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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING ON MEDICAL REGULATION ISSUES

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PUBLIC MEETING

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Nuclear Regulatory Commission
Commission Hearing Room
11555 Rockville Pike
Rockville, Maryland

Thursday, June 13, 1997

The Commission met in open session, pursuant to notice, at 9:00 a.m., the Honorable SHIRLEY A. JACKSON, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission
KENNETH C. ROGERS, Member of the Commission
GRETA J. DICUS, Member of the Commission
EDWARD McGAFFIGAN, JR., Member of the Commission
NILS J. DIAZ, Member of the Commission

STAFF AND PRESENTERS SEATED AT COMMISSION TABLE:

KAREN D. CYR, General Counsel

JOHN C. HOYLE, Secretary

HUGH THOMPSON, JR., Deputy EDO

CARL PAPERIELLO, Director, NMSS

DONALD COOL, Director, Division of Industrial & Medical Nuclear Safety, NMSS

P R O C E E D I N G S

[9:00 a.m.]

CHAIRMAN JACKSON: Good morning, ladies and gentlemen. Today the NRC staff will brief the Commission on its proposed program for revision of 10 CFR Part 35, Medical Uses of Byproduct Material.

In a March 20, 1997, Staff Requirements Memorandum the Commission directed the staff to submit a program for Commission approval for revising 10 CFR Part 35 and associated guidance documents and the Commission's 1979 Medical Policy Statement, if necessary.

The staff's proposed program was submitted to the Commission in SECY-97-115 dated June 5, 1997, and currently is under review by the Commission.

Today's presentation provides the Commission with an opportunity to request clarification from the staff regarding specific issues of individual concern by the Commissioners as well as for the staff to provide preliminary feedback to the Commission gained from its recent meetings with professional organizations.

We look forward to hearing from the staff on its program for achieving the goals of the SRM. I understand that copies of the paper and slides are available at the entrances to the meeting room.

Unless my fellow Commissioners have anything to

add, Mr. Thompson, why don't you begin.

MR. THOMPSON: Thank you, Chairman Jackson. I appreciate the opportunity to meet with the Commission this morning. This is one of the most important rulemaking activities that we have underway, particularly in the nuclear material side of the house.

Part of the reason is the current Part 35 has been, as you know, one of the more controversial activities, and our program had really been to strive to achieve early widespread input from the medical community as well as the other affected parties, such as the Agreement States and members of the public, since this is where radiation is intended to be delivered for good purposes, and we obviously have the issues associated with the practice of medicine and not interfering with the practice of medicine.

With me today is Dr. Paperiello, who will have some opening remarks, and Dr. Don Cool, who will be the primary presenter.

We are aware of the Commission's concerns with respect to the timing in the current paper, and we are prepared to address that issue and provide some alternatives if the Commission would be interested in ways that we are able to address the alternative approaches to accelerate the time frame in which this rulemaking could be conducted.

Carl.

MR. PAPERIELLO: Dr. Cool is going to make the presentation for NMSS, but I want to basically describe the issue on the time line and how we got there.

The rule is going to be complicated because of the volume of material, and it's not just the rule, but the licensing guides and the standard review plans that we are going to prepare for all modalities to go in parallel with the rule.

When the Commission paper came to me last week, the proposed time line met the Commission target of completion by June of 1999, but each of the three periods for public comment that I was given were so short, 45 days, that with the volume of material to be reviewed, I feared we would be accused by the medical community of deliberately not giving them adequate time to review all of the relevant material. So I directed the staff to add more time for input. The paper went forward.

After discussions last Friday, I realized that while I had been very conscious of the Commission direction to consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process, I was less sensitive to the Commission target date.

Subsequently we have prepared a revised time line that I believe ought to meet both goals with a little

technical innovation. We have to present this as a backup slide.

What we would do is drop one of three rounds of facilitated meetings and public comment period. We would use the Internet as a forum to present the rule as we actually draft it and invite continual public comment on it as we write it. Then the Commission would get the proposed rule by next May, and assuming the normal rulemaking process thereafter, we would meet the target date of mid-1999.

CHAIRMAN JACKSON: You have this in a backup slide?

MR. PAPERIELLO: Yes.

CHAIRMAN JACKSON: Why don't we hear your plan overall and the feedback you have gotten, and then let's revisit it with your backup slide again.

MR. PAPERIELLO: That's what we would propose.

MR. THOMPSON: Don.

MR. COOL: Thank you.

Good morning. If I can have the first slide.

[Slide.]

DR. COOL: Things that I wanted to try and touch on today very briefly was the plan program, as the Staff Requirements Memorandum had indicated.

Some of the conceptual ideas that we have been looking at and discussing with various groups, the states,

and several of the medical societies already.

Some of the feedback that we got from those groups that they told us over the last couple of weeks.

So that's roughly where we are going to be going.

The next slide, please.

[Slide.]

DR. COOL: To try and provide right at the very beginning some of what you mentioned in terms of clarifications.

We have used the words "enhanced participatory rulemaking" a great deal on the advice of the Special Counsel for Public Liaison and the folks in OGC, who indicated to us that any time per the SRM direction we get beyond the formal Administrative Procedure Act process we are enhanced in some mechanism.

Having said that, the degree to which it is enhanced, the mechanism by which it is enhanced are all open for consideration, debate, modification, and otherwise. We took an approach, as I am going to be going through in a few minutes, which had several opportunities, each of which had specific reasons. There were pros and cons for each one of those.

The second term that was used, which I think may well have been misconstrued, was the phrase "blank piece of paper." That was not an indication that we had an empty

head or no ideas, but rather an opportunity to let folks at the beginning stages of the process, before any formal drafting had been written down, provide views with regards to how they would write the rule

In certain specific areas there are some places, as the SRM directed us, to go and get industry codes and standards and practices; how to capture precursor events; a couple of the other items that you have asked us for where as you get into the levels of detail, while there are some conceptual ideas that the devil is always in the detail of exactly how you write it and where you stop, that was our intention in terms of providing them an opportunity before already seeing language which might be construed as "the concrete already poured; perhaps we can change the way we mark the lines on the sidewalk, but it's already there" and provide that opportunity as one of the possibilities for enhancing the process.

CHAIRMAN JACKSON: Yes, Commissioner.

COMMISSIONER McGAFFIGAN: I want to pursue this. I've listened to you and to the medical community for the nine months I have been here. On a lot of issues there is a tremendous commonality of views; on some there isn't; and on some the Commission and the staff may well end up in a different place in the medical community.

It strikes me that the comments we have received

thus far -- and you have been receiving comments for four or five years on this subject -- have been all up here at the level of grand vision. I haven't seen anybody getting down to saying Part 35, section 1202 should read as follows.

I think the game that has to be played is somebody has to be brave enough to write those words down without saying this is locked in concrete.

I used to go through this in acquisition policy. We need to do more commercial-like activity, use more commercial activities. No one ever said that means in Title 10 U.S. Code 2503 you need to write it as follows, until we had what was called the Section 800 Panel.

In order to get from grand vision, Packard Commission visions down to what does Part 35, section 1202 look like, you have to put something down on paper. In my view, it's all a matter of how it is put on paper and the degree to which you give any indication that this isn't anything but a discussion draft, that this is truly a means to get people focused as opposed to this is our final word and we are going to be willing to change the adverb "maybe."

CHAIRMAN JACKSON: Did you have some issues that you were prepared to pencil in? Pencil as opposed to pen in. Where you planning to proceed along the line that the Commissioner has --

MR. COOL: Yes. In fact I agree with him

completely. That is specifically what I talked about with ACNP/SNM last week. That's what I talked about this week with the American College of Nuclear Physicians; that's what we talked about with the Agreement States at this year's CPD meeting: the time for the high ideas was done; we need to have draft language; and that's what we need to try and proceed with.

The object here was to try and get exactly that. You've always got people who are not going to do that sort of thing. They're going to stay up at a higher order level, but our hope was to have at least a few folks who would get down, would go back, as I think you suggested to the ACMUI, take a look at your license, take a look at the rules that pertain to your area and write me a draft.

We were really in hopes that we would have several of those folks, staff included. We weren't going to be sitting there going, well, let's see what they bring us and try and crank our own ideas. So I had a melting pot and poured them all into the pot of specific language so that we could stir them around to try and come up with a draft.

CHAIRMAN JACKSON: You can speak for yourself, but in order to move the discussion along, the question becomes, if all of that solicitation from the interested parties doesn't work, are you prepared to pencil as necessary to get the conversation going?

MR. COOL: Absolutely. We are not only prepared but planning to do our own cut on the version along the way as they were giving us versions.

MR. THOMPSON: I think we are actually getting a large degree of enthusiasm on the industry's part to participate in this. That's the good news.

CHAIRMAN JACKSON: The not good news or the question that follows from that is -- and as you point out, you've heard me say this to individuals who have come -- we have to put some pencil to paper here. If they have some specific ideas, they need to come forward with them, and if not, then you are prepared to lay some issues on them.

MR. COOL: We're ready to go do. Yes, ma'am.

CHAIRMAN JACKSON: I think Commissioner Diaz has something.

COMMISSIONER DIAZ: It's in the same vein. It's on the issue of what you put out there first, something that already has some direction so people can see where we are going, and then have people write, change and everything. It's in the same vein.

COMMISSIONER McGAFFIGAN: I think this is a good discussion, and hopefully the community hears it. Another way to try to shorten things and yet have people focused on the level of detail you need is to perhaps even put options out there. You said earlier Internet. You can have options

A and B and C and have people discussing the options. There is no better way to imply that you have an open mind than to have several options, if indeed all of them look viable.

MR. COOL: I think we will go ahead and proceed. A number of the things that we heard in the meetings over the last few weeks bear on this point, and I'll get back to them when we get down to the slide on what we heard out there.

Go to the next slide.

[Slide.]

DR. COOL: Conceptually the proposed steps of this plan was to provide two additional opportunities in a more formalized sense to interact with the community, with the states and others during the development phase, before there was the formal proposed rule process.

The first of those, an early input phase, as we have been talking about, to try and get people to give us very detailed specifics, their version of the rule so we could stir those together.

To try and develop those more refined into a set of options, because you will always have some measure of shotgun. The more controversial the issue, the greater the spread of the BB's.

To provide the Commission an opportunity to take a look at what has been developed and the sort of options on

the table as a mechanism of ensuring that if there were some that we needed to say, well, that scatters a bit out of the range that we would really like to consider, that we would have that opportunity.

Then to go in in a second round of some facilitated discussions, sit around the table and say, here's some language, here are some alternatives, here are some particular concerns. Training and experience will be one of those, I think, and some of the others. And to hammer around on that language such that the proposed rule that would come forward would have the benefit of those discussions, would have the benefit of the input and activities such that I would hopefully be able to represent to you that there was, while not consensus, because there is just simply too wide a range to ever hope that you would actually be able to have a consensus from the various and divergent groups, but at least a strong central tendency towards the things that were being brought forward as an actual proposed rule.

CHAIRMAN JACKSON: You mentioned in your paper the possibility that the public meetings you might have facilitated by a contractor.

MR. COOL: Yes.

CHAIRMAN JACKSON: Have you given any thought to having the actual working group sessions when you are trying

to resolve what may be quite juxtaposed positions also facilitated to help you see what the path through the forest is?

MR. COOL: Had not directly, although that is certainly an option. The working group -- and we'll get to that in a minute -- of state and NRC people as adequacy and compatibility sources has been used in a number of cases in a fairly small group. While generally run in a notice session as if it were a Federal Advisory Committee Act committee such that they are open to the public, those have at least in the past been very much limited to public observation and opportunity just to express views towards the end and have not been, except in the one case where the group ran a deliberate facilitated or more open meeting, an interaction with folks other than on the committee itself, those five or six people. So I hadn't actually looked to facilitation, but that would be an additional option.

CHAIRMAN JACKSON: Commissioner Diaz.

COMMISSIONER DIAZ: It's probably the way that it's written, but if I were to come and get in here and look at this, it will give me the impression that this process is just really a beginning or a start. We have been doing this for years. We have been gathering information; we have been calling people who have been talking about it; and now we will be talking some more. Isn't it time that we say we

have got at least a percentage of the knowledge known and now we go forward?

This is a great plan to start the whole process, but we are not starting it. I believe there is something in here that is not compatible.

CHAIRMAN JACKSON: I think what you are being asked is the following, if I can paraphrase. Aren't you at a point where you can at least lay out some binned options to begin the discussion, to provide a framework for the discussion? There have been discussions. You kind of know in the large what people's concerns are. The knowledge base has evolved and enlarged. Should that not allow you along the lines of what you have been hearing to lay some options onto the table, to begin to have what I will call the binned discussion so that things are not all over the planet?

MR. COOL: The answer to that question is yes.

CHAIRMAN JACKSON: Is that how you intend to proceed?

MR. COOL: We can jump straight to the alternative if you would like.

MR. THOMPSON: One of the things we kind of paralleled, and maybe this is not particularly the most wonderful example of success, was the decommissioning criteria. That was one where we really had criteria for cleaning up sites for years and years; we knew what we were

doing; but we really were trying to develop in a controversial area, to try to establish as much input, to build as much foundation as we could. We have quite a bit of experience of how we would change it where there are some things that we don't like. We're not sure that we have all the input from the affected parties of how they would see this change being made.

CHAIRMAN JACKSON: Let me just say the following. I think there are two ways things can evolve. The affected communities can go back, look at their licenses, whatever. As I had suggested, they can come forward and see how the existing regulations cause them egregious problems and come back with some suggested language in certain areas. Absent that, we know from discussions what the big concerns are. That should allow you to frame out some options.

MR. COOL: That's correct.

CHAIRMAN JACKSON: Nothing focuses attention like having specific things to look at. If you can't focus the attention otherwise, you will focus it and you will then get a lot of input, because when people see the words on paper, then they begin to really think about how it's going to affect their lives. I think that's all we are really talking about here.

Why don't we move on?

MR. COOL: I think perhaps we are in what around

my office we refer to as nearly violent agreement.

CHAIRMAN JACKSON: Exactly. So we are preaching to each other, to the choir.

MR. COOL: Next slide.

[Slide.]

DR. COOL: This was a little graphic. It mirrors one of the things that is in the paper, the conceptual framework and input process. Not to say that the staff would not have been working on a variety of its own drafts and otherwise during each of those processes; a developmental process to refine those.

One of the things I know I feel very strongly about is that development process goes way beyond the rule. The rule is merely the simpler half. All of the guidance that goes along with it, the actual what are you going to submit, what kinds of things are we actually going to look at in the review, what sorts of things are we going to have in there as hooks in terms of enforcement, how much will we need to go looking for other specific pieces of information if we run into a difficulty, all of those variety of things also have to be developed in parallel with that. So there was a whole series of developmental activities.

And then providing an opportunity for the Commission to review and approve that.

This was a conceptual step-wise model that we had

proposed to use on each of those phases.

COMMISSIONER DIAZ: One comment on the presentation. If I walk in and look at this, it looks the very first thing you are going to do is public input. Don't you think there should be a big rectangle on the top that says the process that we already have gone through with time, all the things that actually come before the public input? We have been working on it for years.

I know you know. I know you have been working on it, but it doesn't strike me as right to start with public input. It should start with a massive analysis and things, and then we solicit public input.

CHAIRMAN JACKSON: High order concerns and issues. Then public input.

MR. COOL: Should I go ahead and proceed?

CHAIRMAN JACKSON: Please.

MR. COOL: The next slide, please.

[Slide.]

DR. COOL: In terms of the actual staff development work, the proposal entails the use of a steering group/working group format. This is something which is actually in the management directive for development of rulemaking. It has been used on a number of occasions, Part 20, the decommissioning criteria, some of the NRR financial assurance documents, and otherwise.

There are a couple of new little pieces to this. While we have had Agreement State individuals participating in a variety of groups, adequacy, compatibility and a variety of others, this would, I think, be the first time where we had asked someone from the states to actually participate on a group that was actually drafting a regulation.

We found that to be a rather important component to us, for a couple of reasons. There are now 30 agreement states out there. The states were very interested in participating, and we wanted to get their input in an ongoing process. The individuals nominated, including the individual who is on the CRCPD, suggested state regulation group to try and have a close liaison to that activity.

The organizations also suggested to us that one of the individuals be from a non-Agreement State. Although the actual individual nominated is in sort of the middle zone, being from Ohio and well along in the process to becoming an Agreement State, I think in fact their projected schedule could have them be an Agreement State before 1999 and the actual date of this rule.

To have that view and flavor because of the impact that this rule has traditionally had, and others, with all of the other things that happen in medicine and some of the difficulties that have been experienced in times past, some

of the things in misadministration definitions and a variety of things, where the states go back and look at those definitions and say, well, that's really nice if you are talking about this little box over here that is AEA. I have to have a set of regulations that deals with this box and deals with these other boxes associated with the x-rays and otherwise. If you just change these few things over here, then the definition could have been more uniformly applicable.

So our suggestion as part of this plan was to involve those people in the drafting process.

The steering group, which I would chair, management level folks to review this. Also the suggestion to include someone from the states, probably a program director level person, to again provide that kind of input. This is a new wrinkle to the process, although not entirely new in the sense that the impact management review boards have a state program person who serves on each of the boards in a liaison capacity.

We have tried to take some of these ideas that have been generated in other forums, and this is, very frankly, the first time that it would be attempted in a rule process.

We also are very much in hopes to use some consultants and to heavily use the Advisory Committee on

Medical Use of Isotopes; the medical visiting fellow, who was still within the NMSS staff; have each of these folks playing key roles, writing down immediately their particular areas; Myron Pollycove, our medical visiting fellow, a wealth of experience, particularly in the therapy area with unsealed materials, one of the areas where there will be some controversies in training and experience and otherwise. So in hopes to reach out and get a number of these folks.

We have been working with the Office of General Counsel in terms of conflict of interest and how to deal with some of those kinds of issues, because obviously the people who have the immediate information and have the online experience are also the people who are going to be affected by the rule. So we have to walk a little bit of a careful line in that process.

Go to the next slide, please.

[Slide.]

DR. COOL: Getting back to the point that several of you have already made, there is a lot of data. There are a lot of things out there. We have been and need to continue to pull, distil, gel a number of things which we have our hands on: the event databases; our experience in inspection and enforcement; some of the analyses that we have done, such as what happened in terms of the quality management rule and some of those other activities.

We have been trying to establish and I think have been successful in establishing some contacts internationally. The International Atomic Energy Agency and some of the things that are going on in that arena. Our understanding is that the European Community is revising some of their directives in this arena more or less in parallel, although I think they are slightly ahead of us. Have some contacts there to try and establish and have some liaison there.

The variety of professional societies, the states and organizations, and the whole range of the various subgroups that are out there, to try and tap into databases and information which they have, including, for example, some of the accreditation processes, JCHAO and some of the other folks, which may have pieces which could serve as models for a more performance oriented examination of what might be useful to us as we look at enforcement, as we look at credentialing.

CHAIRMAN JACKSON: Commissioner Dicus.

COMMISSIONER DICUS: On the professional societies, I noticed in your paper you listed quite a few as potential sources of contacts, and so forth. But absent from that list was anyone representing pharmacies or even the medical technologists. Is that intentional or did you just not consider that?

MR. COOL: The list was a short list so as not to have a long paper. I have signed over 50 letters to a much longer list of various societies and otherwise, including folks in that arena, asking for opportunities to meet with them; our interest in interacting with them through this process. We wrote a sort of short list of the bigger ones. That is not intended to be inclusive or exclusive.

COMMISSIONER DICUS: So you are including the radio pharmacies?

MR. COOL: We would very much want to do so, yes.

COMMISSIONER DICUS: I may have another question about that. We'll come back to it.

MR. COOL: The next slide, please.

[Slide.]

DR. COOL: Continuing along the same vein, there are a number of things which have floated around which have been sitting in limbo, if you will, in various stages. Some of the things which came out of the Indiana, Pennsylvania, event from several years ago where a brachytherapy source broke off from its wire and remained in the patient. A number of the action items came out of that. That was the actual genesis even of the medical management plan.

There are a number of rulemakings that were tossed onto the table at various times. As the SECY paper 97-062, which came up a month or two ago with the semiannual

rulemaking update, indicated in that paper, the intention would be to subsume those more individualized actions into the overall revision and deal with them. Again, there are background documents and thinking that has gone into some of those which would be incorporated.

There have been some other issues papers that have been generated to try and lay out ideas and thoughts in brachytherapy and some of the other areas.

There are some of the internal staff audits, the one that Dr. Paperiello did a couple of years ago, and some others.

Again, there are a whole bunch of things which are already on the table and serve as a baseline for this activity.

Next slide, please.

[Slide.]

DR. COOL: Having said all those things, there are a series of issues. This again is not meant to be all inclusive, but some of the bigger ticket items, some of which match items which are in the Staff Requirements Memorandum, some of which will be on that.

We are specifically looking at the issues with the association of the quality management rule, which one of the objectives, how many of the objectives, how much other detail, and where those apply in a graded basis to the

various kinds of modalities and treatment.

Medical practice and treatment is a vast range, from very, very small amounts of material to very, very large quantities of material, from unsealed materials to sealed materials, and the kinds of things that are needed in a variety of these areas.

Obviously if you are wanting to rank them by risk, to be varied by those areas, right now these are a single place in the regulation and sit there without a whole lot of variation on the theme.

The issues associated with what kind of events to capture, precursor events and other activities. Our thought here is really how do we get to those events which are of more regulatory interest, those for which they indicate concerns which really need to be propagated to other licensees because they may have generic implications.

Or issues of how particular things are done or otherwise. Things that are associated with breakages, failures.

Other sorts of things for which particular actions are necessary, or which would indicate that there is a flaw or otherwise within the regulatory structure, either in the material that is submitted in response to the rule or in the rule itself, but which have an actual influence on that, and try and get a way to the extent we can to whether or not you

missed on that patient for some rather unique and singular reason which doesn't have more generic ramifications by 5 percent or 10 percent or otherwise, particularly in situations where within the medical realm there is a typical range of practice within which physicians choose prescriptions and treatment plans on a routine basis. If you went around and sampled them, you would find that kind of variation. So maybe you are off by a few percent in that particular one. If there were no more specific implications, you were inside that kind of typical range; not at all clear why we should be concerned with that particular activity.

The issues of training and experience. This, I think, will be one of the more difficult ones. It gets to a couple of points.

Who do we specify requirements for? In some cases the individual who has the most influence on whether or not it works right is not the physician at all; it's the medical physicists, the individuals who are doing the treatment plans and otherwise. In this particular case, teletherapy, brachytherapy, the higher risk modalities, the bigger doses.

The physicians themselves. The whole concept, as on the next slide we will get to in a little bit, of the authorized user, a concept which goes way, way, way back, and which in the medical community today, while still very

much used because it has grown and everybody has sort of adapted and followed this approach, may not in all cases actually track the way medicine is done these days in terms of groups of physicians, in terms of HMOs and referrals and cross-referrals and other activities; as to who that particular individual who ends up being the one who is hooked needs to be and trying to sort that out without getting in the middle of turf fights, without getting in the middle of the way in which a particular medical community or large institution might wish to practice the activity and conduct the referrals.

There are a number of issues there, particularly in radionuclide therapy and in some of the things like brachytherapy, high dose rate gamma stereotactic therapy, which has an incredibly large number of sources and can do a whole lot of damage if you miss and for which the physician simply says "I want it there" and for which a team of individuals goes in then implements that process.

Capturing emerging technologies. This is one of the places where the technology changes faster than they have annual meetings to go see what the new stuff is. You walk around the floor, as I did, down in San Antonio and you'd just be amazed at the kinds of innovations and changes and new things that they are popping out on the floor every few months in terms of equipment and modalities and

activities. It's going to be a thing which constantly is changing, constantly is modifying and otherwise.

How to best capture that, how to best structure the organization, which we believe is by more or less all-inclusive modality blocks so that you can go in and add or modify one without affecting all the others or having to consider quite so much those ramifications.

In some cases we may know that there is something coming. We may not be smart enough right now to know exactly what. Monoclonal antibody therapy is still very much in a research developmental stage. It may look a lot like radionuclide therapy. Then again it may not in certain contexts that might be important from a regulatory standpoint.

Accreditation process. As I mentioned a little bit earlier, there are a number of things which happen on the medical community side of the house irrespective of NRC or irrespective of use of radioactive materials in terms of accreditation of hospitals, in terms of accreditation of programs and systems and other activities. What we very much want to do is to look at some of those and see if there are things which we can piggyback and use, reference or otherwise.

As you had requested in one of the specific line items in the SRM, to look at that. We view those processes

as being within the scope of industry codes and standards in terms of things which may be useful to us. Some of them may not be, and we will just have to see where they are. And it may be very variable. There may be some in some modalities which are usable and not in other modalities. I would anticipate at this point a great range within what we have available that we can actually use.

We can go ahead to the next slide.

[Slide.]

DR. COOL: As we have been going through this and applying a lot of thinking to it already, we keep coming back to what does someone mean when they toss out, sometimes rather glibly, that little phrase, "well, medical judgment" in this particular area.

As I start to look at the questions of what do you need to report and what is an event and what are the experience requirements you have to do, and what constitutes a prescription, and all those sorts of things, all of those evolve back to somewhat of a root of what exactly is the purview -- this has always been a line that we have had to deal with -- of the medical judgment, which is the right and direction of the physician in dealing with that particular patient, versus the point at which it moves over into a protection standpoint and those activities and how that evolves in the process.

The sophistication of the practice. As I mentioned a little bit earlier, we have a huge range both in terms of the isotopes and risks and in terms of the sizes of the institutions that are out there. You have private practice clinics. They do rather limited things. They will do some scans. They are a small group; limited resources, limited activities.

You have on the other end of the spectrum the huge, broad-scoped medical research, treatment and everything else you can think of program who have got lots and lots of resources, lots and lots of grants and activities; a variety of things that they have the ability to do simply because of the size and structure which they have.

How again to construct a set of requirements which is sufficiently robust that the smaller organizations for which the phrase "tell me what the number is and how to do it and I'll go do it" may well apply versus the large organizations who really don't want to be told how to do it because they have a variety of things and under certain circumstances they may want to be doing something slightly different because they know a lot about it; they are in a research kind of mode; they are working with FDA or otherwise, and they have a variety of activities. So trying to deal with that span which is not too restrictive or too

loose on the ends of the spectrum.

What I have nicknamed on this chart the "bad apple" factor for lack of a better way to reference it. How do we deal specifically with the enforcement activities with the relatively small percentage of folks who, for whatever reason, are not in compliance, don't want to be in compliance or otherwise with the requirements in dealing with specific issues?

The more you move to a performance orientation the more difficult in one sense it becomes to be able to take a specific, very simple citation "you did X and Y improperly. Bang! Here's your citation. You did it wrong." Everybody says, "yeah, I agree. X and Y are very clearly written as X and Y."

There are some tradeoffs back and forth between those sorts of things. The medical community continues to struggle with this on its own in terms of malpractice and other activities, and self-regulation; what constitutes acceptable standards of performance and care.

It's not one which is or can be divorced completely from some of the other ongoing activities which are going on in this community. This community is more unique and more diversified than a lot of the other kinds of licensees that we need to deal with. Once again, these are the only folks around for whom we give them a license to

specifically put radiation and radioactive materials and people in the same spot. Everybody else it's much simpler. The concept of keeping the two apart makes it a whole lot simpler trying to write up the requirements.

The last one on this chart I have already talked about in terms of the authorized user and the potential impacts for that and how the regulation is written.

CHAIRMAN JACKSON: I don't know what would help deal with it. It would be dependent on who your consultants are, et cetera, but it strikes me that an issue here or a hidden issue or an overarching one is the one that relates to the changes in the practice of medicine with the formation of HMOs and other kinds of structures, which, as you went through this list of issues, I can see affecting or being affected by any number if not all of these. I would just urge you to ensure that, if you haven't already, you fold into your thinking the effect, and ensure that you get some input, whether it's in the form of a consultant or on your steering committee or whatever; that you get some input along that line. Otherwise, you could end up with a rule that is meant to address some longstanding issues that is outdated the day it hits the street.

MR. COOL: I agree with you. That's part of the reason as consultants we are trying to look at folks who are practicing out there in the community. I'll be very frank

with you. The key source of people that we are in hopes to use is to probably try and provide modifications to existing contracts with the individuals who already are under contract to the Commission to look at misadministration events. A number of those are individuals who are also on the ACMUI. One of the things on ACMUI is in fact an individual who is a hospital administrator.

CHAIRMAN JACKSON: A hospital administrator in the traditional sense is a very different individual than those who are running medical businesses. So I'll be very honest with you and say that you need to extend beyond your existing source of contractors so that you get the right kind of perspective and information that you need. There is no point in our going through this effort and, as I say, ending up with a rule that is outdated the day it hits the streets.

MR. COOL: I agree.

We can go ahead and go to the next slide.

[Slide.]

DR. COOL: The organizational outline that we have been looking at and that we have tossed onto the table already as a pencil idea, and which when we get to the next slide I will say has been received quite favorably thus far, is a modality approach.

I want to start by saying that a modality approach

is not new. There have been groups going way, way, way, way, way back in the medical field. Some of those may no longer correspond to actual risks; some of them may be folded together; other ones may need to be created.

The current Part 35 is to some extent modality based. In you go in and look at it, you will find 100, 200, 300, 400 which deal with specific activities, but a large part of the current Part 35 then has other things around it. Those have tended to be the things that have caused us the aggravation, the quality management, the training and experience, some of the definitions. The proposal that we have tossed out on the table is to take all of those and make those modality-specific.

In essence, the organization would be something on the order of a series of subparts such that if what you wanted to do was diagnostic imaging with unsealed materials, you could go to Subpart A and everything that you would need to have, who was going to be licensed and what kind of license or registration or otherwise, what do you need in terms of technical things, what do you need to do in terms of surveying, in terms of access controls, what do you need in terms of training and experience, what do you need in terms of reporting to us, what do you need in terms of events and records and everything else, it's all there in that one part.

You can have a second part for maybe therapies; another part for low dose rate or manual brachytherapy; another one for the high dose rate and pulse brachytherapies where the sources are a lot larger and the equipment more complicated; another one for teletherapy type units perhaps; another one for gamma stereotactics where a whole other series of complexities come in.

I may have left out some we have been thinking through. We end up with six or seven possibilities right now, trying to derive them both on the basis of the risk or doses that could be derived or generated by some of those practices, and at the same time keeping in mind that medical practice, being what it is and that they are to some extent binned with different groups performing different things, that the rule or organization ought to more or less mirror the kinds of things that they are doing so when they go grab whatever it is, if they are in teletherapy, it's Subpart E, and there it is.

To go along with that, what we are in hopes to do under this model would be for the guidance document to match that modality approach. So you grab the rule, you grab the guide that goes along with that rule, and you have everything that you would need and everything that the license reviewers would be looking at in that particular arena.

CHAIRMAN JACKSON: Chairman McGaffigan

COMMISSIONER McGAFFIGAN: How do you deal with emerging technologies that don't fit one of the parts? Do you have a subpart called emerging technology that says that this is how we do it?

MR. PAPERIELLO: That's what we would do. We would have a sort of a catchall category, and as we got experience, then we would eventually drop another module over that particular modality.

COMMISSIONER McGAFFIGAN: So you would have something in there so that you wouldn't be a hinderance?

MR. PAPERIELLO: Obviously.

COMMISSIONER McGAFFIGAN: You would have a place-setter, and then as it got a formal title, it would get its own subpart over time.

MR. COOL: Exactly. A set of things which would in general lay out the kinds of minimum criteria for these sorts of things, which you would then look at on a license-specific basis as they started to develop that, and as you develop the set of criteria and the practice itself and got to the point where it was probably moving from a research developmental kind of mode into a routine use mode, then you could mirror that with a new subpart.

This organization, quite frankly, is likely to result in more words in Part 35, because there will be to a

certain extent repetitions.

CHAIRMAN JACKSON: You mean I am not going to be able to tell the Vice President that we have eliminated so many pages of regulations? We get asked that every year.

MR. COOL: That is in fact a downside, but if you were a diagnostic group, you've actually eliminated a bunch of pages, because they only need Subpart A. So it sort of depends on how the Vice President wants to count.

CHAIRMAN JACKSON: I'll take you along with me.

MR. COOL: I'm sure that would be a wonderful discussion as well.

MR. PAPERIELLO: I would make an observation. We have put entirely too much prescriptive requirements in Part 35. Surveying once a week. That is absolutely unnecessary to be in a rule. On the other hand, surveying a patient after brachytherapy before you release them, I probably would leave that prescriptive requirement in the rule because it's a simple thing, and if you do it, you can prevent one hell of a lot of damage. How many times you survey your laboratory -- I don't know. Tell me how much you do in a laboratory.

COMMISSIONER McGAFFIGAN: It sounds like they have an outline at least for their rule.

CHAIRMAN JACKSON: It's well hidden to this point.

COMMISSIONER McGAFFIGAN: So the pencils can start

working.

CHAIRMAN JACKSON: All right. Let him show his last viewgraph.

MR. COOL: If I can have the next slide, please.

[Slide.]

DR. COOL: We have already had several interactions, some of which you are very much aware of. In terms of the ACMUI meeting back in April, they presented their views to you in a meeting a little over a month ago.

We went out and had discussion at the Conference of Radiation Control Program Directors meeting. That was in late May. We presented them with the ideas and thoughts, presented them with this modality approach as an idea; tossed some rocks at it, and very much encouraged them as we did in each of these cases that we need to get down to the real words, the real language. That was echoed by a number of the individuals in the meeting on the need to provide specific, explicit language.

In this first round of meetings, not surprisingly, they sort of got it tossed at them for the first time: okay, the process that they have been talking about and we have been talking about, and we're waiting. Well, okay, now it's go.

Didn't get a whole lot of "30.32 really should be written this way at this point," but I believe a number of

folks went away from that with the idea that they were going to go back and start to look at their particulars. Interacted specifically with the people who have been nominated to work with us on that working group. Very much interested in talking in terms of schedules and ideas and when things would be coming up, some of the ideas which they had going on.

A week ago, down in San Antonio the Society of Nuclear Medicine had their annual meeting. They carved a two-hour block out in the middle of their schedule for us to come down and talk. Presented again the same sorts of views. Had it on the table.

Most of the feedback during that actual meeting, not surprisingly, dealt with process rather than individual details of the rule language. The process that was being pushed for by individuals in the audience was a much more participative process than the staff proposal.

I can summarize it in two words. It looked for all the world like negotiated rulemaking. The comments were almost universally along the lines of we want to be in the beginning, we want to be writing with you. At one point we wanted to have an equal vote and sit around the table so NRC doesn't have an overriding vote. Some of those sorts of things.

Separately while I was in San Antonio I met with

the leadership of the group, who expressed perhaps a slightly more moderate view. Again, very interested in participating and writing. They indicated they would come in and talk to several of you. I'll take it at face value that they did so, and your views of what happened during that interchange are probably different from their views of what happened in that interchange.

They were very supportive of having a chance to write early and told me that they were going to go start trying to write down specific pieces, Society of Nuclear Medicine being particularly interested in the unsealed area and in the diagnostic arena, which is an area where likely there are going to be significant changes because that's an area which we can probably walk away from a lot of the stuff that is there now.

I believe that they are in a position, after having talked with their leadership, to get us specifics in language. They are very interested in that process. They are also very interested in participating around the table to hammer out the details of the work.

This week, in Tahoe, the American College of Medical Physicists annual meeting. These are the folks who are on the line dealing with higher risk activities, translating prescriptions into treatment plans, teletherapy, brachytherapy, and otherwise. These are the higher risk

folks. Again, very, very interested in the process, very, very much wanting to be participating, and indicating to us that they will have us written stuff within the next month, and wanting to be very heavily involved in the process.

So the feedback at the first level has been more related to process. We've seen a great level of interest out there. Have a number of at least verbal commitments that written materials and details would be forthcoming, which can only be judged as we get down the line and see to what extent we actually get that.

Sort of the two ends of the spectrum, the unsealed materials and the lower risk materials, very much interested, and the medical physicists and the higher risk arena, also in the same sort of position. That's in general the kind of feedback that we have gotten to date, which has been generally appreciative.

CHAIRMAN JACKSON: Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: He essentially answered it in the second part, which is within a month, which you said for the second group, that you will be getting some words. The first group, they have a chance to write early; they are anxious. To some degree these folks have had many years to write. If they will get something in, it would be useful. Do you have a sense it will be soon?

MR. COOL: We didn't talk days. They were

indicating that someone of the government relations group would probably be here in the audience. Our expectation is we will get back to them with more specifics as soon as we knew it. The impression, because we did not talk days and schedule because I couldn't talk days and schedule, was that they wanted to participate, and if that meant that they needed to move quickly, that at least the leadership was prepared to do so.

CHAIRMAN JACKSON: Let's see your backup slides.

MR. COOL: If I can have backup slide 1, Alternative One.

[Slide.]

DR. COOL: Alternative to the process that we have laid out is to walk away from the formal first round of interactions. Much along the lines that you said, there are a number of background documents. Go ahead and start putting pencils and otherwise to paper.

These slides are not in your book. These have been generated over the last couple of days. I apologize that we don't actually have paper copies for you.

CHAIRMAN JACKSON: Do you have at least two copies? It's very difficult to see from here.

MR. COOL: I don't know that we have any. Let me give you mine. I think I know what I wrote.

To fundamentally walk away from the first formal

round of interactions. So under this alternative, rather than the notice of proposed rulemaking and solicitation of early comments, begin immediately with a process of drafting, of laying out alternatives. Simultaneous with that, being receptive to and open to any input which we would get from the medical community and otherwise.

In other words, keep moving and keep doing the sorts of interactions that we have been doing with medical community, encouraging them to get things in early. This would up the time frame, because the drafting would be very much more running on a shorter fuse.

The object of this would be to have some drafts which could be discussed with some options by the time certainly that we got to the Agreement State meeting in October;

To start interacting with the ACMUI early this fall;

To move from there to the facilitated public meetings, which were viewed in terms of bang for the buck, if you will -- several of you have already indicated this -- where there are things on the table much more likely to get very specific section, paragraph, line, chapter, verse changes and additions and otherwise, such that a proposed rule which would include those interactions could come to the Commission in May of next year, and then enter into the

more normal, traditional proposed rule and comment process.

You could still very well hold a couple of meetings during the formal proposed rule period. Those have not been specifically marked on the chart. That would not directly impact the schedule if you wanted to hold a meeting or two during the formal 90-day public comment period. That public comment period was set at 90 days. That is the minimum under the Administrative Procedure Act. From there, to move into the development of the final rule with all the associated documents and all of the guidance documents that have been laid out.

MS. CYR: Ninety days is not the minimum. Seventy-five is the minimum under the NAFTA.

MR. COOL: Thank you. I can take 15 off. Thank you very much.

MR. THOMPSON: We do take our advice from counsel.

CHAIRMAN JACKSON: Take 15 days off the schedule.

COMMISSIONER DIAZ: Shouldn't the informal public interaction finish before you develop a rule maybe to set some urgency to people to get it before you actually get to the time line?

MR. COOL: That's actually the part that we are walking away from, because we will be drafting, and within six to eight weeks we would have the working group looking at and refining ideas. Under this alternative, while we

would be open and continually open to interacting in informal interactions, we would be moving forward.

The plan would be to have drafts publicly available, put them in the public document room, put them on the net. They would be more than welcome to E-mail us.

To the extent that the various societies are off drafting their own things and a few weeks from now would come in and say, here's some draft language, wonderful. I'll notice the meeting; we'll sit down; we'll refine it. If they want to go off and refine it some more and come back and interact with us, we'll be open to all of that. But the sense of urgency would be very much increased, because we would start harder development, somewhere between a pencil and a pen, laying down some of the ideas so that we could have a draft, or in areas like training and experience, some key options laid out that we could be in a position to hammer at a round-table discussion later this year.

CHAIRMAN JACKSON: I was going to mention this in my closing remarks, but I actually think you need to within the next day or two send a supplement to the Commission that lays out this expedited schedule, fleshing out some of what you are saying, because we are not going to sit here and look at this in great detail sitting here at the table. They might.

COMMISSIONER McGAFFIGAN: Just to echo

Commissioner Diaz' point, clearly the message should go out to the professional societies and the public getting something to you early is better than getting something to you on May 31, 1998, the last date under this proposal the informal public interaction will end, and you'll give us a SECY paper the next day for us to think about it, if I am reading this right. So the earlier the better on the public comment. As in any process, getting your thoughts down on paper earlier has a bigger influence.

MR. COOL: That's correct.

MS. CYR: The Commission ought not to lose sight of the fact that a proposed rule is in fact supposed to be -- too often in this agency we think that when we go out with a proposed rule stage that we have somehow written in stone at that point, and we ought not to convey that impression.

CHAIRMAN JACKSON: Exactly right.

MS. CYR: Yes, we are going to have this early interaction, but it seems to me that the proposed rule is only that.

CHAIRMAN JACKSON: Exactly right.

MS. CYR: You are certainly looking for public comment and expecting to make changes in response to that. You have a whole period under this schedule for another year and a half in which you are going to be developing a final

rule. It has to be a logical outgrowth of what you propose, but you can develop a final rule which could look substantially different from what you have proposed.

CHAIRMAN JACKSON: I think that your caveat is good, Karen. I think we can't ourselves get locked into the idea that sending out the proposed rule means that it's somehow cast in concrete. That's where the inherent flexibility lies, but it also addresses the issue of putting some initial flesh on the bones in a more refined way.

Commissioner Rogers.

COMMISSIONER ROGERS: Just a couple of observations. It does seem to me that one has to be a little careful here in developing a program by analogy to the decommissioning rule effort, which really had quite a different kind of impact on the general public. It seemed to me there we had to deal with a broad collection of public interest groups rather than professional interest groups. When we talk here about public input, we are probably talking about the input from the professional groups.

MR. COOL: That's correct.

COMMISSIONER ROGERS: I think you've had a lot of trouble trying to get what you might really call Mr. John Q or Mrs. John Q Public to get any interest in this thing at all. We have really fallen very flat on that and almost given up on it.

In a certain sense the technical term of public interaction may be correct, but it really isn't broad; it's really the collection of professional interest groups that have to be involved here rather than some broad public. We've heard a lot from them. I'm not going to repeat everything that is said. So it does seem to me that the character of this enhanced participatory rulemaking should be very, very different here from what we were talking about in the decommissioning because the purpose is quite different.

As I listen to it, I don't really quite see why this facilitated public interaction, which is really with these professional groups, can't move earlier on your chart here. That's where the carpentry is to be done; that's where people have to really hammer things out. A mixed metaphor.

At any rate, I think that maybe we are all uncomfortable here, and I'm a bit uncomfortable. Even this new chart seems to me to give perhaps too much time to the so-called informal, because I guess we really don't know what informal means.

Facilitated, I know what that means. You've got a facilitator and you try to drive towards some kind of commonality. It does seem to me that there are real benefits to having a facilitated approach because of the

past complaints that the NRC stuffs everything down people's throats. If you have got a facilitated meeting that actually does come to pretty good common ground, I think that will tend to diminish the credibility of that kind of an argument. The informal one, I don't know what is going to come of that.

All I am saying is I think that I would like to see you try to move as quickly out of the informal into the facilitated and use the facilitated efforts to really come to grips with what these things ought to say and get everybody together in one room and argue it out, and use a facilitator, though, so that there is no complaint that NRC just totally dominated this when everybody else had a different view. Ultimately NRC has the authority and has the responsibility. There is no question about it.

If everybody doesn't like it and we feel we are obligated to do it under the Atomic Energy Act or something, we'll do it, but we don't want to start out that way.

I would urge for more emphasis on the facilitated interactions. If you want to label them public, okay, but we really know that that public is the interested professional society groups, not a broad public. Although I'm sure they would be welcome, they're not going to come. They haven't so far.

The other thing, on General Counsel's observation

about a proposed rule is just a proposed rule. I'm not a lawyer. I'm not going to argue with the general counsel, but I think the history has been that we haven't made very big changes from proposed rules in general. We can.

MS. CYR: That was exactly my point. That has been our practice, but that's not what the legal framework is.

COMMISSIONER ROGERS: I understand.

CHAIRMAN JACKSON: New opportunity.

COMMISSIONER ROGERS: It's a new opportunity, but you have to demonstrate the credibility of that observation, because we have said that many, many times in the past, and the net result hasn't been very different.

CHAIRMAN JACKSON: That's an opportunity for all of us. When we send out the proposed rule and there are substantial comments and concerns, then we have to accommodate it.

COMMISSIONER ROGERS: My point is that facilitated interactions provide an opportunity to kind of diminish the concerns.

CHAIRMAN JACKSON: I'm going to keep going down the line with the Commissioners so we can get the final questions or comments in. But let me ask you this. Can you give us the resource loading for the new schedule? You can send it as the supplement.

MR. PAPERIELLO: It was in the budget. We gave it to the budget review group. We just transcribed the numbers.

CHAIRMAN JACKSON: All you have to do is lift it out and put it in.

Commissioner Dicus.

COMMISSIONER DICUS: On these alternative schedules, I think we have focused on alternative one. I was looking over here at alternative two as well.

CHAIRMAN JACKSON: Alternative two?

COMMISSIONER DICUS: Yes.

On alternative two you have in the fourth quarter of the fiscal year public input, but there is no mention here of facilitated public interactions. Are you planning that, or are you going to come back in the supplemental paper and explain these two alternatives?

MR. THOMPSON: I think we need to do that. We haven't had a full chance for Carl and I to look at that. This was something we developed in recognition that we needed to have an alternative approach in general concept, and we need to flesh this out a bit more.

COMMISSIONER DICUS: I think having the public input early is addressing Commissioner Roger's concern.

CHAIRMAN JACKSON: What is the current due date on this paper?

MR. HOYLE: I don't have that with me.

CHAIRMAN JACKSON: Let us agree, since we do it as a public vote, that we want this supplement with these things fleshed out. We'll give you one extra week, and we will extend the due date on the vote on the paper for one extra week. Can we all agree on that?

MR. HOYLE: June 20 was the due date.

CHAIRMAN JACKSON: So June 27, but with the understanding that within the week the supplement will come.

COMMISSIONER DICUS: A couple other points. I want to be sure to make it unanimous that I was equally concerned with the time line that we saw in the original paper and appreciate the fact that you were able to do a quick recovery and try to shorten this at least to the time that we wanted as we put it out in the DSI.

A couple of quick comments, probably preaching to the choir, and I hope I am preaching to the choir here.

A couple things to keep in mind as you go forward with this process. I mentioned the radio pharmacies. I think you are already aware of this, but when we revise Part 35 there are other parts of our regulations that could be impacted. This happened to us in Part 20, and we didn't catch all of those. And also with the reg guides. So you have got to think outside the box on this.

I'll give you one particular, and it's Part 32

with the licensing of radio pharmacies. You've got to be sure that as we revise 35 we look at 32 as well, particular the reg guides. I think you already know there is a conflict there with the reg guide. I think we are going to have to watch this as we go forward.

The second comment I would like to make is I think the people you will be dealing with, particularly the professional societies, the other stakeholders and the states, and non-Agreement States as well, will help with this, but we always have to remember that the NRC does, after all, regulate only a partial segment of the use of radioactive materials in medicine, and certainly only a very small part of the use of radiation in medicine.

Whatever happens with 35 has got to be done thinking in the context of how does this impact the use of an x-ray machine. Even though we don't do that, we cannot do this without keeping those sorts of things clearly in mind.

CHAIRMAN JACKSON: Commissioner Diaz.

COMMISSIONER DIAZ: First, I want to thank Dr. Cool for a wonderful presentation without the aid of viewgraphs.

MR. COOL: Thank you.

COMMISSIONER DIAZ: That was very good.

I think we have said everything. I think time is

the important thing. I just wanted to bring up a side argument following Commissioner Dicus' comments. I haven't seen anything in writing and I know it doesn't pertain to Part 35, but in all of these conversations and meetings has the issue of accelerators been brought out, and if so, could we get a separate report on some of the staff thinking and the information that is being received from the community on the separate issue of accelerators?

CHAIRMAN JACKSON: We should fold it in, but not as part of this particular one.

COMMISSIONER DIAZ: Not as part of this.

MR. COOL: To date the feedback has only been in terms of questions with regard to why the SRM was written the way it was and the questions about why the IOM report was not accepted.

COMMISSIONER DIAZ: I see.

MR. COOL: Beyond that, we really haven't gotten any substantial feedback that I could summarize and report to you. They asked a couple questions. I in fact chose to respond to them by reading the specifics of the SRM. They went on to another question, and that was as far as the Society of Nuclear Medicine. There might have been slightly more colorful language.

CHAIRMAN JACKSON: Get out of Dodge.

Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: On the resource issue, one of the things I noticed in the paper is most of the FTEs and resources are in NMSS, but in FY-98 and FY-99 we still have Research doing a significant chunk of rulemaking with 1.9 and 1 FTE. I don't want to open up the whole discussion of the direction we gave separately about getting rulemaking activities back into the program offices, but does this reflect the current status quo, and as modulo are those people getting transferred into NMSS at some point, and those resources getting transferred in?

MR. COOL: It basically does in the sense I have met with the division in Research. We have reached an agreement with regard to their providing an individual. They're part of the team working on it. This is irrespective of any of the other possible changes. Our intention is to use some of the contract vehicles; the Internet capability that has already been developed in terms of posting things. Some of that support, because the infrastructure sits there, it only makes sense to try and tap it.

CHAIRMAN JACKSON: But you can't presuppose it, because we haven't made that formal decision about where the rulemaking gets done.

COMMISSIONER McGAFFIGAN: We've made the decision in principle in the SRM and the DSI to take rulemaking out

of Research, but the details the staff hasn't proposed to us yet.

MR. THOMPSON: We have not, and this really reflects the current organizational structure and responsibilities.

COMMISSIONER McGAFFIGAN: The second point. I think I agree with Commissioner Rogers about the facilitated only because I think it will get the pencil working faster. It sounds like to go into a facilitated discussion on, say, section 30.32, you have to have something to say about it. It's really the same comment, but I think if the facilitated discussions occurred earlier, it might force pen to paper both here and in the community earlier.

CHAIRMAN JACKSON: By the way, I would like to kind of make an addendum to this. We have to be careful if we keep talking about blank sheets. I know this is just for purposes of discussion. You want to rewrite Part 35. You are not necessarily looking section by section at the existing Part 35 and saying "I want to change it."

COMMISSIONER McGAFFIGAN: That's what I said earlier. I think they've got a new outline.

CHAIRMAN JACKSON: You basically have to write a new Part 35.

COMMISSIONER McGAFFIGAN: They have a new outline; they know what they want to fill in; a lot of it is going to

come from the current Part 35.

CHAIRMAN JACKSON: I agree, but not to do it necessarily as a section by section, line in, line out kind of thing.

MR. PAPERIELLO: The other thing is we need to develop the licensing guides to go with it. Frankly, there are a lot of areas of low risk that I intend that we are going to reduce the effort both on our part and the licensees. Diagnostic nuclear medicine, and I define that as less than 5 REM TEDE --

CHAIRMAN JACKSON: You don't have to tell us the rule today.

MR. PAPERIELLO: I want to make sure we don't add requirements through the licensing back door that we take out of the regulations. That has happened in the past.

I also want a very honest game. For four years the staff has been accused of lying to the Commission, being stupid and incompetent.

CHAIRMAN JACKSON: Not this Commission.

MR. PAPERIELLO: I wanted to build a record to show when we have the final rule we did an honest job and the like.

CHAIRMAN JACKSON: We think you are honest in the absence of evidence to the contrary.

[Laughter.]

COMMISSIONER ROGERS: And not stupid.

CHAIRMAN JACKSON: In the absence of evidence to the contrary.

MR. THOMPSON: But there are those out there who would like to paint the staff in that role.

CHAIRMAN JACKSON: Let me make sure you understand this. You've gotten various individual and collective inputs today. I don't believe there is an adversarial issue between this Commission and the staff. So let the record show this. I think we are just trying to move this process along.

I would like to thank you for today's briefing. The discussion we have had of the logistics issues associated with your proposed program for revision of Part 35 as well as feedback that you have gotten from recent meetings with professional organizations will assist the Commission in its review of the SECY paper.

There is a lot of work to be done on the issues presented today within the new proposed time line that is now consistent with the time line of the SRM. There are going to be a lot of long hours spent on these issues and getting the rule done, but in the long run I'm sure we all realize the benefits of taking an honest and, the operative word is, "fresh look" at what are undoubtedly controversial issues.

So I anticipate that with the information provided today the Commission is going to vote on this paper modulo the revised schedule in the very near future, but I think you've heard enough to know of the need to provide a framework for public input and decision-making, folding in what you have already learned over the years from interactions with the medical community and other stakeholders.

I reemphasize the need to get input from individuals who can give you current views relative to the practice of medicine so that the rule is not DOA, and then you are going to provide us with the supplement on the amended schedule to flesh out what that all means. With that we can take account of all the concerns and give you some fast feedback so you can get started on this.

Thank you.

[Whereupon, at 10:20 a.m., the public meeting was concluded.]

CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON MEDICAL REGULATION ISSUES

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Thursday, June 13, 1997

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Michael G Paulus

Reporter: Michael G. Paulus

Program to Revise/10 CFR Part 35 "Medical Uses of Byproduct Material"

Donald A. Cool, Director
Division of Industrial & Medical Nuclear Safety
Office of Nuclear Material Safety & Safeguards
June 13, 1997

TOPICS TO BE COVERED

- Plan for revision to Part 35
- Conceptual Ideas
- Initial Feedback from Professional Organizations

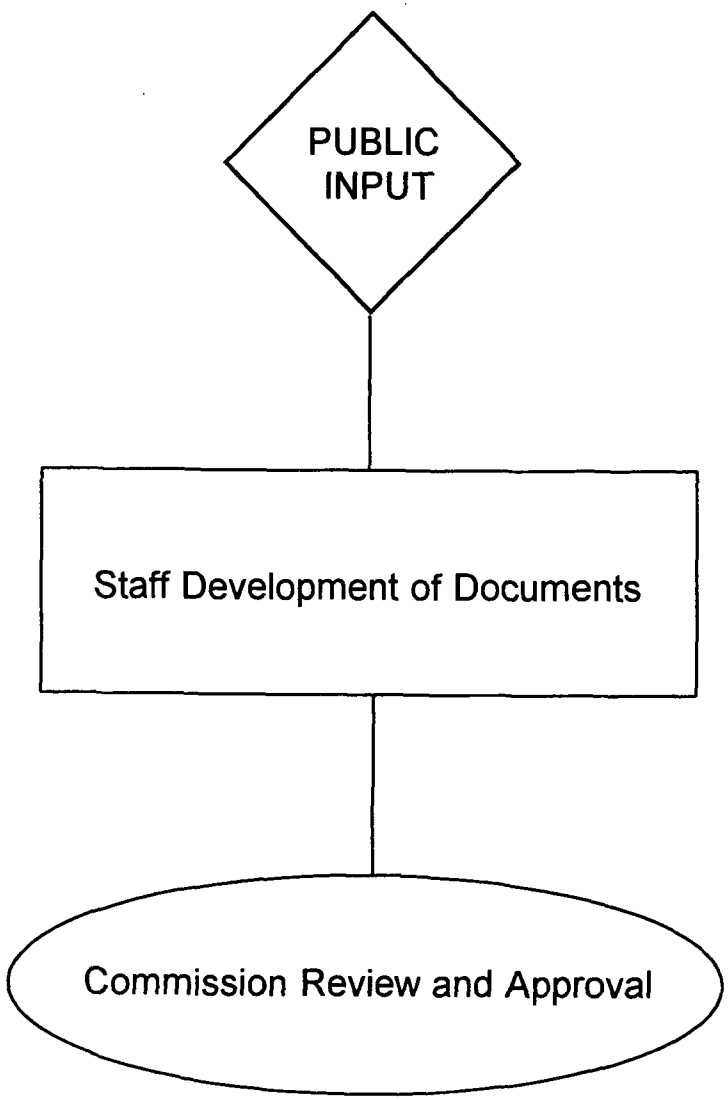
FUNDAMENTAL OPERATING PLANS

- Enhanced Participatory Rulemaking
- "Blank Piece of Paper"

PROPOSED STEPS TO PLAN

- Early Input
- Validation of Rulemaking Initiatives
- Proposed Rule
- Final Rule

PROGRAM FOR REVISING 10 CFR PART 35, ASSOCIATED GUIDANCE DOCUMENTS, AND 1979 MEDICAL POLICY STATEMENT



PROJECT ORGANIZATION

- Steering Group
- Working Group
- Consultants/ACMUI

SOURCES OF DATA

- NRC
- International Organizations
- Professional Societies

ISSUES SUBSUMED

- Indiana Pennsylvania Incident Investigation Team
- Open Rulemakings
- Medical Issue Papers
- Internal Staff Audits

ISSUES

- QM Requirements
- Misadministration
  vs. Medical Event
- Training and Experience
- Capturing Emerging Technologies
- Accreditation Process

Issues (Cont.)

- Medical Judgment
- Sophistication of Practice
- "Bad Apple" Factor
- Authorized User

Modality Approach

- Who Licensed
- Technical Issues (e.g., surveys, access controls)
- Training and Experience
- Licensee Event Reports (Misadministrations, etc.)
- Records

Meetings to Date

- ACMUI
- CRCPD
- SNM/ACNP
- ACMP

RULEMAKING ISSUE
(Notation Vote)

June 5, 1997 SECY-97-115

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: PROGRAM FOR REVISION OF 10 CFR PART 35, "MEDICAL USES OF BYPRODUCT MATERIAL" AND ASSOCIATED FEDERAL REGISTER NOTICE

PURPOSE:

To obtain Commission approval of: (1) the staff's proposed program for revising 10 CFR Part 35, associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary; and (2) a Federal Register notice (FRN) of proposed rulemaking for publication to solicit public comments regarding 10 CFR Part 35 restructuring into a risk-informed, more performance-based regulation.

CATEGORY:

This paper addresses significant rulemaking issues requiring Commission consideration and approval.

BACKGROUND:

The Commission, in its "Staff Requirements Memorandum (SRM) - COMSECY-96-057, Materials/Medical Oversight (DSI 7)," directed the staff to submit a program, for Commission approval, for revising Part 35, associated guidance documents, and, as necessary, the Commission's 1979 Medical Policy Statement (Attachment 1).

CONTACTS: Catherine Haney, NMSS/IMNS
(301) 415-6825

Susanne Woods, NMSS/IMNS
(301) 415-7267

SECY NOTE: TO BE MADE PUBLICLY AVAILABLE AT COMMISSION BRIEFING ON JUNE 13, 1997

The staff was also directed to describe how Part 35 could be restructured into a risk-informed, more performance-based regulation. In addition, a listing of issues was provided for staff consideration during development of the program. The staff reviewed the Commission's direction and is prepared to move forward with the revision to Part 35 and associated guidance documents.

DISCUSSION:

The staff plans to establish a steering group and a working group. This approach is described in Management Directive 6.3, "The Rulemaking Process." The steering group will be comprised of representatives, at the Division Director level or higher, from the following offices: Office of Nuclear Material Safety and Safeguards (NMSS); Office of Nuclear Regulatory Research (RES); Office of the General Counsel (OGC); Office of Enforcement (OE); and Office of State Programs (OSP). The Director, Division of Industrial and Medical Nuclear Safety, NMSS, will chair the steering group. In addition, the steering group will include an Agreement State Program representative. The working group will be comprised of Nuclear Regulatory Commission staff and representatives from both an Agreement State and a non-Agreement State.[1] Representation will include NMSS, RES, OGC, and OSP. The nominated Agreement State representative is also a member of the Conference of Radiation Control Program Directors (CRCPD), Inc., Suggested State Regulation Committee (SSR) on Medical Regulation. The staff plans to work toward parallel development of the NRC rule and the CRCPD suggested state regulations to facilitate state development of their corresponding rules.

Attachment 2 describes the staff's proposed program for the revision to Part 35 and associated documents. The staff plans to use a fresh start approach, soliciting initial ideas and suggestions from the medical community and the public. Previously identified issues will also be factored into the revision, including: recommendations of the Indiana, Pennsylvania, Incident Investigation Team; recommendations from internal staff audits; open rulemakings and results of analyses in medical issues papers.

The staff plans to use a process for revising Part 35 and associated guidance documents that provides more opportunity for input from potentially affected parties than is provided for by the typical notice and comment rulemaking process. This process includes solicitation of public comment on several occasions. The first opportunity begins with the publication of an FRN (Attachment 3) that solicits initial input into the development of Medical Policy Statement options and regulatory alternatives. To the extent possible, commentors will be asked to provide specific examples of draft rule language. During this period, two public meetings are planned to further solicit the initial public input. The second opportunity for public input will include a public comment period and a set of facilitated public meetings based upon draft rulemaking alternatives. The staff plans to provide the draft rule alternatives to the Commission prior to soliciting comment. During these meetings the staff will work with participants to review and refine the details of the proposed rule. Based upon the results of these public interactions, a proposed rule, regulatory analysis, and environmental assessment

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[1]The Organization of Agreement States recommended that the non-Agreement States be represented on this working group.

will be prepared, along with draft guidance documents. Following Commission approval, the proposed rule will be published for comment, and a second set of facilitated public meetings would be completed. The meetings are expected to be focussed upon areas of controversy, and upon the draft guidance, as a mechanism to refine the rule and guidance into final form.

The revision of the medical regulations will be a complex and controversial process, because of the diversity of activities, modalities and risk that fall within the umbrella of medical use, the corresponding diversity in medical community positions, and the varied availability of professional codes and standards. Given these facts, the proposed program represents an aggressive schedule. The staff emphasizes that the proposed plan does not account for any possible requests for extensions on public comment periods associated with the initial FRN, the notice requesting comment on the rulemaking alternatives, or on the proposed rule. Requests for comment extensions cannot be granted without causing a change to the end dates for the final rulemaking. The staff projects that the final rule will be published in April 2000 (Attachment 2).

The staff plans to provide NRC's medical licensees, professional medical societies, and the Agreement States (for distribution to their licensees) with copies of the initial FRN of proposed rulemaking. The staff plans to meet with and solicit comments from several professional societies, including, among others: (1) Society of Nuclear Medicine; (2) American College of Nuclear Physicians; (3) Health Physics Society; (4) American Association of Physicists in Medicine; (5) the American College of Cardiology; and (6) the American College of Radiology. The staff will also attempt to identify patient's rights groups and forward them copies of both the FRN and applicable documents for their comment. To this end, the staff arranged for a two-hour discussion with the American College of Nuclear Physicians and Society of Nuclear Medicine at their combined meeting in San Antonio, Texas, on June 4, 1997. The staff intends to make documents pertaining to this rulemaking and electronic comment submittal available on the Internet, using a separate page within the current RES rulemaking bulletin board.

Contractors and consultants are expected to assist the staff during the rulemaking process. Contractors, in particular, will be used to consolidate public comments and prepare the regulatory analyses for the revised rule. In addition, the staff will pursue the use of technical medical experts as consultants to the working group. Specifically, the project is expected to enlist experts for diagnostic and therapeutic uses of radioactive material. Further, the use of contracted facilitators for public meetings is being considered, in addition to the support of the OGC Special Counsel for Public Liason and Agreement State Programs.

The staff believes that, at this time, providing the Commission with a description of how Part 35 can be restructured, without the benefit of public comment, is premature and that it may lead stakeholder groups to believe that the staff has already decided on a particular approach. Ideas generated at the first stages of comment will be validated and tested during the subsequent facilitated public meetings planned for spring 1998 and early 1999. The result will be the staff's proposed rule and associated guidance for Commission consideration in December 1998.

The staff used the guidance in the Strategic Assessment Direction Setting Issues Papers Number 7, "Materials/Medical Regulations," and Number 12, "Risk Informed, Performance-

Based Regulations," as well as the SRM (COMSECY-96-057) to prepare a proposed FRN and associated press release (Attachments 3 and 4). The FRN of proposed rulemaking contains a list of issues, presented in the form of questions, for consideration by the public. The staff recognizes that the questions are to assist with the formulation of comments and that the commentary received need not be limited as response to the questions presented. Rather, the overriding issues are both the identification of necessary changes (additions and deletions) to Part 35 requirements and the assessment of risk for a risk-informed, more performance-based regulation with sufficient oversight of public health and safety. The staff also poses the question of whether quantitative or qualitative criteria should be considered in determining the "risk" for each modality. Public comments, the Commission SRM issues, and the staff reports on medical issues (as previously noted) will be used for developing the framework and associated text of the proposed rule.

The staff discussed revision of Part 35 with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) at the April 1997 Committee meeting. As a mechanism for generating discussion during the last two public meetings of the ACMUI, the staff identified a possible approach for restructuring Part 35 by modality (e.g., teletherapy, radiopharmaceutical therapy), based upon risk. ACMUI comments addressing the Part 35 revision are summarized in the proposed FRN (Attachment 3). The ACMUI's discussion will be available as additional background information for public commentors, and will be considered by the working group in preparing rulemaking proposals. The staff intends to continue active involvement of the ACMUI in the ongoing development process, including Committee meetings, additional reviews of guidance documents developed during the Part 35 revision process, and possible supplemental technical input from ACMUI subcommittees.

RESOURCES:

The Offices of Nuclear Material Safety and Safeguards, Research, General Counsel, and State Programs have identified the following resource requirements for this effort in their recent budget submissions. These resource levels will be considered in the FY 1999 budget review process.

	FY 1998		FY 1999		FY 2000	
Office	**$K**	**FTE**	**$K**	**FTE**	**$K**	**FTE**
NMSS	39	3.0	60	3.0	0	0.3
RES	150	1.9	50	1.0		
OGC*	0	0.3-0.6	0	0.3-0.6		
OSP	0	0.5	0	0.5		

*OGC effort includes any process design and the possible option of facilitation support for the public meetings from the Special Counsel for Public Liaison and Agreement State Programs.

NMSS management will monitor resource use closely for this rulemaking.

RECOMMENDATION:

That the Commission approve the following: (1) the proposed Part 35 revision program; (2) issuance of the attached FRN; and (3) the attached press release.

COORDINATION:

OGC reviewed this paper and has no legal objection. The Chief Financial Officer has no objection to this paper. The Office of Chief Information Officer has reviewed the plan for information management implications and concurs in it; however, since the revision to 10 CFR Part 35 contains information collection requirements, it must be submitted to the Office of Management and Budget for review no later than the date the proposed rule is published in the Federal Register.

L. Joseph Callan
Executive Director
for Operations

Attachments: 1. SRM dated March 20, 1997
2. Program for Revising
10 CFR Part 35 and Associated Documents
3. Proposed Federal Register notice
4. Press Release

DISTRIBUTION:
Commissioners
OGC
OCAA
OIG
OPA
OCA
CIO
CFO
EDO
SECY

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Friday, June 20, 1997.

Commission staff office comments, if any, should be submitted to the Commissioners NLT June 13, 1997, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

Action: Paperiello/NMSS
Morrison, RES
Cys: Callan
Thompson
Jordan
Norry
Blaha
Bangart, SP
Ross, AEOD

SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 20, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - COMSECY-96-057
MATERIALS/MEDICAL OVERSIGHT (DSI 7)

With respect to the overall materials program, the Commission continues to support its preliminary views on this issue which were a combination of two options -- Continue the Ongoing Program with Improvements (Option 2) and Decrease Oversight of Low-Risk Activities with Continued Emphasis in High-Risk Activities (Option 3). For the longer term, the Commission also believes that consideration should be given to broadening NRC's regulatory oversight to include one or more of the higher-risk activities identified in Option 1.

With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued.

The Commission continues to support the use of ACMUI and professional medical organizations and societies in developing regulatory guides and standards as was proposed in the Commission's preliminary views. In the longer term, the Commission would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation but such efforts should not divert resources from the 10 CFR Part 35 rulemaking discussed below.

In lieu of a rulemaking plan in the context of Management Directive 6.3 the staff should submit a program for Commission approval for revising 10 CFR Part 35, and associated guidance documents, and the Commission's 1979 Medical Policy Statement, if necessary. The program should describe how 10 CFR Part 35 can be restructured into a risk-informed, more performance-based regulation by a suspense date of 6/30/99. In developing the program the staff should consider the following:

(1) Focusing Part 35 on those procedures that pose the highest risk.

(2) For diagnostic procedures, staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures.

(3) The staff should address how best to capture not only relevant safety-significant events, but also precursor events.

(4) Changing the nomenclature from "misadministration" to "medical event" or comparable terminology.

(5) Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.

(6) The Quality Management Program provisions (10 CFR Part 35.32) should be re-evaluated and revised to focus on those requirements that are essential for patient safety, e.g., confirming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed. Given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.

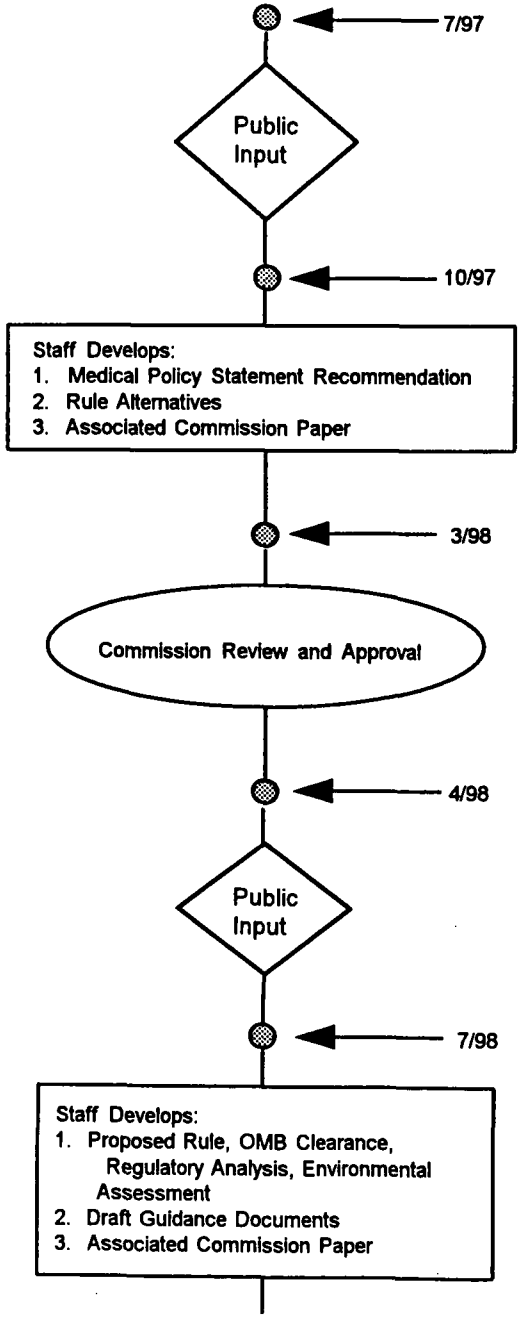
(7) The staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC needs.

(8) The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties than is provided by the normal notice and comment rulemaking process but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

The staff's program to implement the above should be submitted to the Commission for its consideration no later than June 6, 1997. The program should target June 30, 1999 as the date for completing the rulemaking process. This rulemaking and associated guidance development is a very high priority for the Commission. The Commission is prepared to provide additional resources to the extent necessary to complete the rulemaking process on this schedule.

(NMSS/RES) (~~EDO~~ - Program) (SECY Suspense: 6/6/97) 970006
(NMSS/RES) (~~EDO~~ - Complete Rulemaking) (SECY Suspense: 6/30/99) 970006

PROGRAM FOR REVISING 10 CFR PART 35, ASSOCIATED GUIDANCE DOCUMENTS, AND 1979 MEDICAL POLICY STATEMENT*



Publish Federal Register notice for early input with 90 day comment period
ACMUI input, professional society meetings, and two public meetings

Working group, Steering Committee, and consultant develop documents with review and approval from Steering Committee

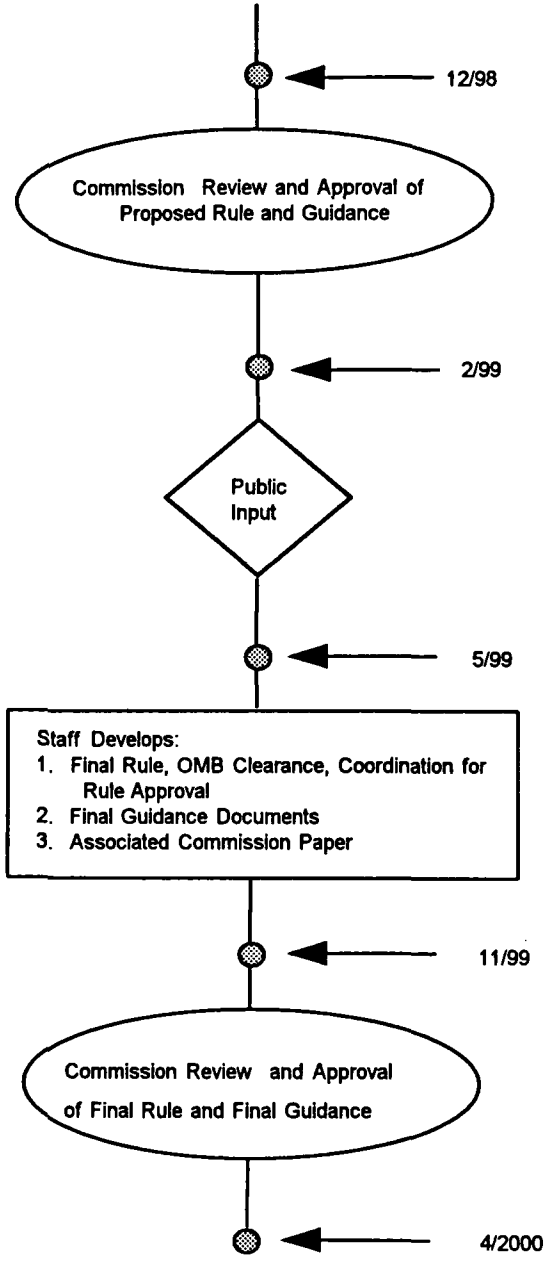
Commission review and approval of Medical Policy Statement recommendations and rule alternatives for public release and publication in Federal Register

Proposed rule alternatives published in Federal Register for 90-day comment period
Two facilitated public meetings to examine alternatives in detail

Working Group, Steering Committee, and consultants develop documents, with review and approval of Steering Committee
Preparation of OMB clearance and supporting documents
Review with ACMUI and Agreement States
Additional coordination as necessary

Attachment 2

PROGRAM FOR REVISING 10 CFR PART 35, ASSOCIATED GUIDANCE DOCUMENTS, AND 1979 MEDICAL POLICY STATEMENT* (Continued)



12/98 Commission review and approval for Federal Register publication and public comment

2/99 Publish proposed rule and announce availability of draft guidance in Federal Register, including 90 day comment period
Two facilitated public meetings focusing on high risk activities, controversial issues and guidance

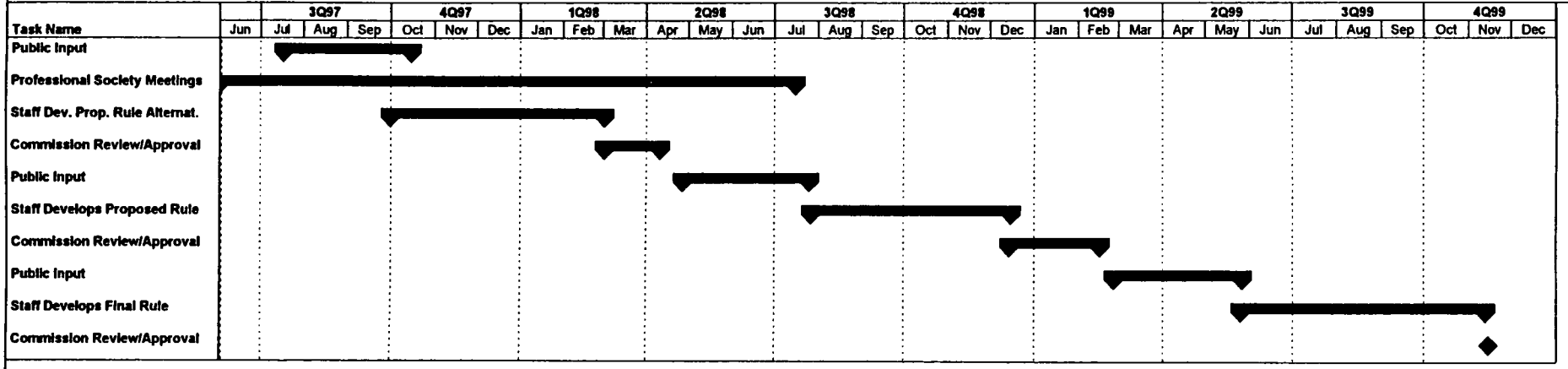
5/99 Working Group, Steering Committee, and consultants develop documents, with review and approval of Steering Committee
Preparation of OMB clearance and supporting documents
Review with ACMUI and Agreement States
Additional coordination as necessary

11/99 Commission review and approval of final rule and final guidance for release to the public

4/2000 Publish Final Rule

*The program presented represents ongoing efforts of the Working Group, Steering Committee, and project consultants, including extensive NRC Office coordination, ACMUI consultation, Agreement and non-Agreement State interaction, and numerous meetings with professional organizations, stakeholders, and the public.

PROGRAM FOR REVISING 10 CFR PART 35,
ASSOCIATED GUIDANCE DOCUMENTS , AND THE 1979 MEDICAL POLICY STATEMENT



NUCLEAR REGULATORY COMMISSION

RIN-3150-AF74
Medical Use of Byproduct Material:
Issues and Request for Public Comment

AGENCY: Nuclear Regulatory Commission

ACTION: Notice of Proposed Rulemaking

SUMMARY: The U. S. Nuclear Regulatory Commission (NRC) is developing a program for revision of 10 CFR Part 35, "Medical Use of Byproduct Material." The decision to revise Part 35 resulted from the NRC Strategic Assessment and Rebaselining Initiative (SA), a process involving identification of the direction-setting issues and associated options for the future of NRC activities. Specifically, the SA effort included medical use regulation. With this notice, the Commission is initiating a proposed rulemaking action which will culminate in the developement of a final rule for approval in late 1999. This notice describes issues proposed to be included in this rulemaking. The Commission plans to further propose specific rulemaking text for public comment during 1999 (approximately February 1999).

In order to provide the public the most effective opportunity to participate in developing the rule text, the Commission is requesting public comment on the issues identified by the questions in this notice within 90 days of the issuance of this notice. Comments received after this initial 90 day period will be considered along with the comments received on the proposed text anticipated for publication in 1999. However, because of schedule requirements, it may not be practicable for the Commission to consider those comments received after the 90 day period in preparing the detailed proposed rulemaking text.

DATES: The comment period expires _____ (90 days after the FRN is issued).

ADDRESSES: Send written comments and suggestions to Secretary, Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Service Branch. Hand-Deliver comments to 11555 Rockville Pike, Rockville, MD, between 8:00 a.m. and 4:00 p.m. on Federal workdays.

Written comments may also be submitted electronically on the Internet via NRC's interactive rulemaking web site, through the NRC home page (http://www.nrc.gov). This site provides the ability to upload comments as files (any format), if your web browser supports this function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail CAG@nrc.gov.

FOR FURTHER INFORMATION REGARDING THIS NOTICE CONTACT:

Catherine Haney, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6825 or Susanne Woods, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-7267.

SUPPLEMENTAL INFORMATION:

Background

NRC examined the issue of its medical use program in great detail during the last four years. This process started with NRC's 1993 internal senior management review report; continued with the 1996 independent external review report by the National Academy of Sciences, Institute of Medicine; and culminated in NRC's SA process. In particular, medical oversight was addressed in the Strategic Assessment Direction-Setting Issue Paper Number 7 (DSI 7) (released September 16, 1996).

In their "Staff Requirements Memorandum (SRM) - COMSECY-96-057, Materials/Medical Oversight (DSI 7)," dated March 20, 1997, the Commission directed staff to revise Part 35, associated guidance documents, and, if necessary, the Commission's 1979 Medical Policy Statement. Further, the SRM stated, "With respect to the medical program, the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine (IOM) report that recommends that NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated and that the recommendations should not be pursued."

The Commission SRM specifically directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. Further, during development of the rule and associated guidance, as well as during review of the Medical Policy Statement, the NRC staff was directed to consider the following issues:

1. Focusing Part 35 on those procedures that pose the highest risk.
2. Regulatory oversight alternatives, for diagnostic procedures, that are consistent with the lower overall risk of these procedures.
3. The best way to capture not only relevant safety-significant events, but also precursor events.
4. The need to change from the term "misadministration" to "medical event" or other comparable terminology.
5. Redesigning Part 35 so that regulatory requirements for new treatment modalities can be incorporated in a timely manner.
6. Revising the requirement for a quality management program (10 CFR 35.32) to focus on those requirements that are essential for patient safety.
7. The viability of using or referencing available industry guidance and standards, within Part 35 and related guidance, to the extent that they meet NRC needs.

The NRC staff discussed items 1-7 and solicited preliminary views from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) at the April 1997 Committee meeting. [Transcripts of this meeting are available by contacting the NRC Public Document Room and

on the Internet (as specified in the reference information provided).]

The ACMUI discussed their views and recommendations during a briefing of the Commission on May 8, 1997. The ACMUI concurred with NRC's position to continue the ongoing medical program with improvements, and to decrease oversight of low-risk activities with continued emphasis of high risk activities. The committee supported the use of professional medical organizations and societies in developing a performance based regulation. The ACMUI recommended consideration of a quality improvement approach as an alternative to the present Quality Management Program. Further, the committee recommended, to the Commission, that the 1979 Medical Policy Statement be revised to reflect that NRC will regulate radiation safety of patients only where justified by the risk to the patients and only where voluntary standards or compliance with the standards are inadequate. The ACMUI believed that the assessment of the risks justifying regulations should reference comparable risks and comparable modes of regulation for other types of medical practice. In addition, they believed that the NRC should not intrude into medical judgments affecting patients and into other areas that the ACMUI considered to be traditionally a part of the practice of medicine.

This notice initiates a proposed rulemaking action which will culminate in the development of a final rule for approval in 1999. In order to provide the public the most effective opportunity to participate in developing the rule text, the Commission is requesting public comment on the issues identified by the questions in this notice and on the ACMUI recommendations within 90 days of the issuance of this notice. Comments received after this initial 90 day period will be considered along with the comments received on the proposed text that is anticipated for publication in 1999. However, because of schedule requirements, it may not be practicable for the Commission to consider those comments received after the 90 day period in preparing the detailed proposed rulemaking text. Further, the staff recognizes that the questions are to assist with the formulation of comments and that the commentary received need not be limited as response to the questions presented. Rather, the overriding issues are both the identification of necessary changes (additions and deletions) to Part 35 requirements and the assessment of risk for a risk-informed, more performance-based regulation with sufficient oversight of public health and safety. The NRC staff is interested in ideas, proposals, and comments on the structure and content of a revised Part 35, given the Commission guidance and direction as described above. To the extent possible, commentors are asked to provide specific examples of draft rule language.

Requests for Comments on General Considerations

NRC has identified the following areas of Part 35 for consideration and is seeking comments on these issues, as well as any others, offered for consideration during the revision to Part 35:

1. How should the Part 35 requirements be revised to be risk-informed and more performance-based? How should performance be measured to provide both NRC licensees and NRC with an objective basis for determining regulatory compliance?

2. How should risk be assessed for medical uses and the regulation be modified to focus on procedures posing the highest risk? What quantitative or

qualitative criteria should be considered in determining the "risk" for each modality?

3. What oversight should exist for diagnostic procedures that is commensurate with the associated risks?

4. What specific events or incidents should be reported to NRC? [e.g., machine failure, leaking source, software failure, hardware failure] What criteria should be used for determining if the event is reportable (e.g., threshold)? Are there modality-specific events that should be reported? Should the term "misadministration" be changed to "medical event" or comparable terminology?

5. How should the regulation be redesigned to incorporate necessary regulatory requirements for new modalities? Should Part 35 be structured such that requirements for a particular modality are grouped together?

6. Which Quality Management Program provisions should be re-evaluated and revised to focus on requirements that are essential for patient safety? Are different provisions appropriate for each of the different modalities?

7. Which standards and guidance developed by professional societies and other organizations are applicable to NRC-regulated medical uses of radioactive material and how could they be incorporated within the regulatory framework of Part 35 and/or associated guidance?

8. How should the issues of training and experience be addressed? What individuals or groups should be subject to such requirements?

9. Which new issues/modalities should be incorporated into Part 35?

10. Should the 1979 Medical Policy Act Statement (44 FR 8242) be modified to increase flexibility for a risk-informed, more performance-based approach to medical regulation?

Reference Information

1. Strategic Assessment Direction-Setting Issues Paper Number 7 is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

2. The memorandum "Management Review of Existing Medical Use Regulatory Program (COMIS-92-026)" (dated June 16, 1993) is available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

3. Radiation in Medicine: A Need for Regulatory Reform (1996) is available from

the National Academy Press at 2101 Constitution Avenue, N.W., Box 285, Washington, DC 20055.

4. Summary minutes and transcripts of the ACMUI April 1997 meeting or transcripts of the May 8, 1997, Commission briefing are available by writing to the U.S. Nuclear Regulatory Commission, Attention: NRC Public Document Room, Washington, DC 20555-001. [Telephone: (202) 634-3273; fax: (202) 634-3343].

   Transcripts of the May 8, 1997 briefing are also available by Internet at http://www.nrc.gov.

5. The NRC Medical Policy Act Statement of 1979 was published in the Federal Register, Volume 44, page 8242, on February 9, 1979.

Dated at Rockville, Maryland, this day of May, 1997.

For the U. S. Nuclear Regulatory Commission

John C. Hoyle, Secretary of the Commission

ATTACHMENT 4

Draft press release, 5/22/97, 3:00 p.m.

NRC SEEKS COMMENTS ON PLANS TO REVISE

REGULATIONS ON MEDICAL USES OF LICENSED RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission is seeking public comments on planned revisions of its regulations on medical uses of licensed radioactive material.

The Commission has examined its medical use program in great detail during the last four years. It conducted an internal management review, commissioned an external review by the National Academy of Sciences' Institute of Medicine, and included medical use as one of the issues examined during its recent strategic assessment and rebaselining initiative.

The Commission has now directed the NRC staff to revise its regulations, associated guidance documents and, if necessary, its 1979 medical policy statement. Notwithstanding the Institute of Medicine's recommendation that the NRC should not be the federal agency involved in the regulation of ionizing radiation in medicine, the Commission believes the report's conclusions were not substantiated and therefore should not be followed.

In developing revisions to the medical use regulations, the NRC intends to focus primary attention on procedures that pose the highest risk. Issues on which the NRC would like public comments include:

- How should risk be assessed for medical uses and the regulation be modified to focus on procedures posing the highest risk? What quantitative or qualitative criteria should be considered in determining the risk?
- What oversight should exist for diagnostic procedures that is commensurate with the associated risks?
- What specific events or incidents should be reported to the NRC (for example, machine failure, leaking radiation source, software failure, hardware failure)?
- How should the issues of training and experience be addressed? What individuals or groups should be subject to such requirements?

Other issues on which the NRC is particularly seeking comments are described in a Federal Register notice published on _____.

Interested persons are invited to submit comments and suggestions by_____ _____(90 days after publication of the Federal Register notice). Written comments should be addressed to the Secretary, Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemakings and Adjudications Staff. Comments may also be submitted electronically, as described in the Federal Register notice.