you have to go to
17 medical school --

18 DR. WOODBURY: That's exactly right.

19 DR. STITT: -- and be licensed. There must be
20 something behind what you're asking and you're not
21 expressing it.

22 MS. HANEY: No. I think your response is --
23 there is nothing really behind this question. But it's just
24 to --

25 DR. STITT: Then what's the question?

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1 MS. HANEY: -- see if that is how this is
2 perceived.

3 DR. WOODBURY: Why does the NRC want to
4 practice medicine? That's what it --

5 MR. CAMPER: No, no, no, no, no, no, no, no,
6 no. We don't want to practice medicine.

7 MS. HANEY: No. It's not that we do want to,
8 but if this question is prompting that.

9 MR. CAMPER: And you've absolutely asked the
10 right question. And trust me when I tell you it's a
11 question we've weighed amongst ourselves. What do you do
12 with this --

13 MEMBER NERP: Well, why do you want it in the
14 first place?

15 MR. CAMPER: Well, let me explain. What do you
16 do with this when you get it? I mean, what are you going
17 to do? Are you going to conduct epidemiological studies?
18 Are you going to have the NRC clinic? I mean, what are you
19 going to do? That's a question, trust me, that we've
20 weighed very heavily.

21 The question might be worded differently to say
22 the following: If you look at the first two bullets up
23 there -- I mean, there are going to be certain
24 circumstances. And the case described here is a situation
25 where this patient's condition, its final outcome, has not

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1 come to closure yet.

2 MEMBER NEMP: "Not come to closure"? Would you
3 define that?

4 MR. CAMPER: Well, the event --

5 CHAIRMAN SIEGEL: Just because he has a
6 fistula, Buzz, doesn't mean that -- Larry chose the wrong
7 word maybe.

8 MR. CAMPER: Yes, bad choice of words. But the
9 event is still ongoing or the consequences of the event are
10 still ongoing and they will be for some time.

11 The question could be asked differently. If
12 you look at the first two bullets up there, is there
13 anything inappropriate about the guidance that currently
14 exists within our management Directive 8.10? Is there
15 anything else we should be doing that we're not doing as
16 described in those two bullets?

17 CHAIRMAN SIEGEL: Yes, actually there is. I
18 can figure out a way to let the medical consultants help
19 the licensees without them being somehow at risk because, I
20 mean, I tell you talking to some of these doctors, I'm an
21 academic person. It's hard for me not to want to teach
22 while I'm on the telephone talking to them. And it's hard
23 for me not to want to say "Listen, here's what you need to
24 do. And I can't tell you exactly what to do long term, but
25 call my friend at" such and such. "And he'll give you some

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1 advice how to handle this patient."

2 I mean, I think medical consultants -- and I
3 know this is a very tricky legal issue at the interface
4 between a special government employee and directing the
5 medical care of a patient, but we can help a lot in helping
6 to make sure that the licensee does the right thing if the
7 licensee seems to not be directed if we only can get the
8 leave to do that.

9 Otherwise it's not clear to me what the NRC
10 wants to do. And I know we've heard this. We've heard
11 this from the Commissioners. I think it was at one of our
12 briefing Commissioner Curtiss said something to the effect
13 that "Gee, it just seems like when a patient has been
14 harmed by some application of byproduct material, we have
15 this ongoing responsibility to make sure that that is
16 ameliorated to whatever extent possible." Now, that is one
17 interpretation of the Atomic Energy Act.

18 You know, the FDA doesn't become the patient
19 advocate in the event that a patient has a drug reaction or
20 gets injured as a result of a device. They just don't do
21 it. I mean, it's assumed that the medical care system and,
22 where appropriate, the tort system will take care of the
23 problem over the long term.

24 I think in a way it's admirable that the NRC is
25 willing to participate in this long-term follow-up and try

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1 to make sure that the right thing is done, but in a way
2 you've tied the hands of the people who can best help you
3 do that by telling us we're not allowed to tell the
4 licensee what to do.

5 MEMBER FLYNN: The instructions, like for the
6 20 that I had, say "Do not offer advice," but the way
7 around that is I ask the referring physician, let's say,
8 "Have you noticed any rectal bleeding? Does the patient
9 have any painful bowel movements?" All of a sudden, the
10 referring physician is thinking, "Gee, maybe that's what I
11 should be looking out for."

12 CHAIRMAN SIEGEL: It's indirect advice.

13 MEMBER FLYNN: Sometimes they ask you what
14 might happen, and you can tell them what might happen. But
15 you can't tell them specifically what to do about it. But
16 you can educate a referring physician very quickly without
17 telling him what to do, without prescribing to him what to
18 do.

19 CHAIRMAN SIEGEL: This has also come up in
20 other aspects of the whole misadministration issue, which
21 is when that first phone call comes into the region 10
22 minutes after the event or an hour after the event has
23 occurred and there is potentially an opportunity for a
24 health physicist at the other end of the phone to suggest
25 "Now, it's real important that you consider the following

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1 things as part of what you're going to do in the next 24
2 hours."

3 In general I know you don't do that because you
4 feel you shouldn't or can't do that. And, yet, here's a
5 real opportunity to ameliorate the circumstance. And that
6 opportunity gets past much of the time.

7 Sometimes it slips in inadvertently. It's hard
8 not to teach. When you know a piece of data that can help
9 someone and they're obviously not expressing it, it's
10 almost irresponsible not to teach.

11 MEMBER FLYNN: One physician asked me "Do you
12 think I should have notified the patient?" And instead of
13 answering him, I just read off the 35.33.

14 CHAIRMAN SIEGEL: "You be the judge."

15 MEMBER FLYNN: And then he notified the
16 patient.

17 CHAIRMAN SIEGEL: "You be the judge."

18 MR. CAMPER: Your analogy to FDA is
19 interesting. I mean, now, we do business a little bit
20 different than FDA --

21 CHAIRMAN SIEGEL: Absolutely.

22 MR. CAMPER: -- in the sense that we're more
23 user-oriented than the FDA. But still there are parallels.
24 And even when a significant event occurs, as you're saying,
25 now, FDA will go through certain evaluations and see if

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1 there are generic implications and this kind of thing.

2 But what you might also be saying in another
3 way is that, really, if you look at the content of the
4 bullets, first two bullets, that's quite a bit. I mean, we
5 are doing a lot there that's worthwhile. And it may be
6 that that in itself is appropriate with the exception of
7 what you've --

8 CHAIRMAN SIEGEL: I'll go it, but I'll go a
9 step further. FDA may be the bad example. Let's take a
10 state licensing board. That's more directly akin. If I'm
11 licensed to practice medicine in the State of Missouri, if
12 I do something that harms a patient, the Board of
13 Registration for the Healing Arts of Missouri doesn't enter
14 into a long-term follow-up arrangement to try to see
15 whether that patient's medical care was delivered
16 correctly.

17 Dennis, go ahead.

18 MR. SWANSON: I think what it boils down to in
19 reality is the role of the NRC in this is really limited to
20 ascertain that the patient has access to medical care.

21 Once you get beyond that, if they do have
22 access to medical care, you're limited by two factors.
23 Number one, you're limited by your own policy statements
24 that you're not going to intrude where voluntary standards
25 are already in place. And, Point Number 2, you can't

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1 intrude into the patient-physician relationship. Okay?

2 So, really, in answer to your question, you're
3 limited to making sure that the patient has access to
4 appropriate follow-up care. That's really all you can do.

5 MS. HANEY: Okay. All right. Well, I'm going
6 to skip over one of the questions I was going to ask
7 because I think it's already been answered as well as
8 probably the last two, but maybe we'll touch on them real
9 briefly.

10 The next one is "Should NRC determine whether
11 patient will consent to follow-up care if the medical
12 consultant recommends long-term follow-up?" The key here
13 is: Should NRC? Again, what is the role?

14 CHAIRMAN SIEGEL: What would you do with the
15 data?

16 MS. HANEY: Okay.

17 CHAIRMAN SIEGEL: Do you have very many folks
18 who are being followed by the Oak Ridge people?

19 MS. HANEY: I'm not aware of what the exact
20 number is. We have made referring physicians, authorized
21 users depending upon who was identified to us aware of the
22 Oak Ridge program. And I'm not sure at this point the
23 number that have actually been fed into that system. But I
24 think we may be in the stage right now where we're making
25 the program aware to the patients or making the patients

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1 aware of the program. Okay?

2 And one last one, which, again, is probably
3 already answered.

4 (Slide)

5 MS. HANEY: This question -- I'll read it and
6 then give you a little background. "In those cases where
7 the referring physician has informed the licensee that in
8 his medical judgment notifying the patient would be
9 harmful, what is the role of NRC when the medical
10 consultant indicates long-term patient follow-up is
11 appropriate?"

12 Now, from what I've heard before, NRC has a
13 limited role. So we probably don't go further into this
14 question. Is that?

15 CHAIRMAN SIEGEL: Well, in part, it also
16 depends on not only whether notifying the patient would be
17 harmful, but also whether the event is likely to cause
18 harm.

19 MS. HANEY: Right. Okay.

20 CHAIRMAN SIEGEL: So, I mean, if the event is
21 unlikely to cause harm, then there's nothing to do there.
22 I mean, again, if the event is likely to cause harm and
23 even though the patient wouldn't have been notified, the
24 amelioration would require that someone likely will have
25 been notified to set the matter straight.

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1 MEMBER NELP: Well, you wouldn't know about it
2 unless someone had realized the mistake and notified you in
3 the first place. So they're already acting on that --

4 CHAIRMAN SIEGEL: I think so.

5 MEMBER NELP: -- mistake by the time you hear
6 about it.

7 MEMBER FLYNN: If you believe that intervening
8 will diminish the harm, then at that point I would say you
9 can intervene, despite what the referring physician says
10 because he's not a trained nuclear medicine physician or
11 radiation oncologist. I don't think that will ever happen,
12 but that's the only circumstance I could see where you
13 would want to intervene.

14 MS. HANEY: Okay. Anything else? Thank you
15 very much.

16 MEMBER NELP: I'm just trying to think of one
17 other thing.

18 CHAIRMAN SIEGEL: Is it practical for the --
19 it's probably not -- NRC to have like another group of
20 names out there who are not NRC consultants that they could
21 tell licensees that "If you wanted more information about
22 physicians, you could contact to figure out more about how
23 to handle this patient. You could call the bureau at the
24 American College of Radiology. And they'll make a
25 recommendation to you in your state about someone who can

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1 do that"?

2 MEMBER FLYNN: Well, Indiana, Pennsylvania. I
3 know that I was just down there giving a lecture -- I mean
4 down in Oak Ridge. I'm sorry. They were telephoned by
5 some of the patients, other visitors and nursing staff.
6 They have given them sort of generic information
7 telephonically, and they know that if they have further
8 questions, they can call there.

9 CHAIRMAN SIEGEL: Just maybe letting people
10 know that REACTS and that group is a resource, that there's
11 an (800) number, and you can call and you'll get a referral
12 or you'll get the information would be one way for you to
13 do it in a very neutral fashion.

14 MEMBER FLYNN: And they're interested in
15 long-term follow-up.

16 CHAIRMAN SIEGEL: Carl?

17 DR. PAPERIELLO: Can I address that issue? We
18 had a big IG investigation and a bunch of other things.
19 I've told people. I've done this in the past. And now I'm
20 told I'm not allowed to do this. And that is when I first
21 got in this business eons ago, I was told I was allowed to
22 tell licensees. As long as I gave them three names of
23 consultants, you know, that way I wasn't -- you know, I'm
24 not allowed to recommend people somewhere.

25 Well, we've been now told we're not allowed to

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1 do that, but we are allowed to refer people to professional
2 organizations. So if somebody turns around and says that
3 "I have a licensee that has an accident. They contaminated
4 part of a building and they don't have the expertise to
5 clean it up," I can refer them to the American Nuclear
6 Society. I can refer them to the Health Physics Society.
7 Obviously in the medical area I could refer them to the
8 American College of Nuclear Physicians or American College
9 of Radiology in that sense. I can't refer them to an
10 individual practitioner or something like that. So we are
11 allowed to do that.

12 CHAIRMAN SIEGEL: Now, tell me what you do,
13 though, when you move in with either an IIT or an augmented
14 team to deal with an ongoing event. How much do you
15 intervene in terms of what's being done under those kinds
16 of circumstances?

17 DR. PAPERIELLO: I would say it the way Dr.
18 Flynn just said. You know, inspectors constantly ask
19 leading questions, "When licensees have problem, have you
20 considered these filter media? Have you consulted what's
21 in NCRP?"; whatever it is that deals with how you make
22 these measurements or deal with this problem in a sense.
23 There are things that you just have to do.

24 My feeling is as long as you are tied to
25 something that represents some kind of consensus standard,

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1 something that is not well, the inspector saying "If I were
2 doing this, I would do it this way"; in other words, you
3 give people altitude, I think we're keeping within the
4 spirit of what our mission is.

5 CHAIRMAN SIEGEL: Got it.

6 MS. HANEY: I'd just like to say one more
7 thing. In the instructions that the consultants get, it's
8 part of the charter. And it's under the category where it
9 says "Things That You Shall Not Do." But there is a
10 statement there where "You shall not recommend a particular
11 expert."

12 But if someone comes to you or you feel as a
13 consultant that an expert is needed, I would recommend you
14 go to your contact at NRC and discuss with them because
15 there are provisions to allow certain information to be
16 given out. And this is what Carl was saying. So be sure
17 if there is a gap there that you do come back to whoever
18 your contact is on that particular case.

19 CHAIRMAN SIEGEL: The other obvious thing if I
20 can make a final joke -- Larry has already heard this --
21 about what you could do if you think a patient isn't
22 getting adequate long-term follow-up care. You can just
23 leak the information to the "Cleveland Plain Dealer," and
24 then the patient will probably get adequate care
25 thereafter.

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1 MS. HANEY: Okay.

2 CHAIRMAN SIEGEL: Okay. Thanks, Cathy.

3 ADMINISTRATIVE MATTERS

4 CHAIRMAN SIEGEL: Next we're on to
5 "Administrative Matters" and up through "Close." I guess
6 the bylaws are first. Am I running this? Okay.

7 You all will remember that at the last meeting,
8 we had some draft bylaws. And with Susan Fonner's indirect
9 help and with our direct editorial work, we did a slash and
10 burn on the bylaws. We reduced them to the bare minimum.
11 And they have since had minor, exceedingly minor, editorial
12 corrections made in them and have been sent by the EDO to
13 the Commission. And the Commission has approved the
14 bylaws. Is that correct?

15 MR. CAMPER: That's correct.

16 CHAIRMAN SIEGEL: As draft bylaws waiting to be
17 adopted by us.

18 MR. CAMPER: Correct.

19 CHAIRMAN SIEGEL: As you will know, I pointed
20 out at the Commission briefing a few weeks ago that if we
21 just changed one word, we won't have to approve these
22 bylaws until the next meeting. However, it is my
23 recommendation that they're pretty neutral at this point
24 and they don't hurt us very much one way or the other. And
25 they do provide some rules of conduct.

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1 MEMBER BROWN: You need a motion?

2 CHAIRMAN SIEGEL: We need a motion to approve.

3 MEMBER BROWN: I make a motion that we approve
4 the bylaws.

5 MEMBER FLYNN: I second.

6 CHAIRMAN SIEGEL: Okay. Is there any
7 discussion on the bylaws?

8 (No response.)

9 CHAIRMAN SIEGEL: Hearing none, I will call the
10 question. All in favor of approval of the bylaws, say
11 "Aye."

12 (Whereupon, there was a chorus of "Ayes.")

13 CHAIRMAN SIEGEL: All opposed?

14 (No response.)

15 CHAIRMAN SIEGEL: Let the record show that we
16 approved the bylaws unanimously. Wonderful. That took a
17 lot of time to do.

18 CHAIRMAN SIEGEL: Next I guess is Commission
19 briefing. You should have all received copies of the
20 annual briefing report, which included the transcript of
21 Carl's presentation as well as my presentation and the
22 slides that Carl used as well as the slides that I used. I
23 think it was despite our reluctance to have a briefing
24 because we didn't think there was much to talk about, I
25 think that the half an hour we spent talking was worth the

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1 time to discuss it with the commissioners. It was perhaps
2 a little bit less formal than we've been in the past, but I
3 think it was quite successful.

4 As you will see, we focused on three things:
5 patient notification, a little bit about brachytherapy, and
6 then this. I finally thought it was time to put the
7 training and experience paradigm on the table and let the
8 Commission be aware that we've really been talking about
9 this over and over and over again and that we want the
10 chance to tackle this in a serious way in Part 35. It will
11 be at least one opportunity to get to this eventually.

12 I'll answer any questions that any of you have
13 about the Commission briefing.

14 MR. QUILLIN: You also made a brief allusion to
15 the Office of General Counsel.

16 CHAIRMAN SIEGEL: Right. And if you haven't
17 read the transcript, I just suggested that our working
18 relationships with OGC have been sometimes tense and we
19 wanted them not to be tense because we need to learn from
20 them because none of us are lawyers and we don't understand
21 the legal constraints under which we operate and we haven't
22 needed to discuss anything with them at this meeting but
23 hope that in the future we can get them to speak with us
24 frankly. And I acknowledge that they always reserve the
25 right to change their minds once they study the issue

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1 thoroughly, as does everybody.

2 Okay. Now you, Larry and Janet.

3 MR. CAMPER: I have several just general issues
4 to go through with you very quickly, the first being the
5 second medical physicist position. You might recall that
6 the Committee has recommended that the second medical
7 physicist position be reinstated. A number of professional
8 societies, AAPM, the ACNP have also requested as such.

9 The staff did send forth to the Commission a
10 paper recommending that the position be reestablished and
11 the Commission has approved the staff's proposal to
12 establish a second medical physicist position. Therefore,
13 we will begin the process of noticing in the "Federal
14 Register" and follow-up selection process and so forth.

15 Medical visiting fellow. We have recently
16 published a "Federal Register" notice calling for
17 nominations for the position of medical visiting fellow.
18 We're seeking an individual with expertise in radiation
19 oncology or therapeutic radiological physics to join the
20 agency sometime during 1995. The current fellow, Dr.
21 Pollycove, is scheduled to complete his term in December of
22 1995.

23 With regards to the radiation therapy medical
24 dosimetrist position, we, of course, you might recall
25 noticed that position. We did receive 11 nominations. The

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1 staff is in the process of putting together a screening
2 panel.

3 Some of the ways in which we go about reviewing
4 the nominations have changed recently at the direction of
5 the Commission in the sense that now a formal screening
6 panel is put together.

7 The panel must include management
8 representatives and so forth. It also must include another
9 federal employee with the same type of technical expertise
10 that is being sought. In this case that would be radiation
11 therapy technologists or medical dosimetrists.

12 We have identified two individuals. And we are
13 sending that information forward to the Commission so the
14 Commission may decide which of those two it would like to
15 have participate in the screening panel.

16 We expect the screening panel to meet within
17 the next few weeks and make its recommendation to the
18 Commission. So we hopefully will have that person known
19 and begin the process of seating him on the Committee in
20 the very near future.

21 And then finally somebody on the Committee, I
22 think Bob Quillin, had asked for a copy of our annual
23 report that we submit for this Committee as with other FACA
24 committees. And that is included for your review.

25 I have nothing to say about it. You may look

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1 at it at your leisure. If you have questions, feel free to
2 give us a call.

3 CHAIRMAN SIEGEL: John Glenn predicted after
4 Bob requested this that we would find it boring. And I
5 agree.

6 MEMBER FLYNN: Can I ask one question?

7 MEMBER NELL: I find it very interesting
8 myself.

9 MEMBER FLYNN: Larry? May I ask one question?

10 CHAIRMAN SIEGEL: Yes.

11 MEMBER FLYNN: I want to make sure I
12 understand. For the radiation therapist/medical
13 dosimetrist, will it be someone who is both a certified
14 radiation therapist and a medical dosimetrist? There are
15 many people like that who are both.

16 MR. CAMPER: No.

17 CHAIRMAN SIEGEL: It's an either/or, though.

18 MR. CAMPER: It's an either/or.

19 MEMBER FLYNN: Really?

20 MR. CAMPER: It's a radiation therapy
21 technologist --

22 MEMBER FLYNN: Yes.

23 MR. CAMPER: -- or a medical dosimetrist.

24 MEMBER FLYNN: But there are many out there who
25 are both.

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1 MR. CAMPER: I understand. And we received 11
2 nominations, some of which may be both. I'm not commenting
3 at all on the nominations.

4 MEMBER FLYNN: Okay.

5 MR. CAMPER: I'm commenting on the individuals
6 who will sit on the panel to screen them and make a
7 recommendation to the Commission, which will consist of
8 management representatives, probably Dr. Glenn or myself,
9 someone in senior management, and this outside individual
10 who has expertise in one or both of these areas.

11 CHAIRMAN SIEGEL: Okay. Good. A few other
12 minor administrative matters. Minutes in accordance with
13 the bylaws we just adopted. This time Torre is going to
14 try to get the first draft of the minutes.

15 We are going to figure out a way to get them
16 pasted into an E-mail message since we are having trouble
17 with electronic enclosures so that I can edit them on line
18 and then get E-mail off to all of you, get your comments
19 back, incorporate them and then send something back to
20 Torre. Maybe we can do a couple of iterations that way,
21 rather than having to burn up the fax wires and mark on
22 paper and stuff like that. So we can try that.

23 For those of you who still don't have E-mail or
24 don't have secretaries whom you've told me about yet, --

25 MEMBER NELP: I will get you my E-mail.

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1 CHAIRMAN SIEGEL: -- please get me your E-mail
2 addresses because then I can harass you all at any time of
3 the day or night.

4 MR. SWANSON: You'll be sorry.

5 MEMBER NELP: Will I be sorry?

6 CHAIRMAN SIEGEL: No, you won't.

7 MEMBER NELP: I'm going to hold out, then.

8 CHAIRMAN SIEGEL: Well, then we won't send you
9 the minutes.

10 MEMBER NELP: Oh, damn.

11 CHAIRMAN SIEGEL: We do need your comments.

12 And then we ideally can get the minutes out much more
13 quickly this way. We're going to try. Torre needs to send
14 out -- and she knows this -- calendars sometime very soon
15 so we can fix the next meeting date.

16 MS. TAYLOR: We have one problem.

17 CHAIRMAN SIEGEL: Yes?

18 MS. TAYLOR: We don't know when this room will
19 be available. We won't know until January. So provide me
20 with your schedule, and I'll try to interact with that --

21 CHAIRMAN SIEGEL: Why is that?

22 MS. TAYLOR: We just don't know this far in
23 advance. Towards the --

24 CHAIRMAN SIEGEL: That's not very far in
25 advance in the real world.

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1 MR. CAMPER: The room, is used for other
2 committees. And their schedule is not always known
3 apparently too far in advance. Now, we're still working
4 through trying to make this work.

5 CHAIRMAN SIEGEL: Why don't we try our best to
6 maybe pick two or three dates that we think are viable for
7 the Committee? And then you can use that as your
8 intersection with room availability.

9 MR. CAMPER: That makes sense. We can do that.

10 CHAIRMAN SIEGEL: In addition to that --

11 MR. CAMPER: At the same time that we're
12 considering the dates, it would be interesting also for
13 feedback on possible agenda items.

14 CHAIRMAN SIEGEL: Yes. Sally?

15 MS. MERCHANT: It's my understanding that ACNW
16 and ACRS make their schedules for an entire year in
17 January. That's why the January date. It's really not a
18 question of in advance. They just do it early in January
19 for the entire year. And then they will know and we will
20 know which days this room is available.

21 CHAIRMAN SIEGEL: I think in the meantime we
22 ought to start potentially locking in two or three possible
23 dates in the May time frame soon so that we have got them
24 as potentials on our calendars so that once you spring a
25 date on us we then don't turn around and say "Oop. I

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1 filled that date." So let's do that.

2 The other thing we need to do is we just
3 committed to having an annual Commission briefing usually
4 in the first or second quarter of each year. Since we just
5 had one in October, my preference would be that we would
6 hold the Commission briefing until sometime after our May
7 meeting.

8 I actually kind of liked doing it in
9 conjunction with the annual briefing. And even though
10 that's not entirely consistent with what the bylaws said, I
11 think if you all will discuss this with the EDO, unless we
12 feel that we're not getting enough time by doing it that
13 way, -- and I didn't really feel that way -- I think doing
14 it as a tag team event was not a bad idea.

15 MEMBER NELL: I agree.

16 CHAIRMAN SIEGEL: So maybe check with SECY or
17 whatever and see if that sits with the Commissioners about
18 if they would like to have it that way. On the other hand,
19 if we feel that we need two hours of the Commissioners'
20 time, then we should say that that's what we want.

21 Do you have a comment, Bob?

22 MR. QUILLIN: Well, actually, you did it the
23 first quarter of the fiscal year, federal fiscal year.

24 CHAIRMAN SIEGEL: I think probably our minutes
25 say the calendar year, but that's okay. Good point.

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1 MR. CAMPER: Another thought. When we send you
2 the information to try to line up possible dates, we'll
3 also ask if you have any thoughts on future agenda items.

4 CHAIRMAN SIEGEL: Okay. Good.

5 MR. CAMPER: So keep that in mind.

6 CLOSING

7 CHAIRMAN SIEGEL: Finally, just a word of
8 thanks. I just want to thank Larry and John and all of the
9 staff for all of the tremendous amount of work they did in
10 putting the big books together, in making the
11 presentations, getting us paper in a timely fashion.

12 I mean, we come here for a day and a half, and
13 we're like experts. Experts are people who make advice but
14 have no responsibility for implementing the advice, someone
15 who is more than 50 miles away from home and has more than
16 5 slides or various definitions of a consultant.

17 For us to come in for this day and a half is
18 incredibly disruptive for the staff getting ready for this.
19 They still have to do all the rest of their work and, yet,
20 be ready to deal with us. And I want to thank them for
21 that. And, as always, Torre, thanks for making all of the
22 logistics work out right.

23 With that, from my perspective we're adjourned
24 unless --

25 DR. PAPERIELLO: Could I have a few minutes?

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1 CHAIRMAN SIEGEL: Sure, Carl.

2 DR. PAPERIELLO: First I want to thank
3 everybody for your assistance. The regulatory process is
4 extremely complicated. I would also describe it as
5 chaotic. There's congressional influence. They're
6 influenced by the press and the events. There are
7 competing agencies because at different times the Congress
8 wrote different laws. Within the NRC there are competing
9 views. And I've got to reconcile all of these. And
10 sometimes we get things that I describe as camels.

11 Like my colleagues in the bureaucracy, we have
12 to make this ssytem that we have work. And I guess my view
13 is if I can't stand the heat, I've got to get out of the
14 kitchen.

15 I think Dr. Marcus in some earlier letters is
16 somewhat correct. The NRC's medical expertise,
17 particularly in the physician sense, is limited.

18 I would disagree with her views on our ability
19 to do dose modeling. The reality of it is we see a hell of
20 a lot of human errors. And most of the mistakes that occur
21 in medicine that we're involved in are not medical
22 mistakes. They're human mistakes that happen to be in the
23 practice of medicine and the like.

24 I need this Committee to deal with the
25 practical implementation of the things that we've got to

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1 do. The discussion today on patient release is a case in
2 point. There are international and national
3 recommendations on dose limits that will allow you to
4 release a patient. The question is: How do I take what's
5 in those recommendations and make it a regulation,
6 essentially move it from science into law?

7 We regulate a broad spectrum of licensees. And
8 you, frankly, represent some of the best institutions
9 around. I think Dr. Pollycove since he's been here has
10 seen some of the things we have to deal with, and our rules
11 have to cover everybody. There is a spectrum of
12 performance in every field, not just medical, but all of
13 the licensees we regulate. So the rules have to cover
14 everybody in that sense.

15 So I do value the feedback that I get here.
16 And, of course, it's one of the pieces of information that
17 we have to reconcile. So again I do want to thank you. In
18 a sense you are helping make this process work.

19 CHAIRMAN SIEGEL: Thank you.

20 John?

21 DR. GLENN: I guess I can do it from over here.
22 I declare the meeting to be officially closed.

23 (Whereupon, the foregoing matter was concluded
24 at 12:06 p.m.)

25

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C E R T I F I C A T E

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

Name of Proceeding: ADVISORY COMMITTEE FOR THE MEDICAL
USES OF ISOTOPES

Docket Number: N/A

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 taken by me and, thereafter reduced to
typewriting by me or under the direction of the court
reporting company, and that the transcript is a true and
accurate record of the foregoing proceedings.

Corbett Riner

CORBETT RINER
Official Reporter
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ACMUI Meeting
November 17 and 18, 1994
U.S. Nuclear Regulatory Commission, Two White Flint North

[illegible]

**"PREPARATION, TRANSFER, AND USE
OF BYPRODUCT MATERIAL FOR MEDICAL USE"**

JOHN E. GLENN, CHIEF

**MEDICAL, ACADEMIC, AND
COMMERCIAL USE SAFETY BRANCH**

MAJOR PART 35 CHANGES

- **Recognizes preparation of radioactive drugs by authorized user (AU) and nuclear pharmacist (ANP)**
- **Sets criteria for training and experience of ANP**
- **Provides for human subjects as well as patients**
- **Permits use of qualified physicians as AU or qualified pharmacists as ANP without amendment**
- **States exemptions regarding Type A specific licenses of broad scope**

RADIOACTIVE DRUG PREPARATION

CURRENT 10 CFR 35.49

Restricted to materials or reagent kits manufactured, labeled, packaged and distributed in accordance with a license issued pursuant to Sections 32.72, 32.73, or 32.74 (or equivalent Agreement State regulations)

RADIOACTIVE DRUG PREPARATION (CONTINUED)

NEW 35.49 - Silent on drugs

NEW 35.100, 35.200, or 35.300

- (a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72, or**
- (b) Prepared by ANP or AU meeting requirements of 10 CFR 35.920 or under the supervision of either**

RADIOACTIVE DRUG PREPARATION (CONTINUED)

CURRENT 35.100

IND or NDA only

CURRENT 35.200

IND or NDA and follow manufacturer's instructions for kits and generators or directions of AU

CURRENT 35.300

IND or NDA and comply with package insert regarding indications and methods of administration or directions of AU in written directive

NEW 35.100, 35.200 and 35.300

Received from authorized supplier (32.72) or prepared by qualified ANP or AU

RADIOACTIVE DRUG PREPARATION (CONTINUED)

SUPPLIERS

CURRENT 32.72

- Radiopharmaceuticals to be NDA, biologic product license from FDA, or IND, or
- Not subject to FDA

CURRENT 32.73

- Generators or reagent kits to be FDA approved or not subject to FDA regulation

NEW 32.72

- Drugs and generators prepared by FDA or State licensed or registered manufacturer or pharmacy or nuclear pharmacy within Federal medical institution

*Index -
Nuclear Drug
Nuclear Pharmacy
Nuclear Medicine
Nuclear Physics*

LABELING - CURRENT

- **Radionuclide**
- **Quantity**
- **Date of assay**
- **Part 35 listed use**
- **May be combined with FDA labeling**

LABELING - NEW

- **Name of radioactive drug or abbreviation**
- **Quantity**
- **Date of assay**
- **Time of assay (short-lived material)**
- **Part 35 listed use**
- **Independent of FDA labeling**

FOR SYRINGES: Clinical procedure or patient or human subject's name

AUTHORIZED NUCLEAR PHARMACIST

- **Board certified as nuclear pharmacist**
- **Named as ANP on NRC or Agreement State license authorizing nuclear pharmacy**
- **Named as ANP on permit of license of broad scope**

AUTHORIZED NUCLEAR PHARMACIST TRAINING

- **Current certification**

OR

- **700 hour structured program**
 - **didactic training**
 - **supervised experience**

AND

- **Signed preceptor statement of competency**

GRANDFATHERING

**Preceptor statement not required for training
received before publication date**

HUMAN SUBJECTS

Current Part 35 is silent

New Part 35

- Patient and human subject provided equal protection
- Research must be conducted, funded, supported, or regulated by another Federal agency who has implemented Federal policy for the protection of human subjects, or
- Otherwise, specific license approval
 - Institutional review board
 - Informed consent

AMENDMENT NOT REQUIRED TO ADD USERS IF:

- **AU OR ANP CERTIFIED BY ORGANIZATION LISTED IN SUBPART J**
- **IDENTIFIED AS AU OR ANP ON NRC OR AGREEMENT STATE LICENSE**
- **IDENTIFIED AS AU OR ANP ON PERMIT ISSUED BY NRC OR AGREEMENT STATE LICENSEE OF BROAD SCOPE**
- **NOTIFICATION AND COPY OF BASIS DOCUMENT REQUIRED WITHIN 30 DAYS**

EXEMPTIONS FOR TYPE A LICENSE

- **No amendment to name AU or ANP**
- **No amendment to add or change areas of use at specified address**
- **No notification of AU or ANP changes**

OTHER CHANGES

- **Misadministration definitions include human subjects**
- **Measurement of alpha- or beta-emitting radionuclides**
 - **Not applicable to unit doses from 32.72 supplier**
 - **Combination of measurements and calculations**

OTHER CHANGES (CONTINUED)

- **Recognize certifications**
 - **American Osteopathic Board of Nuclear Medicine (35.900, 35.910, 35.920)**
 - **American Osteopathic Board of Radiology (35.900, 35.930 AFTER 1984)**
 - **Royal College of Physicians and Surgeons of Canada (35.900, 35.910, 35.920, AND 35.930)**

LICENSING ISSUES

- **More flexibility in uses and forms**
- **Need to bound radiation risks through quantities and operations**
- **New procedures required for alpha and beta measurements and unusual operations to demonstrate compliance with Part 20**

PHARMACY ISSUES

- **Only a pharmacist may be listed as an ANP**
- **Pharmacists current listed as users qualify as ANP**
- **Board certified nuclear pharmacists not required to be listed**

ERRATA

REGULATORY GUIDE 10.8, REVISIONS

APPLICATIONS FOR SPECIFIC MEDICAL USE BYPRODUCT MATERIAL LICENSES

Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs" provides directions for completing Form NRC-313 for the preparation of applications for specific medical use byproduct material licenses. The guide is based on major revisions to 10 CFR Part 35 that became effective April 1, 1987.

On (date), the NRC adopted new medical use regulations (FR) that affect some of the guidance provided in Regulatory Guide 10.8. The purpose of this errata sheet is to provide applicants and licensees with new guidance for completing NRC Form 313 which takes into account the new medical use regulations.

These changes (effective (date)) include the following:

- (1) recognition of pharmacists with specific training and experience in nuclear pharmacy as "authorized nuclear pharmacists;"
- (2) deletion of previous restrictions on the sources of supply for unsealed byproduct material to be used for medical use;
- (3) deletion of previous restrictions on the preparation of unsealed byproduct material for medical use;
- (4) permitting some qualified physician authorized users to work as authorized users without being listed on the license;
- (5) clarification of when specific licenses of broad scope are relieved from submitting amendments; and

- (6) authorizing the use of byproduct material in the conduct of research involving human subjects as a part of "medical use," as defined in Section 35.2.

This guide addresses the effects of these regulatory changes for each Section and Appendix in Regulatory Guide 10.8. Applicants and licensees intending to prepare unsealed byproduct material for medical use by or under the supervision of an authorized nuclear pharmacist or authorized user meeting the criteria in § 35.13 of 10 CFR Part 35 will be referred to Draft Regulatory Guide DG-0006, dated _____, for appropriate guidance.

Section 1. INTRODUCTION

- not affected

Section 2. FILING AN APPLICATION

- not affected

Section 3. CONTENTS OF AN APPLICATION

ITEM 1 - License Information

- not affected

ITEM 2 - Applicants Name and Mailing Address

- not affected

ITEM 3 - Locations of Use

- not affected

ITEM 4 - Persons to be Contacted About Application

- not affected

ITEM 5 - Radioactive Material and ITEM 6 - Purpose

The new rule provides licensees with greater flexibility to prepare radioactive drugs. Specifically, licensees are no longer restricted to only use radioactive drugs that are prepared either commercially or by the medical use licensee, from commercially available generators and reagent kits, in accordance with the manufacturer's instructions. However, because of this increased flexibility to prepare radioactive drugs, there may be increased radiation hazards in the preparation of radioactive drugs. It is possible that applicants or licensees may prepare radioactive drugs for medical use which present radiation safety hazards greater than those normally encountered by the use of radioactive drugs that are prepared either commercially or by the medical use licensee from commercially available generators and reagent kits, in accordance with the manufacturer's instructions. In such cases, licensees should submit the preparation methodologies in sufficient detail for NRC staff to evaluate the associated radiation safety hazards.

Previously, the quantities of radioisotopes could be requested "as needed." 10 CFR Part 30 has been amended to add Section 30.35 "Financial Assurance and Recordkeeping for Decommissioning" after the issuance of Regulatory Guide 10.8, Revision 2. Possession of byproduct material with half-lives greater than 120 days may require the submission of financial assurance documentation to comply with this requirement. Therefore, for any byproduct material with a half-life greater than 120 days, the radioisotope and maximum activity to be possessed at one time should be specified.

Part 35 continues to divide medical use into six types of use. However, it no longer restricts the types and sources of the byproduct material for some of these uses. You should indicate type, form, and quantity of unsealed byproduct material requested (using revised Table 1 as a guide) for each intended use.

You may specify the type and quantity of material using the format shown in Items 5.a through 5.c (of revised Table 1), if you meet the following criteria. You will use prepared radioactive drugs which are: (1) initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State requirements; (2) composed of only radionuclides with a half-life of 120 days or less; and (3) in quantities that do not exceed 100 millicuries in each container. The NRC or Agreement States will have evaluated the radiation safety concerns associated with the preparation of these materials at the commercial manufacturer or nuclear pharmacy prior to granting the distribution license. Licensees having programs limited to this type of photon- or high energy beta-emitting radioactive drugs will normally only need to adopt existing guidance in Regulatory Guide 10.8, Revision 2. However, licensees intending to obtain and use low energy beta- or alpha-emitting radionuclides should demonstrate the capability to measure dosage and contamination with appropriate procedures and equipment.

If unsealed byproduct materials will be prepared for medical use by either a pharmacist or an authorized user (who meet the specific training and experience criteria in §§ 35.980, 35.972, or §§ 35.920 respectively), then you should list individual radioisotopes as shown in Items 5.g through 5.i of Revised Table 1. This format allows NRC to easily review and identify whether the licensee's procedures for the preparation of these unsealed materials need to be reviewed for radiation safety concerns. Licensees will have to identify pharmacists or authorized users preparing these unsealed materials either on the license or in a notification to NRC. This format should also be used for prepared radioactive drugs with a half-life greater than 120 days or in quantities greater than 100 millicuries for any one container. By specifically listing isotopes and the maximum quantities requested for each, additional radiation safety concerns can be identified by the applicant and NRC.

Reviewers

Note: If the applicant has the need to use byproduct material with half-life greater than 120 days, you will need to review the requested limits to determine if financial assurance is required pursuant to 10 CFR Part 30.35. The format for requesting possession limits in Table 1 should permit a quick determination of the need for financial assurance. The Table 1 format should also be used for Items 6, 7, 8, and 9 of the medical use license.

As discussed in more detail in the following paragraphs, this format more clearly indicates the radiation hazards associated with the activities and forms of byproduct material for medical use.

If the medical use applicant receives only radioactive drugs initially distributed by a Part 32 licensee and in individual quantities less than 100 millicuries, you can usually assume that the receiver will be making only minor preparation changes and no significant radiation safety concerns are associated with the type of radioactive material handled.

If the medical use applicant is not receiving prepared radioactive drugs, then you will need to determine whether the planned preparations should involve any special procedures or equipment to provide adequate shielding, ventilation, or contamination control for radiation safety concerns associated with processing and handling unsealed byproduct material. If so, the special procedures and equipment will have to be described in Items 9 and 10.

Specifically listing isotopes and the maximum quantities requested for each, as shown in items 5 "g" through "i" of Table 1, is the format used to identify when commercially prepared radioactive drugs are not used in the preparation of byproduct material for medical use. This format also identifies when you will have to evaluate the radiation safety of the use of long-lived isotopes, large activity in a single container,

preparation procedures, or use of alpha-, low energy photon-, or low energy beta-emitters for radiation safety.

NOTE: You should not seek detailed preparation procedure information about chemical components or reactions having only to do with drug safety and efficacy. Those issues are the responsibility of the FDA and State authorities. You should only seek sufficient detailed commitments from the applicant as are necessary to limit the scope and level of radiation hazard likely to be encountered in preparation and use of radioactive material.

If the applicant indicates the use of alpha-, low energy photon-, or low energy beta-emitting radionuclides, you will have to review the adequacy of the applicant's instrumentation and procedures described in Items 9 and 10 to measure, detect, and safely handle these radionuclides.

If the applicant has not list specific radionuclides and omits the origin of the radioactive material, the half-life of materials, or the maximum activity in a single container, it will be necessary to telephone or write the applicant to determine what possession limits to use and if alpha, low energy photon-, or low energy beta-emitting radionuclides will be used.

Each licensee is permitted by regulation (i.e., without an amendment or special license condition) to make departures from the preparation instructions of prepared radioactive drugs, initially distributed in accordance with § 32.72 of 10 CFR or an equivalent Agreement State requirement, provided the preparation is made by or under the supervision of an authorized nuclear pharmacist or an appropriate authorized user. However, if the applicant intends to receive unsealed byproduct material that was not initially distributed in accordance with § 32.72 of 10 CFR Part 32 or an equivalent Agreement State requirement, the types of preparation procedures and associated radiation safety program should also be described in Items 9 and 10.

Guidance provided for sealed sources in Regulatory Guide 10.8 was not affected by the (date), rule but specification of radionuclide and maximum quantity should be submitted to permit evaluation of radiation safety hazards.

ITEM 7 - Individuals Responsible for Radiation Safety Programs.
Their Training and Experience

The regulations now recognize a new individual who may be responsible for the radiation safety program, i.e., the authorized nuclear pharmacist.

The regulations also permit certain pharmacists and physicians to work as authorized nuclear pharmacists or authorized users respectively without requiring them to be identified on the license. If the applicant takes advantage of this provision, then the Commission must be provided with a copy of each individual's certification, the Commission or Agreement State license identifying the individual as a authorized user or authorized nuclear pharmacist, or permit issued by a license of broad scope identifying the individual as an authorized user or authorized nuclear pharmacist. This documentation must be submitted to the Commission no later than 30 days from the date the licensee allows the individual work as an authorized user or authorized nuclear pharmacist.

In accordance with § 35.13(b), these physicians and pharmacists must be (1) certified by an organization specified in paragraph(a) of §§ 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, or 35.980; (2) identified as a physician authorized user or an authorized nuclear pharmacist on a Commission or Agreement State medical use or commercial nuclear pharmacy license; or (3) identified as a physician authorized user for uses specified in § 35.200 or an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State medical use license of broad scope. Although not required, the applicant or licensee may elect to identify a pharmacist who is currently board certified.

The guidance for training and experience provided in Regulatory Guide 10.8 for those individuals that may be identified on the license as "authorized users" was not affected by the (date) rule.

Guidance needed for those individuals that must be identified on the license as authorized nuclear pharmacists is found in Item 7 and Appendix A of Draft Regulatory Guide DG 0006, dated _____. Applicants and licensees may find it convenient to document the training and experience of these individuals in a format similar to Figure A-1 and A-2 in Draft Regulatory Guide DG 0006, dated _____.

Reviewers

The new license applicant must demonstrate its personnel are qualified by training and experience to use the material for the purposes requested. Therefore, the applicant has to identify the authorized users (and authorized nuclear pharmacists, if appropriate) and describe their training and experience. (At renewal, the licensee has to demonstrate the continued existence of trained personnel.) Even though technically they may not have to be listed, you should list these individuals on the new NRC license (or renewal). [Technically, the license would not have to identify any authorized users or authorized nuclear pharmacists, if all the authorized users and authorized nuclear pharmacists met the criteria specified in §35.13(b).]

You should follow the reviewer notes provided in Item 7 of Draft Regulatory Guide DG 0006 dated () when reviewing the training and experience of the authorized nuclear pharmacist.

The license condition listing authorized users should be modified to read:

Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

- (1) Physician, dentist, or podiatrist as defined in 10 CFR 35.2 working as authorized users in accordance with § 35.13 of 10 CFR Part 35, or
- (2) Pharmacist as defined in 10 CFR 35.2 working as authorized nuclear pharmacists in accordance with § 35.13, or
- (3) Authorized nuclear pharmacists John Jones, Mary Smith, or Robert Green, or
- (4.a)

Authorized Users

Material and Use

or,

(4.b) Physicians, dentists, or podiatrists designated to use licensed material in or on humans and pharmacists shall meet the training criteria established in 10 Part CFR 35 Subpart J and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as authorized users and authorized nuclear pharmacists for 3 years after the individual's last use of licensed material.

[Reviewer Note: The specific licensee's authorized users or authorized nuclear pharmacists are listed in "4.a" on limited use medical use licenses. The general statement in "4.b" is used for broad scope medical use licenses.]

Review the applicant's response against the criteria described in the regulatory guide. Ask the applicant to correct any deficiency.

ITEM 8 - Training for Individuals Working in or Frequenting Restricted Areas

If the applicant intends to have unsealed byproduct material prepared for medical use under the supervision of an authorized nuclear pharmacist or authorized user as allowed by § 35.11(c), then the training guidance provided in Item 8 of Draft Regulatory Guide DG 0006, dated _____, must be followed to meet the supervision and instruction requirements of § 35.25 of 10 CFR Part 35.

Reviewers

Review the applicant's response against the guidance provided in Item 8 of the radiopharmacy guide. Ask the applicant to correct any deficiency.

ITEM 9 - Facilities and Equipment and ITEM 10 - Radiation Safety Program

Applicants who want to use unsealed low energy photon-, alpha-, and beta-emitting radionuclides for medical use or prepare unsealed byproduct material for medical use, by or under the supervision of an authorized nuclear pharmacist or an appropriate authorized user, should refer to Items 9 and 10 in Draft Regulatory Guide DG 0006, dated _____, for appropriate guidance to describe the scope of your operations, facilities, equipment, and associated radiation safety programs to handle these uses.

If you use low energy photon-, low energy beta-, or alpha-emitters, you should describe new procedures and programs for the safe use of these radionuclides. The model procedures and programs described in Regulatory Guide 10.8 Appendices B, C, D, I, J, M, N, O, and R were developed primarily for photon-emitting radionuclides. Generally, high energy beta-emitters can be measured or assayed with the same instruments and these model procedures and programs can be used provided additional care is taken to account for energy dependence and geometric considerations. This issue was addressed in Draft Regulatory Guide DG 0006, dated _____.

If you will only use unit dosages of alpha- or beta-emitting radionuclides obtained from a manufacturer or preparer licensed pursuant to 10 CFR Part 32, you are not required to have instruments to measure the alpha- or beta-emitter dosages (§ 35.52 of 10 CFR Part 35). This does not relieve you from appropriate requirements to assay or measure effluent releases, fixed or removable contamination, and doses to your workers or the general public.

Reviewers

Review the applicant's response against the guidance provided in Items 9 and 10, as appropriate, in the radiopharmacy guide. Ask the applicant to correct any deficiency.

ITEM 11 - Waste Management

- not affected

ITEM 12 - License Fees

- not affected

ITEM 13 - Certification

- not affected

ITEM 14 - Voluntary Economic Data

- not affected

Section 4. Amendments to License

The applicant is directed to the revisions in §§ 35.13, 35.14, and 35.15 of 10 CFR Part 35 to see when amendments are needed, changes that now permit notification instead of amendments, and the amendment and notification exemptions granted to medical use Type A Specific Licenses of Broad Scope.

Reviewers

Review the applicant's response against the requirements and exemptions in §§ 35.13, 35.14, and 35.15 of 10 CFR Part 35 and 10. Ask the applicant to correct any deficiency.

Section 5. Renewal of License

- not affected

Section 6. Implementation

- not affected

Appendices

Appendices A, E, G, H, K, P, Q, S, W, and X

- not affected

Appendices B, C, D, F, I, J, L, M, N, O, R, T, U, and V

These appendices may have to be supplemented, as appropriate, to include information on low energy photon-, beta-, and alpha-emitting radionuclides; additional responsibilities of the radiation safety committee to review and approve or disapprove of individuals to work as or be listed as authorized users, authorized nuclear pharmacists, teletherapy physicists, or radiation safety officers in accordance with § 35.22(2) of 10 CFR Part 35; radiation safety programs associated with procedures used to prepare unsealed byproduct material by or under the supervision of an authorized nuclear pharmacist or appropriately trained authorized user; and identify committees and documents needed for human research programs.

In addition, processes in the preparation of radioactive drugs that involve increased potential for radiation doses or releases of radioactive material need to be identified. Additional equipment, shielding, procedural control or monitoring for such processes should be described. Examples of processes which have radiological safety implications beyond those considered in the appendices include, but are not limited to: (1) labeling biologics or compounds with more than 100 millicuries of volatile byproduct material, (2) chemical separation and purification of neutron activated materials or fission products in the preparation of radioactive drugs, (3) batch preparation of large activities (>500 millicuries) of a radioactive drug, and (4) use of alpha and beta emitters to prepare radioactive drugs.

Reviewers

Review the applicant's response against the above guidance. Ask the applicant to correct any deficiency.

Appendix Y Provisions for Research Involving Human Subjects

This attached appendix was added to Regulatory Guide 10.8 to provide guidance for the submission of information required by § 35.6 of 10 CFR Part 35.

The revision of 10 CFR Parts 30, 32, and 35, by the Final Rule "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use" changes a number of requirements for medical use programs. Among other things, the term "medical use" was amended to mean the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user. Specifically, this final rule permits research involving human subjects through the provisions of §35.6 "Provisions for Research Involving Human Subjects". This Appendix is intended to provide licensees with guidance for the submission of the information required by the provisions of § 35.6.

Reviewers

You may ask the applicant if research involving human subjects and byproduct material will be conducted, if this research is conducted, funded, supported, or regulated by a federal agency, and to list the federal agency. If the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the "Federal Policy for the Protection of Human Subjects" (56 FR 28003) (see the list provided) no additional information is needed. (NOTE: NRC is not in the list.) If there is research on human subjects that is not conducted, funded, supported, or regulated by a Federal agency which has implemented the "Federal Policy for the Protection of Human Subjects," then ensure information requested below in Sub Item 2 is provided.

1. RESEARCH COVERED BY ANOTHER FEDERAL AGENCY

No approval by NRC is required to conduct research involving human subjects provided that the research is conducted, funded, supported, or

regulated by a Federal agency which has implemented the "Federal Policy for the Protection of Human Subjects" (56 FR 28003).

Note: The following must be obtained prior to performing the research:

- a. "informed consent"¹ from each research subject; and
- b. review and approval of the research activity, by an "institutional review board."¹

Note: The following fifteen Federal agencies have adopted the "Federal Policy for the Protection of Human Subjects:" United States Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency, Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

2. RESEARCH NOT COVERED BY ANOTHER FEDERAL AGENCY

If the research is not conducted, funded, supported, or regulated by a Federal agency that has implemented the "Federal Policy for the Protection of Human Subjects," the licensee may apply for and must receive a license amendment from NRC.

Reviewer

This section includes research that is either not conducted, funded, or supported by a Federal agency, or conducted, funded, supported, or regulated by a Federal Agency that has implemented the "Federal Policy

¹ These terms are defined and described in the "Federal Policy for the Protection of Human Subjects."

for the Protection of Human Subjects." NRC has not implemented the "Federal Policy for the Protection of Human Subjects." Any application for research described in Sub Item 2 is to be sent to the Division of Industrial and Medical Nuclear Safety as a technical assistance request (TAR).

The licensee should provide the following information:

- a. the type of research, the isotope(s), the physical and chemical form of the isotope(s), and activity;
- b. the sponsor(s) of the research;
- c. the identification of the appropriate reviewing and approving committees (e.g.; Institutional Review Board and Radiation Safety Committee);

In addition, provide a description of how the licensee would ensure the following will be obtained, prior to performing the research:

- a. "informed consent"¹ from each research subject; and
- b. review and approval of the research activity, by an "institutional review board."¹

Reviewers

Review the applicant does not provide the above information, request it.

¹ These terms are defined and described in the "Federal Policy for the Protection of Human Subjects."

EXHIBITS

EXHIBITS 1, 2, 3, 4, 5, 15, 17, 18, 19, 20, 21

- not affected

EXHIBITS 6, 7, 8, 9, 10, 11, 12, 13, 14, 16

These exhibits may have to be supplemented, as appropriate, to include information on low energy photon-, beta-, and alpha-emitting radionuclides, and radiation safety programs associated with procedures used to prepare unsealed byproduct material by or under the supervision of an authorized nuclear pharmacist or appropriately trained authorized user.

Reviewers

Review the applicant's response against the above guidance. Ask the applicant to correct any deficiency.

REVISED TABLE 1

Type of Material	Form	Quantity	Purpose
5.a Any byproduct material with a half-life less than 120 days	Any form for uses described in § 35.100 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	As needed, not to exceed 100 millicurie in any one container	For medical use as described in § 35.100
5.b Any byproduct material with a half-life less than 120 days	Any form for uses described in § 35.200 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	As needed, not to exceed 100 millicurie in any one container	For medical use as described in § 35.200
5.c Any byproduct material with a half-life less than 120 days	Any form for uses described in § 35.300 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	As needed, not to exceed 100 millicurie in any one container	For medical use as described in § 35.300
5.d Any byproduct material in a brachytherapy source as listed in § 35.400	Sealed source initially distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	(Specific radioisotope and maximum quantity requested)	For medical use as described in § 35.400
5.e Specific radioisotope	Sealed source (manufacturer and model number)	(Maximum quantity requested)	For (specific medical use) as described in § 35.400
5.f Any byproduct material in a sealed source for diagnosis as listed in § 35.500	Sealed source initially distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	(Specific radioisotope and maximum quantity requested)	For medical use as described in § 35.500
5.g (Specific radioisotope)	Any unsealed form for preparation and administration as specified in § 35.100	(Maximum quantity requested)	For medical use as described in § 35.100
5.h (Specific radioisotope)	Any unsealed form for preparation and administration as specified in § 35.200	(Maximum quantity requested)	For medical use as described in § 35.200
5.i (Specific radioisotope)	Any unsealed form for preparation and administration as specified in § 35.300	(Maximum quantity requested)	For medical use as described in § 35.300

MATERIALS LICENSE

Amendment No. 67

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. St. Knowwhere Hospital and Medical Center</p> <p>2. 703 Main Street Knowwhere, State OXXXXX</p>		<p>In accordance with application dated October 4, 1994,</p> <p>3. License number 29-XXXXX-02 is amended in its entirety to read as follows:</p>	
		<p>4. Expiration date April 30, 2000</p>	
		<p>5. Docket or Reference No 030-XXXXX</p>	
<p>6. Byproduct, source, and/or special nuclear material</p>	<p>7. Chemical and/or physical form</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p>	
<p>A. Any byproduct material with a half-life less than 120 days</p>	<p>A. Any form for uses described in §35.100 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations</p>	<p>A. As needed, not to exceed 3,700 megabecquerels (100 millicuries) in any one container</p>	
<p>B. Any byproduct material with a half-life less than 120 days</p>	<p>B. Any form for uses described in §35.200 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations</p>	<p>B. As needed, not to exceed 3,700 megabecquerels (100 millicuries) in any one container</p>	
<p>C. Iodine-131</p>	<p>C. Any unsealed form for preparation and administration as specified in §55.300</p>	<p>C. 55,500 megabecquerels (1.5 curies)</p>	

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

29-XXXXX-02

Docket or Reference number

030-XXXXX

Amendment No. 67

(6., 7., and 8. Continued)

D. Any byproduct material with a half-life less (100 than 120 days

D. Any form for uses described in §35.300 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations

D. As needed, not to exceed 3,700 megabecquerels millicuries in any one container

E. Any byproduct material in a brachytherapy source as listed in §35.400

E. Sealed source initially distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations

E. 74,000 megabecquerels (2 curies)

F. Iridium-192

F. Sealed source (Byk Mallinckrodt Model CI L BV)

F. 2 sources not to exceed 370,000 megabecquerels (10 curies) each

G. Cesium-137

G. Sealed source (Amersham/Tech Ops Model 77302)

G. 6,105 megabecquerels (165 millicuries)

H. Uranium depleted in isotope U-235

H. Metal

H. 140 kilograms

9. Authorized Use

- A. Any uptake, dilution, and excretion procedure approved in §35.100.
- B. Any imaging and localization procedure approved in §35.200.
- C. and D. Any radiopharmaceutical therapy procedure approved in §35.300.
- E. Any brachytherapy procedure approved in §35.400.
- F. One source to be used in a Nucletron Corporation MicroSelectron High Dose Rate Remote Afterloading Brachytherapy Device for interstitial, intracavitary, bronchial, intraoperative, or intraluminal therapy and source calibration. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

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(9. Continued)

- G. Non-human use. For use in a Nuclear Associates Instrument Calibrator Model No. 64-773 for calibration and checking of licensee's survey instruments.
- H. Shielding in a linear accelerator.

CONDITIONS

10. Licensed material may be used only at the licensee's facility located at 703 Main Street, Knowwhere, State.
11. The Radiation Safety Officer for this license is Sammy Smith, M.S.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
- A. Physician, dentist, or podiatrist as defined in §35.2 of 10 CFR Part 35, working as authorized users in accordance with §35.13 of 10 CFR Part 35, or
 - B. Pharmacist as defined in §35.2 of 10 CFR Part 35, working as authorized nuclear pharmacists in accordance with §35.13, or
 - C. Authorized nuclear pharmacists Mary Smith, or
 - D.

<u>Authorized Users</u>	<u>Material and Use</u>
George R. Jones, M.D.	§35.100; 35.200; 35.300
Vidor Adams, M.D.	§35.200 for cardiovascular clinical procedures
David E. Baker, M.D.	§35.300; 35.400
Michael E. Kelly, M.D.	Iridium-192 depleted uranium
13. The medical physicist for this license is Carolyn Kim, M.S.
14. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.
- B. Each entrance to the treatment room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.
- C. Electrical interlocks on each entrance door to the treatment room shall be tested for proper operation at least once each day of use.

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CONDITIONS

(14. Continued)

- D. In the event of malfunction of the door interlock, the unit shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
15. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit, a radiation survey shall be made of:
- A. The source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 millirem per hour.
 - B. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:
 - (1) That radiation doses to occupationally exposed individuals do not exceed the limits specified in §20.1201(a), 20.1207, and 20.1208 of 10 CFR Part 20.
 - (2) That radiation doses to individual members of the public do not exceed the limits specified in §20.1301(a) of 10 CFR Part 20.
16. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such service:
- A. Installation and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.
 - B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
17. A high dose rate afterloading brachytherapy unit shall be used in accordance with the following conditions:
- A. The unit may only be used in a permanently shielded treatment room.
 - B. During all patient treatments, both the authorized user and the medical physicist or radiation safety officer must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech.

MATERIALS LICENSE
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License number

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CONDITIONS

(17. Continued)

- C. The licensee shall have and post in the vicinity of the treatment console, written emergency procedures describing the actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. The licensee shall not begin any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded condition.
- D. The licensee shall ensure that personnel are trained in both the routine use of the unit and emergency procedures necessary to return the source to a safe position.
- E. The licensee shall immediately, after implanting the source, visually check the permanently installed room radiation monitor to verify that it indicates an exposed radiation source.
- F. The licensee shall visually monitor the patient during treatment through a continuous observation system.
- G. The licensee shall permit no visitors in the treatment room.

18. In lieu of the source inventory described in §35.406 of 10 CFR Part 35, the licensee shall:

- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each high dose remote brachytherapy procedure.
- B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
- C. Make a record of the survey, including survey instrument used, dose rate, time, date, and name of the individual making the survey.
- D. Retain the record of the survey in lieu of the record required in §35.406(d) of 10 CFR Part 35.

19. In lieu of §35.404(a) of 10 CFR Part 35, immediately after retracting the source from the patient into its shielded position in the remote afterloading device, radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in §35.404(b) of 10 CFR Part 35.

20. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in §32.210 of 10 CFR Part 32, not to exceed 3 years.

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License number

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CONDITIONS

(20. Continued)

- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
- (1) They contain only hydrogen-3; or
 - (2) They contain only a radioactive gas; or
 - (3) The half-life of the isotope is 30 days or less; or
 - (4) They contain not more than 100 microcuries of beta and/or gamma emitting material, or not more than 10 microcuries of alpha emitting material; or
 - (5) They are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

29-XXXXXX-02

Docket or Reference number

030-XXXXXX

Amendment No. 67

CONDITIONS

(Continued)

21. The licensee shall conduct a physical inventory every 3 months to account for all sealed sources and devices containing licensed material received and possessed pursuant to §35.59, 35.400, and 35.500 of 10 CFR Part 35, and every 6 months for all other sealed sources and devices.
22. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
23. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
24. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in §35.31 of 10 CFR Part 35. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated October 4, 1994
 - B. Letter dated December 7, 1994
 - C. Letter dated December 21, 1994
 - D. Letter dated January 22, 1995
 - E. Letter dated March 21, 1995

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DATE: _____

BY: VOID
(License Reviewer)
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Amendment No. 67

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with application dated October 4, 1994,	
1. St. Knowwhere Hospital and Medical Center		3. License number 29-XXXXX-02 is amended in its entirety to read as follows:	
2. 703 Main Street Knowwhere, State OXXXXX		4. Expiration date April 30, 2000	
		5. Docket or Reference No 030-XXXXX	
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	
A. Any byproduct material with a half-life less than 120 days	A. Any form for uses described in §35.100 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. As needed, not to exceed 3,700 megabecquerels (100 millicuries) in any one container	
B. Any byproduct material with a half-life less than 120 days	B. Any form for uses described in §35.200 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	B. As needed, not to exceed 3,700 megabecquerels (100 millicuries) in any one container	
C. Iodine-131	C. Any unsealed form for preparation and administration as specified in §55.300	C. 55,500 megabecquerels (1.5 curies)	

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

29-XXXXX-02

Docket or Reference number

030-XXXXX

Amendment No. 67

(6., 7., and 8. Continued)

D. Any byproduct material with a half-life less (100 than 120 days

D. Any form for uses described in §35.300 initially distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations

D. As needed, not to exceed 3,700 megabecquerels millicuries in any one container

E. Any byproduct material in a brachytherapy source as listed in §35.400

E. Sealed source initially distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations

E. 74,000 megabecquerels (2 curies)

F. Iridium-192

F. Sealed source (Byk Mallinckrodt Model CI L BV)

F. 2 sources not to exceed 370,000 megabecquerels (10 curies) each

G. Cesium-137

G. Sealed source (Amersham/Tech Ops Model 77302)

G. 6,105 megabecquerels (165 millicuries)

H. Uranium depleted in isotope U-235

H. Metal

H. 140 kilograms

9. Authorized Use

- A. Any uptake, dilution, and excretion procedure approved in §35.100.
- B. Any imaging and localization procedure approved in §35.200.
- C. and D. Any radiopharmaceutical therapy procedure approved in §35.300.
- E. Any brachytherapy procedure approved in §35.400.
- F. One source to be used in a Nucletron Corporation MicroSelectron High Dose Rate Remote Afterloading Brachytherapy Device for interstitial, intracavitary, bronchial, intraoperative, or intraluminal therapy and source calibration. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

29-XXXXXX-02

Docket or Reference number

030-XXXXXX

Amendment No. 67

(9. Continued)

- G. Non-human use. For use in a Nuclear Associates Instrument Calibrator Model No. 64-773 for calibration and checking of licensee's survey instruments.
- H. Shielding in a linear accelerator.

CONDITIONS

10. Licensed material may be used only at the licensee's facility located at 703 Main Street, Knowhere, State.
11. The Radiation Safety Officer for this license is Sammy Smith, M.S.
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:
- A. Physician, dentist, or podiatrist as defined in §35.2 of 10 CFR Part 35, working as authorized users in accordance with §35.13 of 10 CFR Part 35, or
- B. Pharmacist as defined in §35.2 of 10 CFR Part 35, working as authorized nuclear pharmacists in accordance with §35.13, or
- C. Authorized nuclear pharmacists Mary Smith, or
- D. Authorized Users Material and Use
- | | |
|------------------------|--|
| George R. Jones, M.D. | §35.100; 35.200; 35.300 |
| Vidor Adams, M.D. | §35.200 for cardiovascular clinical procedures |
| David E. Baker, M.D. | §35.300; 35.400 |
| Michael E. Kelly, M.D. | Iridium-192 depleted uranium |
13. The medical physicist for this license is Carolyn Kim, M.S.
14. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.
- B. Each entrance to the treatment room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.
- C. Electrical interlocks on each entrance door to the treatment room shall be tested for proper operation at least once each day of use.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

29-XXXXX-02

Docket or Reference number

030-XXXXX

Amendment No. 67

CONDITIONS

(14. Continued)

- D. In the event of malfunction of the door interlock, the unit shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
15. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit, a radiation survey shall be made of:
- A. The source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 millirem per hour.
 - B. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:
 - (1) That radiation doses to occupationally exposed individuals do not exceed the limits specified in §20.1201(a), 20.1207, and 20.1208 of 10 CFR Part 20.
 - (2) That radiation doses to individual members of the public do not exceed the limits specified in §20.1301(a) of 10 CFR Part 20.
16. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such service:
- A. Installation and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.
 - B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
17. A high dose rate afterloading brachytherapy unit shall be used in accordance with the following conditions:
- A. The unit may only be used in a permanently shielded treatment room.
 - B. During all patient treatments, both the authorized user and the medical physicist or radiation safety officer must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

29-XXXXX-02

Docket or Reference number

030-XXXXX

Amendment No. 67

CONDITIONS

(17. Continued)

- C. The licensee shall have and post in the vicinity of the treatment console, written emergency procedures describing the actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. The licensee shall not begin any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded condition.
 - D. The licensee shall ensure that personnel are trained in both the routine use of the unit and emergency procedures necessary to return the source to a safe position.
 - E. The licensee shall immediately, after implanting the source, visually check the permanently installed room radiation monitor to verify that it indicates an exposed radiation source.
 - F. The licensee shall visually monitor the patient during treatment through a continuous observation system.
 - G. The licensee shall permit no visitors in the treatment room.
18. In lieu of the source inventory described in §35.406 of 10 CFR Part 35, the licensee shall:
- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each high dose remote brachytherapy procedure.
 - B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
 - C. Make a record of the survey, including survey instrument used, dose rate, time, date, and name of the individual making the survey.
 - D. Retain the record of the survey in lieu of the record required in §35.406(d) of 10 CFR Part 35.
19. In lieu of §35.404(a) of 10 CFR Part 35, immediately after retracting the source from the patient into its shielded position in the remote afterloading device, radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in §35.404(b) of 10 CFR Part 35.
20. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in §32.210 of 10 CFR Part 32, not to exceed 3 years.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

29-XXXXXX-02

Docket or Reference number

030-XXXXXX

Amendment No. 67

CONDITIONS

(20. Continued)

- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
- E. Sealed sources and detector cells need not be leak tested if:
 - (1) They contain only hydrogen-3; or
 - (2) They contain only a radioactive gas; or
 - (3) The half-life of the isotope is 30 days or less; or
 - (4) They contain not more than 100 microcuries of beta and/or gamma emitting material, or not more than 10 microcuries of alpha emitting material; or
 - (5) They are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

29-XXXXX-02

Docket or Reference number

030-XXXXX

Amendment No. 67

CONDITIONS

(Continued)

21. The licensee shall conduct a physical inventory every 3 months to account for all sealed sources and devices containing licensed material received and possessed pursuant to §35.59, 35.400, and 35.500 of 10 CFR Part 35, and every 6 months for all other sealed sources and devices.
22. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
23. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
24. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in §35.31 of 10 CFR Part 35. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated October 4, 1994
 - B. Letter dated December 7, 1994
 - C. Letter dated December 21, 1994
 - D. Letter dated January 22, 1995
 - E. Letter dated March 21, 1995

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DATE: _____

BY: VOID
(License Reviewer)
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

MATERIALS LICENSE

Amendment No. 18

uant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. XYZ Nuclear Pharmacy</p> <p>2. 1234 A Street N.W. Washington, D.C. 20000</p>		<p>In accordance with the letter dated January 10, 1995,</p> <p>3. License number XX-XXXXX-01MD is amended in its entirety to read as follows:</p>	
		4. Expiration date	May 31, 2000
		5. Docket or Reference No	030-XXXXX
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	
A. Any byproduct material initially distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. Any form initially distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations	A. (List of specific isotopes and the maximum quantity requested for each by the licensee)	
B. (Specific Isotope)	B. Any form	B. (List of specific isotopes and the maximum quantity requested for each by the licensee) 50 millicuries	
C. Any byproduct material listed in paragraph 31.11(a) of 10 CFR Part 31	C. Prepackaged units for <u>in vitro</u> diagnostic tests	C. 50 millicuries	

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number XX-XXXXX-01MD

Docket or Reference number 030-XXXXX

Amendment No. 18

(6., 7., and 8. continued)

- | | | |
|--|---|---|
| <p>6. Byproduct, source, and/or special nuclear material</p> | <p>7. Chemical and/or physical form</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> |
| <p>D. Any byproduct material authorized under paragraph 35.57(a) of 10 CFR Part 35</p> | <p>D. Any sealed source listed in paragraph 35.57(a) of 10 CFR Part 35 that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations</p> | <p>D. 50 millicuries millicuries</p> |
| <p>E. Any byproduct material listed in Sections 35.400 and 35.500 of CFR Part 35</p> | <p>E. Any sealed source that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations</p> | <p>E. 500 millicuries</p> |
| <p>F. Uranium (depleted in the isotope Uranium 235)</p> | <p>F. Metal encased in stainless steel</p> | <p>F. 180 kilograms</p> |

9. Authorized use

- A. through B. Preparation and Distribution of radioactive drugs (includes Mo99/Tc99m generators) to authorized recipients.
- C. Redistribution to specific licensees or general licensees pursuant to 31.11 of 10 CFR Part 31 provided the packaging and labelling remain unchanged.
- D. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 35.57(a) of 10 CFR Part 35 or under equivalent licenses of Agreement States.
- E. Redistribution of sealed sources as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions to authorized recipients for use and storage.
- F. Shielding for Mo99/Tc99m generators.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number XX-XXXXX-01MD

Docket or Reference number 030-XXXXX

Amendment No. 18

(9. continued)

Pursuant to Sections 32.72, and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through E. of this license to persons licensed pursuant to Sections 35.100, 35.200, 35.300, 35.400 and 35.500 of 10 CFR Part 35, or under equivalent licenses of Agreement States.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 12354 A Street, N.W., Washington, D.C.
11. A. Licensed material shall be used by, or under the supervision of:
 - (1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 32.72(b)(2) and 32.72(b)(3) of 10 CFR Part 32, or
 - (2) authorized nuclear pharmacists John Jones, Mary Smith, or Robert Green.B. The Radiation Safety Officer for this license is Jane Doe.
12. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
E. Sealed sources and detector cells need not be leak tested if:
 - (i) they contain only hydrogen 3; or
 - (ii) they contain only a gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number XX-XXXXX-01MD

Docket or Reference number 030-XXXXX

Amendment No. 18

(12. continued)

CONDITIONS

- (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
- 13. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
- 14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.
- 15. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
- 16. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:
 - A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number XX-XXXXX-01MD

Docket or Reference number 030-XXXXX

Amendment No. 18

CONDITIONS

17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in the application dated January 31, 1995.
18. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material so that at no time is a quantity of radioactive material possessed in excess of a quantity which requires decommissioning funding in accordance with 10 CFR 30.35(d), 10 CFR 40.36(b) or 10 CFR 70.25(d).
19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated January 31, 1995
 - B. Letter dated February 25, 1995
 - C. Letter dated April 12, 1995

For the U.S. Nuclear Regulatory Commission

ite _____

By _____

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

**IMPLEMENTATION OF THE
QUALITY MANAGEMENT AND
MISADMINISTRATION RULE**

Sally L. Merchant
U.S. Nuclear Regulatory Commission
(301) 415 - 7874

ASSESSMENT OF OVERALL IMPLEMENTATION

- **Contractor reviews**
- **Inspection Results**
- **Reactive Inspections**
- **Enforcement Actions**
- **TI - Field Notes**

CONTRACT SUPPORT

- **Review 1700 submitted QMPs (LLNL)**
- **Misadministration events analysis (INEL)**

QMP REVIEW FINDINGS

Letters generated: 1709

Letters No. 1: 35

*QMP, as written, appears to meet
the objectives listed in 10 CFR 35.32*

Letters No. 2: 278

*QMP, as written, has weaknesses, but
appears to meet the objectives listed
in 10 CFR 35.32*

QMP REVIEW FINDINGS

(Continued)

Letters No. 3: 1228

*QMP, as written, fails to meet
at least one of the objectives listed
in 10 CFR 35.32.*

Negative Declarations: 168

*Declaration, in writing, that radioactive
drugs, applicable to 10 CFR 35.32, are not
being administered.*

Findings that met the category 3 (deficiency) letter criteria, (72% of QM plans), varied in their safety significance.

Example: Lack of 1 element in required written directive versus lack of brachytherapy patient treatment plan.

Failure to Meet Required Objectives - Teletherapy
Modality (126 QMPs)

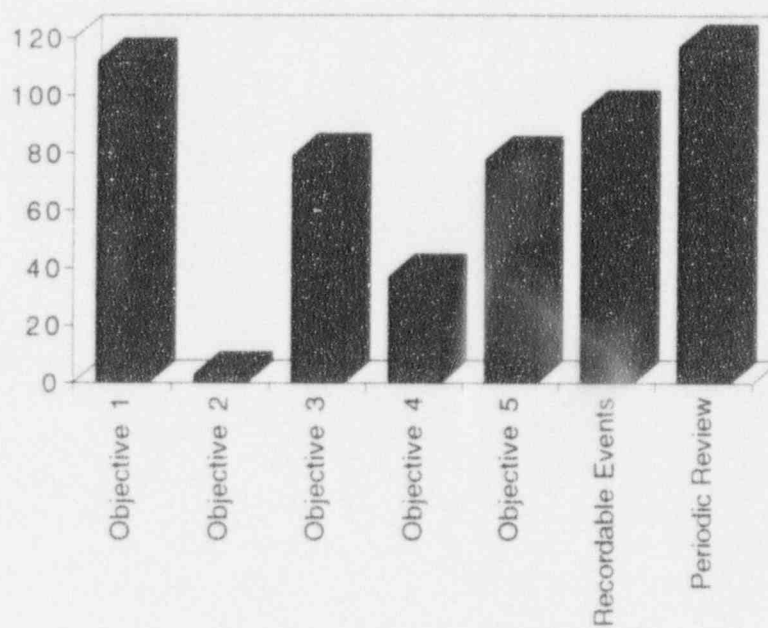


Figure 15

**Failure to Meet Required Objectives - HDR
Brachtherapy Modality (75 QMPs)**

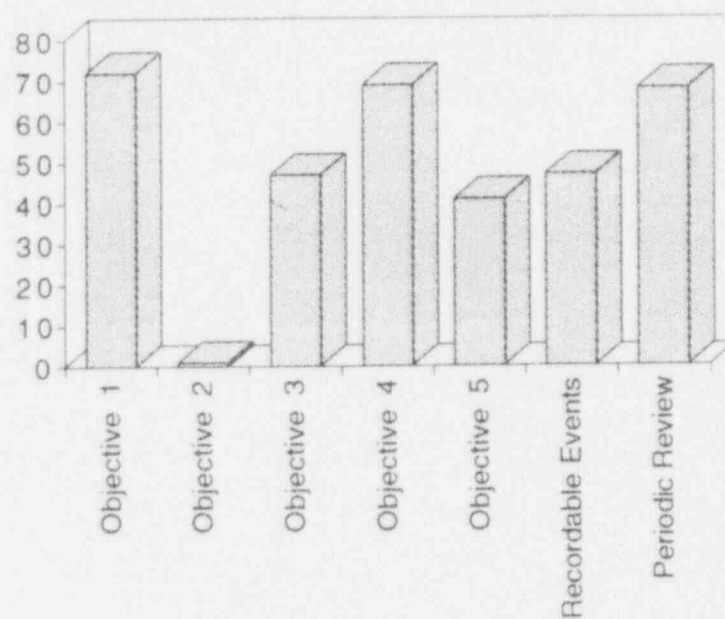


Figure 17

Failure to Meet Required Objectives - Brachytherapy
Modality (435 QMPs)

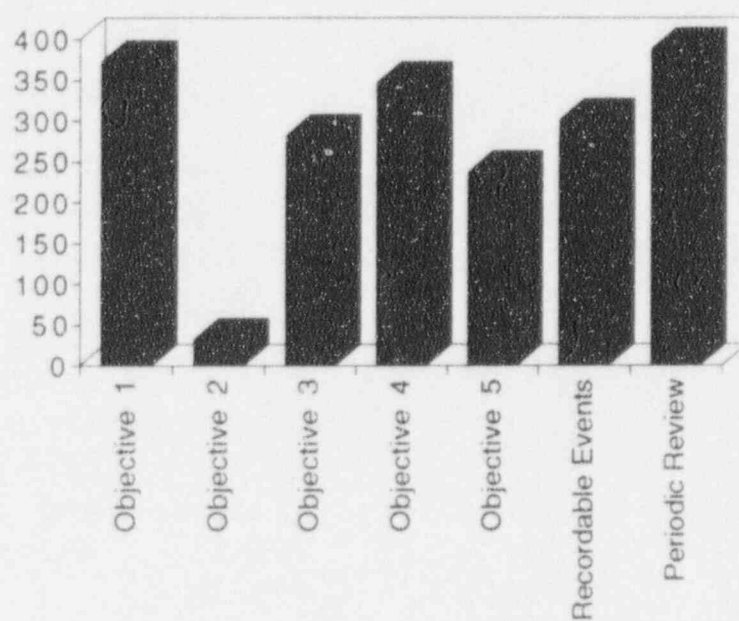


Figure 18

Failure to Meet Required Objectives - I-125 and/or I-131
> 30uCi Modality (1347 QMPs)

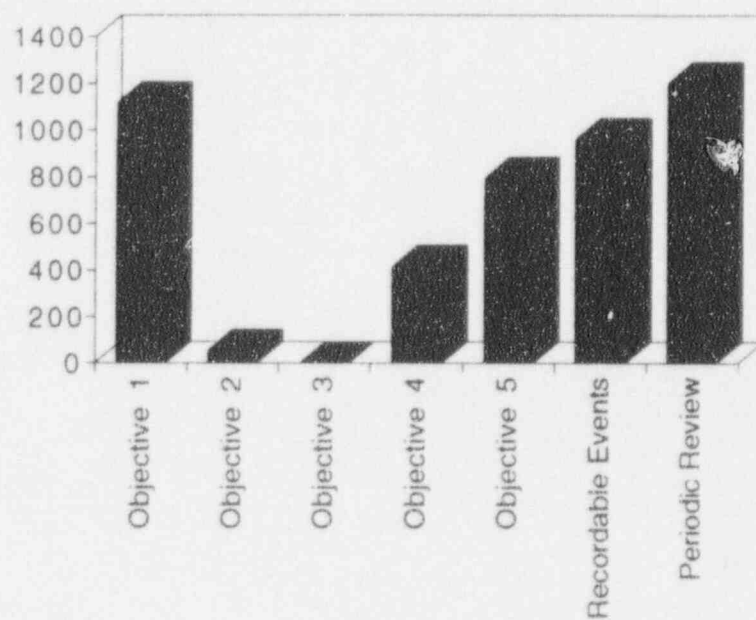


Figure 19

**Failure to Meet Required Objectives - Other
Radiopharmaceutical Therapy (881 QMPs)**

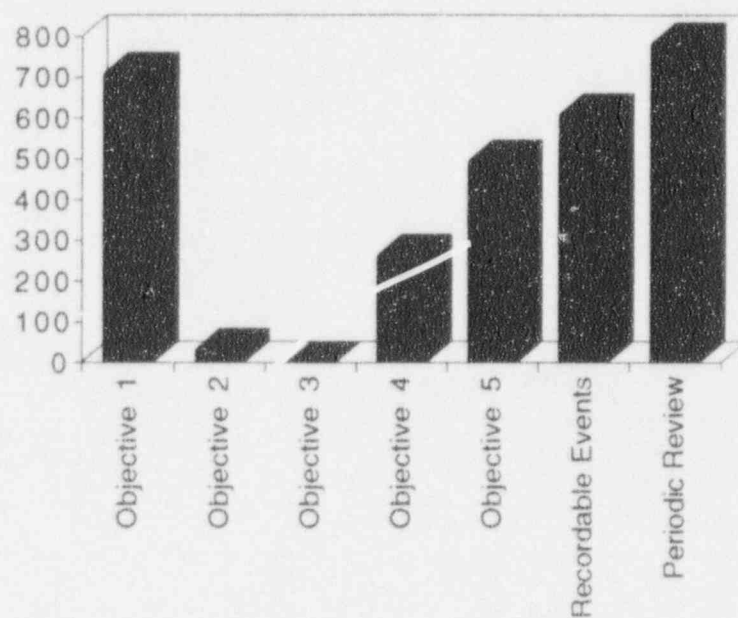


Figure 20

TEMPORARY INSTRUCTION (TI) FOR REVIEW OF QMPs

- **Issued August 1994**
- **In effect for 2 years**
- **Findings entered into database**

REVIEW OF NEW AND REVISED QMPs

- **Prior to inspection**
- **License renewal**
 - New licenses**
 - Amended licenses**

REEXAMINATION OF THE NRC ENFORCEMENT POLICY

BILL BRACH, DEPUTY DIRECTOR

**DIVISION OF INDUSTRIAL AND
MEDICAL NUCLEAR SAFETY**

NOVEMBER 17, 1994

OBJECTIVES OF THE REVIEW

- Determine whether the defined purposes of the enforcement program are appropriate
- Determine whether the implemented program is consistent with defined purpose (practices and procedures)
- Recommend changes as appropriate

PURPOSE OF THE ENFORCEMENT PROGRAM

- Promote and protect health and safety, the common defense and security, and the environment
- Four Objectives:
 1. Ensure compliance
 2. Obtain prompt corrective action
 3. Deter future violations
 4. Encourage improved performance

SPECIFIC AREAS TO BE EXAMINED

- Balance between deterrence and incentives
- Appropriateness of NRC sanction
- Amount of civil penalties
- Different policies/programs for large and small licensees (e.g. reactors and materials)
- Open enforcement conferences

APPROACH

- Review other Federal agencies' enforcement programs
- Obtain views of Regional and Program Office Managers
- Obtain public comments (Licensees, Agreement States, public interest groups, industry organizations)
- Federal Register Notice of August 23, 1994, 60 day comment period

Federal Register Notice

Requested Input On:

1. Purpose and Objectives of the Program
2. Severity Levels
3. Enforcement Conferences
4. Notices of Violation (and use of Form 591)
5. Civil Penalties
6. Adjustment Factors
7. Timeliness of Actions

Simulators and CT scanners

J. Van Dyk and K. Mah

1. Introduction

The process of radiation therapy for malignant disease is complex and involves many steps, as is shown in the block diagram of *Figure 7.1*. It begins with patient diagnosis, contains a number of steps to patient treatment, and carries through with on-going follow-up. One crucial step in this process is the determination of the location and extent of disease relative to adjacent critical normal tissues. This can be done in a variety of ways, ranging from simple clinical examination to the use of complex imaging modalities sometimes aided by contrast agents. Another step of the process is the selection of the necessary radiation beams to provide an adequate coverage of the tissues at risk while minimizing the dose to healthy normal tissues. Before treatment is initiated, this treatment plan needs to be confirmed by an imaging procedure to ensure that the beams traverse the desired anatomical volume and correlate accurately with respect to critical structures.

Computerized tomography (CT) scanners and radiation therapy simulators play a very important role in these components of the radiation therapy process. Both simulators and CT scanners can be used for localizing tumour extent and normal tissues. In addition, CT data may be needed for accurate dose calculations accounting for external contours and for variations in internal tissue densities. The simulator is essential for the verification of the location of the treatment ports since it simulates the actual treatment geometries. Based on the approved simulated fields, reference marks are placed on the external skin surface of the patient and used for the daily treatment set-up.

The need for spatial accuracy in these stages of the planning process must be emphasized. Uncertainties in patient reference marks as well as other imprecisions

generated by the simulation or CT procedures will be carried throughout the entire treatment course. Therefore it is important for the users of these devices to understand their limitations and capabilities and to develop strict quality assurance programmes which regularly monitor their performance.

2. Definitions related to patient planning

The International Commission on Radiation Units and Measurements (1), in an attempt to standardize radiation therapy terminology and dose specification procedures, has provided a number of relevant definitions. The terminology related to the planning process is summarized in this section with the aid of *Figure 7.2*.

2.1 Target volume

Figure 7.2(a) illustrates a CT image with a tumour of the lung clearly indicated. Generally, a volume which is larger than the tumour needs to be irradiated to a uniform high dose to account for factors such as occult microscopic disease, local invasive capacity of the tumour and its potential to spread, expected motion, and variation in daily treatment set-up. The **target volume** contains those tissues that are to be irradiated to a specified absorbed dose according to a specified time-dose pattern. While *Figure 7.2(a)* demonstrates a target volume in a two-dimensional plane, it needs to be emphasized that all target volumes contain a third dimension which is different from that on the central plane.

2.2 Treatment volume

Because of the geometric arrangement of radiation beams, the high dose region is usually larger than the

DIAGNOSIS

- tumour pathobiology
- staging

THERAPEUTIC DECISIONS

- cure/palliation
- treatment modalities

TARGET VOLUME LOCALIZATION

- tumour/normal tissue definition
- patient measurements
- field shaping

TREATMENT PLANNING

- selection of technique
- computation of dose distribution
- optimization

SIMULATION

- treatment verification
- confirmation of measurements
- confirmation of shields

FABRICATION OF TREATMENT AIDS

- blocks/shields
- compensators/bolus
- immobilization devices

TREATMENT

- verification of set-up
- verification of equipment performance
- dosimetry checks
- record keeping

PATIENT EVALUATION DURING TREATMENT

- treatment tolerance
- tumour response

PATIENT FOLLOW-UP

- tumour control
- normal tissue response

Figure 7.1. The various steps in the process of external beam radiation therapy. While all the steps are shown, not every patient will require each step nor will the steps always be in the order indicated.

target volume. The **treatment volume** is the volume enclosed by an isodose surface, the value of which is the minimum target absorbed dose. Sometimes the treatment volume is nearly the same as the target volume while at other times the treatment volume is substantially larger, depending on the complexity and geometry of the radiation beams. Figure 7.2(b) illus-

trates the treatment volume used to cover the target volume of Figure 7.2(a).

2.3 Irradiated volume

During patient treatment, radiation beams must traverse normal tissues in front of and/or behind the target volume. The **irradiated volume** is that volume, larger than the treatment volume, which receives an absorbed dose which is considered significant in relation to tissue tolerance. The significant absorbed dose level can be expressed as absorbed dose as a percentage (e.g. 50 per cent) of the specified target absorbed dose. Figure 7.2(b) also illustrates the irradiated volume based on the two-field technique used to treat the required target volume.

When planning a patient for treatment, an irradiation technique is developed which provides a maximum and uniform dose to the target volume and minimizes both the treatment volume and the irradiated volume. The resultant optimized treatment plan will depend strongly on these parameters as well as on the limiting doses to critical normal tissues. The critical normal tissues in the example illustrated in Figure 7.2 are the spinal cord and the uninvolved lung tissues.

It should be noted that the ICRU has commissioned a new report which is intended to update and replace Report 29(1).

3. Methods of deriving patient-specific data

3.1 Patient positioning

One of the major uncertainties in dose delivery to the patient relates to the ability to set up the patient accurately and reproducibly from day to day. Therefore it is important that, at the outset of the planning process, a comfortable and reproducible patient position is developed. The specific patient-positioning strategy will depend strongly on the volume to be irradiated. High dose, small volume techniques might require millimetre precision, whereas some large volume techniques might allow a somewhat larger tolerance. Examples of the former are small-field eye treatments or stereotactic radiosurgery, and examples of the latter are whole abdominal fields and half- or total-body irradiation.

A number of techniques can be used to aid in reproducible patient positioning. These are summarized in Table 7.1 and are broadly divided into four



Figure 7.2. (a) Squamous cell carcinoma of the maxillary sinus. (b) Target volume (tumour mass) and irradiated volume (50 per cent isodose) using a 11 x 1 cm field, each of 18 MV x-rays.

categories: (i) immobilization, (ii) positioning, (iii) monitoring technique, and (iv) positioning pillows, headrests, etc. It is possible to use a combination of these techniques to achieve a reproducible patient position.

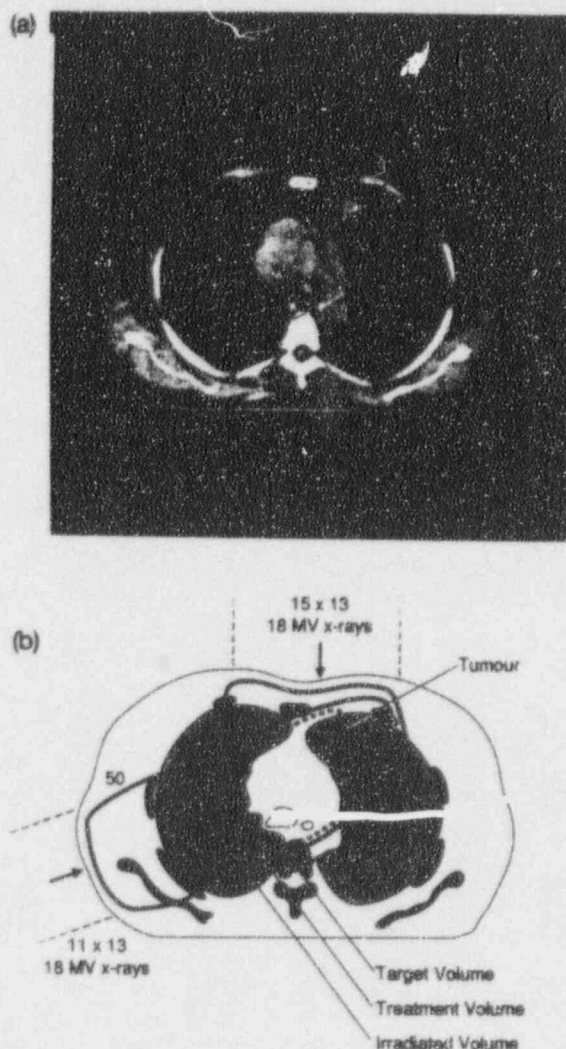


Figure 7.2. (a) A CT image of the mid-thorax showing a squamous cell carcinoma of the lung showing the obvious tumour mass and the proposed target volume; (b) a schematic transverse section of the patient in (a) showing the tumour mass, the target volume, the treatment volume (100 per cent isodose), and the irradiated volume (50 per cent isodose) using one anterior and one right oblique posterior field, each of 18 MV X-rays.

categories: (i) no immobilization, (ii) simple immobilization, (iii) complex immobilization, and (iv) monitoring techniques. Category (i) involves only patient-positioning aids such as three-point laser set-ups, pillows, head rests, etc. For these set-up procedures, it is possible that the patient position might change

during the actual beam-on time. Hence a review of patient set-up immediately after treatment will give some indication of its stability. Category (ii) involves some restriction of movement and requires the patient's voluntary help. Category (iii) involves individualized immobilization devices which restrict patient motion and ensure reproducible patient positioning. Category (iv) includes techniques for monitoring patient positioning and reproducibility of set-up, and may or may not be used in conjunction with immobilization devices. However, the results of these monitoring techniques provide input information as to improvements that may be required in the immobilization techniques used. Television monitoring provides a means of detecting obvious changes in patient position. Real-time electronic portal imaging provides a means of observing patient positioning, although the resultant image gives a beam's eye perspective of the irradiated volume. Both these techniques allow the radiographer (technologist) to make positioning adjustments either before giving a full daily

Table 7.1. Patient positioning aids.

No immobilization

Head or neck rests
Three-point laser set-up
Upper body elevator (breast technique)
Well-defined measurements (e.g. chin to sternal notch)
Vacuum sandbags
Foam cushions
Specially constructed couch attachments
Pillows
Styrofoam shoulder wedges

Simple immobilization

Tape chin or body straps
Lateral head supports
Bite blocks

Complex immobilization

Casts, shells, moulds
Expandable Styrofoam
Stereotactic head frame
'Bunny wrapping' for children

Monitoring techniques

Remote TV viewing
TV monitoring with difference images comparing present set-up to initial set-up
Port films
Repeat simulator films
Real-time electronic portal imaging

primarily developed for iridium wire. These systems are intended for standard source arrangements based on the volume to be treated. Precalculated tables are available to derive the total time required to deliver a treatment dose defined in a way that is specific to the dosimetry system. Many systems have been developed for gynaecological brachytherapy; the Manchester system is described in Section 6.7.

6.1 Dose prescription and reporting

When radium was first used, clinicians prescribed a quantity of radium to be put in place for a specified time depending on the site of the tumour, whether it was interstitial or intracavitary treatment, and the treatment volume. This is the origin of the source-related prescription given in the units milligram hours (mg h).

As dosimetry systems developed in parallel with the developments in dose quantities and units, prescription methods evolved in terms of exposure or dose within the standard dosimetry system. For example, in the Manchester system for gynaecological treatment, the specification changed from milligram hours to the exposure to point A. In the Paterson-Parker system for interstitial planar implants, the average dose to the treatment plane at a distance of 0.5 cm from the sources is used as a basis for prescription. In other systems the minimum peripheral dose for a given target volume was specified, and the more recent Paris system utilizes 85 per cent of the mean value of defined dose minima in a central plane. Thus, when doses to tumours and dose rates used for brachytherapy are discussed, a particular system should always be quoted, otherwise the meaning of dose is very imprecise. A particular example concerns the HDR iridium sources where dose rates and doses are frequently quoted without any explanation of their precise meaning. The instantaneous dose rate from such a source may be, for example, of the order of 5 Gy min^{-1} at 1 cm. However, if the source is moved throughout treatment the average dose rate will be different and will depend on the movement parameters.

With the availability of brachytherapy computer planning systems, which can rapidly calculate and display isodose curve patterns for any source arrangement, it may seem appropriate to use these to choose an isodose rate curve in the same way that an isodose curve is chosen from an external beam plan. However, there is a vast difference between these two

types of plan. In external beam therapy fairly uniform doses are achieved throughout the target volume with a relatively rapid fall off at the periphery. It is usual to prescribe to an isodose such that the maximum dose within the target volume is no more than 5–10 per cent greater. For brachytherapy, the dose within the target volume is very inhomogeneous; the dose to tissue in contact with the sources can be very high. At the periphery an isodose rate curve can be chosen for prescription, but the dose rate may change by a factor of 2 or more over distances of a few millimetres. Therefore, although computer systems are attractive tools with which to produce isodose rate curves in three dimensions around a source array, dosimetry systems continue to have an important role, in particular as the starting point in the planning/prescribing process. This is true even if the final precise calculation is made by computer. One of the benefits of computers is that they permit a degree of optimization of source arrangement, or dwell times, to be made quickly, which was not possible with traditional systems.

Standard dosimetry systems are likely to continue to be used for gynaecological treatments since the source arrangements and strengths for these treatments are based on many years of clinical experience, and changes in method, particularly dose rate, can compromise results significantly. The currently recommended method for reporting gynaecological brachytherapy treatment in full is given in ICRU 38 (18). This is discussed in section 6.7.3.

The full reporting of interstitial brachytherapy will be the subject of a future ICRU publication, which will probably include the following:

- (i) the minimum central dose;
- (ii) the total air kerma, i.e. the product of source strength and treatment time;
- (iii) the regions of low and high dose within the target volume, where high dose is greater than twice the prescribed dose and low dose is less than 90 per cent.

The Paris method of determining the 85 per cent isodose rate curve relative to the minimum central dose gives consistency to implant therapy prescribing and reporting, but any of the systems of dosimetry where there is a large clinical base of evidence that the prescription produces the right result is preferable to the arbitrary choice of isodose rate curve from the computer print-out.

corded despite apparent correct field-edge placement and lead shielding positioning. Phantom measurements will give information on whether the dose is as a result of some form of electron contamination or is due to internal or external scattered radiation. Daily set-up inaccuracies can also be excluded as a source of error. Phantom measurements are necessary to establish the relationship between surface dose measurements and doses at depth.

2.6.3 Checks on dose calculation

Phantom measurements should be made to ensure that new treatment techniques are satisfactory in terms of dosimetry before they are used for patient treatments. Computer calculations often give inaccurate results when calculating the dose to a critical structure outside the plane of the treatment plan and may not represent the effect of patient contour and tissue inhomogeneities accurately.

Treatment-planning algorithms should be verified by designing appropriate phantoms to test potential weaknesses. For example, electron calculation algorithms have difficulties simulating isodoses immediately below sharply changing contours, as might be found when additional build-up material is used to boost a skin dose. Step phantoms can be used to measure the potential calculation error in these situations.

In vivo measurements can be made but, because they introduce additional uncertainties, surface doses are not a useful test of dose calculation algorithms. If a convenient body cavity is available, TLD dosimeters can often be inserted in an appropriate package. Dynamic treatments should be verified before using them on a patient. This can be done by calculating a similar plan for a phantom. Film is a convenient way of measuring the dose distributions produced especially as its continuous nature means that localized hot spots will easily be identified. Manufacturers are developing new approaches to these problems and recent developments include multiplexed diode arrays and thin flexible sheets of TLDs spaced on 5 mm centres which are read out in a special reader. These methods are still under evaluation.

3. Verification of positional accuracy

There is increasing awareness that it is the positional accuracy with which the dose is delivered that is both the most significant avoidable cause of treatment fail-

ure and the most difficult to control. The traditional method of assessing positional accuracy has been to take a port film. Digital imaging methods allow contrast enhancement to be carried out, and imaging is now a powerful method of ensuring positional accuracy.

3.1 Verification requirements

The target volume in radiotherapy comprises three elements:

- (i) the overt tumour;
- (ii) an allowance for microscopic spread of the tumour (the biological margin);
- (iii) an allowance for set-up variability and inaccuracy (the technical margin).

In modern radiotherapy the aim is to reduce the technical margin to the minimum width since, for a typical 60 mm diameter target volume, an increase of 5 mm (8 per cent) in the margin will increase the volume of tissue irradiated by 27 per cent. However, if the beam is not precisely located, the probability of undertreating cancerous tissue will increase.

The primary aim of verification is to ensure that the position of the radiation beam is as close as possible to its intended position. Regular checks can then be carried out to quantify the uncertainties in field placement and so define the necessary size of the technical margin. Two secondary possibilities arise. Firstly, if it were possible to obtain an instant indication of the field placement error it would be possible to adjust the set-up to correct the error. Secondly, because a portal image is essentially an attenuation map of the patient, there is the potential for dose verification through transmission dosimetry.

3.2 Limitations to verification

The major difficulty in verification is that megavoltage beam images have inherently poor contrast. A 10 mm thick bone that produces a contrast of 18 per cent at 50 kV will produce a contrast of only about 2 per cent at 6 MV. Since it is often impossible to identify the tumour on a diagnostic film, it is almost always impossible to identify it on a megavoltage film. Therefore it is usual to base decisions on bony landmarks and air cavities. One way of overcoming these limitations is to attach a diagnostic tube to the head of the therapy machine so that by rotating the gantry through a fixed angle an exact replication of the therapy situation can be achieved (25), but this is rather cumbersome.

IRRADIATED VOLUME

That volume, larger than the treatment volume, which receives an absorbed dose which is considered significant in relation to tissue tolerance.

The significant absorbed dose level can be expressed as absorbed dose as a percentage (e.g., 50%) of the specified target absorbed dose.

ABNORMAL OCCURRENCE CRITERIA

ROBERT J. PRATO

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE FOR ANALYSIS AND EVALUATION OF OPERATIONAL DATA
OCTOBER 25, 1994

BACKGROUND

- 1974 - SECTION 208, ENERGY REORGANIZATION ACT.
- 1977 - PUBLISHED INITIAL AO CRITERIA ON FEBRUARY 24.
- 1980 - ISSUED MISADMINISTRATION REPORTING REQUIREMENTS.
- 1981 - DEVELOPED MISADMINISTRATION REPORTING GUIDANCE.
- 1984 - DEVELOPED MISADMINISTRATION REPORTING CRITERIA.
- 1994 - STAFF DEVELOPED A PROPOSED POLICY STATEMENT THAT REVISES THE EXISTING AO CRITERIA, TO REFLECT APPROPRIATE CHANGES TO REGULATIONS AND INCLUDE NEW CRITERIA AS DIRECTED BY COMMISSION.

REVISIONS TO ABNORMAL OCCURRENCE REPORTING CRITERIA

- MAY 19, 1994 - DIRECTION FROM THE COMMISSION
 - MEDICAL MISADMINISTRATION CRITERIA
 - OVEREXPOSURE CRITERIA
 - PART 20 CHANGES
 - "OTHER EVENTS OF INTEREST," GUIDELINES
- OTHER COMMISSION DIRECTIVES
 - LOST, STOLEN, AND ABANDONED SOURCES CRITERIA
- OTHER REGULATORY REQUIREMENTS
 - ONGOING RULEMAKING

REPORTING THRESHOLDS

CRITERION 1 - OVEREXPOSURE TO ADULTS

- 25 REMS TEDE
- 50 REMS CRITICAL ORGANS
- 250 REMS ALL OTHER ORGANS, SKIN, AND EXTREMITIES

CRITERION 2 - OVEREXPOSURE TO MINORS, FETUSES, AND EMBRYOS

- 5 REMS TEDE

CRITERION 6 - LOST, STOLEN, AND ABANDONED SOURCES

- $0.01 \times A_1$ VALUES FOR NON-DISPERSIBLE SOURCES
- THE SMALLER OF THE A_2 OR $0.01 \times A_1$ VALUES FOR DISPERSIBLE SOURCES

REPORTING THRESHOLDS CONTINUED

MEDICAL MISADMINISTRATION CRITERIA

- 100 RADS FOR CRITICAL ORGAN -OR- 1000 RADS OTHER ORGAN
- -AND-
- 50% GREATER THAN PRESCRIBED -OR- WRONG RADIO-PHARMACEUTICAL, WRONG ROUTE, WRONG TREATMENT SITE, WRONG TREATMENT MODE, OR LEAKING SOURCE

OTHER EVENTS OF INTEREST

- RECURRING EVENTS OR CONDITIONS
- MULTIPLE MISADMINISTRATIONS WITH COMMON CAUSE
- REACTIVITY ADDITION
- 5 REMS UNINTENDED RADIATION EXPOSURE TO AN ADULT

REVIEW OF REPORTED EVENTS

- 30 OF 51 MISADMINISTRATIONS PREVIOUSLY REPORTED AS AOS WOULD NOT HAVE BEEN REPORTED UNDER THE NEW CRITERIA.
- 4 OVEREXPOSURES, 1 LSA, 1 CONTAMINATION, AND 2 "OTHER" EVENTS PREVIOUSLY REPORTED AS AOS WOULD NOT HAVE BEEN REPORTED UNDER THE NEW CRITERIA.
- 2 MISADMINISTRATIONS, 1 FUEL CYCLE, 1 TRTR, 1 CONTAMINATION, AND 1 "OTHER" EVENTS REPORTED AS "OTHER EVENTS OF INTEREST" WOULD NOT HAVE BEEN REPORTED UNDER THE NEW CRITERIA.
- 2 EVENTS INVOLVING LOST OR STOLEN SOURCE NOT PREVIOUSLY REPORTED WOULD HAVE BEEN REPORTED UNDER THE NEW CRITERIA.

MILESTONES

- Publish proposed policy statement, Fall 1994
- 90 day comment period
- 120 day comment resolution period
- Commission review and approval
- Publish final policy statement, early Summer 1995

OVEREXPOSURE CRITERIA

1. ANY UNINTENDED RADIATION EXPOSURE TO AN ADULT (ANY INDIVIDUAL 18 YEARS OF AGE OR OLDER) RESULTING IN AN ANNUAL TEDE OF 250 mSv (25 REMS) OR MORE; OR THE SUM OF THE ANNUAL DEEP DOSE EQUIVALENT AND COMMITTED DOSE EQUIVALENT TO ANY INDIVIDUAL ORGAN OR TISSUE, OTHER THAN BONE MARROW, THE LENS OF THE EYE, OR GONADS OF 2500 mSv (250 REMS) OR MORE; OR AN ANNUAL DOSE EQUIVALENT TO BONE MARROW, THE LENS OF THE EYE OR GONADS OF 500 mSv (50 REMS) OR MORE; OR AN ANNUAL SHALLOW-DOSE EQUIVALENT TO THE SKIN, OR EXTREMITIES OF 2500 mSv (250 REMS) OR MORE.
2. ANY UNINTENDED RADIATION EXPOSURE TO ANY MINOR (ANY INDIVIDUAL LESS THAN 18 YEARS OF AGE) RESULTING IN TOTAL EFFECTIVE DOSE EQUIVALENT OF 50 mSv (5 REMS) OR MORE IN ONE CALENDAR YEAR, OR A DOSE EQUIVALENT OF 50 mSv (5 REMS) OR MORE TO AN EMBRYO OR FETUS.

UNINTENDED RADIATION EXPOSURE

AN UNINTENDED RADIATION EXPOSURE FOR THE PURPOSE OF REPORTING AS AN AO INCLUDES ANY OCCUPATIONAL EXPOSURE, EXPOSURE TO THE GENERAL PUBLIC, OR EXPOSURE AS A RESULT OF A MISADMINISTRATION INVOLVING THE WRONG PATIENT (AS DEFINED IN 10 CFR 35.2) THAT EXCEEDS THE REPORTING VALUES ESTABLISHED IN THE REGULATIONS. ALL OTHER REPORTED MISADMINISTRATIONS WILL BE CONSIDERED FOR REPORTING AS AN AO UNDER THE CRITERIA FOR MEDICAL LICENSEES.

IN ADDITION, UNINTENDED RADIATION EXPOSURES INCLUDE ANY EXPOSURE TO A NURSING INFANT, FETUS, OR EMBRYO AS A RESULT OF AN EXPOSURE (OTHER THAN AN OCCUPATIONAL EXPOSURE TO AN UNDECLARED PREGNANT WOMAN) TO A NURSING MOTHER OR PREGNANT WOMAN.

LOST, STOLEN, AND ABANDONED SOURCES

ANY LOST, STOLEN, OR ABANDONED SOURCES THAT EXCEED 0.01 TIMES THE A_1 VALUES, AS LISTED IN 10 CFR PART 71, APPENDIX A, TABLE A-1, FOR SPECIAL FORM (SEALED/NON-DISPERSIBLE) SOURCES, OR THE SMALLER OF THE A_2 OR 0.01 TIMES THE A_1 VALUES, AS LISTED IN TABLE A-1, FOR NORMAL FORM (UNSEALED/ DISPERSIBLE) SOURCES OR IF THE FORM IS NOT KNOWN. EXCLUDED FROM REPORTING UNDER THIS CRITERION ARE THOSE EVENTS INVOLVING SOURCES THAT ARE LOST, STOLEN, OR ABANDONED UNDER THE FOLLOWING CONDITIONS: SOURCES ABANDONED PER THE REQUIREMENTS OF 10 CFR 39.77(c); SHIELDED AND LABELED SOURCES SECURED IN RUGGED CANISTERS; RECOVERED SOURCES WITH SUFFICIENT INDICATION THAT AN UNNECESSARY EXPOSURE(S) DID NOT OCCUR DURING THE TIME THE SOURCE WAS MISSING; AND UNRECOVERABLE SOURCES LOST UNDER SUCH CONDITIONS THAT SIGNIFICANT ADVERSE HEALTH EFFECTS WERE NOT KNOWN TO OCCUR.

MEDICAL MISADMINISTRATION AO CRITERIA

- A MISADMINISTRATION RESULTING IN A DOSE EQUAL TO OR GREATER THAN:
 - (A) 1 GRAY (GY) (100 RADS) TO A MAJOR PORTION OF THE BONE MARROW, TO THE LENS OF THE EYE, OR TO THE GONADS; OR
 - (B) 10 GY (1000 RADS) TO ANY OTHER ORGAN; AND

- A MISADMINISTRATION REPRESENTING EITHER:
 - (A) A DOSE OR DOSAGE AT LEAST 50 PERCENT GREATER THAN PRESCRIBED IN A WRITTEN DIRECTIVE; OR
 - (B) A PRESCRIBED DOSE OR DOSAGE THAT: (I) IS THE WRONG RADIOPHARMACEUTICAL¹; OR (II) IS DELIVERED BY THE WRONG ROUTE OF ADMINISTRATION; OR (III) IS DELIVERED TO THE WRONG TREATMENT SITE; OR (IV) IS DELIVERED BY THE WRONG TREATMENT MODE; OR (V) IS FROM A LEAKING SOURCE(S).

¹The wrong radiopharmaceutical as used in the AO criterion for medical misadministrations refer to any radiopharmaceutical other than the one listed in the written directive or in the diagnostic clinical procedures manual.

MEDICAL MISADMINISTRATION AO CRITERIA

- A MISADMINISTRATION RESULTING IN A DOSE EQUAL TO OR GREATER THAN:
 - (A) 1 GRAY (GY) (100 RADS) TO A MAJOR PORTION OF THE BONE MARROW, TO THE LENS OF THE EYE, OR TO THE GONADS; OR
 - (B) 10 GY (1000 RADS) TO ANY OTHER ORGAN; AND
- A MISADMINISTRATION REPRESENTING EITHER:
 - (A) A DOSE OR DOSAGE AT LEAST 50 PERCENT GREATER THAN PRESCRIBED IN A WRITTEN DIRECTIVE; OR
 - (B) A PRESCRIBED DOSE OR DOSAGE THAT: (I) IS THE WRONG RADIOPHARMACEUTICAL¹; OR (II) IS DELIVERED BY THE WRONG ROUTE OF ADMINISTRATION; OR (III) IS DELIVERED TO THE WRONG TREATMENT SITE; OR (IV) IS DELIVERED BY THE WRONG TREATMENT MODE; OR (V) IS FROM A LEAKING SOURCE(S).

¹The wrong radiopharmaceutical as used in the AO criterion for medical misadministrations refer to any radiopharmaceutical other than the one listed in the written directive or in the diagnostic clinical procedures manual.

"OTHER EVENTS OF INTEREST" GUIDELINES

1. A SERIES OF TWO OR MORE RECURRING EVENTS OR CONDITIONS AT A SINGLE OR MULTIPLE FACILITIES (WHERE THE INDIVIDUAL EVENTS ARE NOT OF MAJOR IMPORTANCE IN THEMSELVES) THAT HAVE THE POTENTIAL TO BE SIGNIFICANT FROM THE STANDPOINT OF PUBLIC HEALTH AND SAFETY.
- 2 MISADMINISTRATIONS IN WHICH THE ADMINISTERED DOSE EXCEEDS THE PRESCRIBED DOSE AND INVOLVE MULTIPLE PATIENTS ATTRIBUTABLE TO A COMMON CAUSE.
3. AN UNPLANNED AND/OR UNCONTROLLED REACTIVITY ADDITION REQUIRING LICENSEE INTERVENTION TO PREVENT AN ACCIDENTAL CRITICALITY.
4. AN UNINTENDED RADIATION EXPOSURE TO AN ADULT OTHER THAN A RADIATION WORKER RESULTING IN A TEDE OF 50 mSv (5 REMS) OR MORE.

1993 ABNORMAL OCCURRENCE REVIEW

Event Type	93 AO	New Criteria	93 App C	New Guidance	Other Events	Reports 93	New Criteria
Power Reactors	1	1	7	3	6	0	0
Medical Misads.	22 ¹	11 ¹	2	0	16	0	0
TRTRs	1	1	1	1	0	0	0
Overexposure	4	4	0	0	2	0	0
LSA Sources	2	1	0	0	2	0	2
Contamination	1	0	0	0	0	0	0
Fuel Cycle	0	0	1	0	2	0	0
Others	1	0 ²	0	1 ²	2	0	0
Total	32	18	11	5	30	0	2

¹ Two events from previous years.

² One event converted from an AO to an Appendix C item.

1992 ABNORMAL OCCURRENCE REVIEW

Event Type	92 AO	New Criteria	92 App C	New Guidelines	Other Events	Reports 92	New Criteria
Power Reactors	3	3	4	2	0	0	0
Medical Misads.	16	4	0	0	0	0	0
TRTRs	0	0	1	0	0	0	0
Overexposure	1	1	0	0	0	0	0
LSA Sources	0 ¹	0 ¹	0	0	0	0	0
Contamination	0	0	0	0	0	0	0
Fuel Cycle	0	0	0	0	0	0	0
Others	0	0	0	0	0	0	0
Total	20	8	5	2	0	0	0

1 One events could be categorized under LSA source but reported as a misadministration AO.

1991 ABNORMAL OCCURRENCE REVIEW

Event Type	91 AO	New Criteria	91 App C	New Guidelines	Other Events	Reports 91	New Criteria
Power Reactors	0	0	7	3	0	0	0
Medical Misads.	13 ¹	6	0	0	0	0	0
TRTRs	0	0	0	0	0	0	0
Overexposure	5 ²	1	0	0	0	0	0
LSA Sources	0	0	0	0	0	0	0
Contamination	0	0	1	0	0	0	0
Fuel Cycle	2	2	0	0	0	0	0
Others	1	0	1	0	0	0	0
Total	21	9	9	3	0	0	0

1 Two events converted from an AO to an Appendix C item.

2 One event converted from an AO to an Appendix C item.



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**ADMINISTRATION OF RADIATION
AND RADIOACTIVE MATERIALS
TO PATIENTS**

10 CFR Parts 20 and 35

**Donald A. Cool and Stephen A. McGuire
Radiation Protection and Health Effects Branch
Office of Nuclear Regulatory Research**



United States Nuclear Regulatory Commission

- **Background**

- ✓ *NRC enforcement action related to administration of materials to a wrong patient*
- ✓ *Commission SRM dated May 10, 1994 directed the staff to prepare rulemaking*
- ✓ *Proposed rule prepared, but being held pending ACMUI review at this meeting*



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- **Proposal**

- ✓ *Revise Part 20 to make clear that all medical administrations of radiation or radioactive materials to any individual is regulated by Part 35.*

(Does not affect other exposures, for example exposure to stray gamma or x-rays. Those non-administration sources would continue to be regulated by Part 20.)

- ✓ *Seek comment on notification of wrong patients where doses exceed public dose limit in Part 20, but are not misadministrations under Part 35.*



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- *Approach*

- ✓ *Currently considering modifying Scope, definitions of public dose, and occupational dose, and § 20.1301(a) to explicitly exclude doses "due to any medical administration the individual has received."*
- ✓ *Uses the term individual rather than patient so that any administration is covered by Part 35 rather than Part 20 (no need to define patient)*



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- **Schedule**

- ✓ *A draft proposed rule can go to the Commission after this meeting*
- ✓ *If the Commission approves, the proposed rule would be published in the Federal Register around end of year*



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10 CFR PARTS 20 and 35

Patient Release Criteria

**Donald Cool, Stewart Schneider, and Stephen McGuire
Radiation Protection and Health Effects Branch
Office of Nuclear Regulatory Research**



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- **Status**

- ✓ *Comment period for the proposed rule, draft regulatory guide, NUREG-1492 expired August 29, 1994*
- ✓ *Proposed rule, 56 comment letters*
 - ▶ *Over 80% from physicians or medical groups, Agreement States-4, Other-4*
- ✓ *Draft Regulatory Guide, 6 comment letters*
- ✓ *NUREG-1492, 1 comment letter*



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- Major Provisions of Proposed Rule
 - ✓ *Modify the application of the public dose limit in 10 CFR 20.1301(a)(1) and (a)(2) to exclude the dose received from patients released under the provisions of 10 CFR 35.75*
 - ✓ *Modify 10 CFR 35.75 to specify a 500 mrem (5 mSv) Total Effective Dose Equivalent dose limit criterion for the individual likely to receive the greatest dose*



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- Major Provisions of Proposed Rule
 - ✓ *Modify 10 CFR 35.75 to require that when the dose to an individual is likely to exceed 100 mrem (1 mSv) from any patient release:*
 - ▶ *Licensees provide written information on methods for reducing the exposure of individuals*
 - ▶ *Licensees keep a record of the release for 3 years (to provide basis for summing doses)*



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- Major Issues Raised by Commentors and NRC Staff
 - ✓ *Recordkeeping for doses > 100 mrem*
 - ✓ *Written instructions to patients*
 - ✓ *How should exposure to a breast-fed infant/child be addressed?*



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- Comments on Recordkeeping for Doses > 100 mrem
 - ✓ *The strongest opposition to the proposed rule*
 - ✓ *Commenters asserted that excessive costs in time, effort, and money to find previous administration records*
 - ✓ *Commenters asserted that NRC underestimated the cost of record generation and retrieval*



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- Options Being Considered to Reduce Recordkeeping Burden
 - ✓ *No requirement for recordkeeping in the final rule; performance based*
 - ▶ *Address compliance in Regulatory Guide only*
 - ▶ *Guidance cover issues such as potential for multiple administrations*
 - ✓ *Require records for releases based on case-specific calculations but not for use of tables*



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- Comments on Written Instructions to Patients
 - ✓ *Instructions do not need to be written; oral instructions should be sufficient*
 - ✓ *A major health maintenance organization strongly supported the requirement that the instructions be written*
 - ✓ *A sizable fraction of patients will not behave as instructed*



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- Options Being Considered on Written Instructions Issue
 - ✓ *Provide oral instructions only*
 - ✓ *Provide written instructions as proposed*
 - ✓ *Address degree of patient compliance in the Regulatory Guide*



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- How should exposure to a breast-fed infant/child be addressed?
 - ✓ *The 500 mrem/year limit might be exceeded if breast-feeding continued for some diagnostic tests (e.g., Tc99m as pertechnetate for brain scans and I-131)*
 - ✓ *Although clearly identified in the proposed rule notice, few comments.*
 - *One commenter viewed the breast-fed infant/child as a special case that should not be considered in complying with the annual limit*
 - *One stated that the breast-fed infant/child should be addressed as a part of patient-physician decision to conduct the procedure*



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- *Breast-Feeding Infant/Child Protection - Generic Policy Issue*
 - ✓ *Radiation protection standpoint; focus on consistent protection of individuals*
 - ✓ *Patient-physician standpoint; focus on balancing all factors and maximum flexibility*



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- *Breast-Feeding Infant/Child - Radiation Protection Rationale for Treating Infant/Child as Individual*
 - ✓ *The infant/child is physically separated*
 - ✓ *Infants/children may never breast feed, so inequitable protection*
 - ✓ *No clear break point since breast-feeding times vary over wide range*
 - ✓ *Optimization considerations: 1) before study, mother could pump breast and store enough milk in freezer for feeding the infant/child and 2) standard medical practice for radioactive and nonradioactive pharmaceuticals is to consider interrupting breast-feeding*



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- *Breast-Feeding Infant/Child - Problems under Proposed Rule if Considered as Individual*
 - ✓ *Does not include preventative action before administration*
 - ✓ *Difficulty in calculating doses*
 - ✓ *Could limit decisions by physician and patient*
 - ✓ *Potential for patient confinement in many more cases (i.e., diagnostic procedures)*



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- Resolution Under Consideration by RES
 - ✓ Rule: No change
 - ✓ Regulatory Guidance:
 - ▶ Include discussion of preventive measures in introduction to but not position of guide
 - ▶ Limit consideration of nursing to specified dosages and radiopharmaceuticals
 - ▶ Provide a table of acceptable times to resume nursing
 - ▶ *Clarify that reliance on instructions to breast-feeding women in the regulatory guide is acceptable*



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- Schedule
 - ✓ *Final rule and Regulatory Guide to the Commission summer of 1995*