

ORIGINAL

RETURN TO SECRETARIAT RECORDS  
NUCLEAR REGULATORY COMMISSION

---

IN THE MATTER OF:

PUBLIC MEETING  
POLICY SESSION 78-12

Place - Washington, D. C.

Date - Thursday, 2 March 1978

Pages 1 - 84

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U. S. NUCLEAR REGULATORY COMMISSION  
MEETING OF THE COMMISSIONERS

PUBLIC MEETING

POLICY SESSION 78-12

Commissioners' Conference Room  
1717 H Street, N. W.  
Washington, D. C.

Thursday, 2 March 1978

2:45 p.m.

COMMISSIONERS PRESENT:

Chairman Joseph M. Hendrie  
Commissioner Richard T. Kennedy  
Commissioner Victor Gilinsky  
Commissioner Peter A. Bradford

STAFF MEMBERS PRESENT:

Assistant Secretary John Hoyle  
Thomas Dorian  
R. M. Bernero  
R. E. Cunningham  
W. Dircks  
A. Kenneke

P R O C E E D I N G S

CHAIRMAN HENDRIE: Since we have a quorum, why don't we go ahead?

The Commission is meeting this afternoon for a briefing and discussion on medical uses of isotopes. I believe Dick Cunningham bears the principal responsibility. Bob Bernero apparently put his finger in the pencil sharpener. He can hardly be trusted with medical applications.

(Laughter.)

Let's see, who will have the lead? Dick, will you lead off, or Bill?

MR. DIRCKS: Dick has the lead, Mr. Chairman, but we just want to remind you that this is another one of those program comprehensive briefings we've been bringing down to you in recent weeks. We're trying to lay out not only what's going on in the regulatory area of medical isotopes, but at this time we bring forth a proposal, a staff proposal to the Commission, regarding the issuance of a proposed rule.

As you noted, Dick Cunningham of NMSS will present the briefing, along with Mr. Bernero, but I think we'd like to stress that this represents the views of all the program and staff offices of the agency. We do have other offices with heavy involvement in this particular area, including emphasizing the role of Inspection and Enforcement.



1     Whatever they're saying will represent the views of the  
2     other offices.

3             MR. CUNNINGHAM: May I have the first slide,  
4     please?

5             (Slide.)

6             Mr. Chairman, in November of 1976 we had a  
7     meeting with the Commission to discuss some issues dealing  
8     with nuclear medicine, some rather difficult policy issues,  
9     and at that time the instructions of the Commission were to  
10    develop policy guidance which will guide the course we take  
11    in subsequently developing regulations for nuclear medicine.

12            What we did was get public involvement in develop-  
13    ing this policy. We have now done that, Mr. Chairman, and  
14    what we have today are some policy statements which we would  
15    propose to publish for public comment prior to adoption,  
16    in addition to some proposed rules that we would like to  
17    have published for public comment.

18            Before we go into the policy statements and the  
19    proposed rules, Mr. Chairman, I think we would like to take  
20    this opportunity to give you a background briefing on our  
21    medical licensing program. It is a rather large program in  
22    that it affects a lot of people, and it isn't one of those  
23    programs that are up before the Commission very often. We  
24    would like to take this opportunity to give you a background  
25    briefing.

1 May I have the next slide, please?

2 (Slide.)

3 When we talk about nuclear medicine, of course,  
4 or the medical radioisotope industry, it's necessary to  
5 start with the reactor that produces the radioisotopes.  
6 From there they're transported to the drug manufacturer, who  
7 changes these radioisotopes into a drug of pharmaceutical  
8 quality, and from there it goes to the hospital or nuclear  
9 medicine laboratory, where it is administered to the patient  
10 in one way or another.

11 COMMISSIONER BRADFORD: Dick, could you give me  
12 some idea of the numbers that go into each of those boxes,  
13 how many people produce radioisotopes?

14 MR. CUNNINGHAM: Basically there are only two  
15 reactors in the United States that were producing radio-  
16 isotopes. Those were the GETR in Balacitos and the Union  
17 Carbide reactor in Sterling Forest. When the GETR shut  
18 down because of the seismic issues, a great deal of the  
19 slack was picked up by the high-flux reactor, HFR, I guess  
20 it is, in Oak Ridge, as well as Sterling Forest's reactor  
21 increasing their production.

22 In terms of quantity, the quantity of isotopes  
23 are a few hundred or thousand curies a week. It's not a  
24 lot in terms of the curie to radioisotopes produced.

25 COMMISSIONER BRADFORD: When Oak Ridge produces

1       them, that's at a Government facility?

2               MR. CUNNINGHAM:   Yes.

3               COMMISSIONER BRADFORD:   Do they then sell them  
4       just the way G.E. would?

5               MR. CUNNINGHAM:   To my knowledge, they do.   They  
6       sell them -- it's cost recovery, and I think they sell them  
7       just the way G.E. would.

8               The University of Missouri had a high-flux reactor  
9       that picked up some of the slack.

10              Some of these production procedures require a  
11     reactor with relatively high flux, and it does create a bit  
12     of a problem when these reactors go down.   You can't stockpile  
13     the radioisotopes that are used in medicine; you have to  
14     keep the system full, so it does create some problems if  
15     you don't have the flexibility of shifting from one reactor  
16     to another.

17              COMMISSIONER BRADFORD:   And how many manufacturers  
18     are there?

19              MR. CUNNINGHAM:   There are, I would say, half a  
20     dozen major manufacturers that are the major suppliers of  
21     radioisotopes of pharmaceutical quality, radiopharmaceuticals.  
22     There aren't very many manufacturers.

23              So far as the medical users go, I do have a  
24     graph that I'll be getting to, but there are thousands.

25              COMMISSIONER BRADFORD:   And they are all supplied

1 by those half-dozen manufacturers?

2 MR. CUNNINGHAM: Yes, essentially half a dozen.  
3 There are others in the business, but it's essentially half  
4 a dozen.

5 Incidentally, our reactors produce radioisotopes  
6 that are used -- practically all the medical radioisotopes  
7 used in Japan are produced in this country, as well as quite  
8 a few of the European uses of radioisotopes come from reactors  
9 in this country.

10 But for purposes of today's briefing, when I  
11 talk about the medical program, the people involved, the  
12 risks, the types of things that are going on, I'm directing  
13 my talk to the medical use, what happens in nuclear medicine  
14 laboratories, not any risk that might be involved in operat-  
15 ing the reactor or in making radiopharmaceuticals or in  
16 the transportation among these groups. That's covered  
17 elsewhere, so really I'm talking about what's happening in  
18 the nuclear medicine laboratory.

19 May I have the next slide, please?

20 (Slide.)

21 Medical uses of radioisotopes can be broken down  
22 into two categories: diagnostic applications, where you try  
23 to determine what is happening in the body; and therapeutic  
24 applications, where you're trying to cure something.

25 May I have the next slide, please?



(Slide.)

Diagnostic applications are really four categories.

In vivo, as you may recall, means inside the body as opposed to in vitro, which means that you take a sample outside the body and manipulate it somehow to get information.

In vivo function studies involve things like the rate at which the thyroid will take up iodine when you inject a quantity of radioactive iodine into the body and measure the thyroid. Renal function studies, blood volume studies and that sort of thing.

In vivo scanning studies are for the most part looking for tumors inside the body. The radioisotope most commonly used is technetium 99 metastable. It has a short half-life. Depending upon what chemicals you combine it with, it has selective uptake in various parts of the body and you can look for tumors in places like the brain, thyroid, liver, kidney, what-have-you -- almost anywhere you want to, really.

In vitro diagnosis, these are mainly radiobioassay studies that really are used to measure concentrations of things like hormones in the blood. They're used quite a bit. As a matter of fact, to show that somebody can still do something in this radioisotope business, Dr. Yahlo of the Bronx V.A. got a Nobel Prize this year for her work in developing radioimmunoassay procedures.

1           You can measure down to nanocuries per gram or  
2 picacuries per gram with these procedures, so they're very  
3 sensitive.

4           And the diagnostic devices: The bone mineral  
5 analyzer is a typical use. You just measure the density of  
6 the bone for various reasons.

7           Next slide, please.

8           (Slide.)

9           Therapeutic applications are basically three  
10 types, where you inject a large -- comparatively large  
11 quantity of a radiopharmaceutical into the body that goes  
12 to a selected organ. It's mainly used for thyroid cancer,  
13 hyperthyroidism, polycythemia vera, where you have an overpro-  
14 duction of red blood cells. You inject P-32. Metastatic  
15 bone disease, again P-32, where the phosphorous goes in the  
16 bone.

17           Teletherapy. This is using a cobalt 60 source  
18 that is used in a shielded container outside the body to  
19 try to irradiate tumors in the body.

20           Brachytherapy. These are interstitial implants  
21 that are sewn right into tumors, usually near the surface  
22 of the skin.

23           May I have the next slide, please?

24           (Slide.)

25           To give you some idea of the extent to which these

1 are used, there are about 15 million in vivo procedures  
2 conducted per year, 20 million in vitro procedures and about  
3 7 million teletherapy procedures.

4 The significance of this is that there are a  
5 lot of people that are coming under the umbrella of the  
6 licenses we issue in nuclear medicine.

7 May I have the next slide, please?

8 (Slide.)

9 An idea of the size of the industry from a money  
10 standpoint. Of the \$118.5 billion spent on health, about  
11 \$2.2 billion is spent on nuclear medicine services.

12 May I have the next slide, please?

13 (Slide.)

14 Looking at the size of the program from the  
15 licensing standpoint, we have about 1600 licensees for  
16 hospitals to do diagnostic and therapeutic work; about 600  
17 to physicians; 450 teletherapy licenses; and a fairly large  
18 number of people who register under general licenses to do  
19 very limited types of work.

20 I should say these are just NRC medical licenses.  
21 If you include the agreement states, you do a little bit  
22 better than double those numbers.

23 The number of people that are occupationally  
24 involved under our licenses we estimate -- and it's only an  
25 estimate, but we think it's about 30,000 people under these

1 medical licenses.

2 Now, in developing -- may I have the next slide?

3 (Slide.)

4 That is just by way of background. When we consider de-  
5 veloping our policy to guide us in our future regulatory  
6 work in medical licensing, there are really two major con-  
7 siderations: what's the risk to the patient, general public  
8 and the workers; and, secondly, what are other people doing  
9 that are also involved in regulating or in somehow impacting  
10 on the control of nuclear medicine.

11 There are a number of subsets of questions you  
12 can ask about this. For example, in arriving at policy you  
13 have to ask yourself what regulations truly benefit the  
14 patient and the public and at what point do regulations  
15 really inhibit the physician's ability to make decisions on  
16 patient management to the detriment of the patient.

17 If you overregulate a physician, of course, he's  
18 not free to make judgments very quickly.

19 Another set of questions might be how much regu-  
20 lation is necessary to prevent misuse of nuclear medicine,  
21 where it might be used as a fad rather than a legitimate  
22 tool by qualified physicians, or the converse of that, at  
23 what point do we regulate physicians to the point that they  
24 avoid using nuclear medicine, again to the detriment of the  
25 patient -- make it so difficult for them that they'd rather

1 not get involved with it.

2 Finally, of course, you have the question of  
3 what can NRC regulate best and what should better be left  
4 to other people to regulate.

5 May I have the next slide, please?

6 (Slide.)

7 On the question of risk in nuclear medicine,  
8 in the first place the risk to the patient, in diagnostic  
9 procedures the risk is usually low. A typical scan using  
10 technitium 99 is about -- results in about a whole body dose  
11 of about 250 milligrams -- not a very large dose for medical  
12 purposes.

13 Therapeutic procedures, however, can be another  
14 story. There, of course, you're trying to actually kill  
15 certain cells in the body. In doing so you irradiate cells  
16 you don't necessarily want to irradiate.

17 Typical teletherapy exposures can range as high  
18 as 2- to 6,000 rem over a course of treatment. Now, when  
19 you consider that the LD-50 for radiation is somewhere in  
20 the neighborhood of 450 rem, you can see how important --  
21 how a little error can produce very adverse results.

22 Patients receiving teletherapy treatment very  
23 often suffer the typical radiation, acute radiation syndrome  
24 thing. They vomit, they have erythema, they lose hair --  
25 all these sorts of things happen to them. So there is a risk

1 in these therapeutic doses.

2 May I have the next slide, please?

3 (Slide.)

4 The risk to the public is pretty low. A typical  
5 surface dose from a patient for a very short time after he  
6 receives a diagnostic quantity of material is about 10 MR  
7 per hour, and that goes away very quickly. Of course, if  
8 you're giving therapeutic doses you hospitalize the patient  
9 if they're given internal therapeutic doses. Teletherapy  
10 treatment, of course, doesn't involve radiation inside the  
11 patient -- I mean administration of radioactive material  
12 inside the patient.

13 Again, when I talk of risk to the public I'm  
14 not talking about the whole nuclear medicine industry if  
15 you consider the risk of operating the reactor, making  
16 pharmaceuticals and so forth.

17 As for risk to the public who may be in or  
18 around a nuclear medicine laboratory, you always must remem-  
19 ber that nuclear medicine laboratories are in hospitals and  
20 hospitals have people wandering around the corridors.

21 MR. DIRCKS: And it excludes transportation.

22 MR. CUNNINGHAM: Yes, it excludes transportation  
23 and all this sort of thing.

24 May I have the next slide, please?

25 (Slide.)



1           The risk to workers. There is some risk if good  
2 health physics procedures aren't followed, and there is some  
3 risk even if good health physics procedures are followed.

4           Every once in a while, for example, the shutter  
5 on a teletherapy unit will jam for some reason or another.  
6 Somebody has to go in and pull the patient out of the tele-  
7 therapy treatment room. That's a risk.

8           Very often you have quite sick patients. You  
9 have emergencies on your hands. You can't follow the best  
10 procedure. You have to balance what happens to the patient  
11 against following all the nice procedures you would like to  
12 follow, so there's always that tradeoff.

13           In most nuclear medicine laboratories they handle  
14 a lot of technetium. When you generate or eluate to get  
15 the technetium, the vial, right after it's eluted, will be  
16 hundreds of R per hour at the surface of that vial. If it's  
17 picked up or mistreated it can result in problems.

18           Nevertheless, I think our surveys that we have  
19 conducted to try to find out what typical exposures are to  
20 medical workers, they're running around .5 rem per year;  
21 so it's not too bad on the whole.

22           That summarizes the risk to workers. Now I'd  
23 like to talk -- if I may have the next slide --

24           (Slide.)

25           -- a little bit to our interface with other people who

1 regulate nuclear medicine.

2           You can see here that we've drawn a little sche-  
3 matic of all these groups, whether they're regulatory groups  
4 or peer groups, what-have-you, who one way or another are  
5 involved in the regulation or setting standards of practice  
6 for the practice of nuclear medicine.

7           We have to define what we best can do and what  
8 can best be left to others.

9           Probably the two most -- well, three most important  
10 groups -- if I may have the next slide.

11           (Slide.)

12           These are just peer groups, all of which we have  
13 to work with. We have done quite a bit of work in the past  
14 to get the American Board of Nuclear Medicine established.  
15 We heavily supported that work a few years ago so we can  
16 get some standards, professional standards, of practice and  
17 physician qualification, although we're still looking at  
18 physician qualifications.

19           All of these are peer groups that in one way or  
20 another impact on the quality of nuclear medicine practice.

21           May I have the next slide, please?

22           (Slide.)

23           Again, state health organizations. States  
24 license physicians to practice medicine. They license  
25 paramedics, and in some instances they license pharmacies.

1 This is all relating to the quality of medical practice in  
2 one way or another.

3 And, of course, we have the agreement states,  
4 and I don't need to expand on that.

5 May I have the next slide, please?

6 (Slide.)

7 I guess our major interface in regulating nuclear  
8 medicine comes with the Food and Drug Administration. Food  
9 and Drug, FDA, controls good manufacturing practices. This  
10 is the control of the radiopharmaceutical manufacturer to  
11 be sure the drugs are good pharmaceuticals. There you're  
12 worried about things like sterility and that sort of thing --  
13 drug quality.

14 They assure that the drug or device is properly  
15 labeled. That means that it has a label that says it's  
16 safe at applications for such a purpose, giving the indicat-  
17 ions on it, counterindications, dose range and so forth.

18 And they do control investigational use of  
19 drugs. This is the control of the use of drugs before  
20 they're ready to say it's safe and effective.

21 These investigational use laws, or the most  
22 recent ones, flowed out of the thalidomide scandal a decade  
23 or so ago.

24 Until very recently, within the past two years  
25 or so, we regulated for radiopharmaceuticals the investigational

1 use of drugs and decided when they should be put into routine  
2 use until FDA got staffed up and into a position where they  
3 could take this function over.

4 They have new legislation now covering medical  
5 devices, and they aren't yet in a position to completely  
6 regulate those. I'll get to that a little bit later, but  
7 that's one of the things coming up.

8 In developing a policy -- if I may have the  
9 next slide, please.

10 (Slide.)

11 As I said before, we were before the Commission  
12 in November of '76. In May of 1977 we held public meetings  
13 on questions of policy and the direction in which we should  
14 be going in policy to guide us. We also held a meeting  
15 with our Medical Advisory Committee. We now have a pro-  
16 posed policy statement.

17 I think in developing this policy what we want  
18 to do, of course we don't want to overregulate physicians  
19 and we don't want to underregulate physicians. If this  
20 policy is adopted, specific regulations that come in the  
21 future will be reviewed in the context of this policy.

22 May I have the next slide, please?

23 (Slide.)

24 So the three policy statements that we have,  
25 the first one is that we believe the NRC should regulate

1 the medical uses of radioisotopes as necessary to provide  
2 for the radiation safety of the workers and the general public.

3 This is practicing our role in just health  
4 physics, if you will, as we do in other facilities. This  
5 is one of the things that we know how to do, and we can do  
6 it, I think, fairly well.

7 May I have the next slide, please?

8 (Slide.)

9 Now, the next policy statement, we start entering  
10 into the qualifications of the physician to practice medi-  
11 cine and to the physician-patient relationship. This gets  
12 a little bit more difficult.

13 The next policy statement, though, is that NRC  
14 will regulate the radiation safety of patients where justi-  
15 fied by the risk to patients and where voluntary standards,  
16 or compliance with these standards, are inadequate.

17 This implies that we will not regulate in areas  
18 where there are standards mandated by other agencies and  
19 these other agencies have competence to impose, or to en-  
20 force their regulations.

21 May I have the next slide, please?

22 (Slide.)

23 The third policy statement is that we will mini-  
24 mize our intrusion into medical judgments affecting patients  
25 and into other areas traditionally considered to be a part

1 of the practice of medicine.

2 I might say here that the AEC, and now the NRC,  
3 is the only Federal agency that ever regulated the quality  
4 of the practice of medicine. I don't know whether that's  
5 good or bad. Nuclear medicine has grown tremendously over  
6 the years, and we haven't had any major scandals. I don't  
7 know if they've done that in spite of us or because of us,  
8 but we are the only agency who has done that sort of thing.

9 Now, the question of how we implement the policy.

10 May I have the next slide, please?

11 (Slide.)

12 Looking at specific items of interest: physicians'  
13 qualifications. We have requirements, minimum requirements,  
14 I might add, for physicians' qualifications to practice  
15 nuclear medicine. We have repeatedly brought up this ques-  
16 tion to our Medical Advisory Committee and peer groups as  
17 to whether or not we should continue to license physician  
18 qualifications.

19 We got into licensing physician qualifications  
20 to practice nuclear medicine when there were no other  
21 standards and when nuclear medicine was new. This started  
22 long before the time, I guess, of any of us here in AEC,  
23 back in the late '40s when AEC was first formed.

24 since that time a Board of Nuclear Medicine has  
25 been established. The Board of Radiology has subgroups



1 approving nuclear medical physicians. Nevertheless, the  
2 advice of our Medical Advisory Committee is to still con-  
3 tinue this practice, not turn it over completely to the  
4 peer groups, because there has to be some mechanism for  
5 the approval of some physicians for certain things that  
6 the peer groups don't approve.

7 We accept with certain limitations board certifi-  
8 cations as an indication of qualifications, but I have to  
9 stress that our criteria for physician qualification are  
10 minimal and about the best, probably, that we set for this  
11 is that it keeps people who aren't serious about this busi-  
12 ness out of the field. It doesn't let people dabble in  
13 the field.

14 Selection of patients, that's a medical judgment.

15 Selection of instruments to diagnose patients,  
16 that again, we feel, is a medical judgment.

17 Selection of drugs, we limit those to drugs  
18 approved by the FDA, approved for investigation by the FDA.

19 And selection of the procedures. That is the  
20 purpose for which the drug is used. We do this to a limited  
21 extent, and Bob Bernero will talk to you about that a little  
22 bit more.

23 Next slide, please.

24 (Slide.)

25 Selection of patient dose. That's a physician

1 judgment call.

2 Measurement of dose. We do require under our  
3 regulations -- we're in the process of doing this for  
4 teletherapy licensees -- that the dose be measured, so we  
5 are moving in that direction. That's just good practice,  
6 and we feel we can impose that.

7 Calibration of diagnostic instruments. We do  
8 require dose calibrators to be calibrated. The scanners  
9 and things like that, that's an open question.

10 There is a question whether or not we should pass  
11 on the qualifications of paramedics to assist in nuclear  
12 medicine laboratories. This is an open question. Lots of  
13 states do license their paramedics. There are paramedic  
14 certification programs, but nevertheless this is an open  
15 question. There aren't consistent rules, certification  
16 procedures, that can be applied.

17 It would be a difficult thing to do. In the  
18 first place, there are probably on the order of five to ten  
19 paramedics working in a nuclear medicine laboratory for  
20 each physician. That gives an increased workload. And  
21 the ways in which paramedics are used vary quite markedly  
22 from one laboratory to another, and their professional  
23 qualifications vary, too. A paramedic may be a technician  
24 with a high school education, or he may be a Ph.D. physicist.  
25 It depends just on how they're used.

1           If we get into this--we're exploring it, but  
2 we're not sure where we come out on this question.

3           Misadministrations, the reporting of mis-  
4 administrations. This is a question that's been up to  
5 the Commission once. We've gone back to the drawing board,  
6 and we do have a proposed rule that Bob will discuss.

7           That really ends my presentation on the policy.  
8 There is one other thing I would like to bring to your at-  
9 tention in deliberating about these rules.

10           I might say that over the years the direction  
11 we have been going on licensing nuclear medicine is to exer-  
12 cise less control over the practice of nuclear medicine.

13           Two things are happening, of course. The field  
14 is maturing. We know what the problems are now much better  
15 than we did years ago. And there are other peer groups set-  
16 ting standards for practice, so the industry in a way can  
17 be self-regulated.

18           In addition to that, there are other agencies  
19 who can regulate some areas better than we can. For example,  
20 FDA in the quality of drugs.

21           I will show you one last slide before I turn this  
22 over to Bob, and that is the manpower we're expending on  
23 medical licensing. It's not very much when you consider  
24 the population of licensees we have, the population of people  
25 we are regulating and the population of people that are

1 receiving radioisotopes.

2 (Slide.)

3 Six people in our organization responsible for  
4 evaluating and issuing licenses; I&E has ten inspectors;  
5 and Standards is putting three manyears into regulatory  
6 effort.

7 I suspect that might even be a little bit high,  
8 but for the size of the population and the things that are  
9 going on in nuclear medicine laboratories, we feel that  
10 this is indeed a modest program.

11 If we were to do things like evaluate the quali-  
12 fications of paramedics and do some other things, of course,  
13 the number of people that would have to be involved in this  
14 would have to expand.

15 If there are no questions on this, I'll defer  
16 to Bob at this point.

17 MR. BERNERO: What you've just heard is the  
18 policy question, the overall medical policy. That's one  
19 separate action that's put to you today.

20 And there are two other distinct actions. They  
21 are proposed rules which are developed consistent with that  
22 proposed policy, walking that line between underregulation  
23 and overregulation.

24 Now, the two parallel and separate actions that  
25 I will cover here relate to clinical procedures and

1 misadministration.

2 May I have the next chart, please?

3 (Slide.)

4 The clinical procedures, we'll cover that first.

5 Our regulations, Part 35, are set up so that radiopharma-  
6 eutical licenses can be handled in groups where the activi-  
7 ties involved are put into categories of increasing com-  
8 plexity, increasing demands in skills, in training, in  
9 procedures and in equipment.

10 Those licensing groups are listed here. Groups  
11 I to III are for diagnostic radiopharmaceutical uses and  
12 generators and kits. We're getting up to that level of  
13 complexity where the radioisotope is actually contained in  
14 a device, and the procedure is to get the material out for  
15 actual administration to the patient.

16 May I have the next slide, please?

17 (Slide.)

18 Groups IV through VI are for therapy and devices  
19 which are more complex, involve higher doses, more com-  
20 plexity, more difficulty to -- more demands of the skill  
21 of the user of the radiopharmaceutical material.

22 So what we are looking to here is a way to  
23 simplify our regulation on the diagnostic or lower risk  
24 side of these licensing groups.

25 May I have the next slide, please?

1 (Slide.)

2 The proposed rule we have here is to go into  
3 Groups I, II and III -- again, the diagnostic radio-  
4 pharmaceuticals -- and to delete the clinical procedures  
5 from the regulations.

6 Let me have the next slide, please.

7 (Slide.)

8 What this really means, if we go into an example,  
9 in our current rule, currently Part 35.100, it would list,  
10 as you see here, for any given isotope at least several,  
11 a number of variations of the use of iodine 131. It would  
12 list for that one isotope a list of chemical forms, and  
13 associated with each chemical form is a procedure, a clinical  
14 procedure -- the measurement of thyroid uptake or a liver  
15 function study, or whatever.

16 The physician operating under that license is  
17 constrained to use that isotope in that chemical form for  
18 that clinical procedure, and he is constrained by the  
19 labeling on the radiopharmaceutical to the path of admini-  
20 stration and the dose involved.

21 Now, the simplification we propose -- may I  
22 have the next slide, please?

23 (Slide.)

24 -- is to take out the clinical procedures and just have  
25 the rule cover the radioisotope in question and list the



1 chemical forms, the forms of this isotope, which can be  
2 used by the physician operating under this license.

3 Now, we would by that -- may I have the next  
4 slide, please?

5 (Slide.)

6 We would by that means leave the physician the  
7 option of using it for some procedure, some clinical pro-  
8 cedure, which is not the direct approved, FDA-approved  
9 procedure. He would still be constrained to the same  
10 chemical and physical form, the same route of administration,  
11 and the dosage range. These are all covered by the labeling.  
12 But he has the freedom to practice medicine to the extent  
13 of his skill and to move out for a different clinical pro-  
14 cedure within these constraints we hold him to.

15 Now, the reason for allowing this is, first of  
16 all, we're dealing with diagnostics, where the risk is  
17 fairly low; and by using an approved isotope in approved  
18 chemical form and route of administration we have already  
19 seen that the patient is provided with sufficient evidence  
20 of safety, and one is left with only a question perhaps of  
21 efficacy: Is the procedure he's using it for as effective  
22 as the approved one?

23 If we were to wait for approved clinical pro-  
24 cedures only, as our regulations are presently constructed,  
25 then the physician would be constrained from an additional

1 use of this radiopharmaceutical until the FDA approval has  
2 been obtained. This could be very many years, and in the  
3 case of some radiopharmaceuticals, having obtained one  
4 FDA approval, the manufacturer may not be as inclined to  
5 invest the large amount of money and time to get a second  
6 or a third.

7 So by holding off the use of this radiopharma-  
8 ceutical for another clinical procedure, we could be denying  
9 the patient a valid use of that radiopharmaceutical.

10 COMMISSIONER GILINSKY: Right now they are  
11 denied that?

12 MR. BERNERO: Yes, in effect right now Part 35.100  
13 says you may use that isotope in that form for that pur-  
14 pose -- that liver scan or whatever it might be.

15 If that same liver scan would provide that  
16 physician what is to him an important and valuable insight  
17 into another organ, the regulation does not permit him to  
18 use it for that other purpose.

19 COMMISSIONER GILINSKY: So you're proposing to  
20 open up the use of these isotopes?

21 MR. BERNERO: Modestly. He still is constrained  
22 to use that isotope in that form, administered in that  
23 path -- some vein or whatever -- and in that dosage range.  
24 Those are not changed.

25 COMMISSIONER GILINSKY: And this is at the request

1 of doctors to make this kind of change?

2 MR. BERNERO: No. I believe this was staff-  
3 inspired originally.

4 MR. CUNNINGHAM: It's a combination of things.  
5 I think some physicians did suggest it. The FDA has supported  
6 this position, and the staff supports it simply because it  
7 certainly cuts down on the administrative burden of the work.

8 What you're really doing -- and the FDA has a  
9 policy position on that where they support this kind of  
10 thing -- but you're making a tradeoff.

11 On the one hand you're allowing the physician  
12 more flexibility to practice medicine as he sees fit within  
13 certain constraints. You know what the radiation dose is  
14 going to be.

15 What you're losing is the question of whether  
16 or not a drug used for a purpose other than for which  
17 the safety and efficacy has been established, you're losing  
18 something in knowing whether or not you would get a false  
19 positive or a false negative reading. We're not worrying  
20 about radiation risk, but if he tries to diagnose something  
21 other than what the label says to use it for he runs a higher  
22 risk of making a false negative or a false positive reading.  
23 This could be important to the patient if you miss a  
24 tumor or think something's there and operate on him and  
25 it isn't there.

1 MR. BERNERO: That's indeed been the medical  
2 judgment part. This change would be consistent with the  
3 FDA policy with respect to the drugs.

4 COMMISSIONER GILINSKY: What is the significance  
5 of FDA approval if you can go beyond it? Why is the FDA  
6 suggesting that we not pay attention to their approvals?

7 MR. CUNNINGHAM: The FDA has its own position  
8 on this. They did not suggest to us that we should do it.  
9 And the FDA has done it for some time.

10 MR. DIRCKS: But they're not opposed to it.

11 MR. CUNNINGHAM: Oh, no, not at all.

12 COMMISSIONER KENNEDY: They're not opposed, you  
13 say?

14 MR. DIRCKS: They're not opposed.

15 MR. CUNNINGHAM: They're not opposed to it, not  
16 at all.

17 That's a little bit hard for me to explain in  
18 FDA's case, more than it is in NRC's case, because what  
19 it really gets to is the safety and efficacy of drugs, which  
20 we think is an FDA question, not an NRC question.

21 It certainly does, to my way of thinking, circum-  
22 vent some of the investigational drug rules, but the inves-  
23 tigational drug rules, as I understand it, are for fairly  
24 large-scale investigations.

25 COMMISSIONER GILINSKY: But these proposed

1 procedures would circumvent those rules. Is that what  
2 you're saying?

3 MR. CUNNINGHAM: Well, FDA's policy circumvents  
4 their own investigational drug rules to some extent.

5 COMMISSIONER GILINSKY: The policy on what?

6 MR. CUNNINGHAM: That you can use a drug for  
7 a purpose other than that which is on the label.

8 MR. BERNERO: In effect the FDA, when it makes  
9 a finding on a drug, is saying that this drug is safe and  
10 efficacious for some purpose, administered in some way,  
11 concentrations and what-have-you.

12 They do not then say that under no circumstances  
13 can the same drug administered in the same way be used for  
14 some other purpose. They leave that available to the  
15 physician.

16 Of course, in that case the physician is going  
17 beyond the clear labeled and call it certified use of  
18 the drug, and he takes it upon himself or herself a much  
19 greater level of responsibility in the practice of medicine.

20 But FDA in their statements does not forbid  
21 that. It is not their policy.

22 COMMISSIONER GILINSKY: Do we have the views  
23 of some medical group on this?

24 MR. CUNNINGHAM: Yes, this was brought up before  
25 our Medical Advisory Committee and in the public meeting,

1 and I think all groups supported this. There was some dis-  
2 cussion, but so long as we control the route of administra-  
3 tion and the dose the only other remaining question would  
4 be the efficacy of the drug. They feel that for these  
5 diagnostic procedures the freedom given outweighs any dis-  
6 advantages that might accrue.

7 What we're really dealing with here, what we're  
8 really controlling in that case, is drug safety and efficacy,  
9 which we believe -- we agree with FDA that it's an FDA  
10 problem, and FDA is treating these drugs the same as they  
11 do any other drug.

12 I can read the statement here. We have it in  
13 the staff paper. There is a statement of the FDA position  
14 on this in which they say that there are reasons to do this  
15 and it would not be in violation of the Food, Drug and  
16 Cosmetic Act. It's on page 16, Enclosure 1, of the staff  
17 paper that was sent to you.

18 MR. BERNERO: In essence FDA is recognizing that  
19 the approved use of the drug may not be as up-to-date as  
20 it could be to be fully useful to the practicing physician,  
21 so the practicing physician can take the responsibility to  
22 be up-to-date and use this radiopharmaceutical in what is  
23 already an approved method. It's a question of the pro-  
24 cedure and the purpose of the use.

25 COMMISSIONER GILINSKY: This is strictly in



1 diagnostic applications?

2 MR. BERNERO: Strictly in diagnostic. There is  
3 no attempt here to go into the more grave actions or quanti-  
4 ties involved with therapeutic doses. It's strictly in  
5 diagnostic, so it's in Classes I, II and III.

6 COMMISSIONER KENNEDY: Where the quantities are  
7 very small.

8 MR. BERNERO: Yes, we're speaking of small  
9 quantities. What one is really weighing are the relative  
10 merits of what may be a superfluous or an unnecessary ex-  
11 posure to some small degree against what may be a medically  
12 useful thing for the doctor working with the patient.

13 COMMISSIONER GILINSKY: What sort of doses do  
14 you end up getting?

15 MR. CUNNINGHAM: Typically technetium is the  
16 most commonly used diagnostic isotope -- 20 millicuries on  
17 a diagnostic procedure results in about 250 millirem total  
18 dose.

19 COMMISSIONER GILINSKY: Millirem?

20 MR. CUNNINGHAM: Yes, millirem.

21 MR. BERNERO: Millirem quantities, not rem --  
22 orders of magnitude difference with therapeutic.

23 COMMISSIONER GILINSKY: Say that again.

24 MR. CUNNINGHAM: About 250 millirem total dose  
25 for a diagnostic procedure. That's typical. It varies,

1 of course.

2 COMMISSIONER GILINSKY: That's a whole body dose?

3 MR. CUNNINGHAM: Whole body dose, yes.

4 MR. BERNERO: I'd like to go on to the next  
5 related paper, which I think may lend further insight to  
6 the judgments being made here.

7 This is on misadministration.

8 May I have the next slide, please?

9 (Slide.)

10 We're defining a misadministration here as is  
11 listed on the slide. It's the wrong act to the wrong  
12 patient through the wrong path. And we're inserting here  
13 a quantitative judgment to define sharply the difference  
14 in diagnostic uses and therapeutic uses on a percentage  
15 basis. It's a matter of judgment for us to define it to  
16 say a misadministration is more than a 20 percent error  
17 in diagnostic use and a 10 percent error in therapeutic  
18 use.

19 These numbers have been drawn based on the capa-  
20 bility of measuring and administering these things, and  
21 they do reflect with the tighter constraint of 10 percent  
22 that therapeutic, of course, involves greater quantities,  
23 greater exposures.

24 May I have the next slide, please?

25 (Slide.)

1           The misadministration goes back a number of years.  
2       There was an original rule back in 1973. GAO did a study  
3       and recommended that AEC regulatory take action on that,  
4       and in implementing this GAO regulation there was a mis-  
5       administration rule proposed then which would specify the  
6       activities that a licensee could delegate to others, the  
7       sort of training required for technicians, and it did bring  
8       up the subject of reporting misadministrations.

9           That proposed rule back in 1973 had in it a  
10       proposed requirement to report misadministrations to the  
11       patient or family of the patient. That was a staff-inspired  
12       change, not a GAO recommendation.

13           Now, that proposed rule got a lot of comment.

14           May I have the next slide, please?

15           (Slide.)

16           There was a lot of comment at that time, and, of  
17       course, the medical policy was in a state of evolution since  
18       the Government regulatory policy was in some state of  
19       evolution at the same time.

20           The principal comments, of course--many of them  
21       you could expect to see--misadministration reporting, especially  
22       involving patient notification, brings up the idea of self-  
23       incrimination.

24           COMMISSIONER GILINSKY: Is this on the part of  
25       the doctors?

1 MR. BERNERO: Yes, inviting the increase of mal-  
2 practice suits.

3 Our legal advice is that it's really not self-  
4 incrimination. The question here is not one of Fifth  
5 Amendment or anything like that. We're not dealing with  
6 a felony here.

7 COMMISSIONER KENNEDY: But we're dealing with  
8 malpractice suits, though.

9 MR. BERNERO: Yes, but that question is certainly  
10 a substantial one, challenges on -- interfering or meddling  
11 in medical ethics and pointing out that where are comparable  
12 requirements on other drugs -- why should radiopharmaceuticals  
13 have this unique requirement.

14 So this was the general thrust of all the comments  
15 on that.

16 Well, with this new policy, this presently pro-  
17 posed policy we have here -- may I have the next slide?

18 (Slide.)

19 We have a new NRC proposal on misadministration  
20 by which we would withdraw the 1973 proposal and require  
21 that the licensee keep records of misadministrations as de-  
22 fined on that earlier slide -- wrong act, wrong place and  
23 so forth, and using those quantitative limits -- and we would  
24 further require by this rule that the licensee report to NRC  
25 all the therapy misadministrations -- all therapy, because

1 it's a grave matter. There are high doses, large quantities.  
2 And all serious diagnostic misadministrations -- serious  
3 being where one is dealing with clinically detectable  
4 adverse effects.

5 It's an almost undefinable thing to say a serious  
6 diagnostic misadministration is exactly this or exactly  
7 that. There is a great deal of medical judgment involved  
8 in judging or reading what is serious.

9 COMMISSIONER GILINSKY: Well, let me ask you.  
10 Suppose the wrong patient got one of these diagnostic  
11 doses we were just referring to. Would that fall in this  
12 category?

13 MR. BERNERO: Not unless there was a serious  
14 effect, a clinically detectable adverse effect.

15 COMMISSIONER GILINSKY: You mean after-the-fact?

16 MR. BERNERO: After-the-fact. But if it were  
17 merely the wrong patient, it would be a recordable mis-  
18 administration. I'm speaking of a diagnostic act, not a  
19 therapeutic act.

20 A diagnostic administration that went to the  
21 wrong patient -- you know, two people named Brown sort of  
22 thing -- that would be a recordable misadministration, not  
23 a reportable one, unless it had an after-the-fact adverse  
24 effect.

25 COMMISSIONER GILINSKY: You really have to get

1 up into many, many rems before you got an observable effect.

2 CHAIRMAN HENDRIE: I think the clinically  
3 observable is more likely to be a chemical pharmaceutical  
4 effect.

5 MR. BERNERO: Yes, an allergic reaction or  
6 something like that.

7 By their nature the diagnostic procedures are  
8 relatively mild and are not likely to induce any serious  
9 effect, but if the wrong patient got it and there were some  
10 allergic reaction to the drug, some purely chemical thing,  
11 it would at least bring that out as an immediately report-  
12 able misadministration.

13 COMMISSIONER GILINSKY: Well, let's take this  
14 case here. I don't know what form the material comes,  
15 but suppose he got a dose which was too large by a factor  
16 of 100. Would that fall in this category?

17 MR. CUNNINGHAM: By a factor of 100?

18 MR. BERNERO: Oh, yes.

19 COMMISSIONER GILINSKY: Would there be an observ-  
20 able clinical effect?

21 MR. BERNERO: Excuse me. You don't need both.  
22 If--let's take one patient. It's not the wrong person.  
23 We're dealing with the right person, and that patient is  
24 supposed to get a diagnostic procedure of some number of  
25 millicuries that would give him a dose of 250 millirem. And

1 the technician, or whoever caused the mistake, doubled the  
2 dose, 100 percent increase -- that would be a --

3 COMMISSIONER GILINSKY: I asked about a factor  
4 of 100, but you go ahead.

5 MR. BERNERO: That would be a recordable mis-  
6 administration, but it would only be reportable if the  
7 patient reacted to it.

8 COMMISSIONER GILINSKY: That's what I'm asking.  
9 What would require a report to the NRC?

10 MR. BERNERO: If the mistake was made on a  
11 therapeutic, a defined mistake made on a therapeutic, or  
12 on a diagnostic where there is a clinically detectable  
13 adverse effect, and only there; all of them are recorded  
14 for NRC scrutiny.

15 You see, the distinction really is how quickly  
16 will we learn of the event. The recordable one waits for  
17 the inspector to show up to read it; the reportable one by-  
18 passes the inspection process and time by notifying us  
19 promptly.

20 COMMISSIONER GILINSKY: Then what do we do with  
21 it when we get it?

22 MR. BERNERO: Well, I'll get to that. There are  
23 a variety of things we can do with this.

24 May I have the next slide?

25 (Slide.)

1 MR. DIRCKS: I think an issue that should be  
2 brought out is now we're not getting any reports, reportable  
3 or recordable.

4 COMMISSIONER GILINSKY: Right now?

5 MR. BERNERO: Yes. The West Virginia and all  
6 of those things are by guess and by gosh picked up. There  
7 is no regulation that says those have to come in.

8 COMMISSIONER KENNEDY: An interesting point  
9 that you didn't cover on the other slide, which I gather  
10 is also new -- or is it? -- is that you'd be requiring the  
11 licensee in those reportable cases to at the same time  
12 report the fact to the attending physician.

13 MR. BERNERO: Yes, indeed.

14 COMMISSIONER KENNEDY: Who may not be the same  
15 individual who was supervising the procedure.

16 MR. BERNERO: Typically isn't. The licensee is  
17 typically a licensed radiologist or someone like that, and  
18 he would be required in reporting to us to report to the  
19 physician, the real doctor for the patient.

20 And then the referring physician is the one in  
21 the position to determine should the patient be told, would  
22 it be unnecessarily alarming, or how should the patient  
23 be told: should the wife or the husband or whatever.

24 COMMISSIONER KENNEDY: Is that physician in a  
25 position to make that kind of a judgment? I know he is



1 vis-a-vis the patient himself, but does he know the level  
2 of seriousness? Is he able to assess that?

3 MR. BERNERO: Well, he's in a position to know  
4 the patient and to consult with the radiologist and any  
5 other authorities he deems necessary to make a judgment of  
6 whether some sufficiently grave consequences are involved  
7 that he should inform the patient.

8 Now, the choice there, of course, is a broad one.  
9 We could go to the one extreme and leave it to the doctors.  
10 Current medical practice is that the licensee would be re-  
11 porting to the referring physician; that would be the  
12 typical medical practice, and we could just not require  
13 anything. Or we might go even further.

14 COMMISSIONER KENNEDY: If that is regular prac-  
15 tice, why would we require it by regulation?

16 MR. BERNERO: Perhaps as a matter of clarification,  
17 to show what we feel is an appropriate requirement on our  
18 part with respect to this misadministration.

19 The question logically comes up: Should we not  
20 require the licensee to report to the patient? That's  
21 one alternative that was discussed at great length: Just  
22 be adamant about the thing; go down there and report that  
23 to the patient.

24 The obvious challenge can be raised. You could  
25 take a person who's already ill and unnecessarily alarm them

1 with a relatively minor thing.

2 Another alternative is to insist that the  
3 licensee report to the patient subject to the veto of the  
4 referring physician. That gets sort of complicated. And  
5 how much different is that from just giving it to the re-  
6 ferring physician?

7 As a matter of clarity, the rule would say report  
8 to NRC these defined misadministrations and report them to  
9 the referring physician, and leave it at that; leave it  
10 for the referring physician to determine.

11 COMMISSIONER GILINSKY: Do physicians typically  
12 report this to a patient?

13 MR. CUNNINGHAM: They're supposed to. I think  
14 that it hasn't been followed in all cases.

15 COMMISSIONER KENNEDY: Isn't that a matter of  
16 patient-doctor relationship?

17 MR. CUNNINGHAM: Yes.

18 COMMISSIONER KENNEDY: Isn't that a matter of  
19 the medical judgment of the doctor himself?

20 MR. CUNNINGHAM: That's right.

21 MR. BERNERO: Yes. And the issues that people  
22 raise are, "Well, won't he protect his colleague from a  
23 malpractice suit?"

24 COMMISSIONER GILINSKY: Well, it's more than a  
25 colleague here. I mean, it's somebody to whom he referred

1 the patient.

2 MR. BERNERO: Oh, yes. He referred the patient  
3 to that radiologist, whatever the licensee is.

4 MR. CUNNINGHAM: Are you talking about liability  
5 of the referring physician for something another physician  
6 does or fails to do?

7 COMMISSIONER GILINSKY: Well, he's involved in  
8 the matter.

9 MR. CUNNINGHAM: Yes, I think so.

10 MR. BERNERO: Yes, there's a level of involve-  
11 ment.

12 MR. CUNNINGHAM: The fact is that the referring  
13 physician is the one that's managing the patient and should  
14 be the one to make the medical judgments necessary.

15 Now, if he doesn't follow medical ethics, that's  
16 a problem we can't do a whole lot about; but he's the one  
17 in the best position to make those kinds of judgments of  
18 what's best for the patient.

19 MR. BERNERO: You know, in a way it's like filter-  
20 ing out the selfish acts. We can look at the licensee and  
21 say we expect him to report it if he makes such a mistake,  
22 but in order to filter out those who won't to protect them-  
23 selves we will apply the filter of requiring, having a  
24 license requirement that they be reported.

25 We could apply a second level of filtration and

1 go to the referring physicians and say let's make sure that  
2 they're not charlatans either, and so we get a fraction of  
3 a fraction thereby removed. There is a matter of degree,  
4 how far we can go.

5 COMMISSIONER GILINSKY: Well, it's not a matter  
6 of charlatans, I think, here. It's a question of whether  
7 there's some obligation to the patient that he be informed.

8 MR. BERNERO: Yes, and whether that responsibility  
9 for deciding on that reporting should be held by us,  
10 delegated to the licensee as far as we're concerned, or  
11 delegated to the referring physician.

12 And our recommended choice is in effect to dele-  
13 gate the decision to the referring physician, the one  
14 closest to the patient and well removed from the fault,  
15 from the misadministration responsibility, removed by one  
16 step.

17 COMMISSIONER BRADFORD: Why is it ever going to  
18 harm the patient to be told that there was a misadministra-  
19 tion? Why would that information ever be withheld?

20 COMMISSIONER KENNEDY: Because doctors typically  
21 withhold a great deal of information on the simple assumption  
22 that to provide it to the patient would do him more harm than  
23 good, from a psychological if no other point of view. It's  
24 a rather typical thing, to make a judgment about whether  
25 informing the patient is going to help him in his recovery or

1 hinder him or make it impossible, which is also possible.

2 MR. CUNNINGHAM: I think it's fairly easy to  
3 construct some instances where you don't want to tell a  
4 patient this. If you have a patient that has a bad cardiac --  
5 a pulmonary embolism or a cardiac patient or somebody who  
6 has just had surgery and you tell them, "Well, we made a  
7 mistake and your thyroid's been burned out," this may add some  
8 shock that really doesn't do the patient very much good at  
9 that time.

10 COMMISSIONER BRADFORD: Well, nobody has said  
11 anything about the timing of when you tell him, but what's  
12 the other side of that coin? Is it possible for a patient  
13 who has been in some way overexposed and doesn't know it to  
14 be traveling or move to another part of the country and to  
15 expose himself or herself far more than they would if they  
16 knew that they'd been overexposed before?

17 MR. CUNNINGHAM: It's hard to imagine that  
18 being very much of a problem.

19 COMMISSIONER GILINSKY: Let me ask a related  
20 question. Suppose you went from one doctor to another doctor  
21 and started a new radiation therapy. Would they be required  
22 to inform the new doctor of the maladministration?

23 MR. BERNERO: Well, let's reconstruct that a  
24 little. The original referring physician has a procedure  
25 done or asks for a procedure to be done. A misadministration

1 occurs. The original referring physician knows about it  
2 and perhaps chooses not to tell the patient.

3 The patient now goes to another physician al-  
4 together, and the new referring physician is in charge of  
5 the case. Typical medical practice is he immediately con-  
6 sults with the original referring physician.

7 Our regulation wouldn't speak to that issue,  
8 but the choice is clearly left with the original referring  
9 physician to advise him of the medical history "as I knew  
10 it and saw it, and this is where I left the patient."

11 (Simultaneous discussion.)

12 COMMISSIONER BRADFORD: Why should that be a  
13 choice at all? Whatever there is to be said for not telling  
14 the patient, surely there's nothing to be said for not tell-  
15 ing the second physician?

16 MR. BERNERO: Oh, no. It's just that our regula-  
17 tions don't speak to that sort of thing. That's typical  
18 medical practice to do so, the full explanation.

19 For instance, the second physician might be told  
20 by the first physician that "I've been giving this a patient  
21 a lot of placebos to keep her from worrying," and he won't  
22 tell the patient that because it would defeat the whole pur-  
23 pose of what he's prescribing. That's medical practice.

24 Our regulation doesn't speak to that issue. It  
25 gets too complicated to set up these hypothetical situations.

1 But we do speak to this question of informing  
2 the patient or family, and we stop short of that in the  
3 recommendation.

4 COMMISSIONER GILINSKY: Why not have some formula-  
5 tion whereby the patient would be informed unless the  
6 doctor would say -- you know, unless he would certify to  
7 NRC that it would be harmful to the patient to be informed?

8 MR. BERNERO: Well, this is the one option that  
9 was ventilated in the paper and we considered, and that was  
10 that we would require the licensee to report to the referring  
11 physician and with some tag lag, some conditional character,  
12 report to the patient and/or family subject to a veto.

13 Well, this raises some complicated questions.  
14 One is timing and administration so that the thing is properly  
15 handled. A timely report and yet a timely opportunity for  
16 the referring physician to make a judgment.

17 secondly, what would be the level of veto? How  
18 would one go about doing this without really getting awfully  
19 deep in the doctor-patient relationship?

20 Would we judge the referring physician criteria,  
21 motives or logic for saying yea or nay?

22 COMMISSIONER GILINSKY: Well, this is off the  
23 top of my head. You might not judge it at all. In other  
24 words, you might leave it up to the doctor, but he would at  
25 least have to certify that was the case. If it came up

1     sometime later there would be a record of it.

2             MR. BERNERO: There would be a bias on the act  
3     in the sense that there would be a pressure to inform  
4     where his action would be to stop it as against no pressure  
5     and his action to pass it on.

6             COMMISSIONER GILINSKY: That's right.

7             MR. BERNERO: And, of course, I agree there would  
8     be a record later on that he formally said, "No, don't tell  
9     him."

10            COMMISSIONER KENNEDY: What would that record do  
11    for whom, other than being interesting?

12            MR. BERNERO: In a malpractice suit.

13            COMMISSIONER GILINSKY: Well, if it were abused  
14    in some way.

15            CHAIRMAN HENDRIE: Well, you have a record in  
16    the other case.

17            MR. BERNERO: Yes, there's a record of the mis-  
18    administration.

19            COMMISSIONER GILINSKY: Except the patient  
20    doesn't get informed.

21            CHAIRMAN HENDRIE: If the patient is not informed,  
22    you know the information went from A to B and didn't go to  
23    C. So that's a matter of record.

24            MR. BERNERO: The record is there with the re-  
25    quirement to inform the referring physician.



1 COMMISSIONER BRADFORD: First of all, by whom are  
2 these kinds of issues handled with regard to other, non-  
3 radioactive drugs? Is this a Federally handled matter, or  
4 is it normally handled at the state level -- or not handled  
5 at all?

6 MR. CUNNINGHAM: They aren't.

7 MR. DIRCKS: It's a regulation of medicine which  
8 no one really has approached.

9 MR. CUNNINGHAM: As far as we can tell, there  
10 are ethical practices that physicians are supposed to meet.  
11 This is one of the issues, of course: Why is NRC getting  
12 into this business when no other field of medicine requires  
13 such reporting?

14 MR. BERNERO: We're uniquely deep into the  
15 doctor-patient relationship already.

16 COMMISSIONER GILINSKY: Well, not yet.

17 MR. KENNEKE: In this respect.

18 MR. CUNNINGHAM: In the way we regulate nuclear  
19 medicine, we are. As I said earlier, we're the only Federal  
20 agency that gets involved in the physician-patient relation-  
21 ship.

22 COMMISSIONER BRADFORD: What does the FDA do?  
23 Do they approve a drug for use and once it's approved it's  
24 fair game?

25 MR. CUNNINGHAM: Actually, FDA is tied to ICC

1 rules. What they do is approve -- their approval says the  
2 drug is labeled in accordance with the way it's going to  
3 perform; it's safe and efficacious if used in this dose  
4 range, for this purpose, with these indications, with  
5 these counterindications. It's allowed to be introduced  
6 into interstate commerce.

7 They have no direct regulatory control over the  
8 physician except in the case of investigational drugs,  
9 and there a physician is required to file an investigational  
10 plan.

11 MR. BERNERO: When we look to requiring mis-  
12 administration recording and reporting, what we see that  
13 we would do with the information is look for some generic  
14 implications, misadministrations that may be a serious  
15 problem in many institutions and might call for some sort  
16 of publicity or advice campaign.

17 COMMISSIONER KENNEDY: Or an institution which  
18 seems typically to be involved in the misadministration  
19 syndrome.

20 MR. BERNERO: Then one can look to the licensee:  
21 Are the corrective actions appropriate? Is this licensee  
22 responding in a proper way? Do we see a trend here of  
23 perhaps sloppy practice, of too many misadministrations at  
24 one licensee?

25 These are valuable tools for the inspector, for

1 the licensing body to have this information for an individual  
2 licensee.

3 But we're not using the misadministration report-  
4 ing or recording for a direct action with respect to par-  
5 ticular patients. The focus is more on individual licensees  
6 or licensees as a class. The focus is not on the single  
7 patient.

8 COMMISSIONER GILINSKY: Do we have any idea of  
9 what the rate of misadministration is?

10 MR. CUNNINGHAM: I'll try to answer that. When  
11 this issue first came up, we looked at some studies that  
12 had been done in medicine. The misadministration rate, as  
13 I recall, was something like about 5 percent.

14 CHAIRMAN HENDRIE: This is generally.

15 MR. CUNNINGHAM: Generally. Now this can in-  
16 clude such minor things as the nurse giving a pill to the  
17 patient before dinner instead of after dinner, giving the  
18 wrong pill to the patient, or very serious things, like  
19 giving the wrong blood type to a patient, which could kill  
20 you pretty quickly.

21 It covers a vast range of things, but it's  
22 somewhere around -- some estimate 5 percent and some esti-  
23 mate it as high as 12 percent.

24 We think nuclear medicine, because we have in  
25 fact been involved in this because of its special nature,

1 that probably the misadministration rate is much lower than  
2 that.

3 There have been some fatalities from misadministra-  
4 tion of radiopharmaceuticals, however.

5 COMMISSIONER KENNEDY: Radiopharmaceuticals?

6 MR. CUNNINGHAM: Yes, sir. It has happened.

7 CHAIRMAN HENDRIE: Pharmaceutical overdose sort  
8 of thing?

9 MR. CUNNINGHAM: No. I could give you an example.  
10 Most of these are just human errors that are hard to explain.

11 One patient I recall a few years ago. One treat-  
12 ment for cancer patients is to give a colloidal phosphate.

13 CHAIRMAN HENDRIE: Oh, this is a therapeutic?

14 MR. CUNNINGHAM: Yes. And they gave the wrong --  
15 they gave a soluble phosphate. So things like that happen.

16 Actually, hospitals aren't all that safe places  
17 to be. Avoid them if you can.

18 (Laughter.)

19 But we think that the misadministration for  
20 radiopharmaceuticals is low.

21 CHAIRMAN HENDRIE: If you feel ill, gentlemen,  
22 ask to be taken to your nearest nuclear power plant.

23 (Laughter.)

24 COMMISSIONER KENNEDY: We'd be safer than coal-  
25 or oil-fired plants, because the President of the United States

1 just said so.

2 CHAIRMAN HENDRIE: At least safer than hospitals.

3 MR. CUNNINGHAM: Well, things do happen, but we  
4 think the misadministration rate of radiopharmaceuticals is  
5 lower than the general average; but we can't prove it. We  
6 have no reporting requirement.

7 CHAIRMAN HENDRIE: Let's see, should we perhaps  
8 proceed onward with this briefing, which I suspect has not  
9 nearly run its full course?

10 MR. BERNERO: I would like to terminate the por-  
11 tion I've been covering and turn it back to Dick Cunningham  
12 to give you the broader perspective of how this relates  
13 to all the other medical policy things and things you're  
14 going to see in the near future.

15 MR. CUNNINGHAM: May I have the next slide,  
16 please?

17 (Slide.)

18 We can just wind this up in about 2 minutes  
19 probably.

20 There are some additional rule changes coming  
21 up. The teletherapy calibration rule was published as a  
22 proposed rule and will now be up to the Commission as a  
23 final rule.

24 Measurement of doses, there's a minor rule  
25 change.

1           Plutonium powered cardiac pacemakers -- again,  
2 this was a proposed rule and is coming to you as a final  
3 rule.

4           FDA recently -- well, within the last couple of  
5 years, I guess -- got new legislation over medical devices,  
6 which covers everything from sutures to heartpumps, to  
7 regulate medical devices in the same manner they do drugs.  
8 They're trying to get geared up to do this. It's a tre-  
9 mendous undertaking. When they do, we will develop some  
10 Memorandum of Understanding with them so that we don't over-  
11 lap in our work. I would assume that they would be taking  
12 over some of the things that we are currently doing when  
13 they're properly staffed to do it.

14           And the qualifications of paramedical personnel  
15 is one that requires some more staff work to find out where  
16 we are on that.

17           CHAIRMAN HENDRIE: That comes up -- what? In  
18 terms of training, for instance, for nurses or laboratory  
19 technicians --

20           MR. CUNNINGHAM: Yes, sir.

21           CHAIRMAN HENDRIE: -- who may be preparing for  
22 administering these things?

23           MR. CUNNINGHAM: That is correct. Paramedics  
24 may be the technicians that run the scanners, the technicians  
25 and nurses that administer the drugs, people that do the

1 calibration work, or it may be a physicist who does the  
2 calibration on a teletherapy unit -- a whole raft of things.

3 CHAIRMAN HENDRIE: Isn't that establishment of  
4 qualifications much better placed in the professional groups  
5 in the field rather than fall under Government regulation?

6 MR. CUNNINGHAM: Certainly this is the opinion  
7 of very many medical groups. There are certification organi-  
8 zations. This is one of the issues we're looking at.

9 The question was originally raised by GAO in  
10 one of their reports. We think that a lot has happened with  
11 certification of paramedical people since that GAO report  
12 came out.

13 If our work finds that professional organizations  
14 are doing a job that appears to be adequate, we certainly  
15 don't want to get into it. Among other things, it will be  
16 costly for us.

17 CHAIRMAN HENDRIE: I was going to say, with the  
18 greatest affection and respect for our good friends in GAO,  
19 they do have a tendency to swing first, saying, "Boy, you  
20 ought to get in and really fix this up," and then five years  
21 later they come along and say, "What? You've got a thousand  
22 people working on this on the Government payroll? That's  
23 outrageous. How dare that happen!"

24 I think what we've seen is the first swing. And,  
25 sort of in line with some of the general thrusts of our

1 standards-setting activity, I would think we would be better  
2 off, if we're not altogether pleased with the professional  
3 group certifications, to encourage them to do a little better.  
4 If we are going to write anything into our rules that covered  
5 it, it would probably much better be to put some mild re-  
6 quirement that administerers of these things be certified  
7 by the professional group, but then on the other hand you  
8 would encourage the professional group to upgrade the  
9 standards rather than going into NRC licensing and testing  
10 and so forth.

11 MR. BERNERO: We don't want to add it to Part 55.

12 MR. CUNNINGHAM: Certainly, Mr. Chairman, this  
13 is the direction we're going. I hope to see within the  
14 next few years that we can get out of looking at physician  
15 requirements to practice medicine, also. We're moving in  
16 that direction. We have made progress, although our advisors  
17 say, "Don't do it yet."

18 MR. DIRCKS: I think we might want to mention  
19 some of the related issues.

20 MR. CUNNINGHAM: Oh, yes, there's one more slide,  
21 Mr. Chairman.

22 (Slide.)

23 There are some related issues, of course. There's  
24 the fertile women question.

25 COMMISSIONER KENNEDY: We discuss that once each



1 year at about this time.

2 MR. KENNEKE: In the spring.

3 MR. CUNNINGHAM: It's important here, because  
4 of that 30,000 population of workers under the medical  
5 licenses, a large percentage -- I suspect over 50 percent --  
6 are women, which isn't typical of the other industries.

7 Transportation question -- very important. Medical  
8 pharmaceuticals, or radiopharmaceuticals must be transported  
9 on passenger-carrying aircraft. The half-lives of these  
10 materials are short. Cargo services in the United States  
11 just won't get them to the hospitals in time.

12 This is an issue that has been raised now and  
13 again. It is covered in the GEIS on medical transportation.

14 MR. BERNERO: Yes, NUREG 0170 identifies this.

15 MR. CUNNINGHAM: But it has been subject to a  
16 lot of question.

17 Then we have NARM, which stands for Naturally  
18 occurring Radioactive Materials. There is a question whether  
19 or not we should --

20 CHAIRMAN HENDRIE: Let's see, it's Naturally  
21 Occurring and Accelerator Produced Radioactive Materials.

22 MR. CUNNINGHAM: Yes. Some hospitals are going  
23 to greater and greater use of accelerators. We will see  
24 more of it, I guess, as time goes on. The agreement states  
25 have raised this question, and it will be something we will

1 be coming up to you with, with some recommendations.

2 And, of course, we have the occupational exposure.  
3 I left that for last even though it's first. We are trying  
4 to apply the \_\_\_\_\_ Principle to medical uses of radio-  
5 isotopes.

6 I think that covers what we had, Mr. Chairman.  
7 We have the proposed policy for publication for public com-  
8 ment, and we have these two rules that Bob has gone over  
9 with you for publication for public comment.

10 CHAIRMAN HENDRIE: Al, I had a note that you want  
11 to make a comment on 68.

12 MR. KENNEKE: Across the board, Mr. Chairman, we  
13 think the policy statement is moving the Commission in the  
14 right direction. The staff job is well reasoned and fully  
15 sound, and, as Dick and Bob have pointed out, it's a con-  
16 tinuation of a trend of thinking that's been going on for  
17 some time.

18 We would, however, point out that it seems that  
19 the reluctance to go beyond the diagnostic, changes with  
20 the diagnostic list, seems somewhat inconsistent with the  
21 policy statement you're about to issue, which is to say that  
22 you are going to minimize intrusion into the physician-  
23 patient relationship.

24 As Dick and Bob have both indicated, the residual  
25

1 rules that would exist even after your approval of the  
2 changes to Part 35 will maintain a strong degree of NRC in-  
3 volvement in the physician-patient relationship by going  
4 beyond what FDA itself requires with regard to the use of  
5 these materials.

6 So you might wish to consider what more might  
7 be done or what further steps you might take to examine  
8 moving still further in the direction of being fully con-  
9 sistent with the policy you're about to issue.

10 The other point that we wish to make was on --

11 CHAIRMAN HENDRIE: I didn't understand that last  
12 one.

13 MR. KENNEKE: Assuming that you approved this  
14 policy, then the change that's being made to Part 35 --

15 CHAIRMAN HENDRIE: Perhaps doesn't go as far as  
16 you might want to go?

17 MR. KENNEKE: As far as the policy seems to  
18 indicate it would go.

19 CHAIRMAN HENDRIE: I see.

20 MR. KENNEKE: The other point that we would  
21 suggest might be looked at a little bit in terms of a few  
22 word changes in the policy statement is, to improve the  
23 response for the 90 or so commenters about the rule on mis-  
24 administration, to better describe, as has been done here  
25 today and is done in Paper No. 70, the reasons why these

1 changes in fact don't intrude into the physician-patient  
2 relationship. We think in that case a somewhat better  
3 description could be provided to foreclose that. Much of  
4 the discussion that has gone on here is indication of that.

5 MR. CUNNINGHAM: If I may make a point, Mr.  
6 Chairman, as I indicated earlier, we do have a Medical  
7 Advisory Committee that is quite active in giving us advice.  
8 It assists us on applications and has guided us through a  
9 lot of these policy issues over the years.

10 In our consultations with not only that committee  
11 but with various peer groups that I have listed, one senses --  
12 well, they state quite emphatically that they don't want  
13 NRC to completely withdraw from physician qualification,  
14 physician-patient relationship entirely, because that opens  
15 up the field of nuclear medicine to people who aren't  
16 serious about it.

17 Nuclear medicine has developed with tight control  
18 without these major scandals, and I think people recognize  
19 that. We are phasing out, but I don't think anybody that  
20 I've talked to wants it to be precipitous.

21 This policy will point us in the right direction,  
22 but it recognizes we aren't completely out of it yet.

23 CHAIRMAN HENDRIE: So you think in fact that,  
24 although indeed Al's comment is correct, that the Part 35  
25 changes proposed do not back all the way out, but at this time

1 it's a little premature to do that.

2 MR. BERNERO: We're not ready to justify getting  
3 out of Classes IV through VI there.

4 CHAIRMAN HENDRIE: And with regard to improved  
5 language in response to comments, I take it you're always  
6 glad to receive suggestions for improved language.

7 COMMISSIONER GILINSKY: Let's see, the 98 comments  
8 were on what?

9 MR. BERNERO: The 98 comments were back on that  
10 '73 rule, which was misadministration and delegation of  
11 authority and qualifications of technicians.

12 COMMISSIONER GILINSKY: They're rather old com-  
13 ments?

14 MR. BERNERO: Yes, they're dated, and now it's  
15 a fresh slate. That history is available, but it is better  
16 now to have this singular rule on misadministration.

17 MR. DIRCKS: And we're going out for comment.

18 MR. BERNERO: All of this is proposed to go out  
19 for comments, and in a sense it's in light of this new  
20 proposed policy: Here's the correlary proposed rule for  
21 misadministration and the correlary proposed change to  
22 part 35.100. So we would go out for comment on all three.

23 COMMISSIONER GILINSKY: Who sits on your  
24 medical advisory group? Are they all doctors?

25 MR. CUNNINGHAM: Well, we have four physicians.

1 We're right in the process of rotating some members.

2 COMMISSIONER GILINSKY: No patients?

3 MR. CUNNINGHAM: No patients. These are chosen  
4 strictly for their medical credentials.

5 COMMISSIONER KENNEDY: Hopefully you'd have to  
6 rotate those pretty rapidly.

7 (Laughter.)

8 MR. CUNNINGHAM: The Advisory Committee has, I  
9 think it's six physicians really, one medical physicist,  
10 and we also have a radiopharmaceutical consultant plus  
11 another medical physicist consultant.

12 Incidentally, I think we spent \$11 thousand in  
13 fees, services, travels to the meeting and everything last  
14 year for this committee, and I think it's one of the best  
15 bargains NRC gets.

16 CHAIRMAN HENDRIE: How much?

17 MR. CUNNINGHAM: Eleven thousand dollars.

18 CHAIRMAN HENDRIE: How much does it cost us to  
19 run the ACRS?

20 MR. BERNERO: No invidious comparisons intended.

21 CHAIRMAN HENDRIE: Let's see, we have your  
22 recommendation on the policy question and the publication of  
23 the proposed policy statement in the Federal Register in-  
24 viting public comment and so on. This matter, I guess, is  
25 before the Commission at the moment.

1 MR. DIRCKS: Yes, sir.

2 MR. BERNERO: All three. There are three separate  
3 actions in effect.

4 CHAIRMAN HENDRIE: I'm prepared to have limited  
5 objective right at the moment.

6 Let me first ask about the 68, which is the  
7 policy statement that the Commission is concerned and does  
8 propose to regulate the radiation safety of patients where  
9 justified by the risk and where voluntary standards or  
10 compliance with these standards is inadequate, and to publish  
11 in the Federal Register the policy statement, statement  
12 of considerations, for public comment.

13 I wonder if it's at a stage where you might be  
14 able to vote it up or down or would like to consider further?

15 COMMISSIONER GILINSKY: I'd like to consider it  
16 further, just to get a better feel for what it implies for  
17 the other items.

18 CHAIRMAN HENDRIE: Okay.

19 COMMISSIONER BRADFORD: I was going to say some-  
20 thing more limited in the same way, which is you can't  
21 separate it from Number 70 because Item 10 in here overlaps  
22 with the -- it contains a commitment to publish the mis-  
23 administration standard concurrently. Or, if you published  
24 a different misadministration standard, you'd have to change  
25

1 Item 10 in 68.

2 CHAIRMAN HENDRIE: Okay.

3 COMMISSIONER GILINSKY: On the misadministration  
4 paper --

5 CHAIRMAN HENDRIE: Well, I'm going to hold on  
6 a vote for that and ask for discussion on the other items.

7 COMMISSIONER GILINSKY: I notice that there are  
8 some offices that favor informing the patient, and I wonder  
9 if we could hear from those.

10 MR. DORIAN: There is one office that favors  
11 the veto procedure. It's the Legal Director's Office.

12 COMMISSIONER GILINSKY: Well, let's hear about  
13 that.

14 MR. DORIAN: We think that there will be more  
15 of an inclination for the doctors to tell the patients if  
16 something goes wrong if the NRC stands in the middle of  
17 that, that is, if we say please inform the patient unless  
18 the doctor thinks there is something wrong with that. If  
19 there is a veto relationship, the doctor would be more in-  
20 clined to inform the patient.

21 COMMISSIONER KENNEDY: Why? That would imply  
22 his medical judgment would be affected somewhat?

23 MR. DORIAN: It might imply that we think --

24 COMMISSIONER KENNEDY: Isn't he going to tell  
25 the patient what he thinks is wise from the point of view



1 of patient care? Isn't that what his obligation is?

2 MR. DORIAN: He might think twice as opposed to  
3 simply dismissing it in a cursory way. He might be more  
4 inclined to think of it knowing that someone may be peering  
5 over his shoulder.

6 COMMISSIONER KENNEDY: I hope you guys don't  
7 come around when I have another case of heart surgery. I  
8 could die waiting for them to get around to deciding.

9 CHAIRMAN HENDRIE: Unless you propose that in  
10 making the veto you're going to ask physicians in general  
11 to sit down and develop elaborate briefs as to why they  
12 chose not to pass the information on. I presume that's  
13 not the intention -- or is it?

14 MR. DORIAN: The intention is that we don't want  
15 to make more work for lawyers on this one.

16 (Laughter.)

17 COMMISSIONER KENNEDY: You could have fooled me.  
18 I can't see who else it's going to help.

19 CHAIRMAN HENDRIE: If the referring physician  
20 simply decides on the one hand that "Yes, I'll pass it on,  
21 because the patient can know and it's not harmful to him,"  
22 that's one way of doing it. On the other hand, if he simply  
23 says, "I decide to veto," unless you're going to require  
24 some elaborate -- let me take the word "elaborate" out --  
25 some procedural step of substance on the veto side, I find

1    them indistinguishable and I find the former procedurally  
2    easier.

3           MR. DORIAN: Well, the idea was that -- to make  
4    the doctor think twice as opposed to simply thinking once.

5           COMMISSIONER GILINSKY: Well, let's see, isn't  
6    there a difference --

7           CHAIRMAN HENDRIE: I find it splendid that  
8    lawyers think doctors ought to think twice.

9           COMMISSIONER KENNEDY: I think doctors ought  
10   to think that about lawyers.

11          COMMISSIONER BRADFORD: I'm sure they do.

12          COMMISSIONER KENNEDY: More often, I would add,  
13   and with good cause.

14          COMMISSIONER GILINSKY: Well, suppose a doctor  
15   did not tell the patient and there really wasn't any good  
16   reason for not having done so.

17          COMMISSIONER KENNEDY: But is that our business?

18          COMMISSIONER GILINSKY: Well, it's a question  
19   of what the obligations are to a patient.

20          COMMISSIONER KENNEDY: Well, that's his business.

21          CHAIRMAN HENDRIE: I don't find in the Atomic  
22   Energy Act a requirement that we regulate physicians'  
23   obligations to patients.

24          COMMISSIONER BRADFORD: It's just in the public  
25   health and safety, I think.

1 COMMISSIONER GILINSKY: I mean, you're licensing  
2 that stuff, and it seems to me that telling people when the  
3 stuff is abused is a requirement.

4 Now, the only reason, it seems to me, for not  
5 doing it is in the peculiar circumstances when you're deal-  
6 ing with sick people and it may be in some circumstances more  
7 harmful to tell them. You could imagine circumstances like  
8 that. If it were not for that, it seems to me the obligation  
9 would be to tell them. That's the only factor here which  
10 would hold you back from insisting that the patient be told.  
11 And the question is how one deals with that situation.

12 MR. BERNERO: Perhaps I should have emphasized  
13 it more when I was talking on the subject. The distinction  
14 of our focus of attention in regulating nuclear medicine  
15 is on the prospective safety of the patient, to see to it  
16 that the patient is being treated by qualified people with  
17 appropriately selected procedures. When we look at mis-  
18 administration reporting/recording and what-have-you, our  
19 attention is focused on prospective uses of it, to protect  
20 the next patient and the next one after that, and not on  
21 the carrying out of due process and justice for the patient  
22 who may have suffered a misadministration.

23 COMMISSIONER GILINSKY: Let's say there are re-  
24 leases from reactors. You could apply the same logic there.  
25 You could say, "There's a release; let's focus on preventing

1 the next release and making sure that people around another  
2 reactor are not going to be subjected to the release that  
3 people were around this reactor.

4 The fact is that some of these people are going  
5 to have heart conditions or whatever, and it may not do them  
6 much good to know that the reactor in their neighborhood  
7 had a release; yet we insist on telling them. I don't think  
8 the situation here is all that much different.

9 Now, it may be useful to put in some safeguards  
10 for special circumstances. But it seems to me the first  
11 obligation is to the party.

12 MR. KERR: Mr. Chairman, our office was one of  
13 those, also, who commented on this state program. We feel  
14 the patient should be informed in those cases where a  
15 report is to be made to NRC.

16 We feel the person that's most affected is the  
17 patient. He should know if the regulator is going to be told.

18 COMMISSIONER KENNEDY: That would argue equally  
19 for not telling the regulator.

20 MR. KERR: Perhaps. Now we also suggested in  
21 there that if the patient is not able to absorb the shock,  
22 in those cases where it might be injurious to his health,  
23 that a responsible relative be informed.

24 COMMISSIONER KENNEDY: There is a matter of  
25 patient relationship there, isn't there? If I understand

1 medical ethics, and maybe even the law -- and I certainly  
2 would not suggest that I understand the law -- I think the  
3 patient himself, if he's able to do so, would have to  
4 authorize a doctor to tell a relative.

5 MR. KERR: I think doctors do tell relatives a  
6 number of things.

7 COMMISSIONER KENNEDY: Some things. But there  
8 are well understood relationships which have to be carefully  
9 guarded there.

10 MR. KERR: I think our point is that the patient  
11 is the one that is the most directly affected.

12 COMMISSIONER KENNEDY: Someone has to decide  
13 which of those relatives is the responsible one.

14 MR. CUNNINGHAM: If I might go back just a  
15 little bit, we've come full circle on this issue before us.  
16 We have no reporting requirement now. We do have a  
17 limited objective with our reporting requirement, as Bob  
18 said, and that is to correct something before the next  
19 patient.

20 It is also true that something might be done for  
21 a patient after exposure. The way we developed this rule,  
22 it was not intended to specifically address that problem.

23 It has been discussed many times with our Advisory  
24 Committee, with all these peer groups, with the public in  
25 public meetings, and we get about as many ideas on how this

1 should be handled as people you talk to about it.

2 COMMISSIONER KENNEDY: What did the public say  
3 in public meetings on this point?

4 MR. CUNNINGHAM: Well, the public meeting was  
5 really two sets of people: the various medical practitioner  
6 groups was one segment of the public, and then strong state,  
7 agreement state mainly, representation. And I think it  
8 would be fair to say that the medical people aren't overly  
9 enamored with this rule, because it does put an obligation  
10 on them that they don't like particularly. They can point  
11 to things such as hospital ethics committees and what-have-you  
12 that address this very problem of what the physician should  
13 tell the patient and so forth.

14 The state, agreement state, people, I think Wayne  
15 Kerr just reflected the sentiment of the agreement state  
16 groups, who probably tend to -- would like to assert a little  
17 bit more control over the physician and the physician-patient  
18 relationship than we do.

19 COMMISSIONER GILINSKY: Are their comments in-  
20 cluded anywhere in your paper?

21 MR. CUNNINGHAM: They are. They're summarized in  
22 60-68.

23 MR. DIRCKS: They're in Enclosure Number 3.

24 MR. CUNNINGHAM: Yes, Enclosure Number 3 has  
25 comments of various groups summarized -- page 4.

1 MR. BERNERO: And then Enclosure 3 of paper  
2 Number 70 has a summary of comments on the old rule.

3 MR. CUNNINGHAM: I think the point is that this  
4 rule as it is intended is to solve generic problems that  
5 may have resulted in these overexposures. It isn't intended  
6 to take care of the one patient that got overexposed spe-  
7 cifically.

8 And, as I say, there are other --

9 COMMISSIONER KENNEDY: May I ask a question?  
10 The individual has been overexposed.

11 MR. CUNNINGHAM: Yes.

12 COMMISSIONER KENNEDY: What is necessary then is --  
13 there are at least two things that I can think of. One is  
14 that he doesn't get further exposure, at least until some  
15 measurable period of time.

16 The second is, if circumstances suggest, he  
17 ought to get some sort of medical treatment.

18 MR. CUNNINGHAM: That's correct.

19 COMMISSIONER KENNEDY: Now, what does telling  
20 him do about either of those? The doctor would be the  
21 one who would give him the medical treatment, prescribe it  
22 anyway, wouldn't he?

23 COMMISSIONER GILINSKY: He might want another  
24 doctor.

25 MR. BERNERO: Yes, that's the point. The patient

1 would say, "You guys are butchering me. I'd better go some-  
2 where else. It's that option that exists.

3 When we say report to the referring physician,  
4 the misadministration was an act of a therapist.

5 COMMISSIONER KENNEDY: Somebody else, that's right.

6 MR. BERNERO: When we say report to the referring  
7 physician, we take it away from the one who committed the  
8 fault and put it in the hands of the medical judge in the  
9 matter.

10 There is a secondary question of, "Well, you're  
11 the one who referred me to him for this treatment. Aren't  
12 you in some way responsible?" That's a rather derivative  
13 responsibility. We just don't consider it that type or  
14 grade.

15 MR. CUNNINGHAM: I might also add, for the  
16 medical management of the patient, whatever is done in most  
17 cases has to be done pretty quickly for the patient's bene-  
18 fit in the case of a misadministration, and all this re-  
19 porting business to the referring physician catch up.

20 I think there was a case not too long ago where  
21 they gave a therapeutic thyroid dose to the wrong patient,  
22 and it did destroy -- or could have destroyed part of his  
23 thyroid. They had to give an injection of some blocking  
24 solution pretty quickly. Things would have to be done  
25 immediately.



1 COMMISSIONER GILINSKY: Well, presumably if you  
2 have to report to a patient, you're going to be more careful  
3 about administering these doses.

4 MR. CUNNINGHAM: I don't agree with that,  
5 Commissioner. I think that these hospitals do exercise  
6 controls. Again, if you look at how misadministrations  
7 occur, they are hard to explain. They just seem to be  
8 human errors. The things are difficult to explain.

9 We don't think that would improve the misadmini-  
10 stration rate. It might improve subsequent care of the  
11 patient. I don't know about that. But I really can't  
12 believe, from what I understand of how these misadministra-  
13 tions occur, it would lower that rate.

14 CHAIRMAIN HENDRIE: Let's see, the inclination  
15 would be as recommended?

16 COMMISSIONER GILINSKY: I would go with the  
17 proposal concerning the reporting requirements.

18 CHAIRMAN HENDRIE: The veto option.  
19 Peter?

20 COMMISSIONER BRADFORD: I'm inclined in that  
21 direction as well. Is there a way to publish 68 in a way  
22 that leaves -- the only thing standing in the way of publish-  
23 ing 68 is that Item 10.

24 MR. CUNNINGHAM: I'm sure we could split it out.

25 COMMISSIONER BRADFORD: There's probably some way

1 to --

2 COMMISSIONER HENDRIE: I think 69 is not contro-  
3 versial.

4 COMMISSIONER BRADFORD: No, 69 is no problem at  
5 all.

6 COMMISSIONER HENDRIE: That I know of.

7 COMMISSIONER KENNEDY: Why can't we publish both  
8 as alternatives and let the public comment on them?

9 COMMISSIONER BRADFORD: You mean on 70?

10 COMMISSIONER KENNEDY: No, 68, on Section 10,  
11 or whatever it is.

12 MR. BERNERO: We're requesting comments on the  
13 issue, and we could make it sufficiently conditional if  
14 it isn't already.

15 COMMISSIONER KENNEDY: What I'm saying is you  
16 have clearly inferred here, and in the staff indeed, there  
17 are two rather different views of this. Why not put them  
18 out to the public? What we want is public comment, so why  
19 don't we ask for public comment on those particular questions?

20 MR. BERNERO: In fact, as presently constructed  
21 it's not conclusive in Item 10. Item 10 is reporting to  
22 NRC, the patient, and/or the patient's physician. It's a  
23 string of options. It's sufficiently indefinite, I think,  
24 as to be inconclusive.

25 COMMISSIONER KENNEDY: Make sure the statement

1 of considerations -- that point is brought up. Why not  
2 do that?

3 MR. BERNERO: It doesn't foreclose anything.

4 COMMISSIONER BRADFORD: That's the language on  
5 page 2 of -- look at page 22, the last paragraph.

6 (Pause.)

7 MR. BERNERO: The last paragraph of the page?

8 COMMISSIONER BRADFORD: Yes.

9 COMMISSIONER KENNEDY: That's the statement of  
10 what they were proposing.

11 MR. BERNERO: It's a factual reference to what  
12 is there. We could emphatically alter this statement, this  
13 public statement, to make very clear our emphatic request  
14 for comments.

15 COMMISSIONER KENNEDY: That's what I'm suggest-  
16 ing.

17 CHAIRMAN HENDRIE: Depending on what one wanted  
18 to do -- let's see, one could rewrite that last paragraph  
19 on page 22 and not say that there is a new proposed rule  
20 for this reporting requirement elsewhere in the Register.  
21 They could say that the Commission is contemplating one of  
22 two general pathways: One of them as described here, and  
23 the other one in which the radiographer, whatever, report  
24 serious, reportable ones to the NRC and the patient unless  
25 the referring physician recommended against that.

1 COMMISSIONER KENNEDY: There you will have to put  
2 a statement in that Commissioner Kennedy disagrees. I don't  
3 think the radiographer ought to report to the patient at all.

4 If the matter is going to be reported to the  
5 patient, it seems to me it's got to be reported to the  
6 patient by the patient's doctor.

7 CHAIRMAN HENDRIE: We can't do it. We can't  
8 regulate down a whole tier of people.

9 COMMISSIONER KENNEDY: We can't have radiographers,  
10 who see a patient for 20 minutes on one day --

11 CHAIRMAN HENDRIE: They're the licensee.

12 COMMISSIONER KENNEDY: I know, but he has no  
13 relationship with the patient. He's a technician essentially  
14 as far as the patient is concerned. The patient doesn't  
15 even know this guy.

16 If the patient is going to be told that something  
17 has happened to him that may affect his health, it is his  
18 doctor who's got to tell him that.

19 CHAIRMAN HENDRIE: Well, that's a view when  
20 you're going out for public comment.

21 COMMISSIONER KENNEDY: That's right. If you  
22 want to say no, it must be the radiographer who's got to do  
23 it, all I'm saying is I insist that a statement be put in  
24 saying Commissioner Kennedy prefers the following, or  
25 suggest it as another option. That's all. I'm perfectly

1 prepared to get public comment on it.

2 CHAIRMAN HENDRIE: The proposal is to put it  
3 out as two options.

4 COMMISSIONER KENNEDY: No, you dropped an option,  
5 which is the option that was recommended in the first place.

6 CHAIRMAN HENDRIE: To the contrary. That was  
7 option Number 1.

8 COMMISSIONER KENNEDY: But that doesn't get to  
9 their option.

10 CHAIRMAN HENDRIE: Of course not. That's why  
11 I've got option Number 2. And we can comment and wrangle  
12 about this --

13 COMMISSIONER KENNEDY: We need option Number 3.

14 CHAIRMAN HENDRIE: -- and later on you can say  
15 you agree with this one or not, or with that one or whatever.

16 COMMISSIONER KENNEDY: I want three options,  
17 Mr. Chairman. I respectfully suggest. One is the option  
18 which they put forward in the first place, in which the  
19 decision to convey this information to the patient is entirely  
20 with the doctor, the patient's doctor, referring doctor.

21 The second option is the one that our colleagues  
22 are suggesting, a perfectly reasonable point of view, which  
23 is no, that referring doctor, having been told this, must  
24 provide the information to the patient unless --

25 CHAIRMAN HENDRIE: I'm sorry, that's not -- I don't

1 regard that within the proposition.

2 COMMISSIONER KENNEDY: That's what I thought  
3 their option was.

4 CHAIRMAN HENDRIE: Please hear me out. I would  
5 want ELD's opinion on that, and the General Counsel's, whether  
6 in fact this Commission through the Atomic Energy Act can  
7 regulate the general practice of medicine in that fashion.  
8 The referring physician is not a licensee.

9 MR. BERNERO: Excuse me, Chairman Hendrie, if I  
10 could interject.

11 What we're bogging down on here is more of a pro-  
12 cedural question. We do indeed license the radiographer,  
13 whoever he is. That's the licensee. He is the one we can  
14 put a condition on: "You will do this and you will do that."

15 We would be having a requirement that he would  
16 report to the referring physician, and it is a procedural  
17 matter that, if we required him to report to the patient,  
18 it would be done in conjunction with the referring physician  
19 in some way.

20 It is clearly not sending this guy down into the  
21 room saying, "Guess what? I zapped you." It's a procedural  
22 matter.

23 We can't lay a license condition on the referring  
24 physician because we don't license him.

25 COMMISSIONER KENNEDY: We are now really in the

1 practice of medicine.

2 MR. KENNEKE: We're already there with the dose  
3 rate.

4 COMMISSIONER KENNEDY: This is going to put us  
5 there in a way we've never been.

6 MR. DIRCKS: It's a different cup of tea when  
7 you regulate dose limits than when you regulate the behavior  
8 of the physician to the patient. It's much different.

9 COMMISSIONER KENNEDY: A physician who is not  
10 the patient's physician.

11 MR. KENNEKE: You're already restricting the  
12 physician's ability to treat the patient.

13 MR. CUNNINGHAM: Wait a minute. Let's make one  
14 thing clear. We don't regulate doses to the patient.

15 MR. KENNEKE: You restrict them to the label.

16 CHAIRMAN HENDRIE: And we do license the nuclear  
17 medicine specialist, but we don't license referring physicians,  
18 who may be the general run of medical practitioners. You  
19 can't go out and lay requirements on people who aren't  
20 licensees.

21 COMMISSIONER KENNEDY: We can't interfere with  
22 their patients, either.

23 COMMISSIONER BRADFORD: To the extent that that  
24 was what I had in mind, I think you're probably right.

25 COMMISSIONER KENNEDY: I thought that's what you

1 did have in mind.

2 COMMISSIONER BRADFORD: I thought that's what I  
3 had in mind, too, but I hadn't thought of that wrinkle.

4 COMMISSIONER KENNEDY: The other wrinkle is  
5 a very serious one. That one I can understand. It's the  
6 other one I can't.

7 CHAIRMAN HENDRIE: It's an administrative problem  
8 in terms of how do you handle the regulation with the people,  
9 and I just don't see how to do it.

10 COMMISSIONER BRADFORD: I see the point, unless  
11 OELD or the General Counsel feels differently.

12 CHAIRMAN HENDRIE: You can lay a condition on  
13 the radiographer which says, "Radiographer, if there is  
14 a reportable incident, send a notice to the patient; however,  
15 before you do that, you send a letter to the referring  
16 physician. If you don't get one back that says, 'God, don't  
17 do that,' send it to the patient."

18 That's all a set of conditions you lay on the  
19 licensee, and you can do things through that.

20 COMMISSIONER KENNEDY: Can we see that, all  
21 that procedural matter written up so we'll know what we're  
22 talking about, please?

23 CHAIRMAN HENDRIE: I don't want to be ingenious  
24 and then find out we're now in some fashion licensing a  
25 quarter of a million general practitioners with regard to



1 their referring patients to --

2 COMMISSIONER KENNEDY: We're not doing that, but  
3 what we're doing is stepping into their practice.

4 CHAIRMAN HENDRIE: I think there's a problem  
5 just with the practical regulatory aspects of that.

6 COMMISSIONER GILINSKY: I'd like to have OELD  
7 take a look and see what they come up with.

8 CHAIRMAN HENDRIE: Well, with regard to being  
9 able to go forward here, we could either rewrite this para-  
10 graph to say the Commission will soon publish and not indi-  
11 cate what it is. That's Option 1.

12 Or the following statement, policy statement,  
13 could be published in the Register which would include both  
14 of these options, provided some reasonable procedural ar-  
15 rangement for the veto option could be worked out.

16 I don't have any objection to going either way,  
17 but having come this far and spending two hours on the brief-  
18 ing, and having raised our understanding sort of above some  
19 minimal threshold so we're beginning to grasp the elements,  
20 I hate to lose that. If we could indeed act to get these  
21 published here, that would be desirable.

22 MR. BERNERO: These are all proposed policy  
23 statements and amendments.

24 If we could commit to a clarification of that  
25 paragraph on page 22 of the following paper so as not to be

1 so definitive and that's all it is --

2 CHAIRMAN HENDRIE: Well, I think we could in fact  
3 decide which of the two ways that would leave the option  
4 open would be desirable. One way, as Bob says, would be not  
5 to in effect state the thrust of the proposed rule here but  
6 just to say that there will be soon published for comment  
7 a rule. That would be one way to handle it, and that would  
8 allow this thing to go.

9 I assume we could also do the 69 paper, too,  
10 since I think everybody agrees on that.

11 Now, the other way to fix this would be to say,  
12 "Look, we're considering two paths, and we'd be interested  
13 in comment." One of them is as written out here, and the  
14 other one is the one with the veto arrangement; however,  
15 that will require some language that ought to circulate  
16 back to us so we can agree it's a practical regulatory  
17 scheme.

18 COMMISSIONER KENNEDY: Who is it who has to  
19 render this veto in your scheme?

20 CHAIRMAN HENDRIE: The referring physician.

21 COMMISSIONER KENNEDY: The referring physician.

22 COMMISSIONER GILINSKY: Well, either one is  
23 acceptable to me.

24 CHAIRMAN HENDRIE: Any preference? Let me  
25 recommend leaving this in a form which says the rule will

1 be published, without -- and keep it general enough so that  
2 both these things fall under the umbrella.

3 I think the sort of thing that you could possibly  
4 note there, since it would be true in either case, would be  
5 that the referring physician would . . . .

6 MR. BERNERO: Addressing the issue. You know,  
7 the policy paper is not the forum wherein we ever intend  
8 to make the decision. It's addressing the specific issue,  
9 and this paragraph on page 22 associated with the policy  
10 should be speaking -- and a rule will be published addressing  
11 that issue, considering the range of options, words to  
12 that effect, without attempting to tip to a final balance.  
13 It's the wrong forum.

14 CHAIRMAN HENDRIE: Would you like to see that  
15 paragraph?

16 COMMISSIONER KENNEDY: The way Bob's talking  
17 about it right now, I'd sign off now without seeing it  
18 again.

19 MR. BERNERO: The paragraph would be altered so  
20 as to state that a rule will be published which addresses  
21 misadministration and attendant recording and reporting  
22 requirements, considering issues such as whether to report  
23 at all, whether to report to referring physicians and  
24 whether to report to the patients, but not by any stretch  
25 attempting to set up in this forum the decisionmaking.

1 COMMISSIONER KENNEDY: As far as I'm concerned,  
2 I don't need to see it again.

3 CHAIRMAN HENDRIE: Does it sound all right to  
4 you, Peter?

5 COMMISSIONER BRADFORD: Yes.

6 CHAIRMAN HENDRIE: In that case, with the  
7 understanding that page 22 will be thus perfected, and any  
8 other language in the proposed Federal Register statement  
9 will be also perfected to go with it, that that be done,  
10 may I ask for a vote of the Commission?

11 (Chorus of ayes.)

12 So ordered.

13 Before you go, and while you're in a voting  
14 mood, I recommend that we accept the staff recommendation  
15 in the 69 paper on that --

16 MR. BERNERO: Clinical procedure.

17 CHAIRMAN HENDRIE: -- clinical procedure.

18 (Chorus of ayes.)

19 So ordered.

20 MR. BERNERO: And you want 70 back with the --

21 CHAIRMAN HENDRIE: You'd better, then, circulate  
22 back 70 with this alternate language. I think you see the  
23 problem: Who can you tell what things to do? And let's  
24 try to keep in mind reporting requirements and so on and  
25 try to arrange these however we come out so that it's a

1 minimal procedural burden both on them and on us.

2 COMMISSIONER KENNEDY: Let us not forget that  
3 the purpose of this exercise is medicine, not reporting.  
4 Can we possibly do that?

5 CHAIRMAN HENDRIE: Look, if you're going to  
6 raise whole new issues at the last minute . . . .

7 (Laughter.)

8 Okay, I must say that I found the briefing on  
9 a subject that I'm not very familiar with, and it has a  
10 good many twists and turns in it, to be an exceptionally  
11 clear-cut one, a very admirable piece of work for which I  
12 congratulate all the staff concerned. It put the issues,  
13 I thought, fairly forcefully out in an understandable and  
14 simple way. I very much appreciate the quality of your  
15 work.

16 MR. CUNNINGHAM: Thank you, Mr. Chairman.

17 CHAIRMAN HENDRIE: Everybody else, I guess, can  
18 wander out and have a fine Thursday afternoon, but the  
19 Commission has to stay right here and carry on its labors  
20 through an affirmation session.

21 (Whereupon, at 4:40 p.m., the meeting was  
22 adjourned.)

23

24

25

