UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON MEDICAL USE PROGRAM AND MEETING WITH ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES - PUBLIC MEETING

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BRIEFING ON MEDICAL USE PROGRAM

AND MEETING WITH ADVISORY COMMITTEE

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PUBLIC MEETING

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Nuclear Regulatory Commission

One White Flint North

Rockville, Maryland

Thursday, October 20, 1994

The Commission met in open session, pursuant to notice, at 10:00 a.m., Ivan Selin, Chairman, presiding.

COMMISSIONERS PRESENT:

IVAN SELIN, Chairman of the Commission

KENNETH C. ROGERS, Commissioner

E. GAIL de PLANQUE, Commissioner

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STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

JOHN C. HOYLE, Acting Secretary

MARTIN MALSCH, Deputy General Counsel

JAMES TAYLOR, Executive Director for Operations

ROBERT BERNERO, Director, NMSS

DR. CARL PAPERIELLO, Director, Division of Industrial and Medical Nuclear Safety, NMSS

DR. JOHN E. GLENN, Medical, Academic and Commercial Use Branch, NMSS

JANET SCHLUETER, Medical, Academic and Commercial Use Branch, NMSS

DR. DONALD A. COOL, Radiation Protection and Health Effects Branch, RES

DR. BARRY SIEGEL, M.D., Chairman, ACMUI Nuclear Medicine

ROBERT QUILLIN, States Representatives

DR. JUDITH ANNE STITT, M.D., Radiation Oncology

DR. LOUIS K. WAGNER, Ph.D., Medical Physicist

P R O C E E D I N G S

[10:00 a.m.]

CHAIRMAN SELIN: Good morning, ladies and gentlemen.

The Commission is pleased this morning to receive a brief first from the staff, the annual report on the Medical Use Program, including and especially the status of efforts to implement the medical management plan, the quality management program and the misadministrations rule. Then we'll hear from Dr. Siegel, the Chair of our Advisory Committee on the Medical Use of Isotopes, on the Committee status, some of the administrative questions and more importantly their views on some of the key issues on the Medical Use Program.

As I'm sure most of you know, the Medical Use Program has been the recipient of a lot of attention from the Commission and from the staff over the past several years, and so this briefing is an opportunity for the Commission to be brought up to date on the progress in implementing some of these changes which at the time that they were considered seem to be good ideas. I'd like to find out what's worked out and what hasn't worked out.

More than anything, I consider the independent analysis provided by the Advisory Committee to be a significant component in our overall medical use program.

So, we're particularly eager to hear what Dr. Siegel has to say as well.

Commissioners?

Mr. Taylor, the floor is yours.

MR. TAYLOR: Good morning. With me at the table, starting at my far left, is Janet Schlueter, John Glenn, Bob Bernero, Carl Paperiello from the Office of NMSS, and Don Cool, representing Research.

The staff has provided the Commission with a detailed paper reported in this area and today we'll concentrate on the high points of what's in that paper. I believe the paper is available at the door.

Carl Paperiello will be the principal presenter.

Carl?

DR. PAPERIELLO: Good morning. I'd like to first note and apologize for the length and detail of the Commission paper. As Mr. Taylor keeps reminding me, it's 28 pages long. Next year I'll try to be more creative with the use of appendices.

CHAIRMAN SELIN: Or smaller print.

DR. PAPERIELLO: However, I do believe that the staff accomplished a lot this past year. We've certainly consumed a lot of the Commission's resources and many of the things that we're doing in the Materials Program are interconnected, such as the revision of the inspection

program, increased emphasis on the inspection of reported events and the business process reengineering of the materials licensing program.

Can I have the next slide?

[Slide.]

DR. PAPERIELLO: I'm not going to try to cover all the topics in the paper, but I'm going to turn around and touch the high points and those which appear to have created the most stress within the regulated community. I'm going to give a snapshot of the medical management plan. I'm going to discuss the quality management rule implementation. I'm going to present the status of misadministration follow-up and compliance with the rule, revisions of the licensing and inspection program, the status of rulemaking. I'm going to make some observations on the 1979 Medical Use Policy Statement in order to introduce my discussion of what will be needed and the difficulty in revising Part 35. I will touch briefly on the completion of Commission direction presented in the SRMs.

Next slide.

[Slide.]

DR. PAPERIELLO: We've completed over 50 percent of the 90 medical management plan action items that we were tracking.

The National Academy of Science study of the

medical program is well underway, on schedule and --

CHAIRMAN SELIN: I should tell you that the charter for that study that you guys did is terrific. I think it's succinct and it really is right to the point. It was just a first rate piece.

DR. PAPERIELLO: Thank you. And, of course, as each of you know, you've made your own views known to the National Academy last week and I have extremely favorable and positive feedback in the sense that this will help them do their job better and improve the likelihood we're going to get the product we need. That was their third meeting. There will be three more meetings on the schedule.

The NRC/FDA memorandum of understanding has been in place for over a year now. Besides routine exchanges of information and implementing procedures being developed, we have had joint investigations at two NRC license facilities and we've had considerable involvement with them on an HDR remove afterloader.

Next slide?

[Slide.]

COMMISSIONER de PLANQUE: Carl, before you go on, on the Academy study, do you think they'll be on schedule in terms of getting --

DR. PAPERIELLO: So far they are. I hope so. I'm pushing to keep it on schedule and I've had no indication it

won't be. And recently, the Commission has received and approved the ACMUI bylaws.

Now, let's look at the hard parts. Yes, we did over 50 percent of the action items, probably the easier ones. At least those easier for me to do and the things that I can do almost solely with my own staff and with limited concurrences. Most of the inspection and some of the licensing programs can get fixed very quickly.

Rulemaking and obvious things tied to the National Academy study are going to take longer. Things that need to be or should be coordinated with the agreement states, the ACMUI, or should have public input take longer and are more difficult. I believe rulemaking will be the critical path to completion of the program. In order to manage the resources with the great efficiency, we plan to make additions to the medical management plan as necessary. Currently we're going to add the proposed rule and wrong patient and the creation of the medical component of the Commission decision tracking system to the plan in order to manage the resources.

Overall, I think we're in good shape. Some things we finished late, but some we completed early. In my view, there is an appropriate level of stress in the program. I think we --

Next slide.

[Slide.]

COMMISSIONER ROGERS: Just before you leave this, Carl, have you considered rethinking the question of whether everything has to be done by rulemaking? We're in this business now of trying to look to see whether we need a rule for everything. The new reinventing government initiative specifically directed agencies to pay particular attention to whether they needed to do everything by rules or not where they'd done them before. Do you think there's anything to be gained by maybe taking a second look at whether all the things that you're planning to do by rulemaking could need to be accomplished through the rulemaking mechanism where there might be another way of doing it?

DR. PAPERIELLO: I think, Commissioner, you're right, but I think right now I need a rule change to deregulate certain areas of diagnostic nuclear medicine where we've been extremely prescriptive in Part 35. Some things, honestly, I don't believe make a whole lot of sense to having a rule. So, I need that change. You know we are doing whatever you want to call it. I'll call it BPR. I used a different term in here, but when I signed up for it it was BPR in the licensing area and I think we really need to examine what we do in licensing. The concepts are drastic, radical and things like that. The question is why

do we license, what are we trying to do and I think you can't -- I wouldn't want to give up doing in rulemaking something I now -- burden I now put in the licensing process. I've got to look at the cost. Some things might be easier to write in a rule rather than write into a thousand licenses. I don't know, but I think your point is well taken and it's certainly going to be considered.

Can I have the next slide?

[Slide.]

DR. PAPERIELLO: As you know, the QM rule required licensees to submit their QM plans. We had them, about 1700 plans in our possession for some time before we had a contractor review them. As of right now, all reviews have been completed and that's only been within the last month or so. 72 percent of the plans had some kind of deficiency and received a deficiency letter. This does not mean the plans were no good. But rather, there was some aspect of the plan for some modality that did not meet a performance gail. Boilerplates in the letter requested revisions in 30 days. When requested, we routinely gave extensions on this time. We got in the 30 days due to discussions with other offices and when you get into regulatory and enforcement space, looking back at it, we certainly should have given people more time. But the practical matter is when people ask for more time, the usual complaint is, "Look, you guys. You've

had this damn thing for two years now. You turn it around and you want us to revise it in 30 days."

We moved very, very quickly. The contractor essentially reviewed these 1700 plans in about seven to eight months and we got letters out to everybody in that time. When you try to automate all this stuff, they weren't handcrafted. So, we had some rough going on this. But as a practical matter, nobody was severely penalized, I don't believe.

COMMISSIONER de PLANQUE: Carl, was there any lesson to be learned by the kinds of deficiencies?

DR. PAPERIELLO: Yes, definitely. Definitely. I will tell you later, for example, in the radiopharmacy rule, you will be getting the rule very soon in final. The licensing guide is done. I understand OGC just signed off on it. That's done. The inspection procedures will be done. So, by the time that rule takes effect on January 1, if you approve it, all the supporting paperwork and procedures will be in place. That's the way I would like to do business all the time. I wasn't around, but anyway I think we should have had an idea in place what we were going to do. In fact, I would raise the question whether we should have even had the plan submitted and reviewed for a performance-based rule. There's a question there. I won't debate that. I mean it's sort of over and done and

decisions were made in the past and now we're here and now where do we go from here? But you can question it.

And I understand the agreement states who are meeting this weekend, I'll be meeting with them next week, they have a proposed version of the rule which would not require the plans to be submitted to the states. But anyway, we're here and now we make the best of it.

We are not going to rereview all these plans in bulk. What we're going to do is we're going to take the checklist and all the guidance material we gave to contractor. We're in the process of providing training to the regional staff and as we inspect medical licensees, and part of our routine program, we are going to have the inspectors or, if there's a licensing action that comes up, rereview the QM plans by via the regional staff. But this is going to take several years because it's going to be just folded into the routine program.

COMMISSIONER de PLANQUE: I believe down the line we asked for an evaluation of the effectiveness of this. Are you giving any thought as to how that's going to be done and can that be folded into the work you're doing currently?

DR. PAPERIELLO: Well, we're going to -- you know, what we have found is you just can't go by what's in the plan. You have to look at the implementation. So, you're really going to have to do an inspection. What you find, I

understand from the staff, when you do an inspection, sometimes people are doing the right thing, they just didn't write it down. Other times it's a wonderful plan but people don't even know it exists. We've had misadministrations where there was a misadministration plan written by a contractor, maybe signed by somebody at the institution, but the technologist was never told about it.

So, at this point, I don't think we would gain a lot by putting a lot of resources reviewing paper without looking at the implementation. As I'll tell you later, of the misadministrations we've had in the last year and a half, in over half the cases we've found violations of the quality management rule. In about a third of the cases, more than one violation. Now, what I don't know because I haven't dug into enough is a real detailed analysis to say, "Okay, if everybody would implement the QM rule, what would that do to the total number of misadministrations?" I can't tell you that. In fact, I know of some events that I don't know that the QM rule would prevent. I mean if a technologist -- if everybody does the right thing and a technologist or somebody puts their hand on something and grabs the wrong thing and doesn't read the label, something I've personally done to myself without too bad a consequences, I don't know what you can do to stop things like that.

Or let me put it this way. I do know what you can do to stop it, but it would be very expensive. You would need to do two people for everything and people read things. There are ways of doing it, but you're going to double the cost of medical care. So, it's how much are you going to pay to stop it?

We have issued the temporary instruction to inspect the licensee implementation of the rule. It's going to take, as I said, several years to cover all licensees. We have a database that is almost complete that will track not only the completion of the inspections but the data from all of the inspections. So, we'll be able to tell you what licensees are doing and what licensees haven't done.

Can I have the next slide?

[Slide.]

DR. PAPERIELLO: The program, of course as I said, has not been without stress. When you have multiple contractor reviewers complete 1700 reviews in well under a year, they were not perfectly uniform reviews. We've had complaints, we've looked into them. Some have been valid. Frankly, some have not. We've had people tell us, "I'm a consultant. I've written the same plan for five hospitals and they got different reviews." Well, we broke them out ourselves in some cases and they weren't the same plan because the hospitals had different programs. But in some

cases they were right. But different people did the review and we have the same complaints about the NRC, "Well, this inspector finds this problem and somebody else doesn't." The same with the reviewer. You know, it wasn't like we could have one person rereview everything. So, that's why that happened.

As noted earlier, it's going to take some time for the regional staff to review revised plans.

Can I have the next slide?

COMMISSIONER ROGERS: Just again, before you leave that, in your report on page 17 there was a statement, less than 2 percent of NRC licensees informed the staff that they disagreed with the Lawrence Livermore National Lab findings or complained about apparent inconsistencies in the reviews. How do I connect that with what this statement about apparent inconsistencies? Is this just --

DR. PAPERIELLO: It's the same thing.

COMMISSIONER ROGERS: -- 2 percent for the Lawrence Livermore --

DR. PAPERIELLO: No, all of them.

COMMISSIONER ROGERS: All of them.

DR. PAPERIELLO: I mean they were all done by Lawrence Livermore.

COMMISSIONER ROGERS: They were all done by them?

DR. PAPERIELLO: Yes.

COMMISSIONER ROGERS: I see.

DR. PAPERIELLO: But, you know, I went around to the regions and I said, "Okay, how many complaints do you have?" I added them up. It's a little under 2 percent. But I keep hearing rumblings. I'm sure Barry is going to tell you something else. I have to have data, not just rumors. So, the numbers in there are as accurate as I know them based upon a telephone call placed within a couple weeks right before we put that paper to bed of each of the regions, asking how many complaints you've had.

Could I have the next slide?

[Slide.]

DR. PAPERIELLO: Let's talk about misadministrations. The management directive which directs the agency response to medical events was issued early in July. Complementing this, we issued the revised manual chapter in the use of medical and scientific consultant that is consistent with the management directive.

Next slide.

[Slide.]

DR. PAPERIELLO: I have appointed Dr. Dennis Serig as my misadministration/medical consultant coordinator. His primary job is to be the focal point for collecting and disseminating all the information on every misadministration. Everybody that's required by that

management directive, he makes sure he gets and makes sure it goes to AEOD and other people in the agency who need the information. He also coordinates our human factors work and research with other NRC offices.

Since the appointment of our consultants has to be renewed every year, it's important to ensure their timely reappointment and make sure that the initial appointment papers are processed in a timely manner. We currently have 12 consultants. In the past, there have been times, particularly the change of the fiscal year, actually not fiscal year, from June to July, where we have been down to one or two consultants because of paperwork not getting through on time. This year, we only dipped down to about eight at the transition. I'm hoping that in the future there won't be any dip, but we're working on it.

We issued an inspection procedure for event follow-up and this is an example of what I initially mentioned as program overlap. This procedure describes the information needed when responding to any event, not just medical. In a sense, I call it my micro-IIT. You'll recall that when I reported on phase 1 of the regulatory impact survey last year, licensees complained that when responding to an event, inspectors concentrated on violations and were of little help. This procedure will direct the inspectors to do a much greater in-depth inspection identifying the

sequence of events, immediate cause, root cause, licensee response to the event, consequences, radiological and to a certain extent economic. I'm not going to go into dollars, but if a licensee had to shut down a facility for two weeks to clean it up, I want to know that information so we'll be able to when people ask. I also emphasized to people no consequence is a perfectly good number. If you had gauges damaged in fires and they didn't leak, that is a very good thing to know. It means our design criteria was good. And then finally deal with violations after we know about the event.

Problems that remain, misadministrations still occur and a bit more than half involve some violation of the QM rule.

Could I have the next slide?

COMMISSIONER ROGERS: What about the others? Any other common denominators in the other 42 percent or is it just a very big --

DR. PAPERIELLO: No, it's all over the map. Hardware, we're seeing more hardware failures as more remote afterloaders come into use. There are problems in placing orders. We've had a couple of events caused by the orders being placed for the wrong thing. In an agreement state, the wrong length of tube, connecting tube, was ordered for an HDR unit and nobody measured it. Of course, the source

wound up in the wrong place. Obviously, the more recent one is a hospital in which iodine-125 seeds were ordered and they came in in an order of magnitude higher than they should have been. We were never able to figure out where the order was switched, whether it was placed wrong, received wrong, filled wrong. You know, everybody's paperwork looked good and it's almost like if I told you it was 100 microcuries and somebody wrote it down and lost the decimal point at instance, it only occurred in a head and nobody saw it. So, that's a lot of them that are occurring.

COMMISSIONER de PLANQUE: On the 58 percent that are violations of the QM rule, does that imply that the concepts in the QM rule or the procedures in the QM rule weren't followed or that the paperwork connected with the QM rule was --

DR. PAPERIELLO: I can't tell you for sure. I just asked the staff how many involved violations and they told me. There are some cases where I know it was just lack of training. Something was ordered orally. A patient got a whole body iodine scan when it should have been a thyroid scan. The technologist was not trained in the procedure because if he had been he would have had to show the order to get a written directive from the authorized user and no physician would have permitted it to happen. It was just things like that.

Commissioner, I haven't had time to look at all the paperwork to understand myself. I just got a quick check.

Next slide.

[Slide.]

DR. PAPERIELLO: I mentioned the mix is changing. We're seeing fewer teletherapy, but I don't know whether people are getting better or we're just seeing the cobalt go away and being replaced by linear accelerators. We're seeing more remote afterloader events but a lot of hardware. We're seeing some hardware failures and they're not a whole lot, when you talk about going from one to four. And we've seen the first strontium-89 events.

We're still struggling to ensure all notifications are made by licensees. We're rather in good shape for '93 and '94. For earlier years and since 1990, we've had about 17 open cases for which we're awaiting responses from licensees either to NOVs or to letters.

A significant issue here is notification of responsible relative when the physician determines that notification of the patient would be harmful. Physicians have raised issue of who is the responsible relative for competent adults, cases where there are no close relatives. After extensive discussions with the ACMUI, and I'm sure Barry will touch on this, we have drafted a generic letter

to emphasize the importance of the issue. Since there may be letters to the Commission on this from the regulated community if they don't like it, we plan on providing you with a copy of the generic letter before it's issued.

Patient follow-up has been set at roughly six months in the management directive. Currently, we thought we might have two patients in the category. Based on advice from our medical consultant, it looks like we have one patient that we are following and that is the individual that had the I-125 seeds.

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[Slide.]

DR. PAPERIELLO: In addition to the misadministration procedure, we issued a procedure for evaluating and reporting radiological exposures of members of the public and the procedure for inspecting the master licenses currently held by the Air Force and Navy.

Next slide.

[Slide.]

DR. PAPERIELLO: We completed all inspections of the HDR units based on the temporary instruction we issued after the Indiana, Pennsylvania event. I've already mentioned the quality management TI. The ongoing program, of course, our whole basic inspection program, has to be maintained. When a new Part 20 became effective, we had to

revise all materials inspection procedures, including the medical, and that was done on time.

Next slide.

[Slide.]

DR. PAPERIELLO: I wouldn't call this a problem, but more work. There's a draft version of Inspection Manual Chapter 2800. This is the master procedure that orchestrates everything we inspect in the materials program. This is currently out for comments by the NRC offices, the regions and the agreement states. Again I mentioned interconnection. If we are evaluating the agreement states in the performance indicator program and we're using our inspection criteria and program as a basis, obviously if we revise it like we're doing, we need their comments because obviously this is going to affect them.

I consider this revision does several important things. It will ensure the programs expanded by an amendment get early reinspection. If you'll recall last year, that was raised as an issue as a result of the Indiana, Pennsylvania event. We put out a temporary guide. This will make it permanent. It will ensure that new licensees receive timely early inspections. Actually, eventually, I want to put out a special inspection procedure for new licensees that make the initial inspection more didactic than what we have done in the past. A lot of

agreement states do things like that and I think it's useful. It places emphasis on reactive inspections. It's at the beginning of the manual chapter rather than at the end, as has been in the past. Most significantly, it will vary the inspection frequency based on licensee performance. We've kind of had hints about doing that in the past. People have been very willing to increase the inspection frequency for poor performance, but people have not been as willing to back off for good performance and this will direct back off for good performance.

In the past, as I mentioned, rules have gone into effect with no licensing guides and no inspection guides on the day the rule became effective. I plan on going everything I can do to change this. As I assure you, in the pharmacy rule that procedure will be in place.

Next slide.

[Slide.]

DR. PAPERIELLO: In the licensing area, we issued the policy and guidance directive for the license reviewers, the flag to the inspector's major license changes. We've revised and updated our licensing guidance for high dose rate afterloader units.

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[Slide.]

DR. PAPERIELLO: We've issued the standard review

plan for broad scope licensees, including medical licensees and the issuance of the companion regulatory guide is imminent and it may even be out, I don't know. It's something that's changing very, very quickly. It will be out within weeks.

Next slide.

[Slide.]

DR. PAPERIELLO: We are planning an interim update of the appendices to the existing medical licensing guide. The whole guide will be revised after we do something with Part 35, but we are sorely lacking guidance on strontium-89, the HDR units in the regulatory guide, gamma stereotactic surgery and several other appendices are deficient. So, we're not going to revise the whole guide, we're going to make an addition and revision of the appendices to the guide to discuss several topics, and particularly emerging technology. The target is next September and this is a case where needed coordination with both the ACMUI and the agreement states adds to the time to issuance.

The pharmacy guide I mentioned has been revised. I recognize -- on our licensing guides, when we changed Part 20, all the references in our existing licensing guides are in error and we have really a bad problem on revising the old guides because we've never included anything in the

budget to do it. Hopefully there are ways that we can work around it, but that's ongoing.

And we are developing a standard review plan for the master licenses held by the Navy and the Air Force and we may have other government agencies that have individual license may want to take advantage of the same provisions.

Next slide.

[Slide.]

DR. PAPERIELLO: Rulemaking. The pharmacy rule is near completion. The patient release criteria in Part 35 is being worked on. I'll make an observation on this. When I got into this, I wish I had known, they were out and I didn't know them, is the international guidance on both the IAEA basic safety standards and ICRP-60, which exclude -- the class of people we're concerned about on patient release in international criteria are not considered members of the public. Voluntary caregivers and patient visitors are considered -- their exposure is considered medical exposure in the international standards and there is a constraint of 500 millirem. I wish I would have known that when we were preparing all the paper. I didn't. I should have, but I didn't.

Revisions to Part 19 and 20 to ensure licensees, notify members of the public of their over exposures, that change is imminent. When we revised Part 20, we thought we

had moved all the notification requirements to Part 19 and we did for occupational workers. But somewhere in the movement, we lost the fact that in the old Part 20 when a licensee told us, reported that they had over exposed a member of the public, they had to turn around and provide the same information to the person who received the exposure. Somewhere that got lost in the changes, and so we're really restoring things to the way they were under the old Part 20.

The embryo/fetus rule is going to be picked up soon as the radiopharmacy rule work is done.

Next slide.

[Slide.]

DR. PAPERIELLO: We expect and hope to get the advanced notice of proposed rulemaking on Part 35 out early next year. Now, grant it, we cannot change, even come up with a proposed rule on Part 35 until we have the results of the National Academy study and the Commission makes some decisions on what it wants to do based on that study. But we can at least get out on the table some of the issues that are going to have to be resolved and which I would like to start work on.

The wrong patient rule, I understand, is extremely imminent. Maybe Don has --

DR. COOL: It's in office concurrence right now.

I'd expect it within a month.

DR. PAPERIELLO: Okay. Some of these things change from day to day.

Next slide.

COMMISSIONER ROGERS: Just on that, in the paper on page 9, I think there was a comment that with respect to unresolved issues in this rule. Could you say anything about what those are?

DR. PAPERIELLO: I'm sorry. What --

DR. COOL: I'm not sure I know which rule you're talking about. I'm sorry.

COMMISSIONER ROGERS: Wrong patient rule.

DR. COOL: There were a series of discussions within the staff with regard to whether a definition of patient was needed to resolve the problem. We have now resolved that. We believe we've actually gotten around that. One of the little axioms is when you've got a word which causes you a problem, you look to see whether you really need the word. In fact, a more simple solution as it appears to the staff at this point is to go back and remove the word "patient" from the several places it appears in definitions in Part 20 and go to an individual who receives this or who does that and thereby get around that definitional problem.

That issue has now been resolve and that's the

package that's moving forward in concurrence, this paper having been sent up approximately two weeks ago. We were in the process of our working group, steering group resolving that issue at that point.

COMMISSIONER ROGERS: Okay. Was that really the only significant one?

DR. COOL: That was the key issue but sort of fundamental to the way that you craft the rulemaking.

COMMISSIONER de PLANQUE: What were the implications of that if you went from patient to individual? I guess we'll see it. So --

DR. COOL: Well, I could get into a very long discussion.

COMMISSIONER de PLANQUE: Let's have the short version.

DR. COOL: The short version really is that when you go to an individual who has received a medical treatment, then you're no longer involved with the question of whether they were under medical treatment for that particular modality or whether they were there because they had been in an accident and needed an x-ray and got somehow transferred in. It keeps you out of a little bit of a conflict. What about shielding and the typical things between somebody who's walking down the hallway, because there was a little bit of a question with regard to where

Part 20 would, in fact, interface because the normal limits for members of the public should still be enforced when you're dealing with shielding construction and those sorts of things. We believe this has defined that line relatively clearly.

COMMISSIONER de PLANQUE: We'll see.

DR. COOL: We'll see. You will get to see that shortly.

DR. PAPERIELLO: Could I have the next slide?

[Slide.]

DR. PAPERIELLO: The medical use policy statement, the '70 policy statement, is the current basis for the program that I'm currently implementing, along with the rules as they're written and regulatory interpretations from OGC. You have to recognize, and I do recognize, that based on the National Academy study they may make a different proposal and the Commission and/or the Congress may establish a significant different policy. So, when I talk about revision of Part 35, at least tentatively I'm going on the assumption that there's going to be no change in policy. I'm sure that's wrong, but it's in terms of planning assumptions. There's not much more I can do right now.

Can I have the next slide?

COMMISSIONER de PLANQUE: Carl, how are you drawing the line between what you need to spend resources on

to go ahead and correct problems with Part 35 no matter what?

DR. PAPERIELLO: Right.

COMMISSIONER de PLANQUE: Versus doing more creative or different things with Part 35 that may indeed be affected by the NAS outcome.

DR. PAPERIELLO: Well, the rulemaking that I discussed earlier, the things that are kind of ongoing, except for an ANPR, are the things, wrong patient rule, patient release, embryo/fetus, are things that sort of correct the Part 35. I believe even if we change nothing, if the National Academy says, "Don't change anything," or even if they say --

COMMISSIONER de PLANQUE: "Change everything."

DR. PAPERIELLO: Well, "Back off," there's certain things that we need to fix. I think we really need to resolve the issue between Part 20 and Part 35. Right now it's a nightmare of who has primacy. I think we ought to make a claim. If you deal with medicine, it ought to be Part 35 and if you want Part 20 apply, you want to make it explicit. There's too much implicit. So, there's things like that. Not right or wrong and nobody did anything deliberate, it's just that we're dealing in a real world. From the viewpoint of computer science, our regulations are full of spaghetti logic. So, you know, you change something

and you don't know how the rest of the program gets change. And, of course, then the program may do some very strange things. When you execute it you've made a change and you didn't catch all the interconnections.

So, I think there's some things that we need to tidy up. A lot of what I'm doing is just plain efficiency. If I change the licensing program, I'm looking at efficiency. If I changed the inspection program, most of what I'm doing does not deal with medicine as medicine. We need to think about why do we inspect everybody at the same frequency whether they're good or bad. The reality of it is I have had, over my experience with inspections and supervisors over the years, you'd have an event and they'd hide it from you because they were afraid that that would make you go out and inspect it and I would lose ten routine cases and I have a goal to get so many inspections done in a year whether they're needed or not. I mean those are the kind of things. We've got to change our way of thinking.

I really want to do, after we finish licensing, apply BPR to the inspection program and ask really why we're inspecting, what information we're trying to get and whether we can do that program more efficiently. Obviously, I think Commissioner you mentioned, the government is under stress right now to be more efficient in what it does and to rethink everything it's doing. So, a lot of what I'm doing

is in that area.

COMMISSIONER de PLANQUE: Okay.

DR. PAPERIELLO: Let's talk about the current policy. Next slide. Yes.

[Slide.]

DR. PAPERIELLO: For radiography or well loggers, we basically regulate based on the first statement in the policy statement. We look at worker and public safety. We don't determine whether radiographs are any good except a case if you do them at a nuclear power plant, and then we do. And we don't worry about whether the well logger is logging the well right, as long as people don't get exposed, improperly exposed.

However, in medicine, we do turn around and look at whether the licensee does their job as a job well. That creates a great deal of -- the stress occurs between the second and the third objective of the policy. I'm not saying this is good or bad, but we have to recognize that's where all the stress comes with the regulated community. One party will tell us we're not doing enough for patient safety, while another will say we're intruding too far into the practice of medicine. You have to consider medicine as medicine probably has the highest average educational and training requirements of anybody we license. This is higher than all the people who operate nuclear power plants.

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DR. PAPERIELLO: How does this affect Part 35? Medical institutions have a great diversity in management structures. Fundamentally, the model that's sort of implicit in Part 35 just isn't true. Physicians practice in institutions but are not employees and not in the traditional sense. RSOs, authorized users, medical physicists may not be licensee employees in the traditional sense. Part 35.25 describes supervision of technologists by the authorized user, but many authorized users are not, from my viewpoint, the traditional supervisor. I supervise somebody if I write their performance appraisal. This may not occur. The medical physicist may be under contract to the physician, if it's a medical group, may be under contract at a hospital, may be an employee of the hospital. There's very, very complicated organizations out there and some of the misadministrations occur because of communication problems brought about by the fact that people don't -- I'm not here all the time and the employment relations.

Secondly, we have to recognize medical technology as changing rapidly. There are people involved in the delivery of the dose who are not even mentioned in Part 35. I'm told by the people who are involved in gamma

stereotactic surgery that neurosurgeons are a critical part of the delivery team. I understanding the labeling chemist is an important part of the team in monoclonal antibodies. Dosimetrists have caused misadministrations. These individuals don't exist in Part 35, but medical physicists are. Any revision of Part 35 -- again if we stay with the policy as written, we are going to have to make decisions on what we're going to do about the training and qualifications of allied health personnel.

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DR. PAPERIELLO: In the past year, there have been considerable discussions and communications from the medical community on medical training and qualification. I know the Commissioners have received correspondence on this which had to be answered. I think we're going to somewhere have to make the judgment on how far we go on evaluating medical qualifications versus pure radiation safety, and I know Barry is going to talk about this and he can probably say more about it than I can. What about allied personnel, health personnel? Will we leave it to the licensee?

I mentioned medical physicist earlier. It's interesting. We deal with criteria for medical physicists to calibrate teletherapy units, but we're silent on medical physicists who do brachytherapy dose planning.

What about requalification? Currently, once we qualify somebody as an authorized user, they stay forever qualified. However, many medical boards are now requiring requalification. So, these are issues that we're going to have to decide when we change Part 35 unless we make a decision that we are going to reduce our involvement to just occupational safety.

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DR. PAPERIELLO: We have constraints in the revision of Part 35 cost. You constantly hear cost, medical cost, control of medical cost, and NRC cost and how much it's costing us to regulate this community. We have agreement state participation. If we revise Part 35, when we do this, we need the involvement of the agreement states.

Lastly, we have to recognize there is no one medical community. There are different views in the medical community on how we should regulate and the depth of regulation.

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[Slide.]

DR. PAPERIELLO: We're going to need to work extensively with the regulated community and the states to get a good rule. We plan on putting out an ANPR, we plan on holding extensive workshops and hopefully try to, through

negotiations and discussions, resolve some of these issues.

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DR. PAPERIELLO: I've gone back over the SRMs that you have sent us and I believe, just in summary, that we have addressed all of the issues that were raised in them.

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DR. PAPERIELLO: In conclusion, I think the inspection program revision is going well and most of these initiatives would have been done even without the medical management program. Interim licensing guidance should be out by the end of fiscal '95. The major efforts are going to be involved in business process reengineering. We do need efficiency and timeliness in licensing and these two things are interrelated. After we do the licensing program, we will do the inspection program because that's where the bulk of the FTE expenditures are.

Commissioner, you asked about regulatory changes. Most of the changes in the regulations of Part 35, the minor changes, should be done by the end of calendar '95 and, of course, once we get the National Academy study, I guess everything is fair game.

Thank you.

CHAIRMAN SELIN: Commissioner Rogers?

COMMISSIONER ROGERS: Well, let me say that I think this was really a first rate briefing. You really covered an enormous amount of ground and very clearly and I thought it was really a fine job, Dr. Paperiello.

There are a couple of questions in the SECY that perhaps I might just explore a little bit. None of them are --

DR. PAPERIELLO: Sure.

COMMISSIONER ROGERS: Well, I won't say they're not profound, but I don't know if they are or not. But one of the points on page 4 of the SECY had to do with a brachytherapy source IIT event and your decision to refer such incidents to EPA. This is the next to the last paragraph on the page.

DR. PAPERIELLO: Right. No, the event isn't.

COMMISSIONER ROGERS: Well, what my question is is what that really means. For example, is there any question that in such a referral to EPA that the extensive analysis and revelation of the causes of that problem would not take place that did take place? In other words, is it going to change in any way the detail with which we explore how such an event --

DR. PAPERIELLO: No because that event would have come back to us anyway. What the issue came down to is as a result of the IIT, we started developing guidance to go out

to people who handled waste to say, "If you find radioactive material in the public domain, this is what you should do. Here are your contacts." Frankly it would have been primarily use or the agreement states.

When we got into the ferrophosphate incident and we started dealing with it according to our procedures, we were told, "Wait a minute. In the new federal radiological emergency plan, you are not the lead federal agency. It is the EPA." So, it's not so much in the lost brachytherapy source, but what happens now when someone finds radioactivity in the public domain, the EPA is the lead -- and we don't know where it came from, at least the initial, and we don't know where it came from. The EPA is the lead federal agency. In this case, where licensees said, "Guess what? Somebody found one of our sources in their trash," EPA wouldn't be involved. That would be ours.

In fact, I had a discussion with my staff yesterday on this particular event because we had gone well down the road to preparing information and things like that and the discussion came what do we do with it now because it was a proposal to turn it over to the EPA and say, "Well, here it is. You got it, do something about it." I didn't think that would be completely fair.

The other thing is, from the viewpoint of the EPA, they really want the finders to call the state and local

governments and then if they need assistance to call the EPA. My proposal, and of course this is the first time you'll have heard that, my staff knows, I want to get together with the Conference of Radiation Control program directors, work with them. We in the EPA and FDA help sponsor the conference. Let's put this piece of paper out as a conference document because the states are going to get a call first and work out how we'll handle it so nobody gets hurt.

The real issue, of course what we're really getting at and what I was getting at in the report, is people have been finding and reacting to relatively low levels of radioactive contamination in scrap and things like that. The problem is if you get a very hot source, somebody needs to do something quickly and not -- this is not an environmental problem. Somebody could get hurt, which is the case of Indiana, Pennsylvania. That's the background on the problem we were trying to get fixed. But no, if this event occurred in Indiana, Pennsylvania, no, we would be in it from the very beginning.

COMMISSIONER ROGERS: All right. I just wanted to make sure that we weren't cutting off in some way on this.

DR. PAPERIELLO: No.

COMMISSIONER ROGERS: On page 7 of the SECY, in the adequacy of misadministration reporting requirements,

you have a comment there regarding concern of the IG on the adequacy of current NRC misadministration reporting requirements. I guess my question is that the IGs expressed some concern, I know, in a conversation that I had with IG folks a week or so ago about the need to try to establish some base number of administrations so that a reasonable performance indicator can be established. We've commented many times that we know what the number of misadministrations is, but we don't know what the number of administrations is.

DR. PAPERIELLO: Right.

COMMISSIONER ROGERS: And the IG folks in just a conversation with me indicated their rather serious concern about trying to move ahead and establish some kind of a base number that might not be administrations but might be related to administrations that nevertheless could give you some number of misadministrations out of some total number. I think they suggested total number of patients, for example, treated rather than administrations.

Have you had any discussions with the IG further on --

DR. PAPERIELLO: Yes, we have, and there's actually two issues here the IG had. One is getting this denominator. The problem I have is getting it cheaply. We have agreed -- as we do the TI, we will be getting the

licensee's estimate of the number of procedures they did because they have to sample a certain percentage and we will accumulate that in our database. If you have a database, you just call up your report writer and sum up everything that's in that field. I don't know how accurate that will be. Part of the problem I have is we don't define procedure. This comes in a fraction, this comes in one dose. From the viewpoint of a patient, "I just want to get through this whole thing and not have something bad happen. Should I care whether or not -- you know, this procedure is better than this procedure because when I used the number of fractions." So there's a complication there. But we've agreed to get that number.

The other issue the IG --

COMMISSIONER ROGERS: I don't think that issue is going to go away of trying to establish some kind of a --

DR. PAPERIELLO: I asked somebody to look into this and I didn't have a feedback on it. Now, who told me this? Somebody told me that I ought to be able to find a consultant in the D.C. area that could tell you how many medical procedures are performed of the given type. The reason is the drug companies and various companies need this for marketing purposes. I asked somebody to look into it about two weeks ago and they haven't got back to me. I'm glad you reminded me of it because I'm wondering whether or

not I can buy the information. I just may have not looked in the right place.

We have agreed to pick it up when we do the TI. But again, it's the way we have told licensees to do it. My own feeling is if we wanted a very precise number, you would have to go forward with rulemaking, tell the licensees how we're going to count it, to tabulate it the way we want to do it and then report it to us.

COMMISSIONER ROGERS: My question is whether you really need a very precise number for the denominator.

DR. PAPERIELLO: That's my point.

COMMISSIONER ROGERS: You need it for the numerator, but you don't need it for the denominator.

DR. PAPERIELLO: That's my point too. And I'm not sure what I would do with the number.

MR. TAYLOR: We're more interested in the numerator.

DR. PAPERIELLO: Yes.

MR. BERNERO: Yes. We do have the frequency and all the precise number gives you is the rate.

COMMISSIONER ROGERS: But it gives you more because it tells you whether it's going up or down, whether the rate is going up and down. If you don't have a denominator, you can't say anything about it.

MR. BERNERO: You can infer it from frequency.

COMMISSIONER ROGERS: No, you can't. I mean I don't think you can.

MR. TAYLOR: This has been discussed a number of times with earlier commissions too.

COMMISSIONER ROGERS: Yes. Unless you've got some measure of that denominator, you can't tell whether it's going up or down.

MR. TAYLOR: It's the cost of getting it is the big issue and the collection, if we required such information be provided as a cost of information collection.

COMMISSIONER ROGERS: Yes.

DR. PAPERIELLO: So, anyway, I think we've come to an agreement at least in terms of picking it up when we do the TI.

The other issue though that the IG raised here comes out of the deliberate overdosing of patients by technologists when doing diagnostic procedures and whether that should be defined as a misadministration. I would offer my belief, no. Now the issue though is should it be reportable. I guess my believe is it's yes. So, there's two separate things. Let's not make it misadministrations that will be reported. Let's report the right thing.

I look at a more general question that was raised and that's with respect to Part 30, not Part 35. Part 30 would cover all licensees, 31 through 39, on whether or not

the willful violation of a requirement by a licensee employee ought to be reportable because you look at the wrongdoer rule and things like that. I think that would be a fix I would prefer. Don't make something like this, which is not a misadministration because the doses are still in the low range. If the physician had said you can do that or if the physician had written a procedures manual with a range, it would have been perfectly legal and it would not have harmed the patient. The issue was a technologist, deliberately on their own, violated a licensee procedure and that's what ought to be made -- whether or not they deliberately falsified dose calibrator records. So, I think that's the fix.

COMMISSIONER ROGERS: Okay. Turning onto page 14 in your information management system description, I'm very interested in this working group with agreement states to create a prototype event database. Do you feel that there is some reasonable uniformity on reporting among the agreement states?

DR. PAPERIELLO: I can't answer that. I don't know.

COMMISSIONER ROGERS: Yes.

DR. PAPERIELLO: Is there somebody -- I can get back to you. I don't know.

MR. TAYLOR: I think we'll have to come back to

you on that, sir. I don't know.

COMMISSIONER ROGERS: It is a key question in the validity of the database.

MR. TAYLOR: I don't know that we have anybody that has that, but we'll get back to you.

COMMISSIONER ROGERS: Yes. It needs some attention at any rate, if that database is going to be as useful as it could be.

MR. TAYLOR: Yes.

COMMISSIONER ROGERS: The INEL independent analysis described on page 19, there were seven major findings. Item 6 and 7, corrective actions, were often narrow in focus and licensees often lack systematic methods for detecting and mitigating misadministrations. What is the fix for that? It's not so clear to me how you fix that.

DR. PAPERIELLO: I don't know. And I will offer up this is not unique to misadministrations. We deal this with nuclear power plants all the time.

COMMISSIONER ROGERS: Yes, of course.

DR. PAPERIELLO: You know. I think in part though, we have to, ourselves and licensees, identify root causes and people don't do it. We don't do it. In fact, I would argue that in many times when internal auditors in this agency make findings, they don't ask for root causes. I mean it's an easy thing not to do. I've been -- I don't

want to say in an emotional sense, but I've had to shake my head when licensees came in and said, "The reason why the operator didn't do the right thing is they didn't follow the procedure." Well, then the question is why didn't they follow the procedure? Do they never follow the procedure? Was it not there? Was the person incapacitated? You never go any further. So, "Well, we're going to fix it. We're going to retrain the operator in a procedure." I mean that is almost a classic response.

And I think in my event follow-up procedure I said -- I only made the statement, "Find the root cause." AEOD has developed and my staff is working and looking into what AEOD has developed. We have purchased four computer programs that will drive systematic root cause analysis. I wanted to get my event procedure on the street before I had that and where I'm coming from is I participated in an IAEA asset mission a couple years ago in France. They had a short cookbook procedure. If you can teach nine guys in two hours whose native language of some of the people was not English to use this, you ought to be able to have a cookbook little root cause analysis procedure that I can give the inspectors and drive them. We're not there yet. I would say in about a year we're going to get there, but I wanted to get this procedure something on the street. I don't know of what AEOD has we're going to factor in, but we are going

to factor in something.

I have to get people to think that way. Frankly, we in ourselves don't always think, but that's the fix for this problem and I think we're a part of the problem. If we start thinking that way, we'll be driving people to think that way. I wish I had a better answer, but that --

COMMISSIONER ROGERS: Well, it relates also to my previous question about the database. In the database, do you intend to try to include root causes?

DR. PAPERIELLO: I believe in the database there are blank fields to record root cause. Whether or not anybody will really put the right root cause down, I don't know, but at least the database has the fields for them. Again, as I said, we have to teach people to think this way.

The reality of it is we, in fact, train inspectors in this. I've certainly sat through and participated in all kinds of accident analysis training for inspectors. The problem is we then run a program that places so much emphasis on routine inspections that when the inspector follows up an event, they're so pressed for time you wind up getting a report. I picked up the report. They deal with violations and they don't deal with the root causes. That's not uniform. In fact, many of the things get brought out in the course of discussions. I'm trying to get back to the basic inspection procedure.

COMMISSIONER ROGERS: Just one more, the agreement state implementation of the QM rule.

DR. PAPERIELLO: Yes.

COMMISSIONER ROGERS: The dissatisfaction of the agreement states with the division of compatibility assigned to various aspects. How is that coming along?

DR. PAPERIELLO: I'll know after this weekend. Seriously. There's a meeting on Sunday afternoon at the all agreement meeting to hash out what the agreement state rule is going to look like. So, I'll know better then.

COMMISSIONER ROGERS: Well, thank you very much. I think it's been an excellent presentation.

COMMISSIONER de PLANQUE: Carl, with respect to the ANPR and the workshops, again it's sort of related to one of my prior questions. Do you intend those to get into the issues that you defined earlier as issues that need fixes because of inconsistencies now or need improvement because of inefficiencies as opposed to items that may change as a result of the Academy study or Commission reaction to that?

DR. PAPERIELLO: Right now it probably would be both. Right now it would be both and I can imagine your next question, why should we do this.

COMMISSIONER de PLANQUE: Yes.

DR. PAPERIELLO: Maybe that is something to think

about. Maybe we should turn around and change the timing.

COMMISSIONER de PLANQUE: I wonder about it given the resources that you need right now for so many things and the resources are higher than what was anticipated and that doesn't look like it's going to turn around, whether that needs to be relooked at.

DR. PAPERIELLO: Perhaps. That occurred to me getting ready for this meeting. You know, we put together the plan that we presented a year ago or a year and a half ago and we've gone hell bent for leather.

COMMISSIONER de PLANQUE: Right.

DR. PAPERIELLO: And we're now up to this and I've been trying to keep things on schedule. I have to admit I thought about that when putting -- but not until after this paper was complete and I started putting this.

COMMISSIONER de PLANQUE: Okay.

DR. PAPERIELLO: But that is a consideration. On the other hand, it would really help to get the issues out on the table and there are efficiency issues. Let's suppose we keep the current policy. The issue of training and experience is going to be big. You know, what happened is when Part 35 was changed in '86, '87, I didn't realize a year ago we never changed the training requirements. So, the existing training and experience requirements goes back to around '80 or '81. You see some strange things. It

takes more training and experience to do diagnostic nuclear medicine than to do certain therapy procedures. Now, I think the envision was there was only one or two straightforward procedures, but in principle a person could be licensed to engage in working with monoclonal antibodies for therapy with less training and experience than in diagnostic nuclear medicine, and that is obviously a strange place to be. But that's the way the rule is written right now. But what should it look like?

COMMISSIONER de PLANQUE: Yes.

DR. PAPERIELLO: I don't know. I really don't know what it ought to look like. I'm always bothered by hours. We all know that you can turn around and sit in a class and sleep. It doesn't mean you've learned anything. But I don't know what that ought to look -- and I need a lot of help on that one and I think the regulated community can give us that help if we're going to go with that. Now, you're right, if we decide, "Hey, we're not going to worry about it. That's a medical decision," so be it.

COMMISSIONER de PLANQUE: Yes. But I guess I would then ask the question, a similar question, more generically. We've asked you to do an awful lot in the last couple of years and the resources are tight and things are in a state of flux. Is there anything on your to do list that looking at it today as opposed to when we wrote an SRM

a year or more ago, that you would want to reraise as is this something viable that we should be doing now or do we need to take another look at it? I don't ask for an answer right now, but more or less this is something that I would certainly be open to. If we've asked you to do something before that in today's context no longer makes sense and should be taken off the plate or put on hold, I think now is the time to take a look at those.

DR. PAPERIELLO: Okay.

MR. TAYLOR: We'll do that.

DR. PAPERIELLO: We hear you.

COMMISSIONER de PLANQUE: Okay. I would just say I thought it was a terrific paper and an excellent briefing, a very good discussion of some of these issues.

DR. PAPERIELLO: Thank you.

COMMISSIONER de PLANQUE: Thanks.

CHAIRMAN SELIN: My question follows up on Commissioner Rogers' question and it has to do with the QM rule. You have a situation where the agreement states aren't very happy with the rule and we're not very happy with their response. You have a situation where, if I understood correctly, more than half of the misadministrations were misadministrations of the QM rule which might not be the same as misadministrations of delivering proper health care. We did ask for a review of

the QM rule when we passed it, and it sounds like it really is quite right to take a broader look at it, even apart from the National Academy work.

DR. PAPERIELLO: I'd like to make an observation. I attended the meeting of the American College of Nuclear Physicians a couple weeks ago on quality assurance. From what I could hear from the presentations, there's very little in that QM rule that is not the standard of care.

CHAIRMAN SELIN: But it doesn't follow that it therefore has to be an NRC rule.

DR. PAPERIELLO: Well, I understand that.

CHAIRMAN SELIN: And then you're violating an NRC rule as opposed to "medical standards."

MR. BERNERO: Excuse me, Mr. Chairman. I think the meaning of the more than half are violations of the QM rule is that they are violations of good medical practice that also are violations of their own QM rule, not that they are some procedural or formal requirements that aren't related to good medical practice.

COMMISSIONER de PLANQUE: The question is why should you have two sets of rules doing essentially the same thing?

MR. BERNERO: Well, the real point is one of the things that's coming to me in comments on a regular basis is a challenge of the QM rule not because the QM rule develops

plans that are good medical practice, but the fact that we are requiring it, the fact that we're making it force of law rather than leaving it as guidance. That seems to be the biggest edge.

CHAIRMAN SELIN: That's one argument and that's probably the more important argument. But a second argument would say that when you have something which is considered good practice, whether it's qualifications and if you're a member of the right college or the right board qualification or whether it's the QM rule which codifies practice that most people follow, it might be that the appropriate thing is, in fact, to have the rule but to inspect very, very differently, to go in with the assumption that 95 percent of the institutions would have that quality whether or not it was a rule and then 95 percent of the people would be qualified whether or not we required the qualifications. We're just trying to fill in the holes. We're just trying to say, "For the very few institutions that don't follow what is normally considered good practice or for the very few individuals who want to practice some type of radiation medicine but don't have the qualifications," how do we find out if they're out of line with the practice?

Let me be a little more explicit. If the QM rule is not only good practice but it's required by most state medical associations or it's required by various commissions

on accreditation, and all we're trying to do is pick up the few institutions that fall between the cracks, the odd clinic that's not really part of a hospital, it's not part of a broad term, we might apply the rule quite differently. One question is are you satisfying your peers and us? The second question is, do you happen to be in a group where you don't have to follow the QM rule to satisfy your peers or your peers don't exist?

Going back to the qualification of individuals, there's one small number of individuals that we think should be allows to practice this type of medicine, even though they don't have a board certification or a state -- and then your inspection will be completely different. We would assume that for the vast number of institutions which are monitored by the industry, by state associations, what have you, this rule is followed and we don't have to duplicate the regulation and we just have to make sure that those institutions which fall outside of peer groups also follow the rule.

Do you follow what I'm saying? Do you think it's a crazy idea?

DR. PAPERIELLO: I understand, but I'm not quite sure how I would do it. It's almost all regulators' dilemma, it's not just our medical licensees. I think most of our licensees without our intervention would do the right

thing.

CHAIRMAN SELIN: I didn't say that. That's not what I said at all. I said that we believe that the QM rule writes down in language what every state medical association expects of hospital-based medicine, say, and what a wide range of freestanding clinics are expected to do by their own accreditation. But there are some small groups and we've come across groups which just use these devices but they don't happen to fall under the state group because they're not a hospital. They might be a physician operating in his own office and he's not subject to the same state regulation.

So, it's not that we are trying to make sure that the people that fall into a self-regulated group are meeting the rules. We're trying to make sure that the 5 or 10 percent of the practitioners, who just happen not to be in a self-regulated group or in a state-regulated group, are also held to the same standard. I think it's clearer when we're talking about practitioners who we will license to carry out. Most of the people, we don't have to get involved in licensing. They're licensed by state groups or by physician groups, but there are a small number of technicians who don't fall under the state regulation. So, we say, "If you have a certain amount of training and education, you can get an NRC license." Then the inspection would not be to go to

a hospital and see if the hospital, the radiation medicine group in the hospital, is carrying out what the hospital is supposed to carry out. We would rely on the state medical regulation to follow that. But to go to the odd group, the stand-alone clinic that only provides a certain kind of therapy but doesn't fall under the state group because it's not a hospital and it's not a practice, to make sure that they also provide QM or that this odd number of individuals, which are not licensed by the state but are licensed by us, also find the qualifications.

DR. PAPERIELLO: Unfortunately, I don't believe if you look at the actual events that have occurred you could map them on the one class. Unfortunately, events have occurred, again for purely human errors. I gave a presentation to a group of medical people on Tuesday on misadministrations and I said it's really not medical errors. They're human errors made by people in the practice of medicine.

CHAIRMAN SELIN: I grant that. But the thing is, let's say we had a case there was no NRC whatsoever and state regulation of medical use of radiation was perfect in the sense that it covered everybody who carried out what we cover. There's still the errors. We don't believe that the existence of regulation means that there aren't any errors, but they would be subject to the state's finding them. Then

the question is is it really worth spending all this money so that the 10 percent errors that escape state regulation are down to 1 percent because we also have a 90 percent filter that goes on top of that, or should we just concentrate on those classes that somehow fall between the cracks at the state level. Or is the hypothesis just false?

COMMISSIONER de PLANQUE: Is the issue that your hypothesizing a "regulatory" gap, putting regulatory in quotes? And is there such a gap?

CHAIRMAN SELIN: Exactly. I mean why did we feel that we had to regularize QM if that's what's involved in good medicine anyhow? The answer was probably either because we felt that there were some regulators who weren't carrying it out properly or there were some classes of practitioners who were not subject to these mores because they're not parts of self-regulated groups.

MR. BERNERO: Mr. Chairman, I think it boils down to an implementation strategy that can be worthy of consideration. If you go back to when we had what I call the QA rule, we were going to prescribe through our rule everything that was good medical practice and all of that. That was a cause of great consternation and fury. We withdrew from that to QM rule whereby the fundamental premise is we set a performance standard and the agent, the medical facility, the doctor, puts down what is the

appropriate plan or procedure for good medical practice. So, now we have a situation where that good medical practice is set up so that the licensee themselves would be the first line of defense to discover errors and to correct them. Other medical authorities or regulating authorities are in a position to provide oversight and to assist in that and we have an implementation strategy option that says, "We can selectively inspect." Having established that the rule is in place, the performance standards and the criteria are in place, we can go to weak licensees or licensees without such extra oversight and selectively implement.

CHAIRMAN SELIN: I think you're saying just more precisely what I'm trying to say where you don't have a uniform inspection over all licensees but you select classes which for one reason or other are not getting the medical society or the state medical group inspection of their quality management practices and that's where we put the bulk of our inspection.

MR. BERNERO: And Carl has said to me his intentions or desires to have less of the ritual, "It's three years or two years or one year, it's your turn to be inspected" --

CHAIRMAN SELIN: Well, that's true.

MR. BERNERO: -- and more of a discretionary application.

CHAIRMAN SELIN: But I'm suggesting that you add a second criterion for whom we inspect here. First is to try to sort out the strong from the weak performers. If you have some reason to think these are weak performers, they'll get more inspections. The second is to sort out the set that's getting less state oversight than other sets. If it's in a group and in large public hospitals that have state medical groups, they have New York City groups, they have accreditation, but they're getting a lot of inspections anyway, there are other groups like the Indiana, Pennsylvania group who got a lot less inspection. In other words, aren't there sets of licensees, not good ones and bad ones, but types of licensees who are just subject to less other inspection than other sets and therefore should just have a higher likelihood that we will inspect?

DR. PAPERIELLO: There may be. My problem is I don't know who and I suspect that it's going to -- may vary. We have 50 states and we may have -- we regulate in 21 states. We may have 21 criteria. So, when I start looking at the matrix of types of licenses and the states i have, I may have an enormous problem of sorting out who falls into what box. I don't know. I haven't given it that much --

CHAIRMAN SELIN: The way you find out is go inspect them all and see who --

DR. PAPERIELLO: And not only that, my guess is

all programs go up and down and even states fall on financial -- you know, the State of California agreement state program, when the state got into financial difficulties, they lost a large number of their staff. So, their program had problems because of loss of staff and those things happen. So, it might be done. I'm don't know just sitting here how to create the matrix.

COMMISSIONER de PLANQUE: May I?

CHAIRMAN SELIN: Please.

COMMISSIONER de PLANQUE: And I would say further that even if you identified such a box of institutions that didn't get as much oversight, I think you still have to ask the question, "Well, because of that, are they having more misadministrations or more problems?" If not, why would you treat them separately anyway? I'm not sure. I just don't know the answer.

DR. PAPERIELLO: And the data is pretty sparse, when you start breaking into that kind of thing. We're running right now for the last several years in the NRC-regulated states, about 30 misadministrations a year. So, it's not a very big number.

CHAIRMAN SELIN: Okay. Fine. Thank you very much.

MR. TAYLOR: Thank you.

CHAIRMAN SELIN: Obviously we're all quite pleased

with the presentation, although none of us knows exactly what to make of it and what conclusions to draw. It clearly is responsive to the SRM.

Dr. Siegel?

Our big advance in Commission briefings was to put names on both sides of the name tag so both the audience and the participant can see if they were sitting in the right place.

Very nice to see you again.

DR. SIEGEL: Good morning.

CHAIRMAN SELIN: We've be very pleased to hear what you have to say.

DR. SIEGEL: Glad to be here. We're sorry for the sort of on again/off again decisions about whether we were going to have a Commission briefing this year. But once the decision was made, we're glad to be here. As you'll notice, there are only four of us here. It was the consensus of the Committee that a contingent could make the presentation and we originally planned on having six folks here but Dennis Swanson, the new radiopharmacist on the Committee, and Judy Brown, our consumer person, were both unable to be here today.

I'm joined at the table today by Dr. Judith Stitt, who's a radiation oncologist from the University of Wisconsin; Bob Quillin who's in the radiation protection

group in the State of Colorado and he's the agreement state representative; and Dr. Lou Wagner, who's a medical physicist from the University of Texas and who has particular expertise in areas of radiobiology and particularly in exposure, low-level exposure and exposure of pregnant women, and we anticipate that in some of the upcoming discussions we'll value having Lou on the Committee.

I plan to keep my comments pretty brief. It's late and I'm losing my voice.

One of the reasons that we debated a little bit about the need for a briefing this year is we felt a little bit defused in terms of addressing real big issues while the Institute of Medicine deliberations were ongoing and that what we might have to say might not be viewed with as much credence as if the IOM came out with a different set of opinions. So, we've been biding our time a little bit on some of the real big issues. So, I'm going to focus this morning on a couple of small points and one or two big points for your consideration.

CHAIRMAN SELIN: Let me just say to you before you start, we look at this Committee to advise particularly the specialists but also the Commission on the program as it's presently conceived. We've asked the Institute of Medicine to take a look and see are we doing the right program, not

so much are we doing the current program correctly. That's really a secondary piece. So, we value your continued attention to big questions and little questions continuously along the way.

DR. SIEGEL: I forgot to point out that one of our FDA representatives on the Committee, Dr. David Woodbury, is also in the audience. He's part of the floating FDA representation. There are actual several.

If I can have the first slide.

[Slide.]

DR. SIEGEL: I just would like to remind you how we're composed. There are several physicians, actually three nuclear medicine physicians, representing different areas of expertise, a couple of radiation oncologists and then a physicist, radiopharmacist, state representative, FDA representative, a consumer advocate, newly added a hospital administrator and a to be named radiotherapy technologist or a dosimetrist.

Next slide, please.

[Slide.]

DR. SIEGEL: We've had a lot of turnover since we last briefed you. In fact, eight members have rotated off the Committee and we've added several new members, as you'll see. I've more or less arranged them in parallel of who replaced whom. Dr. Marcus, of course, is irreplaceable on

the Committee and we will miss her.

I would point out in the first line on the right column, the dotted lines there, we've not replaced Peter Almond insofar as he's a therapy physicist and I believe you've heard requests from us through the staff that we very much would value having a therapy physicist on the Committee or if not as a member of the Committee a least a consultant who could regularly come to the meetings if Committee size restrictions are the guiding force because we think in the next couple of years we're really going to be dealing with some therapy issues that warrant us having that expertise in the room.

Next slide, please.

[Slide.]

DR. SIEGEL: Since we were here last, we've had three formal meetings and one teleconference meeting and we've addressed a series of issues that I just will essentially list at this point and then go on to a few of them. We've had several discussions related to how the staff was proceeding with the medical management plan and primarily have been asked for technical advice related to resolving some of the radiotherapy issues that were a follow-up to the Indiana, Pennsylvania event.

We've had a number of discussions regarding brachytherapy, focusing on HDR and PDR therapy and Dr. Stitt

will have a few words to say about some of those things in a few moments.

We've helped you evaluate how you should be using medical consultants in misadministration investigations. We've talked a few times about training and experience for physicians particularly in regard to therapy. As that has already been the focus of some discussion this morning, in a few more moments I will talk about this in a slightly broader sense.

We've looked at some work the staff is doing with regard to overall medical radiation safety program guidance and talked about radiation safety officer qualifications and at our last meeting reviewed a fairly large document, a NUREG that is going to talk about the fundamentals of radiation safety programs in medical institutions and I hope we've provided useful information to the staff at that point.

Next slide, please.

[Slide.]

DR. SIEGEL: We've also addressed a series of issues that, as Carl just characterized, I would characterize as collisions between new Part 20 and Part 35, the wrong patient as a patient or an individual versus a member of the public, the problem of the patient as a walking restricted area and whether nuclear medicine waiting

rooms, for example, had to be defined as restricted areas. The whole issue of patient release criteria, which we will be revisiting in some depth again at the meeting coming just a month from now.

I would point out that the wrong patient rule that we're hearing, you're about to get some rulemaking language on, has not yet been discussed as a rule with the ACMUI. We've discussed the concept, but we've not seen the language and I guess we hope we'll get that opportunity.

We've talked a couple of times about patient notification, the issue of referring physician and responsible relative, and I'll have more to say about that in a moment.

And we've spent a fair amount of time at our last meeting revising the bylaws that were drafted initially by the staff. I gather you all have approved them. I understand that as long as we keep making one change at every meeting, we'll never actually have to accept the bylaws because they can only be approved at a meeting when they're never changed. But I think we'll probably approve them in November.

CHAIRMAN SELIN: Or we'll give you two sets of bylaws.

DR. SIEGEL: That's equally okay.

I would describe, and I think this is important to

talk about, that our working relationship with the staff and the tenor of our meetings has really been quite good over the last few meetings. They've been productive. I think the exchange of information has been very good and we have tried our best, and I hope we've been successful, in arriving at consensus positions and making our minutes a bit meatier so that you all can read them and come away with a clearer understanding of what we're feeling and not have to plod through every line of the transcript. We believe that what we say is being heard. We recognize that it will not always be heated and it is not always being heated. As I think I may have pointed out before, the FDA likes to pride itself on bragging rights, if you will, that they follow over 90 percent of the advice of their advisory committees. My sense is that we're maybe batting closer to 600 and not 90 percent and maybe I shouldn't complain about that.

I would say one thing that I do think needs to just be brought out. In recent meetings, there's been some tension between the Advisory Committee and OGC. This has, in some ways I think, interfered with our ability to communicate effectively with you. We're not the enemy. We're special government employees and we're here to advise you and we need to understand, since none of us sitting around the table are lawyers, we need to understand the legal constraints under which the NRC is working in

formulating its rule so that we can give you the best possible advice. I really would hope that that tension will melt and so that OGC can participate in our meetings and exchange ideas with us. We recognize that lawyers always reserve the right to go back and study the issue carefully before they issue a final opinion, but there ought to be an opportunity to talk about things in an open public forum and we shouldn't have any secrets from each other.

Next slide, please.

[Slide.]

DR. SIEGEL: Now, the issue of patient notification is one that although it's a relatively small point, I think it drives at an important philosophical issue in terms of the so-called depth of regulation concept that you raised with your comments, Mr. Chairman, with the IOM the other morning. I would point out just by way of reminder that we're on record as a Committee and certainly sitting right in this room by saying that we believe that notification of the patient in event of a medical error, whether it's a surgery error, a drug error or a radiation misadministration, is nearly always appropriate and it's nearly always appropriate because truth telling in medicine is appropriate. It's our ethical imperative and it's something we would do whether the NRC told us to do it or not.

However, there are judgment issues that are involved and there are important societal differences. For example, patients in Japan aren't told they have cancer. It's just the standard are care that family members are told, but patients are not told. We know that in the United States we have an entirely different approach to what patients are or are not entitled to know. But in the discussions related to this, notifying the patient or the responsible relative or guardian, we really think that the position that we see the staff coming down to is really becoming illogical.

First, the concept that if you have judged that it would be harmful to tell the patient that you can turn around and tell the responsible relative and then assume that the patient won't be told. I mean certainly if a letter shows up from a licensee, as I've said at the Committee meeting, in my house the mail gets opened by whoever gets home first. So, if there's a letter to me and my wife gets home first, she'll open the letter. If the letter was informing me that she'd been injured in a medical misadministration, then I would have just informed her inadvertently. So, we can't ensure that the patient will not be informed.

The issue of what is a responsible relative and how far this extends is the next of kin of third cousin

living in North Dakota because that's the only living relative one can identify. We're very troubled by this concept that a legally competent adult in fact has a responsible relative. We think the language of Part 35, by clearly defining that in an "or" phrase, did not intend that the patient or responsible relative was one in the same unit, even though that seems to be the way it is now being interpreted. It's not at all clear to us how the licensee can compel the referring physician to do this or even how the licensee can compel the referring physician to know enough about the family to know whether it would be harmful to tell the responsible relative.

So, we really think that whole thing is really quite illogical and we would encourage you to do one of two things, either go back to leaving it to physician's judgment and believe that we believe in truth telling, or change the rule and compel notification irrespective of whether or not there's harm to the patient if you believe that society's greater purpose would be served by that. We're not sure that a generic letter is sufficient. We really think you probably need a rule change if that's what you want to do, that you need to define what a responsible relative really is and probably you need to include in that rule a qualified immunity provision for physicians who so inform because of the potential breach of patient confidentiality that may

have occurred, so that it's clear that they're following the law if they, in fact, harm the patient because they informed the patient.

So, even though it's probably something that occurs only a few times a year, the ACMUI thinks it's an important issue that warrants your additional attention.

COMMISSIONER de PLANQUE: Barry, is this issue addressed in any other field of medicine or has this come up only with respect to radiation?

DR. SIEGEL: It's addressed by way of practice standards that you tell the truth and certainly there are -- if there are legal requirements to inform, then physicians must follow the law. The law takes precedence over the patient/physician relationship and we understand that.

COMMISSIONER de PLANQUE: Yes, but what I meant is this kind of approach that the staff is talking about, is that used in any other --

DR. SIEGEL: Not that I'm aware of.

COMMISSIONER de PLANQUE: Okay.

DR. SIEGEL: Next slide, please.

[Slide.]

DR. SIEGEL: This next point gets to a broader issue and it relates, I think, to the whole issue of depth of regulation. It relates to whether the medical program will be recast in its entirety and either made something

larger or smaller, and it has to do with how we decide what is adequate training and experience for the practice of radiation medicine. The slides are directed towards physicians, but I think the concepts could be taken right down the line to physicists, pharmacists, technologists, dosimetrists.

We want to get the physician issue on the table because over the years this has been the knottiest problem. It's been -- you've found yourselves embroiled in a turf war which didn't do you any good and didn't do us any good and I think the ACMUI really does believe that it's time for an overall reassessment of the goals and the strategies of physician licensure as well as other allied personnel licensure, time for a paradigm shift. And it all relates to this disconnect between the Part 20 part of NRC regulations and the extension of Part 35 into patient safety.

Now, if I can have the next slide, and I'm actually taking these out of order if we get them in the right order.

[Slide.]

DR. SIEGEL: Yes, this is slide 8 first rather than 7.

The one paradigm shift would be to say that patient safety is paramount and that we really have to not be in the middle, not have this disconnect, for example,

between diagnostic imaging training and therapy training, but we have to demand that the people who are licensees have absolutely the optimum training for every aspect of their job, protection of the general public, workers, and also complete protection of patients. And we think that if you're going to demand that, that what you're going to have to require is that training be obtained in ACGME or other approved training programs based in medical institutions.

And probably you'll have to go a step further and require that the approving authority, the ACGME, for example, the Accreditation Council on Graduate Medical Education, the boards that certify those physicians and those other professionals in fact be subject to NRC audit of their activities so that you can prove to yourselves that their program content really does meet your requirements. And then the individuals would likely need to either be board-certified or certified by examination by the NRC with recertification, so that would be the extreme direction.

If patient safety is paramount, we really have to demand that absolute experts be the people involved in the game.

Next slide.

[Slide.]

DR. SIEGEL: On the other hand, if you're willing to consider retrenching to the Part 20 boundary line, then a

different model applies. We would think that you could reduce training requirements to the minimum needed for protection of the public and workers, recognizing that that will vary with each category of radioactive material use.

Using technetium for bone scans requires a lot less training than using high-dose brachytherapy to cure cancer, and everybody on the committee recognizes that. The radiation safety aspects of that are things that are well understood. They're not associated with the art of medicine. They're physics for the most part and they're human factor analysis for the most part and those things could be reduced to a course content, a syllabus which NRC could develop or NRC could develop with the aid of professional societies or contractors and the training could be conducted either within the confines of existing medical training programs or could be done by commercial organizations that choose to give this training because it's a profitable thing to do.

Certification of this should be by examination, and I think you all don't want to get in the business of giving tests but you can contract with the National Board of Medical Examiners or others to give an examination for you that could be given a half dozen times a year, could be computer-based so the questions are always randomized and varied so that you can't cheat on the test, and then you

would have a way of validating that the training really did occur.

And then, if you follow that model, then the responsibility for patient safety issues, for credentialing of physicians, should be left to established pathways, to the boards that certify physicians, to hospital credentialing committees, to state licensing authorities, and that would be then getting you out of the business of defining, oh, sort of just enough training to do the job but then having professionals turn around and tell you, "Well, you're letting people in who really aren't adequate to do the job," when what those professionals may be trying to really tell you is, "You're letting someone in who might take business away from me." It's the same thing I said at an ACMUI meeting as a member of the public a least ten years ago and I haven't changed my tune one bit.

I would just point out that at the May '93 meeting the ACMUI unanimously endorses the second position.

CHAIRMAN SELIN: Is the second position a lesser included position than the first one? In other words --

DR. SIEGEL: Say that again?

CHAIRMAN SELIN: -- does anybody who passes the more restrictive standard of the first position automatically pass the second standard also?

DR. SIEGEL: One would hope so.

CHAIRMAN SELIN: So, if we accepted responsibility for patient safety credentialing through established pathways, the only reason we would have to certify by examination would be for those specialties or those functions which were not subject to the established pathways. I mean, we wouldn't need a radiation oncologist to take an NRC exam if that person had a board certification.

DR. SIEGEL: In theory, that should be true. I guess there's potentially some concern and issues that will be raised about whether individual training programs always can contain the necessary requirements and this question has come up often.

One way to satisfy yourself would be to do the examination route, alternatively obtaining greater assurances from the residency review committees and from the boards that they are in fact covering the material that you all expect to be covered and examining it would be an alternative pathway.

CHAIRMAN SELIN: I mean, there is a cost-risk calculation. For us to have to examine a large number of board-certified radiation physicians to see if they know how to lock up a cobalt source seems sort of not going to save the public a lot of risk.

DR. SIEGEL: It does get you out of the turf war,

though. The turf war may have quieted down a little bit recently and maybe that's -- none of the cardiologists are here to disagree with me, in part that's because they're moving into other ways of making the diagnoses and in some cases relying less on the nuclear medicine approaches, but I think that the turf wars are not going to go away.

This has a way of leveling the playing field and doesn't allow board A to say that board B isn't really doing it's job.

CHAIRMAN SELIN: But then what we would have to satisfy ourselves is that both board A and board B at least meet these minimal standards --

DR. SIEGEL: That's correct.

CHAIRMAN SELIN: -- which is a lot less than saying, you know, cardiologists are authorized to do everything that a nuclear medical person is.

DR. SIEGEL: Correct.

Next slide, please.

[Slide.]

DR. SIEGEL: At this point, let me just turn the microphone over briefly to Dr. Stitt who will make a few comments about brachytherapy.

DR. STITT: Thank you, and the key is brief. I have a few comments and some areas of reflection.

The use of radioactive isotopes to treat cancer

has been developed since the time of Madame Curie in the late 1800s and our current and widely used practice of low dose rate manual after-loading has been evolving into high dose rate computer controlled brachytherapy where doses are given in literally minutes rather than in days. But with the advent of high dose rate brachytherapy comes a concern that there may be need to increase regulation of this new technology.

As a medical practitioner and a medical consultant for the NRC, I have reviewed numerous misadministration cases. These medical events violated the QM rule and therefore were by definition misadministrations, however, with one notable exception of the cases I have reviewed, the nature of these errors had no medical consequence to the patient, to the staff or to the public, yet significant paperwork, time and effort were spent to produce a report. As a physician, I feel that parts of the QM rule don't accommodate the overall management of a patient's treatment plan.

The members of the ACMUI have discussed brachytherapy regulation at our meetings and feel that a general review of brachytherapy isotope use is reasonable in view of the increasing medical use of high dose rate brachytherapy, pulse dose rate, interstitial treatments, and the latest and greatest mobile high dose rate units that are

now on the road.

Questions?

DR. SIEGEL: Is that it?

DR. STITT: That's it.

DR. SIEGEL: Okay. Let me just go on then to the last slide.

[Slide.]

DR. SIEGEL: I think this is something you know, but I think it's worth reemphasizing the need for NRC regulations to be cost effective. Carl commented on it a few moments ago.

Despite what you may have heard from Capitol Hill, health care reform is underway and it's underway with a vengeance. The ball is rolling.

CHAIRMAN SELIN: If the federal government doesn't make it happen, it's not actually happening regardless of what you see.

DR. SIEGEL: Would that that were so. Lots of reorganization is going on. Lots of cost cutting is going on. Physicians, hospitals are under intense financial pressure to reduce costs and under simultaneous intense quality pressure to maintain quality because otherwise they'll lose their competitive edge in the managed care environment.

A side point, Carl raised the concern about the

organizational structure of medical institutions where physicians didn't really work for the hospital which was the licensee and the lines were drawn that were kind of fuzzy. That may be changing.

I think it's not too difficult to conceive of a United States where there are six corporations that run all the hospitals and all the doctors are employees of the hospitals, because, if you think about efficiency, the notion that those independent agents the physicians are out there trying to maximize their own revenues, and in fact that is in fact the opposite goal of the organizations, the hospitals, and the opposite goal of the American people and the third party carriers and whatever, it doesn't make sense. And I think we're going to see big changes so that there will be more unified organizations and physicians will be working for the hospitals more and more and more, and so there may be opportunities to take advantage of that in terms of how regulations are structured.

Because of these changes that are really ongoing quite clearly, I think it's really essential as you relook at Part 35 and as you look at new brachytherapy regulations that every component of the regulations be looked at, first of all to make sure that there's a scientifically valid base for having it in place and then to see that it really makes a significant difference to the public health and safety or

patient safety if that's what you choose to pursue.

Just a few nuclear medicine examples.

The notion that you need to check the eluate of a technetium generator every single day for molybdenum is probably not consistent with the technology anymore. It's probably reasonable to check it when the generator first arrives, but it probably doesn't need to be done every time the generator is eluted.

The many survey and wipe testing requirements in medical institutions probably don't have a whole lot of impact on worker safety in those institutions.

And I was struck when I reviewed this NUREG on medical radiation safety programs with the list of audits that a medical radiation safety program is expected to conduct on a periodic and usually annual basis -- audit, audit, audit. What do we uncover with those audits? And there's a lot of time being spent and personnel being devoted to those activities. We need to make sure that something useful is coming out of those.

The QM rule, I think, is an example that I still remain unconvinced -- I unfortunately came into the process a little -- the ball was rolling too far. The original QA rule, which would have been prescriptive, in many respects would have been quite enough.

What you really had -- let's focus on radioiodine,

for example, or radiopharmaceutical therapy. What you really had was a problem where people were getting I-131 and the authorized user didn't realize that was occurring because he wasn't in the loop. And all you really needed to do was make a simple rule that would have said, "In order to give a dose of I-131 more than 30 microcuries, there has to be a written prescription by an authorized user." That would have been enough. That would have solved the I-131 problem because that actually is where most of the I-131 violations that continue to occur are occurring. It's because the QM plans haven't been implemented and they haven't got the message yet that they needed to have a written directive for those procedures. A doctor's office is calling up requesting a procedure, talking to a hospital scheduling clerk and a technologist gives I-131 and the authorized user was never in the loop. Simply getting the authorized user in the loop would have solved the problem.

My guess is, as you review the QM plan and start looking at, at least for nuclear medicine, at looking at the audits that the licensees are going to conduct at a moderate amount of labor on their parts, you're going to find that you're not uncovering hidden recordable events and misadministrations that were slipping through the cracks. Although there are events, more likely events will be discovered in radiation therapy, I think the depth of audit

and the need to have licensees casting their own procedures when relatively simpler more focused things could have done the job is not entirely clear to me.

I think this whole review and then the rewrite of the QM plans is really in a way sort of entertaining. It's kind of like a contest. Here was supposed to be a performance-based rule that you were going to let licensees be very flexible in devising their procedures and then when it turned out those procedures didn't meet the letter of the language in Part 35 and in the regulatory guide you slammed them and said, "Clearly that procedure won't work." So, was it really performance-based? No. It ended up being very, very prescriptive.

So I just want to leave you with that final message that cost effectiveness is really going to be key. The health care system is going to demand it and the survival of certainly nuclear medicine as an entity depends on it being able to compete with other modes of imaging, and I for one would certainly hate to see it drop off the face of the earth just because it was being over-regulated. If it can't compete because the information it provides isn't good enough, that's a different issue, but it shouldn't be because it's too expensive because it's over-regulated.

I'll stop at that point and see if either Dr. Wagner or Bob wants to make any comments, and, if not, we're

ready for questions.

DR. WAGNER: Well, the only comment that I would make is that I feel that paperwork can be contrary to the principles of ALARA. In the state that I'm working in now, I see the radiation safety officers spending more time in their office filling out paperwork in order to meet the letter of the regulations rather than actually spending the time where they need to spend it, and the reason is because we're being inspected by people who are coming down and giving us citations for things and putting us into a lot of difficulty for situations that simply should not have occurred in the first place.

If we can possibly find ways to reduce these numbers of the amount of paperwork that we have to generate and not equate paperwork with quality management or radiation safety, I think it would be an effective way to improve things.

The other thing is that I think the point was made that regulation should be based upon risks. I think we have a lot of regulation that exists that's really not based on risk. It's based upon other standards and we should look at that and make some changes there.

I think I'll leave me comments at that.

DR. SIEGEL: Just one final comment on something that you questioned Carl about earlier relating to the

quality management rule and handling the small number of licensees that might not be being regulated under some other schema.

If you think about what's going on in hospitals, being accredited by the Joint Commission on Accreditation of Health Care Organizations is something you do so as not to be inspected by HCFA in order to be reimbursed by HCFA. I mean, that's really what JCAH is all about. JCAH has deemed status under HCFA regulations to do the job for them. What goes on in hospitals will indeed be looked at by JCAHO.

It's entirely feasible to do the same thing in organizations that would not normally be accredited by JCAHO, and your staff has discussed this at some length. Using practice audits conducted by the American College of Radiology or the American College of Nuclear Physicians is a perfectly good way to get at the same thing, and then even these free-standing facilities that you're concerned might be slipping out of the regulatory loop do in fact have the voluntary ability to achieve that through the deemed status of these accreditation programs and then really NRC might only need to step in if someone says "I don't want any part of JCAH" or "I don't want any part of professional organization accreditation. I take my chances with the NRC."

CHAIRMAN SELIN: There's another question that's

come up which I don't think has ever been put to the committee and that is the question of correct administrations, particularly in the therapeutic area. Have you ever been asked to think about are there cheap and efficient ways to get some very rough estimate of the total number of therapeutic administrations in the country? The absolute number doesn't really matter very much, but we would like to be able to keep some track of the trends so that as we count the misadministrations in some detail we have some idea of what's happening to the denominator.

I mean, I don't really want us to become a center for disease control for radiation disease, because, you know, people on the Hill say "You don't even know the number of administrations," without having any idea about what it would cost to really know the number of administrations. But is there a way, since our requirements are really so crude, is there a way to meet those efficiently? Have you been asked to --

DR. SIEGEL: Well, there are certain databases that you do have access to. I mean, the Medicare database is one way to get a handle on the number of administrations in the Medicare eligible population. Obviously, that doesn't capture the whole population, but, as I think Carl pointed out earlier, there are marketing data being generated with variable degrees of accuracy that are

available and probably would be less expensive than you all trying to do it yourself, to tap into those sources of information where people really have done I think a reasonably good job at getting numbers of procedures, private organizations. Once we have a single payer, it will be easy to get the information from that single payer, but we're not there yet.

Short of that, I'm not aware of any other easily tappable databases.

DR. STITT: We discussed this this summer at a conference at the Idaho National Lab and in the radiotherapy, brachytherapy circumstances I think you don't have to get every last case that was ever done and we've already made that comment here.

You could certainly sample large institutions that are doing the majority of the cases. There are some national groups -- the American Brachytherapy Society, American Radium Society -- that do have some of those numbers, because I've been part of surveys where the groups are trying to get a handle on how many numbers of what types, what body sites, how many numbers of esophagus versus prostate versus cervical are being done.

And so there's at least a good sampling that you could look at and that would be cheaper, should be free, plus the Medicare database, and all hospitals have their

billing databases and you can extract codes for the kind of procedure that was performed, so I think that you could get a good sampling that would at least give you the denominator.

COMMISSIONER de PLANQUE: Are insurance companies a possible source of this kind of information?

DR. SIEGEL: Absolutely. I guess I'm perhaps a little bit unclear about how much trouble the OMB would give you if, as part of your annual licensing fee, you include "Please tell us the total number of nuclear medicine patients you studied and how many patients had brachytherapy and how many had teletherapy," three numbers. That would get you a lot closer to the database, at least for your own licensees. Admittedly, you know, it requires OMB clearance to gather the data, but that would not be an exceedingly time-consuming piece of data for most licensees to come up with. I mean, I can give you my numbers in about three minutes, just open the book and I've got them there.

CHAIRMAN SELIN: Commissioner Rogers?

COMMISSIONER ROGERS: No. I think this has been -- we're very pleased to have had an opportunity to meet with you. I know there was some question about whether there was really enough to talk about that is worthwhile having the meeting, but I think it's always refreshing to meet with you and I'm pleased that we could bring it off.

Thank you.

COMMISSIONER de PLANQUE: Just one question for Dr. Stitt. The changes are occurring so rapidly in the brachytherapy area and have been for the last few years. It's not only difficult for the regulators to keep up with, I'm sure it's difficult for the medical community to keep up with. Is there any better way to deal with this?

DR. STITT: Well, it's frustrating because much of what I do professionally is brachytherapy and I am involved in the brachytherapy professional organizations and we are desperately trying to organize ourselves to get established methods that describe training fairly specifically, what types of procedures, how many, ways that physicians can get training, because very few places in the country are doing high dose rate, therefore if you were trained elsewhere or if you were trained even two years ago you don't have those skills and they actually are quite different than the low dose rate skills.

So the physics groups of the country and the brachytherapy physician groups are trying to address this issue within the groups by establishing some sort of training and education and ongoing seminars and that's in development currently.

COMMISSIONER de PLANQUE: Okay. Thanks.

Well, I'd very much like to thank you for coming.

I know there was some concern about why is this necessary, but, I think, as the Chairman said earlier, while things are being reevaluated for the long term, it's still -- things are going on and it's extremely important, I think, that we do hear your views on these issues, on the little ones as well as the big ones, so I thank you for taking time out of your busy schedules to come.

CHAIRMAN SELIN: Are you aware of the presentation that I made to the IOM?

DR. SIEGEL: Yes.

CHAIRMAN SELIN: I don't want the discourtesy of having told them what I think the questions are without having told you.

DR. SIEGEL: I've seen a copy of your comments. The whole committee doesn't have them yet, but they will.

COMMISSIONER de PLANQUE: Have you seen it for all of us?

DR. SIEGEL: Yes, I have.

CHAIRMAN SELIN: Thank you very much. Thank you for coming in.

DR. SIEGEL: Thank you.

[Whereupon, at 12:12 p.m., the above-entitled meeting was adjourned.]

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 USE PROGRAM - PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Thursday, October 20, 1994

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: Peter Lynch

Reporter: Carol Lynch

ANNUAL MEDICAL USE PROGRAM

COMMISSION BRIEF

OCTOBER 20, 1994

CARL PAPERIELLO

AGENDA

- STATUS OF MEDICAL MANAGEMENT PLAN (MMP) (APPROVED 9/30/93)
- QUALITY MANAGEMENT (QM) RULE IMPLEMENTATION
- MISADMINISTRATIONS
- INSPECTION and LICENSING PROGRAMS

AGENDA (cont.)

- RULEMAKING
- 1979 MEDICAL USE POLICY STATEMENT
- MAJOR REVISION TO PART 35
- STATUS OF STAFF REQUIREMENTS MEMORANDA (SRM): 6/19/91 and 9/30/93

MMP STATUS

ACCOMPLISHMENTS:

- Completed over 50% of the MMP action items
- National Academy of Sciences Study is underway
- NRC/Food and Drug Administration Memorandum of Understanding signed 8/25/93

MMP STATUS (cont.)

- ACMUI Bylaws submitted to Commission for approval (9/16/94)

CHALLENGES:

- Easier Tasks Completed
- Rulemaking is the critical path to completion
- Additions to the MMP

QM RULE STATUS

ACCOMPLISHMENTS:

- Initial review of all required licensee-submitted QM plans performed by contractor
- Deficiency Letters sent to 72% of licensees
- Temporary Instruction (TI) to inspect licensee implementation issued 8/1/94

QM RULE STATUS (cont.)

CHALLENGES:

- Apparent inconsistencies in review of QM plans by contractor
- Review of revised plans by NRC Regional staff
- Completion of TI and compilation of data

MISADMINISTRATIONS

ACCOMPLISHMENTS:

- Management Directive (MD) 8.10, "Medical Event Assessment Program"

- Inspection Manual Chapter (IMC) 1360, "Use of Physician and Scientific Consultants"

MISADMINISTRATIONS (cont.)

- NMSS Misadministration/Medical Consultant Coordinator

- Inspection Procedure (IP) 87103, "Inspection of Incidents at Nuclear Materials Facilities"

CHALLENGES:

- Misadministrations occur - 58% involve violations of the QM rule, and more than 1 QM violation was identified in 36% of those cases

MISADMINISTRATIONS (cont.)

- Mix is changing
  - fewer teletherapy
  - more remote afterloading
  - first Sr-89 events
- Ensuring all notifications required by the rule are made
- Patient followup

INSPECTION PROGRAM

ACCOMPLISHMENTS:

- Misadministration guidance
- IMC 1302, "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public"
- IMC 2810, "Master Materials Inspection Program"

INSPECTION PROGRAM (cont.)

- TI 2800/024, "Remote Afterloading Brachytherapy Inspections" issued
- TI 2800/025, "QM Program Inspections" issued
- IP 87100, "Licensed Materials Program" inspection procedures revised to incorporate Part 20 requirements

INSPECTION PROGRAM (cont.)

CHALLENGES:

- Revise IMC 2800, "Materials Inspection Program" to address several issues

- Revise IP 87100 medical field notes to reflect the final radiopharmacy rule

LICENSING PROGRAM

ACCOMPLISHMENTS:

- Policy and Guidance Directive (P&GD) 94-04, "Identification of Licensees Where Significant Licensing Action Warrants an Onsite Inspection"

- P&GD 86-04, Rev.1, "Licensing of Remote Afterloading Brachytherapy"

LICENSING PROGRAM (cont.)

- Standard Review Plan (SRP) for Broad Scope medical licensees, e.g., university medical center

- Regulatory Guide (RG) 10.5, "Applications for Type A Licenses of Broad Scope" issued soon

LICENSING PROGRAM (cont.)

CHALLENGES:

- Revise and add appendices to RG 10.8, "Guide for the Preparation of Applications for Medical Use Programs," to address all types of authorized use

- Revise nuclear pharmacy guides

- Develop SRP for master materials licenses, e.g., Navy, Air Force

RULEMAKING

NEAR COMPLETION: Radiopharmacy Rule

PUBLISHED FOR PUBLIC COMMENT:
Patient Release Criteria (Part 35)

Revisions to Parts 19 and 20 - Notification of Exposed Members of the Public by the Licensee

PROPOSED RULEMAKING ON HOLD:
Embryo/Fetus and Nursing Infant Protection

RULEMAKING (cont.)

ADVANCED NOTICE OF PROPOSED RULEMAKING (ANPR):
Major revision of 10 CFR Part 35, "Medical Use of Byproduct Material"

PROPOSED RULE UNDER DEVELOPMENT:
Wrong Patient Rule (Parts 20 and 35)

1979 MEDICAL USE POLICY STATEMENT

- Medical use rulemakings evaluated for consistency with the policy statement
- NAS to assess current framework of regulatory program for its consistency with the policy statement

1979 MEDICAL USE POLICY STATEMENT (cont.)

I. Worker and public safety;

II. Radiation safety of patients; and

III. Minimum intrusion into the practice of medicine.

10 CFR PART 35 MAJOR REVISION

ISSUES:

- Great diversity in medical licensee management structures
- Rapidly changing medical technology
- Diversity in personnel involved in the medical delivery system - allied health

10 CFR PART 35 MAJOR REVISION (cont.)

- Education and experience:

  Medical versus radiation safety
  Allied health personnel
  Re-qualification

- Supervision of individuals using byproduct material

10 CFR PART 35 MAJOR REVISION (cont.)

CONSTRAINTS:

- Cost Effectiveness
- Agreement State (AS) participation
- Diverse medical community and public interest in regulatory issues

10 CFR PART 35 MAJOR REVISION (cont.)

CHALLENGES:

- ANPR
- Workshops

SRM STATUS

MARCH 31, 1993: (Result of briefings by staff, AS, IIT, and ACMUI during January-February 1993). Directed the staff to consider or resolve 10 specific items as part of development of the MMP.

SEPTEMBER 30, 1993: (Post annual program brief). Directed the staff to implement the MMP.

ALL ACTION ITEMS IDENTIFIED IN THE SRMs HAVE BEEN ADDRESSED.

CONCLUSIONS

- o INSPECTION PROGRAM
  - most guidance issued by end of FY95
- o LICENSING PROGRAM
  - interim guidance issued during FY95
- o REGULATIONS
  - minor revisions underway
  - future major revision of Part 35
- o NAS STUDY
  - direction of MMP could be modified as a result of findings

BACK-UP SLIDE

DEFICIENT QM PLANS

- Detailed level of review by LLNL
- Identified numerous findings that met the category 3 (deficiency) letter criteria (72% of QM plans) but varied in their safety significance
- Example: Lack of 1 element in required written directive versus lack of brachytherapy patient treatment plan.

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

COMMISSION BRIEFING

BARRY SIEGEL, M.D., CHAIR

OCTOBER 20, 1994

ACMUI Membership

Nuclear Radiologist	Radiation Oncologist (2)
Cardiologist*	Medical Researcher*
Medical Physicist	Radiopharmacist
FDA Representative	State Representative
Consumer Advocate	Hospital Administrator

RT Technologist/Dosimetrist (TBN)

*Also a nuclear medicine physician

ACMUI Membership Changes Since February 1993

Term Completed	New Member
Peter Almond, Ph.D.	. . . . .
Edward Webster, Ph.D.	Louis Wagner, Ph.D.
Capt. William Briner	Dennis Swanson. Ph.D.
Melvin Griem, M.D.	Judith Stitt, M.D.
Carol Marcus, M.D.	Wil Nelp, M.D.
Gerald Pohost, M.D.	Daniel Berman, M.D.
Steven Collins	Robert Quillin
Joan McKeown	. . . . .
	John Graham

Issues Addressed by ACMUI Since February 1993

- Medical Management Plan (emphasis on radiotherapy concerns)
- Brachytherapy (HDR, PDR)
- Use of Medical Consultants
- Training and Experience for Therapy
- Medical Radiation Safety Programs (RSO qualifications, NUREG)

Issues Addressed by ACMUI Since February 1993

- Conflicts Between Part 20 and Part 35 (wrong patient as member of public, patient as "walking" restricted area patient release criteria)
- Patient Notification (referring physician, responsible relative)
- ACMUI Bylaws

Patient Notification

- Requirement that "responsible relative" be notified if it would be harmful to notify the patient is illogical.
- Definition of "responsible relative" unclear.
- Either leave to physician's judgment or compel notification irrespective of harm to patient.

Physician Training and Experience

- Need complete reassessment of goals and strategies (paradigm shift).
- Major problem appears to be related to imperfect coupling of radiation safety training needed for protection of public and workers vs. much more extensive training needed to protect patients.

Physician Training and Experience: Radiation Safety Paradigm

- Reduce training requirements to minimum needed for protection of general public and workers for each category of RAM use.
- Develop course content/syllabi for use by training programs (both based in medical institutions and free-standing).
- Certify by examination.
- Relegate responsibility for patient-safety credentialing to established pathways.

Physician Training and Experience: Patient Safety Paradigm

- Increase required training to optimum needed for protection of general public, workers, and *patients* for each category of RAM use.
- Require training in approved programs based in medical institutions and require approving authority to document program content.
- Require board certification or certify by examination.

Brachytherapy Issues

Need for Cost-Effectiveness of NRC Regulations

- Health-care reform is underway.
- Medical institutions and practitioners are under intense financial pressure and quality pressure.
- Essential that each component of regulatory program is supported by scientifically valid data and makes a *significant* difference.

POLICY ISSUE

(Information)

October 13, 1994 SECY-94-256

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: ANNUAL REPORT ON THE MEDICAL USE PROGRAM INCLUDING STATUS REPORTS ON IMPLEMENTATION OF THE MEDICAL MANAGEMENT PLAN AND QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS RULE

PURPOSE:

To provide the Commission with an update on the medical use regulatory program, including status reports on implementation of the medical management plan (MMP) and Quality Management Program and Misadministrations Rule (QM rule). The MMP is described in SECY-93-244 and identifies 90 action items, including action items resulting from the findings of the Incident Investigation Team (IIT) for the November 1992 therapy misadministration that occurred in Indiana, Pennsylvania.

SUMMARY:

This annual report provides the status of implementation of the MMP and QM rule, as directed by the Commission. It also discusses the increasing role of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), major program areas being addressed by the staff, and associated resource issues. Status reports on implementation of the MMP and QM rule are provided in the "Discussion" section, and specific information and statistics are provided in

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NOTE: TO BE MADE PUBLICLY AVAILABLE AT COMMISSION BRIEFING ON OCTOBER 20, 1994

the eight attachments. At present, approximately 56 percent of the MMP action items are closed, and the QM rule has been in effect since January 1992. All licensee-submitted QM plans have been reviewed and deficiency letters have been forwarded to licensees. "Open" MMP action items are either partially closed, or not yet addressed because they depend on the closure of precursory action items. As a result, the staff continues to address short- and long-term action items to resolve policy issues and specific tasks, while adjusting program priorities in response to unforeseen events and changing needs.

BACKGROUND:

Each year, the staff provides the Commission with a status report on the medical use regulatory program. Historically, this annual report focused on the "Five-Point Plan," originally described in SECY-88-77, "Medical Use Program," to provide improved regulatory oversight of the medical use regulatory program. In recent years, the annual report gravitated toward a discussion of current issues and related actions by the staff to resolve them. Therefore, this year's report primarily focuses on the status of implementation of the QM rule, and MMP, as requested by the Commission in staff requirements memoranda (SRMs) dated June 19, 1991, and September 30, 1993, respectively. The SRM dated June 19, 1991, directed the staff, in part, to provide the Commission with an assessment of the effectiveness of the QM rule at the annual briefing on the medical use program, 3 years after the rule becomes effective. As a result, this annual report provides an assessment of the effectiveness of the QM rule, as will subsequent annual reports.

In an SRM dated May 24, 1993, the Commission requested the staff to provide semiannual reports on the status of IIT action items. The staff provided the first semiannual IIT report as Attachment 4 to SECY-93-244 (August 31, 1993), and the second report via a memorandum dated April 1, 1994. In a memorandum dated April 12, 1994, the Office of Nuclear Material Safety and Safeguards (NMSS) requested that the semiannual IIT report be discontinued in view of the annual MMP report, since the MMP includes the IIT action items. This request was granted; therefore, this annual report provides an IIT status report (Attachment 6), as will each subsequent annual report, until each action item has been resolved.

The direction of the MMP, and in particular, major revisions of 10 CFR Part 35, and those requirements in 10 CFR Part 30 that affect medical use licensees, may be altered significantly depending on the results of the National Academy of Sciences' (NAS') external review of the medical use program, and subsequent Commission direction based on the NAS findings. See Program Area 1, *"Policy Issues"* for further discussion on the NAS study.

DISCUSSION:

This section is divided into the following subsections: *I. "Status Report on the MMP;" II. "Status Report on Implementation of the QM Rule and Its*

Effectiveness;" III. "The ACMUI;" IV. "Major Program Areas Currently Addressed;" and V. "Resource Issues." The MMP status report provides general information on progress to date in the nine major program areas identified in the MMP. The status report on the QM rule discusses steps taken to implement the rule, contract support, inspection and enforcement issues and staff recommendations and a discussion on Agreement State compatibility with the rule. The other subsection titles are self-explanatory.

Six of the eight attachments provide specific information on MMP action items. Attachment 1: a Gantt Chart to demonstrate the status and current due date of MMP action items, by program area; Attachment 2: statistics on MMP action items; Attachment 3: information on progress to date on MMP action items by program area; Attachment 4: a list of documents issued since August 31, 1993, (SECY-93-244); Attachment 5: a list of documents or reports that are scheduled to be completed by December 31, 1994; and Attachment 6: a status report on IIT items. Attachment 7 is data on misadministrations that occurred from January 1993 through June 1994; and Attachment 8 is a list of staff presentations at public meetings, made since September 1993, discussing primarily QM and high-dose-rate remote afterloading brachytherapy issues. It should be noted that Attachment 3 provides an abbreviated version of the information contained in the following discussion of each MMP program area.

I. *STATUS REPORT ON THE MMP*

This section provides general information on progress to date in the nine major MMP program areas. The staff has completed several short-term action items and initiated steps to address many long-term action items. To date, approximately 56 percent (50 of 90) of the MMP action items are closed, including most IIT items.

Program Area 1. *Policy Issues*

The staff has taken the following actions to resolve the major policy issues identified in the MMP: 1) contracting with the NAS to conduct an external review of the medical use regulatory program; 2) evaluating each medical use rulemaking to ensure consistency with the 1979 Medical Use Policy Statement; 3) implementing a Memorandum of Understanding (MOU) with the Food and Drug Administration (FDA) to clarify our respective roles and address issues and events of mutual interest; 4) evaluating sealed source and device jurisdiction issues between the U.S. Nuclear Regulatory Commission, FDA, and the Agreement and non-Agreement States; and 5) working with the U.S. Environmental Protection Agency (EPA) and waste processor industry to address the IIT finding on the inadvertent transfer of licensed material to a non-radioactive waste processor.

The NAS study is underway, and the committee has held two meetings this calendar year and is scheduled to meet on October 11-13, 1994.

Cognizant NAS staff made a presentation to the ACMUI at the May 19, 1994, meeting to discuss the tasks and goals of this study. Additionally, at the request of NAS, NRC staff has briefed the Committee on medical use regulatory issues. This study is discussed in more detail in IV. *"Major Program Areas Currently Addressed,"* item C. *"National Academy of Science Study."*

Consistent with the SRM dated June 23, 1992, the staff is evaluating each medical use rulemaking to ensure its consistency with the 1979 Medical Use Policy Statement. The first proposed rule to be evaluated under this directive was the proposed patient release rule noticed in the Federal Register in June 1994. This rulemaking was determined to be consistent with the policy statement and had explicit evaluation and findings in the Federal Register notice.

The NRC/FDA MOU was signed on August 25, 1993, and has been fully implemented. Recently, NRC and FDA staff jointly investigated radiation therapy events occurring at two NRC-licensed facilities, both of which were caused by the same treatment planning error. The joint staff also investigated and took action to address a device failure involving a high-dose-rate remote afterloading brachytherapy device. In addition to collaborating on inspections, NRC and FDA staff conduct routine monthly meetings to exchange information of mutual interest. On August 25, 1994, the first annual meeting between the agencies was conducted to ensure full implementation of the MOU. The staff forwarded a memorandum to the Commission dated June 23, 1994, to provide a status report on implementation of the MOU. Additionally, NMSS recently issued Policy and Procedures Memorandum 1-45, to identify NRC and FDA staff and management contacts to facilitate the exchange of information.

As a result of the inadvertent transfer of the brachytherapy source in the IIT event, and Commission direction in response to SECY-94-073 regarding the recent contaminated ferrophosphorus incident, the staff will refer all incoming reports of emergencies involving unidentified radioactive material in the possession of an individual or group, not licensed by NRC or an Agreement State, to the EPA. This policy is in accordance with the Lead Federal Agency (LFA) provisions of the draft Federal Radiological Emergency Response Plan (FRERP). Because EPA is the LFA for such incidents, the staff will cease plans to issue guidance to the waste management community regarding events where licensed material is inadvertently received. In a memorandum dated June 21, 1994, the staff provided guidance to the regions regarding the referral of such incidents to the EPA.

Program Area 2. *Misadministrations and Patient Followup*

Evaluating medical misadministrations and determining licensee compliance with reporting and notification requirements have been

complex and resource intensive. The staff continues to provide additional guidance on the investigation of misadministrations, particularly patient notification and followup issues. As a result, two key documents were recently issued: 1) NRC Management Directive (MD) 8.10, "Medical Event Assessment Program"; and 2) Inspection Manual Chapter (IMC) 1360, "Use of Physician and Scientific Consultants." MD 8.10, which received Commission approval in May 1994, provides guidance to ensure that medical events (primarily misadministrations) are investigated in a prompt and consistent manner; that NRC provides the appropriate level of direction for followup of patients who have received an overdose of byproduct material; and to ensure licensee compliance with all notification requirements. It also provides criteria for when a medical event is escalated to involve an Augmented or Incident Investigation Team. IMC 1360 provides additional guidance on the use and role of physician and scientific consultants who augment an NRC inspection effort, and it established the role of the NMSS Misadministration/Medical Consultant Coordinator (MMC).

NMSS designated an individual with human factors expertise as the MMC to assist in the review of misadministration cases, ensure the availability of medical and scientific consultants, and to coordinate the collection and analysis of data. This individual coordinates with regional and Office for the Analysis and Evaluation of Operational Data (AEOD) staff to ensure the accuracy and completeness of event information that is entered into the AEOD Material Events Database (MED). (See Program Area 8, *"Information Management Systems,"* for additional information on MED.)

To ensure licensee compliance with misadministration notification requirements, the staff evaluated therapeutic misadministration data for calendar years 1990-1992, and is in the process of evaluating data for 1993 through June 1994. The results of the 1990-1992 evaluation were submitted to the Commission in a memorandum dated April 14, 1993. Subsequently, Headquarters staff issued guidance to the regions to identify licensees who, at that time, did not appear to be in compliance with 10 CFR Part 35 misadministration notification requirements. After identifying these licensees, a generic form letter was sent to each of them to clarify NRC notification requirements and stress the importance of making the required notifications, verbally and in writing, to the patient (or responsible relative or guardian), and the patient's referring physician. As a result, some licensees subsequently provided documentation to NRC that all required notifications had been made, whereas other licensees remained in non-compliance. In addition, several licensees raised concerns regarding NRC notification requirements, in particular the requirement to notify the responsible relative in certain cases. These concerns were addressed in a memorandum dated March 10, 1994, by the Office of the General Counsel (OGC) staff, at the request of NMSS. Appropriate enforcement action against licensees who remain in non-compliance was discussed at the May

1994, NMSS Counterpart meeting with regional branch chiefs and section leaders. In a memorandum dated July 21, 1994, NMSS, in coordination with the Office of Enforcement (OE), provided instruction to the regions to issue Notices of Violations for licensees who continue to be in non-compliance with these requirements. In cases where the licensee had not informed the patient, the regions forwarded a letter to inform the licensee that, based on OGC guidance, the patient's responsible relative or guardian must be informed regardless whether the patient was a competent, consenting adult. To date, all regions have resolved 100 percent of the cases.

Currently, the staff is reviewing misadministrations that occurred from January 1, 1993, through June 30, 1994. The purpose is to determine licensee compliance with all notification, reporting, and recordkeeping requirements and ensure that the appropriate enforcement action is taken. Current information indicates that licensee compliance with misadministration notification requirements has improved relative to previous years' data. Specifically, for 1993, verbal and written notifications to the patient or responsible relative were made in 90 percent (27 of 30) of the cases; and for 1994, verbal notification was made in 100 percent (14 of 14) of the cases, while written notification was made in 86 percent (12 of 14) of the cases. Neither the 1993 nor 1994 data is firm at this time. The number of misadministrations identified for each year may change as the result of licensee reports, inspection findings, and future interpretations by OGC. The staff will continue working to resolve all outstanding issues. Attachment 7 provides data on the 1993-1994 misadministrations.

Inspections have been conducted to determine the root cause of the misadministrations that occurred during the 1993-1994 period discussed above. Results indicate that violations of the QM rule (including the related training requirement described in 10 CFR 35.25) were identified in 58 percent of the cases (28 of 44), and of those 28 cases, more than 1 violation of the QM rule was cited in 36 percent of the cases (10 of 28).

Single errors that affect multiple patients or facilities warrant continued attention by the staff to ensure that generic issues are addressed and communicated to other NRC licensees. The staff is in the final stages of developing an information notice (IN) to alert NRC licensees to an event involving a computerized treatment planning error. Although not all cases were misadministrations as defined in 10 CFR 35.2, the error resulted in 11 patients receiving an administered dose that exceeded the prescribed dose by 5 to 30 percent. The eleven patients were treated at two NRC-licensed facilities that were serviced by a third facility where the treatment planning error occurred and went undetected by the personnel involved.

The staff continues to clarify and enforce NRC patient notification requirements by publishing guidance to regional staff and medical use licensees through INs and the NMSS Licensee Newsletter. The Enforcement Manual was recently revised to provide additional guidance on how to process enforcement actions involving non-compliance with NRC misadministration notification and reporting requirements. The staff is also developing a generic letter to all medical licensees to clarify patient notification requirements. This generic letter will address several issues and will inform licensees that, in cases where the referring physician decides that, based on medical judgment, telling the patient would be harmful, the patient's relative or guardian must be informed of the misadministration whether the patient is incompetent or is a fully competent adult. The only case in which neither the patient, nor the patient's relative or guardian, is required to be informed is that in which the patient's referring physician decides that, based on medical judgment, informing either of them would be harmful to them.

Lawrence Livermore National Laboratory (LLNL) has reviewed all QM plans submitted by licensees to further reduce the likelihood of misadministrations or errors during the delivery process in those aspects of a licensed medical program that are subject to the QM rule. Also, the staff reviews licensee implementation of their QM plans, as part of reactive and routine inspections, to ensure compliance with the rule and further reduce the likelihood of a misadministration. Further discussion on this effort is provided in Section II, *"Status Report on Implementation of the QM Rule and Its Effectiveness."*

Adequacy of Misadministration Reporting Requirements

In an August 19, 1993 memorandum to the Commission, the Inspector General (IG) indicated a concern regarding the adequacy of current NRC misadministration reporting requirements. Specifically, the IG suggests that the intentional administration of non-prescribed dosages or increased dosages should be reportable to NRC, regardless of whether the event meets the 10 CFR Part 35 definition of misadministration. To address the IG's concern, the staff will consider modifying the 10 CFR Part 35 definitions of misadministration and related reporting requirements, during the major revision scheduled for completion in late 1997. As an alternative, the staff may propose to modify Part 30 to affect all materials licensees.

Program Area 3. *Rulemaking*

The MMP identifies five rulemaking actions that are in various stages of development, including three final rules, one proposed rule and one advance notice of proposed rulemaking (ANPR). Due to workload priorities and resource constraints, some of the rulemaking actions have been delayed.

In addition to the five rulemaking activities identified in the MMP, the staff is also developing one proposed rule, and recently submitted for Commission approval a second proposed revision of the Abnormal Occurrence (AO) Reporting Criteria for reporting materials events to Congress on a quarterly basis. Each effort is discussed below.

Near Completion - Final Radiopharmacy Rule
Currently, the staff is in the final stages of developing the language and associated regulatory guidance for the final rule entitled, "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use." The final rulemaking package, which will include draft regulatory guidance for public comment, is scheduled to be submitted during October 1994, for Commission approval. Since the interim final rule expires on December 31, 1994, the staff anticipates publication of the final rule by November 30, 1994, with an effective date of January 1, 1995. The corresponding draft SRPs and inspection guidance will be made available for use by regional staff by the effective date of the final rule.

Published for Public Comment - Patient Release, and Assessing Public Exposure
A proposed rule for revision of 10 CFR Part 35, and conforming revisions of 10 CFR Part 20 on patient release criteria, was noticed in the Federal Register on June 15, 1994. The rule would clarify that 10 CFR Part 35 governs the release of patients containing residual radioactivity, not 10 CFR Part 20. It also proposes a dose-based, rather than activity/radiation level-based, criterion. The comment period on the proposed rule expired on August 29, 1994, and the staff is reviewing the public comments received. The staff intends to submit a final rulemaking package during June 1995, for Commission approval. The final package will include the final Regulatory Guide.

Proposed revisions to 10 CFR Parts 19 and 20 were published for comment in the Federal Register on February 2, 1994, (59FR5132). Among the changes proposed was restoration of a provision to 10 CFR Part 20 to provide that whenever licensees are required to report exposures of individual members of the public to NRC, then those individuals are to receive copies of the report. While this portion of the proposed rule was not controversial, other portions were. The staff is working to resolve the public comments on these other issues. The final rule is currently scheduled to be submitted by December 31, 1994, for approval by the Executive Director for Operations. As an adjunct to this rulemaking, IMC 1302, "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public," and MD 8.10, "Medical Event Assessment Program," were issued to instruct inspectors to notify the appropriate local officials and provide guidance on evaluation of events. Collectively, these efforts address the issues of notifying members of the public and local

officials, and assessing public exposures from medical events.

Proposed Rulemaking on Hold - Pregnancy and Nursing
The staff effort to submit a proposed rulemaking by December 31, 1994, to reduce the likelihood of an unintended radiation exposure to an embryo/fetus or nursing infant has been delayed. This is due to reallocation of resources to the development of the radiopharmacy rule and supporting guidance.

Advance Notices of Proposed Rulemaking
The staff is in the initial stages of developing an ANPR for major revisions of 10 CFR Part 35. This is a major task that will revise 10 CFR Part 35 in its entirety to address many of the MMP action items currently considered as "open." Such issues include defining adequate training and experience criteria for several categories of individuals using byproduct material and identifying radiation safety requirements for all types of medical use currently authorized. Additionally, the proposed rule will include minor revisions to Part 31, specific to in-vitro laboratories issued a general license. As is the custom for all medical rulemakings, the staff will also solicit input from Agreement State representatives and the ACMUI, at their periodic meetings. The ANPR is scheduled for publication in March 1995. In parallel with the medical use rulemaking, the staff is scheduled to make generic revisions to 10 CFR Parts 30 and 40. These revisions are necessary to emphasize the need for licensee management commitment to provide adequate resources for the radiation safety program and support for the radiation safety officer.

In addition to the rulemaking actions identified in the MMP, there are other rulemaking and policy activities. These are development of a proposed rule on the "wrong patient" issue and revision of the Agency's policy on reporting criteria for abnormal occurrences. These efforts are described below.

Proposed Rule under Development - Wrong Patient
The staff is currently developing a proposed rule that resulted from an enforcement case, and as directed by the Commission in an SRM dated May 10, 1994. Specifically, this rule will clarify that 10 CFR Part 35, not 10 CFR 20.1301, governs any administration involving byproduct material to an individual ("wrong patient rule"). The proposed rule will inform licensees that 10 CFR Part 35 misadministration definitions and associated reporting requirements apply in such cases. However, unresolved issues remain and the staff is working to submit the proposed rule during October 1994, for Commission approval.

Revision of the Abnormal Occurrence Reporting Criteria
During October 1994, the staff submitted, for Commission approval, a Commission policy statement to revise the Agency's criteria for

reporting "Abnormal Occurrences" (AO) to the U.S. Congress. This was submitted in response to an SRM dated May 19, 1994, which directed the staff to resubmit the reporting criteria and consolidate the various changes being considered into a single revision for Commission approval as a Commission policy.

Program Area 4. *Licensing Guidance*

Several licensing guidance documents have been issued and others are under development.

Issued
Policy and Guidance Directive (P&GD) 86-04, Revision 1, was issued to provide guidance for licensing remote afterloading brachytherapy, including high-, medium-, low-, and pulse-dose rate afterloading procedures. Regulatory Guide (RG) 10.5 was revised to provide additional guidance on licensing medical programs of broad scope. It is scheduled to be published for public comment soon, and the associated SRP for license reviewers was issued during June 1994, for use by regional staff. P&GD 94-04, "Identification of Licenses where Significant Licensing Action Warrants an Onsite Inspection," was issued to provide guidance for license reviewers on identifying material licensees whose programs have undergone significant growth and warrant an onsite inspection prior to the next routine inspection. This is a followup action to the inspections of changing/expanding licensed programs that were conducted by February 1994. IMC 1246 was issued to provide additional guidance on license reviewer training qualifications.

Under Development
Although RG 10.8, "Guide for the Preparation of Applications for Medical Use Programs" will not be revised in its entirety until the major revision to 10 CFR Part 35 is completed, evolution in the medical application of byproduct material has created a need to partially revise RG 10.8 in the interim to address all types of medical use currently authorized. Therefore, eight working groups, composed of Headquarters and regional staff, were established to develop new, or revise existing, licensing guidance to reflect current licensing practices. Existing guidance currently under revision includes licensing for teletherapy; mobile nuclear medicine; and remote afterloading brachytherapy. New guidance is under development for gamma stereotactic radiosurgery; manual brachytherapy to include the use of strontium-90 eye applicators; and radiopharmaceutical therapy to include the therapeutic use of iodine-131, strontium-89, and other beta-emitting radiopharmaceuticals for therapy. New guidance will also be developed to clarify NRC's training and experience criteria for physician authorized users. All guidance described above will be issued as appendices to existing RG 10.8, for medical licensees. These draft appendices are scheduled to be published for public comment during September 1995. The Agreement

States and ACMUI will be provided an opportunity to comment on such guidance during the drafting stage. These appendices will be re-evaluated after the major revision to 10 CFR Part 35 is complete. In addition, the staff is revising three regulatory guides to provide guidance for licensees to implement the final radiopharmacy rule.

The staff will also develop licensing guidance for issuing master materials licenses for medical use, such as those licenses currently issued to the U.S. Departments of Navy and Air Force. As discussed below in Program Area 5, the corresponding inspection guidance was issued.

Program Area 5. *Inspection Guidance*

Several inspection guidance documents have been issued and others are under development.

Issued
The staff issued IMC 2810 to provide guidance on the inspection of master materials programs. Temporary Instructions (TI) were issued for inspection of licensees authorized for remote afterloading brachytherapy procedures (IMC 2800/024) and quality management programs (IMC 2800/025). As discussed under Program Area 2, MD 8.10 was recently issued to provide inspection guidance for medical events, in particular, misadministrations. In July 1993, the staff issued instructions to the regions to identify and inspect medical licensees whose programs had undergone significant growth. All such inspections were completed by February 1994, with no significant issues identified. As discussed previously, the staff also issued corresponding licensing guidance to ensure that this category of licensee is promptly identified and an onsite inspection performed, when indicated. Other inspection guidance issued includes Inspection Procedure (IP) 87103, and IMC 1302. IP 87103, "Inspection of Incidents at Nuclear Materials Facilities," was issued to provide additional guidance to management, when determining whether to dispatch one or more regional inspectors to conduct a special inspection in response to an incident, and to provide additional guidance to inspectors for determining the sequence of events leading to the event, the root cause, and the conditions that existed at the time the incident occurred. IMC 1302, "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public," was issued to provide generic and specific guidance on the course of action to follow in situations involving radioactive material in the public domain. The staff also addressed the IIT finding on the PrimeAlert-10 area radiation alarm. See Attachment 6, *"IIT Action Item Update,"* action item 1c., for further information.

Under Development
A working group, composed of Headquarters and regional staff, has been

established to make major modifications to IMC 2800, "Materials Inspection Program." The revised guidance will focus on the core and non-core inspection program for materials licensees, greater flexibility in increasing or decreasing inspection frequencies and more emphasis on performing reactive inspections. The revision to IMC 2800 is scheduled for completion during January 1995.

The staff will continue to explore whether it is feasible for third parties to conduct routine inspections of NRC-licensed facilities, in lieu of a routine NRC inspection. Such third parties could include the American College of Nuclear Medicine, American Board of Radiology, or other medical professional organizations that have an interest in developing or revising an existing audit program, to meet NRC inspection goals. The staff requested and received guidance from OGC indicating there is no legal prohibition on the use of third parties to conduct inspections on behalf of NRC. At present, the issue of third-party inspections is not a high priority action item in the MMP. Additionally, after completion of the Functional Process Improvement (FPI) study (discussed under Program Area 8), the staff will determine whether analogous management principles can be applied effectively to the inspection program to increase efficiency.

Program Area 6. *Enforcement*

The staff has completed several actions to provide additional guidance on NRC's enforcement policy. This includes modifications to the enforcement manual, issuance of enforcement guidance memoranda (EGM), and initiation of an "Enforcement Policy Review Team," that will, as part of its tasks, reassess the materials civil penalty policy.

Enforcement Manual Revisions
Although issued prior to implementation of the MMP, it is important to discuss the following two staff actions to implement the QM rule. In a Federal Register notice dated April 2, 1993 (58FR17321), changes to NRC's enforcement policy were published. The change modified examples to help NRC staff determine the safety and regulatory significance of various violations of the QM rule for medical licensees. Enforcement decisions focus on violations that indicated a programmatic deficiency. The change also reflects the fact that violations that represent isolated mistakes, of limited consequence, that are not associated with a programmatic weakness of the licensee's QM program, will be considered less significant. In addition, on April 3, 1993, EGM 93-005 was issued to provide guidance on this modification to the enforcement manual.

In July 1994, the staff modified the enforcement manual to provide additional guidance on how to process enforcement actions involving non-compliance with NRC misadministration notification and reporting requirements.

Enforcement Guidance Memoranda
On September 14, 1993, EGM 93-008 was issued to provide guidance on the System of Records maintained for enforcement actions against individuals. Further, OE distributes a list semiannually to identify individuals who have any restriction from NRC-licensed activities which license reviewers should review prior to issuance of any licensing action. Quarterly, NUREG-0940, Enforcement Actions, Significant Actions Resolved," is issued and orders to individuals are included in Section A unless a hearing has been requested. Also, copies of NUREG-0940 and orders to, individuals are routinely forwarded to Agreement States.

From late 1992 through early 1994, the staff conducted a weekly enforcement panel, consisting of Headquarters and regional staff, to discuss current inspection and enforcement cases, to ensure consistent application of NRC's enforcement policy in cases involving violations of the QM rule described in 10 CFR Part 35. On March 23, 1994, EGM 94-003 was published to provide additional guidance for distinguishing between programmatic and isolated failures in the implementation of a licensee's QM program.

On February 10, 1994, EGM 94-001 was issued to provide guidance and instruct the regions to include the Board of Trustees for medical licensees on distribution for all NRC escalated enforcement actions against the licensed facility.

Additionally, on July 26, 1994, EGM 94-011 was issued to provide guidance on the "wrong patient" issue, as mentioned previously under Program Area 3. Specifically, the 10 CFR Part 35 definition of misadministration and associated reporting and notification requirements apply to any administration involving byproduct material to an individual ("wrong patient"). As a result, this type of event is not considered a violation of 10 CFR 20.1301.

Program Area 7. *Management and Radiation Safety Officer Responsibility*

Currently, there are primarily three efforts to provide additional guidance, to licensees, on the responsibilities of executive management and the radiation safety officer (RSO) for effective oversight of the licensed program and safe use of licensed material. First, the staff is near completion on development of a NUREG to provide guidance on effective management of radiation safety programs at medical facilities. The NUREG introduces the concept of the "management triangle" whose elements are executive management, the RSO, and radiation safety committee, when required. The draft underwent significant peer review by various aspects of the medical community, and was generally well received. The NUREG will be issued as draft for public comment, to seek additional comments from members of the public and the medical community.

Secondly, as mentioned under Program Area 3, *"Rulemaking,"* the staff will propose to revise Parts 30, 40, and 70 to emphasize a commitment by licensee executive management for support of the radiation safety program including support for the RSO.

Finally, the staff is also initiating steps to evaluate the adequacy of the radiation safety component of training programs completed by RSOs, and physicians who request authorization for the use of byproduct material. Training programs to be evaluated include residency training programs and programs offered outside of a residency program, such as those provided by private or professional organizations or programs in which the physician successfully obtains work and clinical experience in a private office or clinic, while under the supervision of a physician preceptor. This effort is part of the major revision of 10 CFR Part 35 discussed in program area 3.

Program Area 8. *Information Management Systems*

NMSS' Division of Industrial and Medical Nuclear Safety staff developed and uses a tracking system to monitor all division action items, including those identified in the MMP. This system allows the staff to monitor the progress of technical assistance requests from the regional offices, the development of guidance documents, responses to Congressional inquiries, and other routine tasks associated with the regulatory program.

A working group composed of NRC and Agreement State staff developed a prototype event database that was distributed to participants for use and comment during the month of May 1994. This is an enhanced version of the existing AEOD non-reactor event database and is referred to as the Materials Events Database. The purpose of the database is to provide a comprehensive sole source for information on medical events (particularly medical misadministrations), and other non-reactor events, that can be periodically evaluated and analyzed by the staff. The enhanced database includes NRC licensee data and Agreement State licensee data reported to NRC by Agreement States. An interim version of the database was recently distributed to NRC program offices and Agreement States. The staff will continue to modify the database based on current needs.

Although not identified in the MMP, NMSS is currently performing a 7-month study of the materials licensing process, with the objective of identifying recommendations for streamlining and automating the current process. Although not limited to medical licensees, it is anticipated that this project will be of great benefit to medical licensees in terms of providing cost savings in resources expended in the NMSS materials licensing process, improving communications with materials licensees, and decreasing the time needed to complete a licensing action. This

study was originally developed under the Business Process Re-engineering Initiative. Its objective is to use Functional Process Improvement (FPI) to conduct an analysis of the materials licensing process work flow to determine how the NRC processes an application from receipt to issuance, with the long-term goal of establishing a more efficient and potentially automated processing of material license applications and amendment requests. A major goal is to determine ways to streamline, automate, and avoid duplication of effort in processing a license request. NMSS is also analyzing the Licensing Tracking System, to improve its usability by licensees and NRC staff, and its compatibility with other Agency electronic information systems.

Program Area 9. *Research Studies*

Currently, there are three research contracts in progress, with final reports expected by March 1995. Final reports on Human Factors Evaluations for brachytherapy and teletherapy procedures are expected during January and March 1995, respectively. A final report on Quality Control/Quality Assurance (QC/QA) for Gamma Stereotactic Radiosurgery is expected during December 1994. The final report on QC/QA for Remote Afterloading Brachytherapy was received during mid-September 1994, and will soon be published as a NUREG/CR. The risk analysis methodology development, begun during the QC/QA projects, culminated in a workshop held during August 1994, and will be ongoing. The results of all contractor findings will be issued as NUREGs and considered by the staff during the major revision of Part 35 discussed in Program Area 3, *"Rulemaking."*

NUREG/CR-6088, "Summary of 1991-1992 Misadministration Event Investigations," was issued during February 1994, and subsequently distributed to NRC medical use licensees and the Agreement States. There were seven major findings on the root cause and contributing factors for each misadministration investigated. A more detailed discussion of these findings is provided in Item F. *"Independent Analysis,"* in *II. "Implementation of the QM Rule and Its Effectiveness."*

NCRP Commentary No. 9, "Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus or Nursing Child" was issued on May 1, 1994. This commentary was developed to assist the staff in identifying regulatory requirements regarding the unintended exposure of the embryo, fetus or nursing child as a result of medical procedures involving the administration of radioactive material. This commentary supplements NCRP Commentary 7, "Misadministration of Radioactive Material in Medicine - Scientific Background, published November 1, 1991.

II. *STATUS REPORT on IMPLEMENTATION of THE QM RULE and ITS EFFECTIVENESS*

Since the QM rule became effective on January 27, 1992, the staff has completed or initiated several actions to implement the rule. These include: (1) providing training to LLNL staff who review the QM plans submitted by licensees; (2) providing training for regional staff who inspect implementation of a licensee's QM plan; (3) conducting a weekly enforcement panel, consisting of Headquarters and regional staff, from November 1992 to March 1994, to ensure proper identification of violations and consistent application of NRC's enforcement policy; (4) providing additional enforcement guidance; (5) providing clarification of QM requirements and guidance described in associated Regulatory Guide 8.33; (6) assisting the Agreement States with implementation of the rule; conducting workshops; (7) making presentations at professional meetings; and (8) discussing implementation results with the ACMUI.

A. *Early Implementation*

The final QM rule became effective on January 27, 1992, for certain categories of medical licensees. However, in December 1991, the Office of Management and Budget (OMB) expressed concerns regarding the information collection requirements (ICRs) associated with the rule. On June 26, 1992, OMB disapproved the ICR for the final rule. On August 14, 1992, NRC sent a letter to OMB certifying a Commission override of the OMB disapproval. As a result of the OMB issue, medical licensees were confused about whether the QM rule was, or was not, in effect. Therefore, the staff forwarded letters dated April 8, 1992, to all medical licensees, either acknowledging receipt of their QM plan, or reminding them of the necessity of submitting a QM plan. Additionally, in a letter dated September 1992, NRC forwarded a letter to all medical licensees, describing the NRC override of OMB's disapproval of the ICR. This letter stated that NRC would exercise discretion not to take enforcement action for violations that occurred between June 26, 1992, and September 10, 1992, because of the confusion caused by OMB's disapproval. Therefore, full implementation of the QM rule was delayed because of unforeseen events.

B. *Contract Support*

During this time, the staff sought contractual support for the review of QM plans submitted by licensees, to ensure prompt and appropriate implementation of the rule. A contract was let with LLNL during July 1993. Soon after, a pilot program was conducted by LLNL and NRC staff, to compare submitted QM plans with implementation of the plan by the licensee. Ten QM programs were selected based on location and the date of the next scheduled routine inspection. During the pilot program, NRC staff observed that, in nine of the ten programs reviewed, the licensee had implemented a QM program that was much more comprehensive than the

written program submitted for NRC review. NRC subsequently provided training to LLNL staff, and its subcontractors, on various issues, including QM rule requirements, guidance described in RG 8.33, the objectives and conduct of the reviews, and deficiency letter format.

Oversight of the contractor required significant NRC resources partly because of the complexity of medical uses requiring a QM program, and LLNL reviewers' difficulty in determining whether the licensees' QM plans were adequate to ensure compliance with a performance-based rule. LLNL reviewed over 1700 QM plans submitted by licensees, and inherently, because of the number of plans reviewed, there were minor inconsistencies in the reviews, in a limited number of cases. Specifically, there were occasional inconsistencies among reviewers, and by individual reviewers, with respect to the findings identified for similar or identical QM programs reviewed. This was observed in a limited number of cases where the QM plans were prepared by the same consultant. Also, less than two percent of NRC licensees informed the staff that they disagreed with the LLNL findings, or complained about apparent inconsistencies in the reviews. In most cases, the staff did not find evidence to substantiate these comments, based on a re-review of the QM program in question by NRC staff. The contract dollars available for the LLNL reviews allowed for an initial review of each submitted QM plan, and a re-review of approximately 20 percent of submitted plans. The unexpected need to re-review a substantial number of QM programs found to be inadequate (approximately 80 percent of those submitted) resulted in the need to rely on NRC regional staff to conduct the re-reviews. The staff issued a TI to review the adequacy and implementation of licensees' QM programs at the time of a routine or reactive inspection. Additionally, beginning in June 1994, NMSS held several biweekly telephone conferences with regional staff to resolve administrative issues surrounding the review of the QM plans and processing of contractor-generated deficiency letters.

LLNL has completed all task work, including performing the QM plan reviews, and preparing letters for regional staff to forward that either describe weaknesses and or omissions in the submitted plans, or indicate that the QM plan appears to meet the requirements of the QM rule. LLNL also established a database to provide NRC staff with periodic status reports on progress to date on the conduct of the reviews, and its findings. A draft final project report from LLNL on its findings was recently received and is currently being reviewed by the staff.

C. *Staff Effort to Ensure Full Implementation*

Simultaneous with oversight of the contractor, the staff has taken several actions to ensure full implementation of the rule. This includes providing guidance and training to regional staff, licensees, and Agreement States on QM requirements and related inspection;

conducting a weekly enforcement panel consisting of Headquarters and regional personnel, to ensure proper identification of violations and consistent application of the NRC's enforcement policy; and identifying necessary revisions to the QM rule or associated RG 8.33. Each area is described in more detail below.

The staff has provided training to regional staff on the QM rule and its implementation, inspection of QM plans, the purpose of contract support, the regions' role in assisting the contractor, and the status of the reviews of QM programs to date. Additionally, three regional offices, supported by Headquarters staff held licensee workshops that focused on QM requirements, RG 8.33, and the results of prior reviews of submitted QM programs. These workshops benefited both parties highly, and allowed licensees an opportunity to ask questions and to provide input on the rule. The staff has also provided speakers, for many NRC and Agreement State medical licensee seminars and workshops, on the topic of compliance with the QM rule. Since June 1993, each *NMSS Licensee Newsletter* has had an article informing licensees of the progress and findings of the QM program reviews. These articles provide a vehicle for NRC to clarify issues identified by the staff, medical licensees, and interested parties.

D. *Inspection Effort*

A draft TI procedure was provided for use to regional staff during training sessions held in May and June 1992. In April 1994, the regions were provided a second draft TI for use and comment. On August 1, 1994, the final TI (IMC 2800/025) was issued that established areas of inspection and created a procedure for determining compliance with a performance-based rule. Training was provided to regional staff by Headquarters staff during February through March 1994. The staff will compile data collected through this TI to determine the effectiveness of the rule in reducing the number of mistakes or errors in the dose delivery process. This information will also assist the staff in identifying necessary modifications to the rule or guidance and might be useful as an indicator of the number of procedures, performed by NRC licensees, that require a written directive. The number is recorded by inspectors on the QM TI field notes and used to ensure that a statistically valid sampling method is used to evaluate the implementation of a licensee's program. This information, including the number of written directives prepared by the licensee, will be included in the TI data base and available for analysis by the staff.

As discussed in program area 2, *"Misadministrations and Patient Followup,"* a review of preliminary data indicates a total of 48 reported misadministrations for the period of January 1993 through June 1994. Inspections conducted in response to these events identified violations of the QM rule (including the related training requirement described in

10 CFR 35.25) in 58 percent of the cases (28 of 48), and of those 28 cases, more than 1 violation of the QM rule was cited in 36 percent of the cases (10 of 28).

E. *Enforcement Issues*

With respect to enforcement issues, NRC staff established a Quality Management Review Committee to review all violations associated with the QM rule, including those that resulted in a misadministration. The purpose of the weekly committee meeting was to address current inspection and enforcement issues and specific cases to ensure that violations were properly identified and NRC's enforcement policy was applied consistently where QM violations were identified. Committee members included representatives from NMSS including Myron Pollycove, M.D., (NRC's Medical Visiting Fellow), OE, the regions, and during the last calendar quarter, a representative from OGC. The committee met weekly for one year, and as needed thereafter.

F. *Independent Analysis*

NRC contracted with the Idaho National Engineering Laboratory (INEL) to conduct independent team investigations of misadministrations over a two-year period to perform a root cause analysis. The objectives of these reviews were to: 1) develop a more complete understanding of causes and contributing factors that result in misadministrations; 2) use the information to help determine whether the scope and depth of the QM rule are adequate; and 3) provide information to licensees. INEL conducted seven on-site team investigations with a team of three or more members with relevant expertise in the disciplines of radiation oncology, nuclear medicine, medical physics, risk analysis, and human factors. The INEL team investigated three manual brachytherapy, one teletherapy, two high-dose-rate remote afterloading, and one iodine-131 therapy misadministrations.

Seven major findings were identified by these investigations as common to several misadministrations. These findings were: 1) many misadministrations occurred due to a lack of procedures, or procedures that were incomplete or ambiguous; 2) although the QM rule has the potential to prevent many misadministrations, most licensees had not effectively implemented their QM program; 3) a lack of substantial, direct involvement on the part of the authorized users and RSOs is often a direct cause; 4) unique conditions or changes in routine are often factors; 5) hardware failures are rare, but many had severe consequences; 6) corrective actions were often narrow in focus; and 7) licensees often lacked systematic methods for detecting and mitigating misadministrations. In addition, INEL analyzed the AEOD database for Abnormal Occurrences, updated for 1987-1991, and all 1992 misadministrations, to evaluate common causes of misadministrations and

their possible preventability through proper QM program implementation. From the results of this analysis, INEL concluded that proper implementation of QM plans could have prevented a large majority (up to 94 percent) of past misadministrations. Also, based on their review of QM plans, LLNL observed that the '87-91 misadministrations would likely be eliminated or reduced as a result of implementation of the QM rule. INEL issued their final report in February 1994, NUREG/CR-6088, "Summary of 1991-1992 Misadministration Event Investigations." Copies were distributed to all NRC medical use licensees and the Agreement States. The contract with INEL has been continued to allow for team investigations for root cause analysis of up to four misadmininstrations per year.

G. *Staff Recommendations*

In response to the SRM dated June 19, 1991, on the QM rule, the staff submits the following regarding the need for rulemaking on comprehensive quality management, and on the status of the associated ANPR published in the Federal Register on October 2, 1987 (52FR36949). The staff believes that, at this time, no changes in the scope or focus of the rule is necessary. Rather, the staff will continue to gather information by evaluating the adequacy of licensee QM plans at the time of inspection, determining the root cause of misadministrations, identifying violations of the QM rule, and collecting and analyzing licensee data on the number of procedures performed that require a written directive. This will allow the staff to make an informed decision on the need for rulemaking on comprehensive quality management.

At present, the staff does anticipate a need, based on the experience gained during implementation of the rule and the contractor's findings as a result of reviewing the submitted QM programs, to modify 10 CFR Sections 35.2, 35.32, 35.33, and RG 8.33, "Quality Management Program." Modifications are needed to address the administration of fractionated doses in radiopharmaceutical therapy and brachytherapy; addition of strontium-90 eye applicator to the definitions and RG 8.33; and clarification of certain definitions contained in 10 CFR Section 35.2. Recently, the staff identified the need to revise the QM rule and associated guidance to address the use of strontium-90 eye applicators because they were not addressed specifically in the rule. As a result, NRC IN 94-17: "Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use," published on March 11, 1994, clarified this issue and reminded licensees that strontium-90 eye applicators were brachytherapy devices, and a QM plan was required. These issues will be addressed as part of the major revision to 10 CFR Part 35.

H. *Agreement State Implementation of the QM Rule*

A number of Agreement States have expressed dissatisfaction with the division of compatibility assigned to various aspects of the QM rule. This issue was discussed with the Commission during a briefing that occurred on February 8, 1994. A presentation was made by Robert Kulikowski, Ph.D., Director, New York City, Director, Bureau of Radiological Health, serving as Chair of the Organization of Agreement States. Since that time, NMSS staff has been requested to review several suggested Agreement State regulations for implementing the rule and found inconsistencies in a number of the proposed requirements by the States. In addition, the staff has reviewed the model regulations for implementation of the QM rule, as prepared by the Conference of Radiation Control Program Directors, Inc. (CRCPD) SR-6 Committee. Essentially, the staff determined that the language proposed by this Committee would not satisfy the assigned Division Level II compatibility for the QM rule, if adopted by the Agreement States as written. NRC staff has provided these comments to the CRCPD SR-6 Committee and plans to meet with the committee at the Agreement State meeting scheduled for the week of October 24, 1994. Due to the perceived impending revision of 10 CFR Part 35, the Agreement States have expressed a strong reluctance to adopt the current QM rule, and some of the Agreement States will not meet the January 27, 1995, implementation date.

III. *THE ACMUI*

In recent years, the Commission has placed an increased emphasis on the use of the ACMUI, its composition, and administrative procedures. As a result, the committee meets more frequently (at least twice per year), is involved much earlier in the rulemaking and guidance development process, and serves as a major conduit for the exchange of information with various members of the medical community. Additionally the committee membership has increased and diversified to represent other areas of expertise, and to provide advice and recommendations on a wide variety of medical use issues.

A. *ACMUI Administrative Issues*

Currently, there are several efforts to address key administrative issues associated with management and use of the committee. Specifically, the staff is in the process of developing bylaws and changing committee membership to represent additional expertise. The staff is also implementing procedures for the selection of new committee members, as directed by the Commission in an SRM dated May 4, 1994.

The ACMUI currently has 12 members representing various medical specialties and other areas of expertise identified by the staff or Commission. The present members of the committee are: (a) physician specialists in nuclear cardiology, therapeutic radiology, nuclear

medicine research and nuclear medicine; (b) a nuclear pharmacist; (c) a medical physicist with emphasis in nuclear medicine; (d) one individual with experience in State regulation of radioisotopes; (e) a patient's rights and care advocate; (f) a health care administrator; and (g) a representative from the FDA. At present, the staff is evaluating nominations for the position of radiation therapy technologist/medical dosimetrist.

During the May 1994 meeting, the ACMUI strongly recommended that the Commission re-establish a second medical physicist position, with an emphasis in radiation therapy. This is necessary because of the diverse technical expertise required in the medical use areas of teletherapy and brachytherapy, versus nuclear medicine and radiopharmaceutical therapy. The staff agrees with the ACMUI, in that both specialties should be represented to facilitate a meaningful exchange of information, and serve as a resource to the staff and conduit to all portions of the medical community affected by NRC regulations. The staff recently forwarded its recommendation on this issue in a separate memorandum to the Commission, for approval.

To date, the ACMUI has not operated under a set of formal bylaws. In a memorandum dated September 16, 1994, the staff submitted a set of bylaws, developed with input from the committee and discussed at the May 1994 meeting of the ACMUI. The bylaws describe the procedures to be used by the ACMUI in performing its duties, and the responsibilities of the members. They were developed based on those used by the Advisory Committees on Nuclear Waste or Reactor Safety. The bylaws have as their purpose fulfillment of the Committee's responsibility to provide objective and independent advice to the Commission through NMSS, regarding the development of standards and criteria for regulating and licensing medical uses of byproduct radioactive material. The procedures are to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, and the resulting reports represent the best of which the committee is capable. The bylaws will be discussed at the ACMUI meeting scheduled for November 17 and 18, 1994, to be held in the Advisory Committee Conference room, Two White Flint North.

B. *Policy and Technical Issues Discussed with the ACMUI*

In recent years, the number and variety of medical use issues to be resolved by the staff and discussed with the ACMUI have increased significantly. The medical expertise represented by the committee members has proven invaluable when the staff is developing new or revised regulations, and considering the impact of the rule on the practice of medicine. Key issues discussed with the staff during the past year include: (a) implementing the QM rule; (b) developing the final radiopharmacy rule, and proposed rules for revision to Part 35

patient release criteria and prevention of inadvertent administrations of byproduct material to the embryo/fetus or nursing infant; (c) training and experience criteria for the use of byproduct material; (d) defining adequate supervision of individuals responsible for the safe use of byproduct material; (e) misadministration notification and reporting requirements; (f) defining who constitutes the wrong patient; and (g) brachytherapy issues including the safe use of remote afterloading devices and fractionated treatment regimes. In addition, the committee was provided two status reports on the revision of the Abnormal Occurrence reporting criteria. The staff will continue to consult with the ACMUI during the development of regulations, standards, and guidance to fully understand medical use issues and the impact of NRC regulation on the practice of medicine.

IV. *MAJOR PROGRAM AREAS CURRENTLY ADDRESSED*

Within the MMP program areas, some regulatory issues require more resources than others to fully resolve. Such issues include defining adequate training and experience criteria for physicians, physicists, RSOs and other licensee personnel; addressing the evolving medical technology of brachytherapy, particularly remote afterloading procedures; licensing medical research involving human subjects; and conducting the NAS study. Each issue will be discussed in more detail.

A. *Training and Experience Issues*

Soon, a major area of focus will be to identify adequate radiation safety training and experience criteria for individuals responsible for the safe use of byproduct material. Historically, this has been an area of great interest to NRC staff, the ACMUI and the Commission, particularly physician training and experience criteria. These criteria were not revised in the last major revision to Part 35, which became effective April 1, 1987; however, they are likely to be on the critical path in the next major revision of Part 35. During recent months, NRC has received several communications from medical organizations and their members regarding adequate radiation safety training and experience criteria for various types of authorized users of byproduct material. Clearly, there are diverse opinions within the medical community on adequate criteria, and a wide variety of criteria described in Part 35 for different types of authorized use that are not consistent. As a result, there are a number of actions the staff intends to take to address this issue; however, the staff will need to consider the impact of the findings of the NAS study.

As an initial step, the staff will solicit comment in the 10 CFR Part 35 ANPR, discussed previously under Program Area 3, *"Rulemaking."* Questions may include, but are not limited to, "Should different criteria be applied to physicians who request diagnostic

radiopharmaceuticals for single organ imaging?;" "How prescriptive should the regulatory criteria be and at what level in the medical services delivery system should NRC training and experience criteria be applied?;" "How can NRC establish criteria today that will be suitable for the twenty-first century?;" "Should status as an authorized user, in and of itself, be sufficient criteria for an individual to be identified as RSO?;" and "Should NRC narrowly focus on radiation safety, or should overall patient well being and risk be considered?"

Additionally, a related issue that warrants clarification is authorized users' responsibilities for the safe use of byproduct material by individuals who work under their supervision (10 CFR 35.25). Such individuals may include technologists, pharmacists, dosimetrists, physicists, and nurses. It is clear that, in some misadministration cases, supervised individuals have not been provided adequate instruction on licensee procedures, including QM or regulatory commitments, or followed the instructions provided by the authorized user to ensure the safe medical use of byproduct material.

The staff notes that there are a variety of views and interests inside and outside the medical community on the issue of adequate radiation training and experience criteria for individuals authorized by NRC. Therefore, NRC staff will provide several opportunities for input from these various interest groups by making presentations at professional meetings, conducting public workshops, meeting with the Agreement States, discussing these issues with the ACMUI, and issuing the Part 35 ANPR. In this regard, the staff is considering whether a full-fledged enhanced participatory approach should be followed for the major revision of 10 CFR Part 35, as discussed in program area 3, *"Rulemaking."*

B. *Brachytherapy*

The radiation therapy specialty of brachytherapy, particularly remote afterloading brachytherapy, continues to evolve and has become more complex, both to perform and regulate. For example, the staff recently evaluated several events involving errors in the delivery of brachytherapy doses that are fractionated (the prescribed dose is delivered in more than one administration). At the May 1994 ACMUI meeting, the staff sought input from the committee on current trends in brachytherapy. The ACMUI advised the staff that errors in the delivery of the prescribed dose for brachytherapy procedures, such as those recently evaluated by the staff, warranted further review to determine whether additional regulatory oversight is indicated to further reduce the likelihood of such errors. As a result of reviewing recent events, and identifying other emerging brachytherapy issues, the staff developed a matrix to identify regulatory issues associated with the use of all types of brachytherapy currently authorized. This matrix identifies

actions to resolve the regulatory issues, and appropriate time frames for completion of such actions. Most of these issues were identified after development of the MMP, and became apparent as licensees implemented their QM programs. The staff will solicit input from the medical community on brachytherapy issues by making presentations at various meetings of professional organizations during the next six months, and at ACMUI meetings. The information collected will affect the major revision of Part 35 and associated guidance.

C. *National Academy of Sciences Study*

The staff secured contract support from the Institute of Medicine (IOM), NAS to conduct an independent review of the NRC's medical use regulatory program, as directed by the Commission in an SRM dated December 21, 1992. The project has three major goals: 1) an examination of the overall risk associated with the use of ionizing radiation in medicine; 2) an examination of the broad policy issues that underlie the regulation of the medical uses of radioisotopes; and 3) a critical assessment of the current framework for the regulation of the medical uses of byproduct material. The IOM has been asked to provide recommendations on two major issues: 1) a uniform national approach to the regulation of ionizing radiation in all medical applications; and 2) appropriate criteria for measuring the effectiveness of the regulatory program(s) to protect public health and safety. The IOM final report is expected in January 1996, after which the staff will review the findings and propose modifications to the medical use regulatory program, if indicated.

On request, the staff provides NAS with background information regarding various aspects of the medical use program, including: (a) the licensing, inspection and enforcement process; (b) jurisdiction issues; (c) management plans and processes used by NRC managers to provide oversight of the program; and (d) NRC's coordination with the Agreement States, States, and other Federal agencies. Additionally, the staff has prepared written statement or testified before various NAS subcommittees to provide comprehensive information on the regulatory program.

As mentioned previously, if the NAS recommends major modifications to the direction of the medical use regulatory program, the MMP, as described herein, will be revised as directed by the Commission, based on the results of these findings.

D. *Research Involving Human Subjects*

During the last year, steps have been taken to provide explicit, written guidance to regional license reviewers and inspectors regarding permissible activities with human subjects and byproduct material. Long-standing policy had been to authorize, by license condition, only

medical licensees who had licenses of broad scope and who had either a Radioactive Drug Research Committee (RDRC) or Institutional Review Board (IRB) approved by the FDA. This policy was partially expressed in guidance memoranda but had never been included in a Standard Review Plan or Inspection Manual procedure. A revised Standard Review Plan for applications for licenses of broad scope was issued in June 1994 and includes an appendix for regional reviewers to determine when medical research may be authorized by the region, and when NMSS must be involved. RES will soon publish for comment a revised RG 10.5 based upon the new SRP. Specific IP 87100 Appendices were modified March 7, 1994, to include a section on research involving humans. Inspectors are to verify that the licensee's committees (IRB or RDRC) are approved by the FDA, that institutional procedures require review by these committees, and that the licensee has implemented procedures to require that human subjects provide informed consent before initiation of the research.

The final rule would allow licensees, covered by the "Federal Policy for the Protection of Human Subjects," as adopted by another Federal agency to conduct human research without prior NRC approval. If a licensee's activities are not funded by another Federal agency which has adopted the Federal Policy, the licensee must apply for and receive a license amendment prior to conducting research involving human subjects using byproduct material. The proposed research must receive approval by an IRB and the human subjects must provide informed consent. In the proposed rule, the Commission solicited public comment on the number and type of research activities which would not be funded by another Federal agency which has adopted the Federal Policy, and thus would require a license amendment. There were no public comments received on this matter.

V. *RESOURCE ISSUES*

In SECY-93-244, the staff estimated a total of 50 direct staff full-time equivalent (FTE), over an approximate 5-year period, to fully resolve all MMP action items. For budget purposes, it was assumed that the required total FTE would be expended at a constant rate, for all affected offices (NMSS, RES, AEOD, OGC and OE). Inherently, implementation of the MMP during the first fiscal year confirms that the actual rate of FTE expenditure is not constant. In fact, the actual FTE expenditure for FY94 appears to be 50 percent greater than originally estimated (15.0 versus 10.0 FTE), and has been accommodated by reprogramming available resources. This appears to be partly caused by the staff effort to resolve many short-term action items, initiate action on certain long-term action items, promulgate several proposed and final rules, and develop the associated guidance that affects medical use licensees. Based upon FY94 FTE data, the staff projects that the total FTE expended to resolve all MMP action items will probably exceed the original estimate of 50 FTE. Specifically, resolving the action items identified in the misadministration,

rulemaking and guidance program areas will likely require the expenditure of resources in excess of that originally estimated. Additionally, this projection does not account for the impact of unforeseen events such as significant medical misadministrations, events/incidents, Congressional inquiries, the results of the NAS study, or the identification of additional related action items.

Obviously, certain aspects of the medical use program require more resources than others, and may require resources to be expended at unpredictable rates. For example, the medical use of remote afterloading brachytherapy, as discussed previously, has become more complex than predicted and will require more resources than initially estimated. The evaluation and analysis of misadministrations, and clarification of or revision to the related notification, reporting, or record keeping requirements will continue to require significant resources to fully resolve. The staff continues to develop guidance in this area and to evaluate the effectiveness of the QM rule, and the adequacy of RG 8.33, to determine whether modifications are needed to further reduce the likelihood of errors during the treatment delivery process. Additionally, the training and experience criteria issues described above will require significant resources to resolve. Although the staff had identified the need to determine the adequacy of NRC's criteria, the recent receipt of several letters from various medical professional organizations, and the apparent interest in this issue expressed by certain members of Congress, will likely increase the staff effort and may require more resources than originally estimated. To fully resolve these and other regulatory issues as they emerge, the staff will continue to adjust the priority associated with certain MMP action items, or routine work associated with the medical use program, to respond to unforeseen events and accommodate changing needs.

The staff intends to continue the Medical Visiting Fellows Program, thereby providing an additional resource for the staff. To date, two individuals have held the position of Fellow. Mark Rotman, Pharm.D., a board certified radiopharmacist, worked with the staff primarily on radiopharmacy issues for approximately 18 months, from December 1991 until June 1993. Myron Pollycove, M.D., a nuclear medicine specialist, currently works with the staff and will complete his 4-year term in October 1995. The staff will soon issue a Federal Register notice to solicit a physician or physicist with expertise in radiation oncology or therapeutic radiological physics. It is expected that the Fellow will join NRC in late 1995 or early 1996.

CONCLUSION:

In summary, the MMP has been fully implemented and is on schedule. Since receiving Commission approval on September 30, 1993, the staff has addressed many short-term action items while initiating work on long-term action items, such as the development of guidance and rulemakings efforts. The staff does not recommend any modifications to the scope or focus of the MMP, but

recognizes that Commission direction in response to the NAS findings, Congressional inquiries or unforeseen medical events could redefine the MMP and other portions of the medical use regulatory program.

COORDINATION:

OGC has no legal objection to this paper.

James M. Taylor
Executive Director
for Operations

Attachments:
1. Gantt Chart
2. MMP Statistics
3. Information on Action Items by Program Area
4. Major Documents Issued Since 8/93
5. Major Documents Near Completion
6. IIT Action Item Update
7. 1993-1994 Misadministration Data
8. List of Public Presentations

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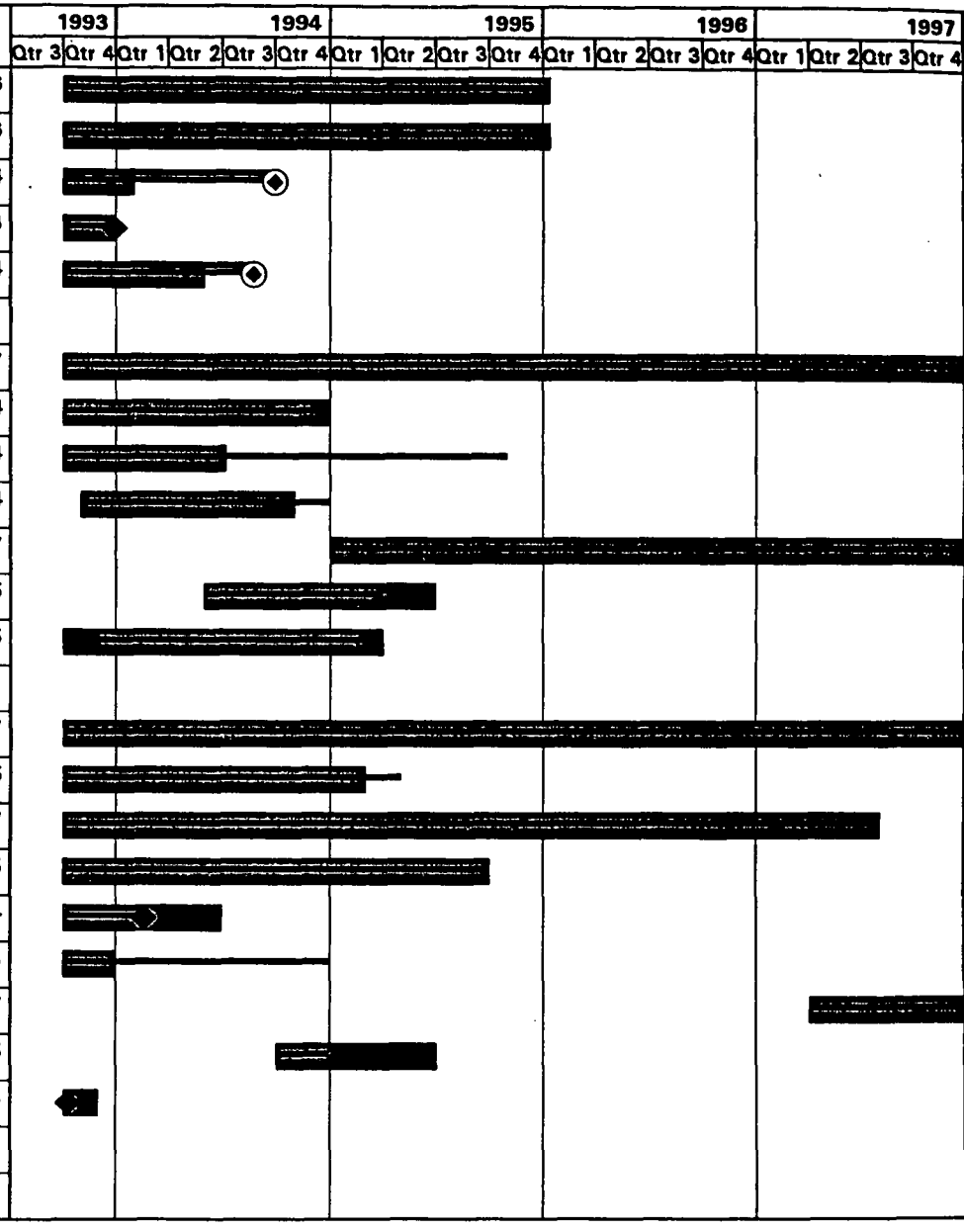
ATTACHMENT 1

GANTT CHART

MEDICAL MANAGEMENT PLAN

Name	Due Date/Completed	Orig. Planned Finish
POLICY ISSUES	1/12/96	1/12/96
National Academy of Science Study	1/12/96	1/12/96
Waste Processor Guidance	9/30/94	1/31/94
RES-1979 Med Policy	12/28/93	12/31/93
NRC/Agmt State Device Jurisdiction (MOU)	8/25/94	6/1/94
RULEMAKING	12/31/97	12/31/97
Embryo-Neonate Protection - Final	12/30/94	12/30/94
Part 20/35 Patient Release Criteria - Final	10/31/95	7/7/94
Pharmacy Rule - Final	1/1/95	11/1/94
Parts 31/35 Revision - Final	12/31/97	12/31/97
Adv. Notice of Proposed Rulemaking	3/31/95	6/28/95
Parts 19/20, Assess./Notif. - Final	2/28/95	3/31/95
LICENSING GUIDANCE	12/31/97	12/31/97
Reg. Guide 10.5 Broadscope - Final	5/1/95	3/1/95
Add Appendices to Reg Guide 10.8	8/1/97	8/1/97
Draft for Comment	9/29/95	9/29/95
Revise MC 1245 (1246) - est. lic. rev. qual.	2/17/94	6/30/94
Master Materials lic/insp manuals	12/30/94	12/31/93
Revise Reg. Guide 8.33	12/31/97	12/31/97
Issue Guidance on Temporary Exemptions	12/31/94	6/30/95
Issue P&GD 86-4 - (HDR)	10/8/93	11/30/93

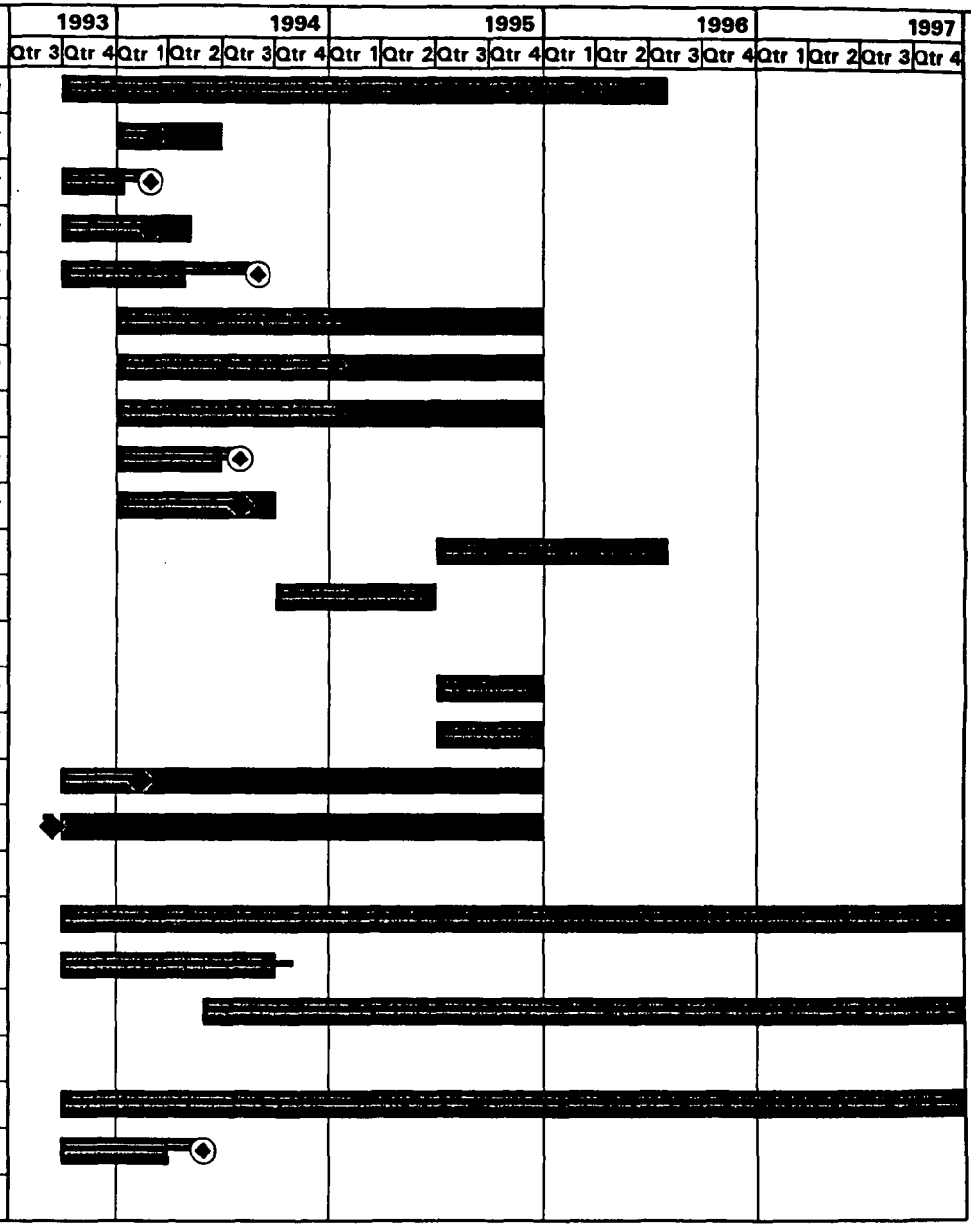


Project: Medical Management Plan
Date: 9/30/94

Planned Finish
Due Date
Early Completion
Finished Late
Finished On Time

MEDICAL MANAGEMENT PLAN

Name	Due Date/Completed	Orig. Planned Finish
INSPECTION GUIDANCE	7/31/96	7/31/96
Event Response Procedure	3/7/94	6/30/94
MC - Assessing Public Exp/Notification	2/28/94	1/13/94
Inspection of Expanding Programs	2/28/94	5/9/94
Prime Alert-10	9/1/94	4/29/94
Revise MC 2800	1/27/95	12/29/95
Program Expansion	1/27/95	12/29/95
Performance Adjustment	1/27/95	12/29/95
Medical Field Notes	8/1/94	6/30/94
QM Inspection Procedure	8/1/94	9/30/94
Third Party Inspection	7/31/96	7/31/96
Allegation Follow-up Procedure	6/30/95	6/30/95
ENFORCEMENT	12/29/95	12/29/95
Revision of the Enforcement Policy	12/29/95	12/29/95
Notifying licensee Boards or Trustees	2/10/94	12/29/95
Identify Indiv. w/lic. restrictions	9/14/93	12/29/95
MANAGEMENT & RSO RESPONSIBILITY	12/31/97	12/31/97
NUREG - Management/RSO	10/31/94	9/30/94
Rulemaking - Parts 30/40 - Final	12/31/97	12/31/97
INFORMATION MANAGEMENT SYSTEMS	12/31/97	12/31/97
Licensee Events - support to AEOD	5/31/94	3/31/94

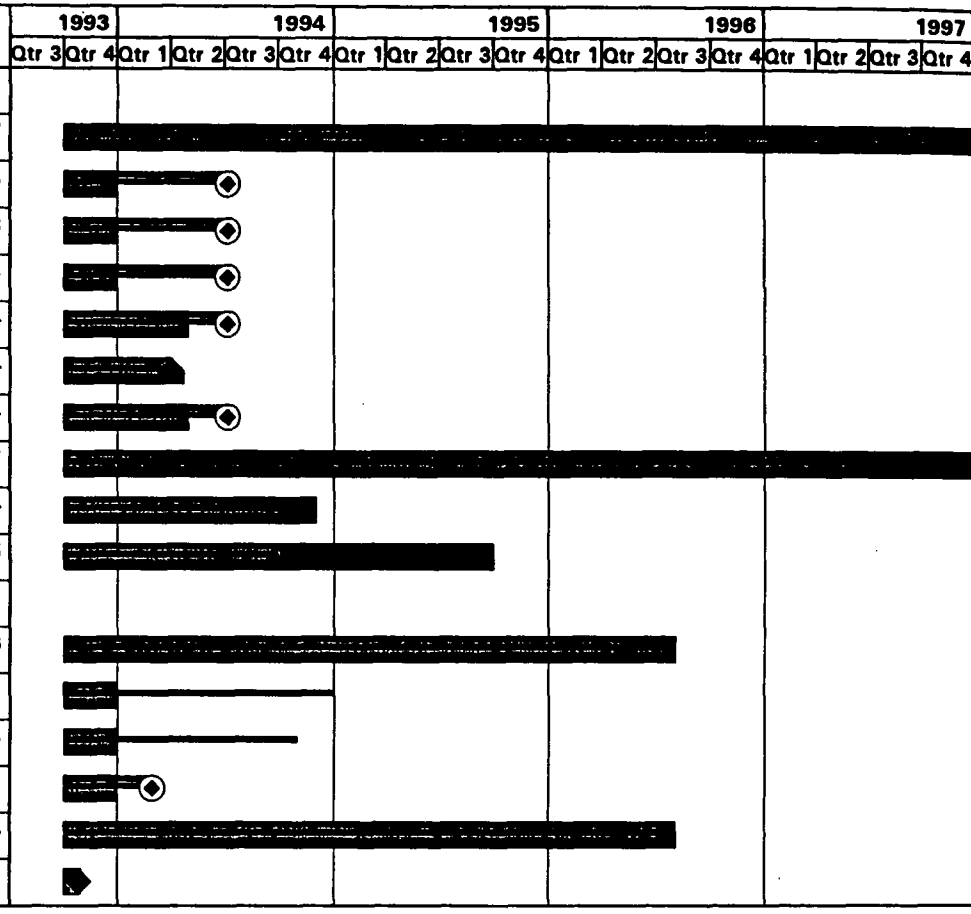


Project: Medical Management Plan
Date: 9/30/94

Planned Finish
Due Date
Early Completion
Finished Late
Finished On Time

MEDICAL MANAGEMENT PLAN

Name	Due Date/Completed	Orig. Planned Finish
MISADMINISTRATIONS	12/31/97	12/31/97
Management Directive	7/6/94	12/31/93
Patient Follow-up Policy	7/6/94	12/31/93
Notification of Local Authorities	7/6/94	12/31/93
AIT/IIT Guidance	7/6/94	4/29/94
Training on QM TI	3/31/94	3/31/94
Medical Consultant Policy	7/6/94	4/29/94
Misadministration Coordinator	12/31/97	12/31/97
Review all QM Plans	9/30/94	12/1/94
QM Rule Commission Briefing	9/30/94	9/29/95
RESEARCH	7/31/96	7/31/96
QA/QC & Risk for Gamma Knife	12/30/94	12/31/93
QA/QC Risk for HDR Afterloaders	10/31/94	12/31/93
Misadministration Events Analysis - INEL	2/28/94	12/31/93
Human Factors Studies	7/31/96	7/31/96
Southwest Research Source-Wire Eval.	10/26/93	10/29/93



Project: Medical Management Plan
Date: 9/30/94

Planned Finish
Due Date
Early Completion
Finished Late
Finished On Time

ATTACHMENT 2

MMP STATISTICS

MMP TRACK STATISTICS

Total # of Tracks:				90 Tracks
# of IIT action items (Tracks):		12%	11/90	
% of IIT Tracks Closed or Near Completion:	82%	9/11		
CLOSED Tracks:				
Percent Closed:			56%	50/90
Breakdown of Closed Tracks by Timeliness:				
% of Tracks Completed Early or on Time:		28%	14/50	
% of Tracks Completed Late:		30%	15/50	
% of Tracks closed prior to 8/31/93:		36%	18/50	
% of Tracks Requiring Ongoing Resources but Considered Closed (MED, Div. Trkng., and Misad. Coord):		6%	3/50	
OPEN Tracks:				
Percent Open:			44%	40/90
Breakdown by Open Status:				
% of "Open" Tracks Near Completion:		33%	13/40	
% of "Open" Tracks Partially Closed:		12%	5/40	
Others:		55%	22/40	

Attachment 2

ATTACHMENT 3

SPECIFIC INFORMATION ON MMP ACTION ITEMS BY PROGRAM AREA

SPECIFIC INFORMATION ON ACTION ITEMS IDENTIFIED BY PROGRAM AREA

The information provided below is an abbreviated version of the information contained in subsection I. "Status Report on the MMP" of this report.

Program Area 1. Policy Issues

- **The NAS study began in January 1994 with a final report expected by January 1996.** See item I, Program Area 1, *"Policy Issues,"* in the Discussion section of this paper for details.

- **1979 Medical Use Policy Statement: ONGOING.** During each rulemaking the staff will ensure the final rule's consistency with the 1979 Medical Use Policy statement (in particular, the impact of the rule on the practice of medicine).

- **NRC/FDA MOU signed: 8/26/93.** The U.S.Nuclear Regulatory Commission and Food and Drug Administration (FDA) staff address issues of mutual interest, on an as needed basis consistent with the Memorandum of Understanding (MOU) signed on August 26, 1993. Routine monthly meetings between the staff are conducted and an annual meeting between agency management was held on August 25, 1994. A memorandum dated June 23, 1994, was forwarded to the Commission to provide a status on implementation of the MOU. Office of Nuclear Material Safety and Safeguards (NMSS) policies and procedures for implementing the MOU were issued August 25, 1994. Additionally, NRC and FDA staff have participated in joint inspections responding to medical events that have occurred at NRC-licensed facilities to determine root cause and ensure effective corrective action.

- **Waste Processor Guidance:** As a result of the inadvertent transfer of the brachytherapy source in the Indiana, Pennsylvania, Incident Investigation Team (IIT) event, and Commission direction in response to SECY-94-073, regarding the recent contaminated ferrophosphorus incident, the staff will refer all incoming reports of emergencies involving unidentified radioactive material in the possession of an individual or group without an NRC or Agreement State license to the EPA, in accordance with the Lead Federal Agency (LFA) provisions of the draft Federal Radiological Emergency Response Plan. Because EPA is the LFA for such incidents, the staff will cease plans to issue guidance to the waste management community regarding events where licensed material is inadvertently received. The staff issued guidance to the regions regarding EPA as LFA for such events by memorandum dated June 21, 1994.

Program Area 2: Misadministrations and Patient Follow Up

- **During 7/94,** NRC Management Directive (MD) 8.10, "Medical Event Assessment Program;" and Manual Chapter (IMC) 1360, revised, "Use of Physician and Scientific Consultants" were issued.

- **Resolving Related Regulatory Requirements: ONGOING.** On May 7, 1993, the staff issued Information Notice (IN) 93-36, "Notifications, Reports and Records of Misadministrations," to provide additional guidance to all NRC medical use licensees on its requirements. Since that time, various issues surrounding these requirements continue to be raised, particularly informing a patient's relative or guardian in the event that the patient is not informed based on medical judgment. As a result, the staff decided to issue a second Information Notice (IN) to clarify these requirements. The proposed IN was discussed with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) during the November 1993, meeting, and the IN was modified to include recommendations by the Committee. The IN has been escalated to a Generic Letter (GL) to emphasize the importance of the requirements to licensees and provide the Commission with an opportunity to provide comment on the staff's interpretation and related policy. The GL will be provided to the Commission in the near future.

  During November 1993 and May 1994, the staff discussed "patient notification," issues with the ACMUI to more fully understand the standards of medical practice and ethics when physicians manage patient information, including information on a misadministration, that could be considered part of the confidential physician-patient relationship.

- **Review of QM Programs: COMPLETE.** See discussion under *II, "Implementation of the QM rule and its Effectiveness."*

- **NMSS Misadministration/Medical Consultant Coordinator: ONGOING.** See item I, Program Areas 2, *"Misadministrations and Patient Followup,"* and 8, *"Information Management Systems."*

Program Area 3. **Rulemaking**

- **Radiopharmacy Final Rule Package: 10/94.** A final radiopharmacy rulemaking package is scheduled to be submitted to the Commission during October 1994, for approval. The staff intends to propose an effective date of January 1, 1995, since the interim final radiopharmacy rule expires on December 31, 1994.

- **Proposed Patient Release Rule: 6/95.** On June 15, 1994, the staff issued a proposed rule for revision to the patient release criteria described in 10 CFR Part 35, and conforming changes to 10 CFR Part 20 (59FR30732). The rule proposes a dose-based, rather than activity/radiation-level based, criterion. Comment period on the proposed rule expired on August 29, 1994. The staff also issued a Draft Regulatory Guide (DG-8015) and Regulatory Analysis, NUREG-1492). The staff is scheduled to submit a proposed final rule by 6/30/95, for Commission approval.

- **Revisions to 10 CFR Part 19 and 20 for Assessing Public Exposures: 12/94.** Proposed revisions to 10 CFR Parts 19 and 20 were published for comment in the Federal Register on February 2, 1994, (59FR5132). Licensees would be required to assess public exposure and notify individuals of their exposures as a result of inadvertent public exposures resulting from medical events. This rulemaking was combined with the 10 CFR Part 20 "controlled area" rulemaking, and is currently

scheduled to be submitted by December 31, 1994, for EDO approval. Adjunct efforts to provide additional guidance include issuance of IMC 1302 as discussed in program area 5, *"Inspection Guidance,"* and MD 8.10 as discussed in program area 2, *"Misadministrations and Patient Followup."*

- **Inadvertent Administrations to Pregnant Patients and Nursing Infants:** The development of a proposed rulemaking package to reduce the likelihood of an unintended radiation exposure to an embryo/fetus or nursing infant has been delayed due to the reallocation of resources to the development of the final radiopharmacy rule and associated guidance.

- **Revisions to 10 CFR Parts 20 and 35: 10/94.** The staff is developing a proposed rule to clarify that the 10 CFR Part 35 definitions of misadministration and associated reporting and notification requirements apply in cases involving the administration of byproduct material to an individual ("wrong patient"). 10 CFR 20.1301 public dose limits do not apply to these individuals. The staff is scheduled to submit the proposed rule during October 1994, for Commission approval.

- **PART 35 ANPR: 3/95.** The staff is in the initial stages of developing an Advanced Notice of Proposed Rulemaking (ANPR) for major revisions to 10 CFR Part 35, and plans to develop minor revisions to 10 CFR Part 30, 31, and 40. The revisions to 10 CFR Part 31 are specific to in-vitro laboratories issued general licenses. The more generic revisions to 10 CFR Parts 30 and 40 are to emphasize a management commitment to provide adequate resources for the radiation safety program and support for the radiation safety officer. For the major revision to 10 CFR Part 35, the staff expects to issue the ANPR in March 1995 and the final rule in late 1997, as scheduled. Final amendments to Parts 30, 31 and 40 are also scheduled to be completed by the end of 1997.

- **Revision of the Abnormal Occurrence Reporting Criteria: 10/94.** During October 1994, the staff submitted, for Commission approval, a Commission policy statement to revise the Agency's criteria for reporting "Abnormal Occurrences" to the U.S. Congress. This was submitted in response to an SRM dated May 19, 1994, which directed the staff to resubmit the reporting criteria and consolidate the various changes being considered into a single revision for Commission approval as a Commission policy.

Program Area 4. **Licensing Guidance**

- **Revised Guidance: 9/95.** P&GD 86-04, Revision 2 Issued 9/94, licensing guidance for remote afterloading brachytherapy. Revised licensing guidance is under development to reflect the final radiopharmacy rule; address teletherapy, and mobile nuclear medicine.

  Regulatory Guide 10.5 has been revised to provide additional guidance on licensing medical use programs of broad scope. It is scheduled to be published for public comment in the near future and issued in final by May 1995.

- **New Guidance: 9/95.** Licensing guidance is under development for gamma stereotactic radiosurgery devices, manual brachytherapy, and radiopharmaceutical therapy.

  Policy and Guidance Directive 94-04 was issued 6/94 to provide guidance for license reviewers on identifying material licensees whose programs have undergone significant growth and warrant an onsite inspection prior to the next routine inspection.

  MC 1246 was issued 2/94 to provide guidance on NRC license reviewer qualifications.

Program Area 5: Inspection Guidance

- **Revised Guidance: 1/95.** A working group has been established to make major modifications to IMC 2800, "Materials Inspection Program." The revised guidance will focus on the core and non-core inspection programs for materials licensees, greater flexibility in increasing or decreasing inspection frequencies, and more emphasis on performing reactive inspections. The revision to IMC 2800 is scheduled for completion by January 31, 1995.

- **New Guidance: 9/93.** TI 2800/024 issued for inspection of licensees authorized for remote afterloading brachytherapy procedures. **7/94:** MD 8.10 issued to provide inspection guidance for medical events, in particular, misadministrations.

  By way of a 7/93 memorandum, instruction to the regions was issued to identify and inspect medical licensees whose programs had undergone significant growth. All such inspections were conducted by 2/94 with no significant findings. Corresponding licensing guidance was also issued.

  IP 87103, "Inspection of Incidents at Nuclear Materials Facilities," was issued 3/94 to provide additional guidance to management when determining whether to dispatch one or more regional inspectors to conduct a special inspection in reaction to an incident; and to inspectors for determining the sequence of events leading to the event and the conditions that existed at the time the incident occurred. IMC 1302, "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public" was issued 2/94 to provide generic and specific guidance on the course of action to follow in situations involving radioactive material in the public domain. This includes notifying local authorities in response to a particular event.

  The staff addressed the PrimeAlert-10 area radiation monitor IIT finding by requesting specific information from the manufacturer on the use of, and problems observed with use of the device. In addition, the staff discussed this issue with participants at the American Association of Physicists in Medicine's Summer School during August 1994. There is no evidence to indicate that there are generic problems with these meters. Therefore, a TI is not needed.

- **Issue of Third Party Inspections: ON HOLD.** The staff has begun to explore the issue of inspection of medical licensees by third parties, such as the American College of Nuclear Medicine, American Board of Radiology, or other medical professional organizations who have an interest in developing, or revising an existing, audit program to meet NRC inspection goals. The staff requested and received guidance from the Office of the General Counsel indicating there is no legal prohibition on the use of third parties to conduct inspections on behalf of the NRC.

Program Area 6: Enforcement

FRN 4/93, changes to Enforcement Policy: The change modified examples to help NRC staff determine the safety and regulatory significance of various violations of the QM rule for medical licensees. Enforcement decisions focus on violations that indicated a programmatic deficiency. The change also reflects the fact that violations that represent isolated mistakes, of limited consequence, that are not associated with a programmatic weakness of the licensee's QM program, will be considered less significant.

EGM 93-005, 4/93: EGM 93-005 was issued April 2, 1993, to provide guidance on the modification to the enforcement manual described above.

EGM 93-008, 9/93: EGM 93-008 was issued on September 14, 1993, to provide guidance on the System of Records maintained for enforcement actions against individuals. Further OE distributes a list semiannually to identify individuals who have any restriction from NRC-licensed activities which license reviewers should review prior to issuance of any licensing action. Quarterly, NUREG-0940, Enforcement Actions, Significant Actions Resolved," is issued and orders to individuals are included in Section A unless a hearing has been requested. Also, copies of NUREG-0940 and orders to individuals are routinely forwarded to Agreement States.

Weekly Enforcement Panel, 11/92 - 3/94: The staff conducted a weekly enforcement panel consisting of headquarters and regional staff to review inspection and enforcement cases and ensure consistent application of the enforcement policy in cases involving violations of the QM rule.

EGM 94-001, 2/94: EGM 94-001 was issued on February 10, 1994, to provide guidance and instruct the regions to identify the Board of Trustees for medical licensees on distribution for all NRC escalated enforcement actions against the licensee.

EGM 94-003, 3/94: EGM 94-003 was issued on March 23, 1994, to provide additional guidance for distinguishing between programmatic and isolated failures in the implementation of a licensee's QM program.

EGM 94-011, 7/94: EGM 94-011 was issued on July 26, 1994, to provide guidance on the "wrong patient" issue. Specifically, the guidance is that the 10 CFR Part 35 misadministration definitions and related reporting requirements apply in cases involving the administration of

byproduct material to an individual ("wrong patient").

Modifications to Enforcement Manual, 7/94.: The staff modified the Enforcement Manual to provide additional guidance on how to process enforcement actions involving non-compliance with NRC misadministration notification and reporting requirements.

Program Area 7: **Management and RSO Responsibility**

- **NUREG: 10/94.** The staff is near completion on development of a NUREG to provide guidance on effective management of radiation safety programs at medical facilities.

- **Rulemaking: 12/97.** The staff will revise Parts 30, 40 and 70 to emphasize a commitment by management for support of the radiation safety program.

Program Area 8: **Information Management Systems**

- **IMNS Tracking System: ONGOING.** The Division of Industrial and Medical Nuclear Safety developed and currently utilizes a tracking system to monitor all division action items, including those identified in the MMP.

- **AEOD database: ONGOING.** A working group composed of NRC and Agreement State staff developed a prototype database for non-reactor events which was distributed to participants for use and comment during the month of May 1994. This is an enhanced version of the existing AEOD non-reactor event database and is referred to as the Material Events Database. The enhanced database includes NRC licensee data and Agreement State data reported to NRC by Agreement States. An interim version of the database was distributed to NRC program offices and Agreement States during September 1994. The staff will continue to modify the database based on NRC needs.

- **Functional Process Improvement Study: ONGOING.** Although not identified in the MMP, NMSS is currently performing a seven-month study of the materials licensing process with the objective of identifying recommendations for streamlining and automating. Although not limited to medical licensees, this project is anticipated to be of great benefit to medical licensees in terms of providing cost savings in resources expended in the NMSS materials licensing process, improving communications with materials licensees, and decreasing the time needed to complete a licensing action. The objective of this study is to use Functional Process Improvement (FPI) to conduct an analysis of the materials licensing process work flow to determine how the NRC processes an application from receipt to issuance, with the long-term goal of establishing a more efficient and potentially automated processing of material license and amendment requests. A major goal is to determine ways to streamline, automate and avoid duplication of effort in processing the license request. NMSS is also analyzing the Licensing Tracking System to improve its usability by licensees and NRC staff, and compatibility with other agency electronic information systems.

Program Area 9: Research

- **Current Research Reports: 12/94, 1/95, 3/95.** Final reports on Human Factors Evaluations for brachytherapy and teletherapy are expected in January and March 1995, respectively. A final report on Quality Control/Quality Assurance (QC/QA) for Remote Afterloading Devices was recently received by the staff and will soon be published as a NUREG/CR. A final report on QC/QA for the Gamma Stereotactic Radiosurgery device is expected in December 1994. All final research reports will be issued as NUREG/CRs.

- **NUREG/CR-6088 Published: 2/94.** NUREG/CR- 6088, "Summary of 1991-1992 Misadministration Event Investigations" was issued 2/94 and distributed to NRC medical use licensees and Agreement States. There were seven major findings regarding the root cause and contributing factors for the events investigated.

- **NCRP Commentary No. 9: 5/94.** NCRP Commentary No. 9, "Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus or Nursing Child was issued May 1, 1994. This commentary was developed to assist the staff in developing requirements regarding the unintended exposure of the embryo, fetus or nursing child as a result of medical procedures involving the administration of radioactive material. This Commentary supplements NCRP Commentary 7, "Misadministration of Radioactive Material in Medicine - Scientific Background, 11/91.

ATTACHMENT 4

DOCUMENTS ISSUED SINCE OCTOBER 1, 1993

MAJOR DOCUMENTS ISSUED SINCE AUGUST 31, 1993 (SECY-93-244)

This list identifies only those documents issued to close, or partially close, MMP action items in the nine major MMP program areas. Additionally, the Gantt chart in Attachment 1 provides information regarding the date of actual versus scheduled completion, as originally identified in SECY-93-244, the MMP.

Inspection Manual Chapters (IMC):

IMC 1246 (2/94): "Materials License Reviewer Qualifications"

IMC 1302 (3/94): "Action Levels for Radiation Exposures and Contamination Associated with Materials Events Involving Members of the Public"

IMC 2810 (6/94): "Master Materials Inspection Program"

IMC 1360 (7/94): "Use of Physician and Scientific Consultants"

Management Directive:

MD 8.10 (7/94): "NRC Medical Event Assessment Program"

NMSS Policies and Procedures Memorandum 1-45:

NMSS Memo 1-45: (8/94) "Implementation of the NRC/FDA MOU"
The policies and procedures memorandum provides instruction to NMSS staff on implementation of the NRC/FDA MOU. Specifically, it describes what types of information should be shared with FDA and how, and provides staff and management points of contact for both agencies. The memorandum was recently distributed to all NMSS staff, although the procedures had already been implemented.

Inspection Procedures:

MC 2800/024: (9/93) "Remote Afterloading Brachytherapy Inspections"

MC 2800/025: (8/94) "Quality Management Program Inspections"
Draft TIs were issued in April and June 1994 for use by the regional staff.

IP 87103: (3/94) "Inspection of Incidents at Nuclear Materials Facilities"

Enforcement Guidance Memoranda and Changes to the Enforcement Manual/Policy:

FRN (4/93): (58FR17321)	Changes to Enforcement Policy published. The change modified examples to help NRC staff determine the safety and regulatory significance of various violations of the QM rule for medical licensees.
EGM 93-005: (4/93)	Provided guidance on the Enforcement Policy modification described previously.
EGM 93-008: (9/93)	Provided guidance on Systems of Records maintained for enforcement actions against individuals.
EGM 94-001: (2/94)	Provided guidance that required that the Board of Trustees for medical licensees be placed on distribution for all escalated enforcement actions.
EGM 94-003: (3/94)	Provided additional guidance for distinguishing between programmatic and isolated failures in the licensee's implementation of the QM rule.
EGM 94-011: (7/94)	Provides interim guidance on the "wrong patient" issue. Specifically, 10 CFR Part 35 applies in cases involving the administration of byproduct materials to an individual.
Enf. Manual: (7/94)	Additional guidance was provided on how to process enforcement actions involving non-compliance with NRC misadministration requirements, including patient notification.

Policy and Guidance Directives:

94-04 (6/94):	"Identification of Licenses Where Significant Licensing Action Warrants an Onsite Inspection. Issued to provide guidance to license reviewers to identify medical use programs that undergo significant growth and may warrant an inspection prior to the next scheduled routine inspection.
86-04 (9/93): Rev.1	"Licensing of Remote Afterloader Brachytherapy." To provide guidance for licensing high-, medium-, low- and pulse-dose rate remote afterloading procedures.

Regulatory Guides:

10.5 (11/93):	"Application of Licenses for Broad Scope" Finalized by the staff and will soon be published for public comment.
DG 8015 (6/94):	"Release of Patients Administered Radioactive Materials" Issued in Draft for comment with the proposed patient release rule.

Information Notices:

IN 94-09 (2/94): IN 94-09: "Release of Patients with Residual Radioactivity from Medical Treatment and Control of Areas Due to Presence of Patients Containing Radioactivity Following Implementation of Revised 10 CFR Part 20."

IN 94-17 (3/94): IN 94-17: "Strontium-90 Eye Applicators: Submission of Quality Management Plan (QMP), Calibration, and Use."

IN 94-37 (5/94): IN 94-37: "Misadministration Caused by a Bent Interstitial Needle During Brachytherapy Procedure."

IN 94-39 (5/94): IN 94-39: "Identified Problems in Gamma Stereotactic Radiosurgery."

IN 94-47 (6/94): IN 94-47: "Accuracy of Information Provided to NRC during the Licensing Process."

IN 94-64 (9/94): IN 94-65: "Potential Errors in Manual Brachytherapy Dose Calculations Generated Using A Computerized Treatment Planning System."

IN 94-70 (9/94): IN 94-70: "Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals."

Staff Papers:

SECY-93-259: "Federal Register Notice - Abnormal Occurrence Reports: Proposed Revision to Appendix A to Policy Statement to Include Examples for Reporting Medical Misadministrations as Abnormal Occurrences and Minor Conforming Changes to Existing Abnormal Occurrence Examples."

SECY-94-054: (3/94) "Proposed Amendments to 10 CFR Parts 20 and 35 on Criteria for the Release of Patients Administered Radioactive Material." SECY-94-054A responding to the Office of the Inspector General's concerns was submitted in April 1994.

Memo (6/94): "Food and Drug Administration, Memorandum of Understanding"

Memo (8/94): "Bylaws for the Advisory Committee on the Medical Uses of Isotopes"

NUREG/CR-6088: "Summary of 1991-1992 Misadministration Event Investigations."

This report was prepared by the Idaho National Engineering Laboratory and provides a summary of findings on the root cause of seven misadministrations reported to NRC, that occurred during 1991-1992. The study resulted in 7 major findings. This report was distributed to NRC medical licensees and the

Agreement States included in the briefing book to the National Academy of Sciences. The staff will consider these findings during the next major revision to Part 35.

Southwest Research's Final Report:

An evaluation of Southwest Research Institute's (SRI) Final report on the Omnitron Source Wire Failure was provided to the EDO's Office via a memorandum dated October 27, 1993. SRI concluded that root cause of the in-service failures of the source wires was environmentally-inducted embrittlement due the breakdown of the teflon lining of the storage cask sleeves in the presence of a high-radiation field and subsequent reaction or interaction with the Nitinol alloy. A copy of the staff's report was distributed to the Office of State Programs, and the findings were presented in an article in the *Sealed Source & Device Newsletter*. The newsletter article was distributed to all State programs which have product registration responsibility, the Atomic Energy Control Board of Canada, the International Atomic Energy Agency, and all vendors which are likely to be affected by the findings of the report.

NMSS Newsletter Articles:

Each quarter, NMSS publishes the *"NMSS Licensee Newsletter."* In each Newsletter, articles are published to provide up to date information to NRC medical use licensees on regulatory issues such as current rulemaking efforts, information notices, bulletins or generic letters published, upcoming events, future staff efforts, meeting notices, and additional guidance based on NRC's experience with implementation of the QM rule.

ATTACHMENT 5

DOCUMENTS NEAR COMPLETION (≤ 12/31/94)

MAJOR DOCUMENTS NEAR COMPLETION (≤ 12/31/94)

The following is a list of documents that are expected to be completed by December 31, 1994.

Rulemaking:

10/94: Final Radiopharmacy rulemaking package to EDO for Commission approval.

10/94: Proposed "Wrong Patient" rule to EDO for Commission approval.

12/94: Final rule on revisions to Parts 19 and 20, for notification of members of the public of their exposure as a result of events involving byproduct material, to the EDO for approval. This rulemaking effort was combined in the "Controlled Area" proposed rule published for public comment in the Federal Register on February 3, 1994.

Other Staff papers:

9/94: Revision of AO Criteria: Final paper to EDO for Commission approval.

9/94: Staff recommendation to add second medical physicist position to the ACMUI membership.

10/94: Staff options paper with a recommendation to issue a generic letter to clarify patient notification requirements, particularly, when the referring physician makes a decision not to inform the patient, and therefore, the patient's responsible relative or guardian must be informed, even if the patient is a consenting, competent adult.

Research Studies:

12/94: Final report on QA/QC for gamma stereotactic radiosurgery is expected in December 1994. (The related report on remote afterloading was received in September 1994).

NUREG:

10/94: NUREG: The staff expects to publish the NUREG on Effective Management of Radiation Safety Programs at Medical Facilities.

Attachment 5

Information Notices:

10/94: Facility Management's Responsibilities for Purchased or Contracted Services for Radiation Therapy Programs. This will stress the importance of management oversight of those portions of the radiation therapy program that are performed or supplemented by contractors.

Generic Letter:

12/94: A generic letter will be issued to address a recent observation by NRC staff regarding errors in the delivery of fractionated brachytherapy doses and gamma stereotactic radiosurgery doses. NRC will require licensees to report such events for review and evaluation for generic implications. This information will be used in part to determine whether modifications to 10 CFR Part 35 are needed to reduce the likelihood of such errors.

ATTACHMENT 6

IIT STATUS REPORT

IIT ACTION ITEM UPDATE (1/94)

Except for Action 1a., the "action plan" described for each item below, is the same information contained in the initial IIT status report provided as Enclosure 4, SECY-93-244, the MMP. The "update" section provides information on action to date since then.

Action 1a. Review Oncology Services Corporation's (OSC) corrective actions in response to the finding of ineffectiveness of the radiation safety program.

Action Plan:

The hearing before the Atomic Safety and Licensing Board (ASLB) regarding the suspension of licensed activities at six facilities owned and operated by Oncology Services, Inc. has been dismissed. On August 31, 1994, ASLB dismissed the hearing based on a joint motion by NRC and the licensee. A civil penalty (CP) in the amount of $280,000 has been imposed, and remittance has not been forwarded by the licensee. The CP is based on two Severity Level II violations ($100K each) and one aggregated Severity Level III ($80K). This action is considered closed.

STATUS: **CLOSED**
CONTACT: NMSS/IMAB: JGlenn

Action 1b. Evaluate the need to further define RSO and Authorized User responsibilities. Tracks 33, 51, 77.

Action Plan:

A task force of NMSS, Regional and Agreement State representatives met during the months of April, May, and July 1993, and is scheduled to meet during September and December 1993. Meetings during 1994 to be determined. The staff expects to publish the NUREG in mid calendar year 1994. Additionally, the staff will evaluate the need to further define and provide guidance on the responsibilities of the authorized user. This issue will be addressed during a major revision of Part 35 scheduled for completion in December 1997.

Update:

The Task Force met during September and December 1993, and January 31-February 2, 1994. The Draft NUREG was distributed for peer review and discussed with the ACMUI at the November 1993 and May 1994 meetings. The staff has addressed comments received and is in the final stages of drafting, and expects to publish the NUREG for comment by October 31, 1994.

STATUS:	Open	
COMPLETION DATES:	Publish NUREG:	10/31/94
	Evaluate authorized users; Possible rulemaking	12/30/97
CONTACT:	NMSS/IMAB/JGlenn	

Attachment 6

Action 1c. Evaluate performance and design of PrimAlert-10 Area Radiation Monitors and take appropriate follow up action. Track 52.

Action Plan:

The staff has written to the manufacturer (Victoreen) and requested an evaluation of the potential for non-ionizing radiation fields or electromagnetic fields (associated with linear accelerators) to cause spurious alarms by the PrimAlert-10 ARM as well as similar models used by medical licensees, such as the PrimAlert-50 ARM. In addition, NMSS will develop a Temporary Instruction (TI) for the Regions to review operation and reliability of PrimAlert ARM's as part of the routine inspection program. The staff will evaluate the information developed by the Regions as well as the manufacturer's response and, if appropriate, will issue an information notice to licensees.

Update:

Victoreen responded in October 1993, and NRC staff forwarded a second letter dated February 9, 1994, requesting additional specific information on instrument response at the high energy spectrum. NMSS evaluated the manufacturer's response and did not identify any generic issues. Additionally, at the American Association of Physicists in Medicine Summer School, NRC staff discussed this issue with the school participants. The commentors did not indicate problems with this device. The staff has not identified any generic issues, and therefore will not issue an Information Notice or Temporary Inspection Instruction. As a result, this item is considered closed as of September 1, 1994.

STATUS:	**CLOSED**	
COMPLETION DATES:	Letter to Victoreen Issued:	09/09/93
	Response Received:	10/20/93
	2nd Letter to Victoreen:	02/09/94
	Decision on IN and TI:	04/29/94
CONTACT:	NMSS/IMOB/Combs	

Action 2a. Evaluate NRC's process for a) assessing exposures and consequences and b) notifying individuals and authorities following an elevated exposure. Track 53.

Action Plan:

The staff has developed guidance to address this recommendation for materials licensees based on the experience of the Amersham source incident. The guidance has previously been approved by the EDO. However, it is being revised to incorporate the lessons learned from the IIT, and will be issued as Inspection Manual Chapter 1302. The staff is in the process of addressing resolution of comments and expects to issue the IMC by 2/28/94.

STATUS:	**CLOSED**	
COMPLETION DATES:	MC 1302 Issued:	02/28/94
CONTACT:	NMSS/IMOB/Combs	

Action 2b. Evaluate the need to further define licensee responsibility for assessing radiation exposure and notifying members of the public and authorities. Track 54.

Action Plan:

The staff will forward a memorandum to OGC to request formal OGC interpretation regarding the applicability of Parts 19 and 20 to licensees for assessing radiation exposure and notifying members of the public and authorities. Staff will incorporate guidance into the appropriate Manual Chapter.

Update:

The staff received guidance from OGC regarding the applicability of Parts 19 and 20 to licensees for assessing radiation exposure and notifying members of the public and authorities. The Office of Research is scheduled to forward a rulemaking package to the EDO by 12/31/94 for approval. The rule makes minor modifications for clarification to Parts 19 and 20 to make reports to members of the public required by Part 20. Additionally, MC 1302 and MD 8.10 were recently issued and provide additional guidance on notifying local authorities in response to an event involving the release of licensed material into the public domain.

STATUS:	Open	
COMPLETION DATES:	Rulemaking package to EDO:	12/31/94
	Estimated Issuance of Final Rule:	03/31/95
CONTACT:	RES/DCool	

Action 3a. Evaluate the need to update licensing and inspection guidance and requirements for HDR afterloaders. Track 55 (See related Tracks 4, 5, 45).

Action Plan:

The staff has undertaken several efforts in this regard. A bulletin was sent to all remote afterloader users, imposing the requirements contained in Bulletin 92-03. Policy and Guidance Directive 86-4, is being revised to incorporate the requirements of the two bulletins. A Temporary Instruction has been drafted to provide guidance on routine inspection of HDR afterloaders. In addition, research efforts are continuing into QA plans for remote afterloaders and human factors related to brachytherapy. The results of these various efforts will be incorporated into a user need memorandum to RES to revise Part 35.

Update:

Policy and Guidance Directive 86-4; Revision 1 was issued September 30, 1993 and TI MC 2800/024 was issued September 23, 1993. The staff continues to monitor and evaluate contractors' findings regarding Quality Assurance/Quality Control and Human Factors Evaluations on Remote Afterloading procedures. These projects are monitored by NMSS and RES. Contractors' findings will be evaluated and incorporated into the proposed revisions to 10 CFR Part 35, when indicated.

STATUS:	Open	
COMPLETION DATES:	Bulletin Issued:	04/20/93
	Final P&GD 86-4 Issued:	09/30/93
	Final TI Issued:	09/23/93
	Evaluate QA/QC study:	11/31/94
	Final report received:	09/30/94
	Evaluate HFE studies:	02/28/95
	Final report expected:	01/31/95
	Issue Part 35 ANPR:	03/31/95
	Revise Part 35:	12/31/97
CONTACT:	NMSS/IMAB/Glenn	
	NMSS/IMOB/Combs	

Action 3b. Evaluate the relative merits of performance-based approach vs. schooling or certifications to verify radiation safety knowledge of HDR afterloader users. Track 56.

Action Plan:

The staff will conduct an evaluation as requested and continue to discuss this issue with the Advisory Committee on Medical Use of Isotopes (ACMUI). The staff will incorporate this issue into the user need memo described in 3a. above, as appropriate.

Update:

This issue was discussed with the ACMUI in May 1993 and will be discussed at future meetings. In addition, the staff's plan to evaluate all current training and experience criteria will include a determination regarding the relative merits of different training approaches to ensure adequate radiation safety knowledge of all users. These findings will be incorporated into the ANPR for revisions to Part 35 scheduled to be published by March 31, 1995.

STATUS:	Open	
COMPLETION DATES:	Discussed with ACMUI:	5/93
	Incorporate into ANPR:	03/31/95
	Revise Part 35:	12/31/97
CONTACT:	NMSS/IMAB/Glenn	

Action 3c. Evaluate the licensing interface among NRC, FDA, and States/Agreement States for sealed sources and devices, including licensee requirements for design reviews and QA/QC. Develop a Memorandum of Understanding with the FDA to further clarify respective roles. Track 57.

Action Plan:

The staff has reviewed FDA's description of its regulatory review of devices such as the Omnitron 2000 and met with FDA staff to clarify the NRC/FDA interface. A MOU has been drafted by both parties and is expected to be signed in the near future. The staff will also review the interface between NRC and the Agreement States with respect to approval of sealed sources and devices and will make appropriate recommendations for improving the definition of that interface.

Update:

The NRC/FDA MOU was signed on August 26, 1993 and NMSS policy and procedures memorandum 1-45 was issued on August 25, 1994. In addition, the staff forwarded a paper to the Commission dated June 23, 1994, to describe implementation of the MOU. The first annual meeting between agency management was held on August 25, 1994 to ensure adequate implementation of the MOU. NRC and FDA staff will continue to conduct monthly meetings.

STATUS:	**CLOSED**	
COMPLETION DATES:	MOU between NRC and FDA Signed:	08/26/93
	Discussed at All Agreement State Meeting:	10/93
	Staff paper submitted:	06/23/94
	Issue NMSS Pol.& Proced. Memo:	08/25/94
CONTACT:	NMSS/IMAB/Glenn and SCDB/Haughney	

Action 3d. Revise the inspection guidelines to trigger consideration for licensees whose programs have significantly expanded or changed. Track 58.

Action Plan:

The staff is currently revising the guidance in Manual Chapter 2800, "Materials Inspection Program," to provide guidance on inspection of satellite facilities, field offices, and temporary job sites. This effort will be expanded to include development of a Policy and Guidance Directive that will provide criteria for license reviewers to use in determining if licensees' programs have significantly expanded or changed.

Update:

A Task Force composed of Headquarters and regional staff met during April and August 1994 to make significant changes to the inspection guidance in IMC 2800, "Materials Inspection Program." Areas to be addressed include guidance on inspection of satellite facilities, field offices and temporary job sites; and adjustment of inspection frequency based on performance. Policy and Guidance Directive 94-04 was issued June 21, 1994 to provide guidance for license reviewers to identify programs that have undergone significant growth and warrant onsite inspection.

STATUS:	Open	
COMPLETION DATES:	Task Force Met:	02/94,08/94
	P&GD 94-04 Issued:	06/21/94
	Draft for Comment Issued:	10/31/94
	Issue Revised MC 2800:	01/29/95
CONTACT:	NMSS/IMOB/Combs	

Action 3e. For near term and where indicated, conduct inspections of licensees whose programs have significantly expanded or changed since last routine inspection. Track 59.

Action Plan:

The staff issued a memorandum to the Regions requesting that they poll licensing staff to identify licensees whose programs (i.e., number of sites, scope of licensed activities, and/or possession limits) have significantly expanded or changed within the last two years, determine if inspections have been conducted since the changes, and where they have not, conduct inspections at those facilities.

Update:

The regions proposed a schedule and completed all inspections by February 28, 1994.

STATUS:	**CLOSED**	
COMPLETION DATES:	Issued memorandum to Regions:	07/09/93
	Inspections Completed:	02/28/94
CONTACT:	NMSS/IMOB/Combs	

Action 4. Evaluate the need for assisting the nonradioactive waste processing industry in establishing guidance for detecting and obtaining expert assistance for handling of radioactive materials. Track 60.

Action Plan:

The staff has already initiated efforts to prepare such guidance. The staff met with representatives from the Agreement States and the waste processing industry on June 29, 1993, to develop the guidance. The guidance will incorporate lessons learned from the IIT.

Update:

The staff received diverse comments from the industry and Agreement States during 10/93. Two forms of guidance were drafted by NMSS. The staff was previously awaiting Commission direction on SECY-94-073, regarding the contaminated ferrophosphorus incident. As a result, AEOD, NMSS and the regions will refer reports of emergencies involving unidentified radioactive material in the possession of an individual or group without an NRC or Agreement State license to EPA, in accordance with the Lead Federal Agency provisions of the draft Federal Radiological Emergency Response Plan. This track is considered closed as of September 1994.

STATUS:	**CLOSED**	
COMPLETION DATES:	Conducted Meeting:	06/29/93
	Publish final guidance (Cancelled):	03/31/94
CONTACT:	NMSS/LLWM/Austin and IMOB/Combs	

Action 5. Evaluate Southwest Research's final report on the source wire failure and document the findings. Track 61.

Action Plan:

Upon receipt, the staff will review the final report and make appropriate recommendations.

Update:

The staff received the final report which confirmed the staff's hypothesis regarding the cause of the source-wire breakage. The contractor's final report was transmitted to the Commission via a memorandum dated October 27, 1993.

STATUS:	**CLOSED**
COMPLETION DATES:	Completed evaluation and Memorandum to Commission dated 10/27/93 to transmit final report .
CONTACT:	NMSS/SCDB/Haughney

ATTACHMENT 7

DATA ON 1993-1994 MISADMINISTRATIONS

MISADMINISTRATION REPORT STATUS FOR 1993 - 1994

			Verbal Notifications			Written Reports	
	Events	Patients	Referring Physician	Patient	Resp. Relative	Patient	Resp. Relative
1993	29	30	29	25	2	24	3
January - June 1994	14	14	12	14	4	12	-

Attachment 7

ATTACHMENT 8

PUBLIC PRESENTATIONS DURING FY 94

PUBLIC PRESENTATIONS DURING FY 94

The following is a list of public presentations made by staff of the 10-member Medical and Academic Section, during FY 94. The purpose of these presentations was primarily to discuss implementation of the QM rule and QM requirements, high-dose-rate remote afterloading brachytherapy, and development of the NUREG currently under development and discussed in program area 7, "Management and RSO Responsibility."

American Association of Physicists in Medicine Summer School

American Association of Physicists in Medicine - Physics Committee

American Association of Physicists in Medicine - South East Chapter

Health Physics Society - Bluegrass Chapter

Health Physics Society - North East Chapter

American Board of Medical Physics - Annual Meeting

American College of Nuclear Physicians - Mid Winter Meeting

Society of Nuclear Medicine - Annual Meeting

Radiological Society of North America - Annual Meeting

American College of Radiation Oncology - Annual Meeting

Association of Freestanding Radiation Oncology Centers - Annual Meeting

American College of Cardiology - Annual Meeting

Organization of Agreement States - Fall Meeting

Agreement State Managers Workshop - Summer Meeting

Advisory Committee on the Medical Uses of Isotopes - Nov. '93 & May '94 Mtgs.

3 Licensee Workshops to discuss the QM rule