UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON MANAGEMENT PLAN FOR REGULATING MEDICAL USE OF BYPRODUCT MATERIAL

Location: ROCKVILLE, MARYLAND

Date: SEPTEMBER 10, 1993

Pages: 64 PAGES

NEAL R. GROSS AND CO., INC.

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BRIEFING ON MANAGEMENT PLAN FOR REGULATING
MEDICAL USE OF BYPRODUCT MATERIAL

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Friday, September 10, 1993

The Commission met in open session, pursuant to notice, at 2:00 p.m., Ivan Selin, Chairman, presiding.

COMMISSIONERS PRESENT:

IVAN SELIN, Chairman of the Commission
KENNETH C. ROGERS, Commissioner
FORREST J. REMICK, Commissioner
E. GAIL de PLANQUE, Commissioner

STAFF SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

MARTIN G. MALSCH, Office of the General Counsel

JAMES TAYLOR, Executive Director for Operations

ROBERT BERNERO, Director, NMSS

CARL PAPERIELLO, Director, Division of Industrial & Medical Nuclear Safety, NMSS

JOHN GLENN, Chief, Medical, Academic & Commercial Use Safety Branch, NMSS

P-R-O-C-E-E-D-I-N-G-S

2:00 p.m.

CHAIRMAN SELIN: Good afternoon, ladies and gentlemen.

The Commission is meeting at this time to receive a briefing from the staff on a proposed staff management plan for the NRC's Medical Use Regulatory Program.

The Commission has been in the process of reviewing this regulatory program for the medical uses of radioactive materials for some time now, at least since the fall of 1992. Since that time, the past scope and implementation of the Medical Use Regulatory Program has received a great deal of Commission attention, as well as congressional and public scrutiny. Today we're going to hear the results of the staff's comprehensive review to identify a plan for major program areas and management direction for the future and the resources necessary to implement the plan.

Copies of the staff management plan should be available here in the conference room.

I would like to stress this is primarily a management plan, not a discussion of the substantive issues. But, of course, these are interconnected.

This is the second major presentation to the Commission on management. We got an interim report from Doctor Paperiello before he started in his current operations. We are vitally interested in establishing what needs to be done to enhance implementation of an effective regulatory program for radiation medicine.

Any of the Commissioners care to remark?

Mr. Taylor?

MR. TAYLOR: Good afternoon. With me at the table at Bob Bernero and Doctor John Glenn and Carl Paperiello from NMSS. Bob Bernero will start the presentation.

MR. BERNERO: (Slide) I'd like to start with a little bit of the historical background that goes back on slide number 1 to the time before Carl Paperiello joined us here at Headquarters.

In calendar year 1992, we felt somewhat numb from the experience of having gone through what is now called the QM Rule. You may recall there was a great deal of controversy in this area developing the rulemaking on quality management in medical uses of isotopes. We had an NMSS senior management conference in August of 1992 and we were trying to look for areas or ways that we could do a management

review or reconsideration of what we were doing in this particular arena. We settled on the medical uses as the scope of it and to develop a management plan for how we conduct our regulation of medical uses. That led to the development of this medical issues paper that's mentioned here in September of 1992, with the intent that we would discuss this matter or these matters with the agreement states and with others and work toward a reappraisal of what we were doing and how we should manage it and come to the Commission.

In the process though events overtook us. I'm sure you're all aware -- I mentioned here the Indiana, Pennsylvania therapy misadministration and the IIT which Carl Paperiello led. That was just one of the events that overtook this activity. So, what we had to do then was go into another agonizing reappraisal of the medical management plan itself. That led to the master agenda that we sent forward in May which is that whole body of tasks where we put them altogether, tried to organize them in some coherent way, get an idea of what the priorities are, what's going on, how we can use the resources.

Then in parallel with that, Carl had been directed to do a senior management review, an independent review and he has reported on that to you.

You mentioned it, Mr. Chairman, in your opening remarks. So, Doctor Paperiello was then left with the independent appraisal of the medical management and now, as of July 1st, he is left with the responsibility to conduct the program.

CHAIRMAN SELIN: He's not independent anymore.

MR. BERNERO: No, he lost it. He spoke to himself. So now, on the other side of the date, he has the full responsibility. I think in this context I think he has excellent credentials and experience already for doing it.

So, Carl, why don't you take over from here.

DOCTOR PAPERIELLO: Okay.

Good afternoon. Today's presentation on the Medical Management Program is intended to provide the Commission with the staff plan for completion of a significant number of actions identified in earlier communications with the Commission. I don't believe there are going to be any new activities really identified. Some of these are staff initiatives, while others are Commission initiatives. I see the staff as requesting Commission endorsement of the planned activities, although some of these things are

already underway in conjunction with earlier direction. Considerable resources are involved in these activities and some of the proposed rulemakings may take several years.

We show the plan for the purpose of budgeting, starting on October 1 of this year. However, a number of actions are underway and some actions, such as the FDA MOU have already been complete. In fact, one of the actions was my own earlier report and that's been complete. Some are expected to be closed very soon. For example, one of the actions is the final analysis of why the Omnitron wire broke when we just this week got the report from Southwest Research. Their conclusion is the same as presented in my original IIT report and that was environment embrittlement caused by the radiation attack on the Teflon and the release in the hydrogen fluoride.

The staff presented the Commission with a master agenda in a memorandum dated May 19th, 1993. In my subsequent medical program review, I recommended several ways in which some of the issues could be combined and addressed through one action. One of these would be the development of a management directive on misadministration follow-up.

By the time my staff abstracted a number of additional actions from my report, we were up to 90 items. To the greatest extent possible in preparing the report that you received today, we consolidated issues into single action items. Since many of the actions that we are proposing involve coordination with the Office of Research, the Office of General Counsel, AEOD, Office of Enforcement and the Office of State Programs, these offices were involved in the time frame projections and the resource allocations you'll find in the paper.

(Slide) Can I have the next slide?

CHAIRMAN SELIN: Doctor Paperiello, I just like to --

DOCTOR PAPERIELLO: Yes?

CHAIRMAN SELIN: In comparing this document with your previous study, the one loop that I think is missing -- the previous study said we had a number of problems. Here are a bunch of steps. What I think we'd appreciate you do at the end is say, "If all these steps are taken, do we solve all the problems, half the problems?" In other words, how far do the steps go in solving the problems that you identified in the earlier report? I mean, it's something that you just might touch on as you go

through.

DOCTOR PAPERIELLO: Okay.

CHAIRMAN SELIN: What gaps will we still have left even if these are all gone?

DOCTOR PAPERIELLO: Sure.

We consolidated even these individual action items. We categorized them into nine major regulatory program areas. Again, in order to improve our ability to manage these, we used a -- and attached to the slides are a time line chart for all these activities. Enclosure 2 of our report shows how the 90 items were incorporated into the actions presented in the time line chart.

Certain complex actions, such as the National Academy study, and several proposed rulemakings are shown with greater structure. Over the next several months, some of the other actions are going to gain similar structure, particularly things that involve changing our inspection program and guidance and the like. We have a computer program called Time Line, which turns out to be very nice to allow you to do this and allocate resources. In fact, when we originally were allocating resources, we had to stretch out the program because the program was showing us that we were just piling too much on the

front end and we just couldn't do the work in the time allocated.

(Slide) Can I have the next slide?

What is the total cost of the program? It's going to cost about 50 FTE, 30 of these from NMSS and the regions, and about $4.24 million. It will run from fiscal '94 through the first quarter of fiscal '98. The length of time is mostly things that involve rulemaking.

COMMISSIONER REMICK: Carl, is that 50 full-time equivalent years or 50 full-time equivalents per year?

DOCTOR PAPERIELLO: No, no, total. No, over -- no, no, no, not per year, no.

COMMISSIONER de PLANQUE: Carl, is that over and above the staff that's currently dealing with the routine medical issues or does it include them?

DOCTOR PAPERIELLO: In the case of NMSS, that is true.

COMMISSIONER de PLANQUE: Which? That was an "or" question.

DOCTOR PAPERIELLO: Dealing with the other offices, I know that Ed Jordan, for example, just this past year has transferred two FTE or put them in the materials area, looking at -- and so, when the other

offices gave me their resources, they indicated they could do it. Now, whether or not they have reallocated or how they got to the point they got, I don't really know.

MR. TAYLOR: AEOD wasn't reallocation.

MR. BERNERO: Yes. But I think to answer your question, this is not the entire medical activities. This is a delta.

COMMISSIONER de PLANQUE: Right. This is over and above --

DOCTOR PAPERIELLO: This is over and above what we would do if we weren't doing all of these things.

CHAIRMAN SELIN: But it's not over and above the previous budget. Some of it is funded through reallocations and not doing some --

DOCTOR PAPERIELLO: That's exactly right. That's exactly right.

MR. TAYLOR: These numbers are within the budget projections for '94, '95.

COMMISSIONER de PLANQUE: Right. But it's the incremental extra needed to do -- carry out what's --

MR. TAYLOR: This plan.

DOCTOR PAPERIELLO: Right. For example,

we will be transferring FTEs which essentially are going to come out of regional inspection effort to this program. We're not going to move the people, we're going to rotate people into positions and we're going to delegate the work out in the field because much of the activity in terms of revising licensing guidance and inspection guidance is best done by people who have a lot of experience in using the procedures. So, that's how some of these resources are going to be obtained.

(Slide) Could I have the next slide?

As I mentioned earlier, all of the affected offices that are involved in this program have been involved and concurred in this particular paper. Two of the FTE within NMSS per year have been reprogrammed from high-level waste and low-level waste, and as I mentioned earlier the other four are coming from the regions. We're going to rotate people in this area.

COMMISSIONER de PLANQUE: Can I just make sure? Is this impact these other programs in any way that we're going to hear about next week or is this --

MR. BERNERO: No. That was done as part of the budget package you just reviewed a few weeks ago. That was -- yes, we foresaw that need, made that

impact. All the impacts were presented there.

COMMISSIONER de PLANQUE: And this is true for what you're doing with the regions as well?

DOCTOR PAPERIELLO: Yes.

(Slide) Can I have the next slide?

Let's just talk about some of the program areas and what's to be accomplished.

In the area of what I call medical policy and coordination, the tasks to be accomplished in this area include the National Academy of Science external review is a major activity. The FDA MOU has already been signed but now has to be implemented. Other activities in this area is waste collector and processor guidance. After a meeting with state representatives and waste processor representatives, a draft guide has already been prepared. It was prepared by my division and Low-Level Waste, the Low-Level Waste people in NMSS and has been sent to the representatives at the meeting and is currently being reviewed. So, that's an activity that's actually in progress.

Pending completion of the National Academy study, we together with Research will look at establishing some type of interim criteria. So when you get rulemaking in the future in the medical area,

there will be some kind of comparison and compare what we're proposing to do with the existing 79 medical policy statement.

COMMISSIONER REMICK: Carl, when I look in the SECY-93-244, the discussion there, a description of program area 1, it talks about securing contract support for a study. I assume that's the National Academy of Science?

DOCTOR PAPERIELLO: Yes. Yes.

COMMISSIONER REMICK: It doesn't identify it as so, but I assumed that was the case.

DOCTOR PAPERIELLO: Yes, that's what it is.

COMMISSIONER REMICK: The Commission spent a lot of time on the statement of work for that study. The description in the SECY doesn't cover that and I'm not saying it should. I would just hope that the staff is keeping in mind the Commission input on that statement of work for the National Academy of Sciences.

DOCTOR PAPERIELLO: We are and I've already had an initial personal meeting with the National Academy and I will be -- even though I will have a staff person assigned, I will be heavily involved in any of their activities.

COMMISSIONER REMICK: Fine.

DOCTOR PAPERIELLO: (Slide) Can I have the next slide?

The second program area I'd like to talk about is the issue of misadministration of patient follow-up. There are actually -- to give you an example, there are 12 action items out of the 90 that fall under this particular area. These 12 action items can be split into two general areas. One is prevention of misadministrations, which is implementation of the QM rule and the second general area is the NRC action in response to once there is a misadministration.

Now, the activities we have in this area that are ongoing, we have a contractor who has initiated a review of the licensee's QM plans. We've issued a draft QM inspection procedure which is going to be piloted at ten licensees over the next several weeks and then, based on that pilot program, be revised and issued to the regions in final form.

The path that we're going down in this area is the contractor will review the plans and the regions will do an in-depth inspection. We do look at QM plans when we currently conduct medical inspections, but the review is relatively shallow in

the sense is there a plan in place and are people trained in the plan and are they following the plan without following the various paths down the plan to make sure all potential therapeutic paths for a particular licensee are followed.

The second major issue that we're working on is the misadministration management directive. I have a staff member who is working on that directive right now and that will cover the topics of how do we inspect when we receive a misadministration report, the role of the medical consultant. I have a -- I'm still working on the paperwork, but I have one of my staff members who is assigned now as a misadministration coordinator. How we will manage the information, and I've had interactions with AEOD on how they're going to put the information in their database, the kind of things I need I think they ought to put in the database, so we want to do a search of misadministrations, and then what are we going to do with the report and the consultant's report to ensure that all the information goes where it's supposed to and is retrievable, a patient follow-up policy, what are the trip points for initiating either an AIT or an IIT for more severe misadministrations, and cover the issue of what do you do when you think that there's

been a severe impact on a patient and should you notify a coroner or medical examiner or some appropriate state or local authority.

COMMISSIONER de PLANQUE: Carl, I sense some policy issues arising as part of this and we're looking at a management directive. How or would you expect to get Commission input on this?

DOCTOR PAPERIELLO: Well, management directive is something I can't -- I mean I can draft it, but somebody else has to approve it because it has to be coordinated.

MR. BERNERO: Yes. Let me take over for a moment here, Carl.

In the preparation of this you may be aware there's a rather lengthy catalogue of questions that I have given to the General Counsel. We are trying to develop this management directive with the full expectation that there's a great deal of legal as well as policy involved in it. It is my intention that when we get to the point where we have both a substantive management directive framework, something that looks like a coherent product, and when we have answers specific to those questions that we will use it in some way, have a vehicle to come to the Commission because it's very clearly the agency's

policy.

It will involve policy issues such as -- right now we have an ad hoc requirement that we have a medical consultant for every misadministration. But the instructions for those consultants are not very clear. What should the consultant do? How far should the consultant go? What is our objective? What do we as an agency want to accomplish by that? That whole thing, that fabric has to be woven to some degree before you can look at it and see what it is. But clearly it will come to the Commission.

COMMISSIONER de PLANQUE: Okay.

CHAIRMAN SELIN: Will it come to the Commission clearly? That's the question.

Doctor Paperiello, as you go through these pieces, you might point out the implications for the agreement statement programs, whether we will have to provide resources out of the agreement state office to do comparable training or comparable development since the question of medical programs in agreement states, of course, is a major issue. For instance, in this area, we're developing really on an exploratory basis how to handle a set of things that we've handled on an ad hoc basis in the past. We're going to obviously want to communicate our views, whether they're

questions of strict compatibility or just some cases, other cases, different types of compatibility. We're going to want to communicate our views with the agreement state programs. This is a major additional workload to go to the other 29 states.

MR. BERNERO: Yes, it will.

CHAIRMAN SELIN: Where will that work be handled?

DOCTOR PAPERIELLO: The paper -- we've talked to State Programs and they've included resources and it discussed in the paper will hold a couple workshops. How much -- currently my division expends considerable resources supporting the Office of State Programs. In other words, we do training, we go out and look at sealed source and devices. I've had a request today for a considerable amount of technical assistance. So, I guess I hadn't really, other than what they gave me, considered any additional burden on them other than what they gave me on --

CHAIRMAN SELIN: Not in this topic per se, but when you go through it all and not so much at the table. We might sit down -- I'm sorry. You might sit down and say, "Can this be handled within the normal compatibility and training support or are we talking

about an additional amount of effort which also should be explicitly budgeted?" Probably any one of these could be handled within your training allowance, but as you start adding them up you may not be able to do that.

DOCTOR PAPERIELLO: If we expect the states to put the same level of effort that we are proposing to put, and which frankly we have put in the past year on follow-up on misadministrations, we are probably going to have to expend resources in training them and, of course, they're going to have to spend resources in receiving the training.

CHAIRMAN SELIN: QM rule is one of the highest priority federal/state programs. So, that's a reasonable assumption.

DOCTOR PAPERIELLO: Yes, I think so.

CHAIRMAN SELIN: Commissioner de Planque?

COMMISSIONER de PLANQUE: I'd like to just expand upon the Chairman's point in that I think it's extremely important as to how and when you get agreement states input on this since it's going to have such a huge impact on them. How that's woven in is, I think, extremely important.

DOCTOR PAPERIELLO: Well, we would share what we do. I suspect from the time I complete a

draft, which I plan on probably sometime in December, there's other pieces that float with this thing in terms of what the consultants do and how we notify the public in the case of the same people are working on it, is probably going to be quite a time before I can get everybody to agree on the draft and it would be floated through the agreement states and other offices for comment.

CHAIRMAN SELIN: As you get down to your second level of planning, which of course is beyond what is required at this point, you'll need to say, "Is this a big enough deal to need a special agreement state workshop? Should the agreement states just be given drafts, et cetera?"

DOCTOR PAPERIELLO: That's already the feeling on the part of state people, the State Program people.

CHAIRMAN SELIN: If I might just take a liberty with Commissioner de Planque's point, I think the point she was trying to make is she believes and certainly I believe and I'm sure the other Commissioners do that in topics of this magnitude we would actually like their input rather than just how they will implement these things once they're done.

COMMISSIONER de PLANQUE: As early as

possible in the process.

DOCTOR PAPERIELLO: Yes. But I would say that we will be addressing many issues that the Commission itself brought up. So, this is not being done in a vacuum. We owe you --

CHAIRMAN SELIN: That doesn't mean that they're right.

DOCTOR PAPERIELLO: And we do owe you a report in the Commission early in 1995 on our views on whether or not the QM rule has been effective in reducing misadministrations.

(Slide) Can I have the next slide?

Medical rulemaking is the next area and this is where we get some long time lines. First, there are three ongoing rulemakings that I sort of inherit. One is the pharmacy rule, which will allow -- which will relieve people of the requirement to strictly follow the package insert. Another significant component of that rule will be that board certified physicians can be selected by licensees to become authorized users and we will receive notification rather than us issuing a license amendment. Actually, from my viewpoint, that's an extremely important point because as a practical matter now we spend an enormous amount of resources,

ours and licensees, on something that is really pro forma. If we get an application in and a physician is board certified, the technical person deals with it like ten minutes and it's mostly an administrative issue. So, this is going to be no decrease in safety and, frankly, we save everybody a lot of resources.

Patient release criteria. Right now there seems to be -- I'll say there's an apparent inconsistency between the new Part 20 and existing Part 35, and the third issue is the exposure of embryos and neonates. It's one of these things you would expect that everybody is concerned about. At least I've been in nuclear medicine departments and you see big signs about ensuring that the patient is not pregnant or nursing, but apparently there are problems out there occasionally. It's not one of these things that's done universal. When it occurs, there is nothing in our regulations right now that makes it a violation or even something reportable to us.

The second major issue, and this is really long-term, and that is a revision, a complete rewrite or reorganization of Part 35. I recognized that we did it. But medical changes, uses are changing fast. We got in and I saw something about a request for

guidance from one of the regions two weeks ago for a device that is known as a pulsed HDR unit. Well, we put out a bulletin and we require people to when you use this machine be able to intervene. Well, you can't possibly intervene with a pulsed HDR because the patient is connected to this thing for several days and you're not going to have a medical physicist and a physician standing next to the machine for three days. So now, how are we going to handle something like this? Fortunately there aren't that many devices like this in the country but we are getting requests to license it.

CHAIRMAN SELIN: Doctor Paperiello, I've spoken to General Counsel about this and this might -- I mean about what I'm about to say, not about Part 35.

DOCTOR PAPERIELLO: Sure.

CHAIRMAN SELIN: It's very clear that when we're in as dynamic an area as the medical area, that we and the agreement states will never be compatible because we change the rules faster than they can bring up the previous rules. So, if you're going to propose rewriting the rule, we need to really change the structure so that you have a core which is the fundamental regulatory stable part and then a set of attachments which obviously will have the same weight,

but can be updated more easily and will not require new legislation. You're really going to have to do a survey of what the states need to implement these pieces so that we can have comments that have the weight of the rule, but don't require the same delay. If they're always three years behind and our mean time between changes is two and a half years, you clearly have an unstable situation.

DOCTOR PAPERIELLO: And the time constant seems to be shorter than three years.

CHAIRMAN SELIN: Exactly.

DOCTOR PAPERIELLO: But rather than going through a couple of the other devices that I'm aware of that we don't address, the goal is to get it to a structure that is like that, a core, make it easy to maintain. I have a slight prejudice. I believe in the diagnostic nuclear medicine area we've been entirely too prescriptive, at least in terms of the number of requirements in the existing Part 35 compared to the risk that's involved.

Another issue that we need to address that we've discussed with the ACMUI is training of experience for RSOs and authorized users in the medical area. As an approach on this thing, whatever we do, what I'm proposing to do is I do want to go out

with advanced notice of proposed rulemaking. I do want heavy medical community and state input on whatever we propose to do to get to where we want to be. That's one of the reasons why this is such a long time on this one.

COMMISSIONER REMICK: Carl, you mentioned the apparent inconsistency between Part 20 and Part 35 on the patient release. I have an interest not only in the medical area but in a broader area of do we have inconsistencies when the new Part 20 goes into effect with other regulations. I bring this up because I have some very important ears there to the left of you. But in other areas -- from time to time I've brought it up and we've talked about moving the dose limits from Part 100 to Part 50, raising the question that the ratio we have there between whole body dose and thyroid doses to me does not seem consistent with what we're saying the organ waiting doses are in Part 20 or ICRP is saying.

So, I ask you in the medical area, but I ask Mr. Taylor and Mr. Bernero in the broader area, are we doing anything to look at making sure that we do have consistency with our new Part 20 and our other regulations where we have doses?

MR. BERNERO: Yes. The one with the

patient release criteria is a relatively simple one. I think you're aware of it. But yes, that's true. We have it in the waste area, we have it in the reactor area. I think that what we're going to have to do, at least this is the perception I have, is we're going to have to modernize all of our regulations to get away from this old whole body thyroid and get to the effective dose equivalent rationally. I mean we have this problem in waste, we have it in the reactor arena and we have it here.

CHAIRMAN SELIN: But you're also going to have to change the structure so that we reference some other rules or other documents. We can't continue to write all these numbers explicitly into each rule. When we change one, we want to change them all. We need to set up a database structure, a reference structure. I think Part 35, if you really are serious about that, would be a very good place to start.

MR. BERNERO: Yes. But I'd just like to add one more thing about the inconsistency of dose. The significance of the change in Part 20 from the old version to the new version, the philosophical basis of that being so different, it is not a simple task to be rational. If you go back to our old material regulations, 10 CFR 30.70, exempt quantities and

things like that, there are many areas of the regulations that were developed with criteria that were developed on the old philosophy. It's not a simple conversion to effective dose equivalent to take care of that. It will take a major activity of modeling and analysis. So, it's not as simple as I would like, but it's necessary. There's no question.

CHAIRMAN SELIN: It will be when you finish.

Doctor Paperiello, please.

DOCTOR PAPERIELLO: (Slide) Could I have the next slide?

The next program areas 4, 5 and 6 deal with licensing, inspection guidance and enforcement policy. These are not what I'd call immediate safety issues. They're more of a matter of efficiency and effectiveness and also an effort to minimize license conditions. What we do, we have licensing guides. The licensing guides have not been maintained and kept up to date. So, what we do to get around that is we issue policy guidance and directives to the regions which are an easier thing to get out. However, licensees don't get to comment on these, nor do they generally have an explicit knowledge, but various regions, of course, will send copies of these things

out to licensees to explain what they have to do in order to get a license for a certain activity. Then on top of that, the regions on specific issues, when they're not covered in either the licensing guides or in the policy guidance and directives, send requests into Headquarters. We call these technical assistance requests, but most of them are not technical assistance, most of them are matters of policy and law for specific guidance.

I started a few weeks ago ensuring that all of them came through me and didn't come to my branch chiefs. I farm them out but I wanted to see what sort of things were being asked. Frankly, if we had better guidance out to staff, we would probably save both our licensees and ourselves time and money over the long run.

In the inspection area, we need to focus more on primary safety issues, including the management of the Radiation Safety Program versus things which are easy to inspect but what I call conventional requirements, the fact that a committee has to meet once a quarter, the fact that you might have to calibrate something on a quarterly basis. As important that equipment be calibrated and records being maintained, but many of these things are not

fundamental safety. They deal with conventions and ways of achieving safety and we really need -- we only have so much time to inspect and we keep multiplying our regulations. We can't just keep -- we have to cut somewhere, but we need to concentrate on the primary safety indicators in issues of exposures, of people's training, of control over material.

Event response. We need to place more emphasis on event response, the small events. The big ones get IITs, they get AITs. But I look at too many inspection reports that concentrate on violations and not understanding why the licensee got into trouble. In the regulatory impact survey that I conducted, licensees complained about that and frankly if we want to -- it's when a licensee has a mistake or an error that we get an insight into systems failure, including management systems failure. We need to understand why these events occur so we can do something or teach people what they need to do to prevent them from occurring.

(Slide) Can I have the next slide?

COMMISSIONER de PLANQUE: Carl, before you go ahead to the next area, if my understanding is correct I think some of the agreement states, or some of the states may have some of these guidance

documents are there. Are we setting up a mechanism to look at those?

DOCTOR PAPERIELLO: I'm going to -- we should have copies. We've asked them at least to provide copies of what they use and I do want to take a look at everything they use. I've talked to them at meetings about this. I don't intend to do any of this, conduct any of these activities in a vacuum. I want everything -- I don't want to rediscover the wheel and if I have an industry document, I'll use it.

CHAIRMAN SELIN: As long as Commissioner de Planque brought up this question, I would just like you to consider something. I'm not sure it's a good idea. But I think you might be, after you've been all through this, ready to have a workshop with the agreement states, not on any particular set of things, but saying, "Look, we're talking about changing in a major way the way we do business and this obviously is going to be a moving target for you 29 folks also," and see if you can talk about a process to shorten the time constant and to, at least for those that care to, to come more directly into concordance with where you're heading and therefore where we're heading.

DOCTOR PAPERIELLO: I'm already scheduled to attend the all agreement states meeting in October.

I do intend to interact. I've met with some of the states at the Radiation Control Program Directors meeting in May and some of these ideas have already been explored with them.

In the enforcement area -- I don't know how to describe this, but it's not clear if I look at the statistics that I can see we're getting results from enforcement. It's clear that you need it and there are some significant problems out there. But let's put it this way. A typical civil penalty in the medical area might be somewhere between $2,000.00 and $5,000.00. Not too many of the licensees are doing things deliberately. They sometimes stumble into things. My feedback I get from at least a sample of people which are very big licensees in the regulatory impact survey, they're primarily concerned with bad publicity. But most of these licensees want to do the right thing. They're not trying to do the wrong thing. But one way of looking at this financially in perspective is that a gamma knife installation cost $4 million, an HDR costs a quarter of a million dollars plus -- that's for the machine, not counting the shielded installation. I'm told that the cost of getting into a nuclear medicine clinic is in the order of $1 million. So, it's not clear that the size of

the fines are a deterrent. I do know the publicity is a deterrent.

On the other hand, I don't see a lot of positive incentives other than you don't get fined as a reward for good performance. One of the things I'm considering is to look at our inspection frequency and see whether or not there is something we can do -- in other words, if we come out to you and we're there -- you know, the last couple of times we've been there, there have been no problems. Can we extend the frequency of inspection, save you the fee, do something to recognize the fact of your good performance? Most of our licensees do good.

CHAIRMAN SELIN: Could I make a suggestion on that?

DOCTOR PAPERIELLO: Sure.

CHAIRMAN SELIN: First of all, the universe almost falls into big licensees and little licensees. Little licensees, a civil penalty is very important to -- and these guys can't reasonably be expected to have a terrific paperwork program, QM, self-assessment. Big licensees, the amount of the civil penalty, almost like reactor guys, although on a small scale, isn't so devastating to them. But even they might be at a margin if you're talking like a big

city hospital. But nevertheless it's the publicity, et cetera.

On the other hand, a little guy can say, "I'm a well logger and I've got 80 --" well, medicine. "I do a few diagnostics, not very much. I get 87 papers from you folks a month. I really can't keep up with them. You can have some sympathy for that.

So, I might suggest that you have a different approach for the two different worlds and for the big folks not only stretch out the amount of frequency but consider going to more self-assessment where we don't just leave them go but we say, "You do the audit." I mean, "You do the assessment. You send it to us and we'll review them on a random basis." For the little folks, then the money really does mean something.

DOCTOR PAPERIELLO: I agree. Well, we need to do something to get problems fixed and to give people an incentive and we ought to concentrate on safety issues.

CHAIRMAN SELIN: One of the things I think we have to do is follow up soon after for people who have been assessed the civil penalty because there's really no credibility if we don't follow up to see if they've actually fixed the problem.

DOCTOR PAPERIELLO: I agree 100 percent.

CHAIRMAN SELIN: I don't believe we do that consistently. One question you should be able to answer when all this is at least do the penalties keep -- we don't know if they're deterrent, but at least do they keep recurrences from happening in the same way licensees?

DOCTOR PAPERIELLO: Well, when I was Deputy Regional Administrator, that's sort of the things I kind of looked at. You know, look at how the office is running. Several years ago I went through and I was looking at open items and I found civil penalties. Actually it was on the reactor side. We issued a civil penalty and a year later we hadn't closed it out. We did, but I'm just saying that was the sort of thing -- you're right, and I agree. You ought to follow-up an escalated action within six months after -- generally, I think it's about right.

CHAIRMAN SELIN: Just thinking about our colleagues on the Agreement State Program, one of the things we're going to come back and ask you, not soon but thereafter, is does enforcement seem a like a unique way to accomplish certain objectives or is it one of several? Because, as you know, we don't require that the agreement states have an enforcement

program. We do require that in some way or another they follow up.

Mr. Bernero?

MR. BERNERO: Yes. I would just add that there's still a residual question and you just raised it. Is enforcement a necessary component? Carl, in the earlier dialogue on this, mentioned the gamma knife. We're right now looking at the risk of gamma knife operations and a misadministration that occurred with one recently. When you look at this $4 million device and the labor rate that goes with it, remember this team of physicians and physicists and nurses and an enormous effort. Is enforcement a necessary component or is this perhaps something like airplane crashes? When you have an event, the principal focus is on discovery of what went wrong and get back into the QM side of it and say, "What does it take to avert that?"

CHAIRMAN SELIN: That's a good question. But the Commission, as a question of policy, is committed to the importance of enforcement for us.

MR. BERNERO: Sure.

CHAIRMAN SELIN: I'm really thinking more of the extension. When you have not just four or five regional material programs to cover the entire

country, but people who are in the individual states, are there, say, substitutes for enforcement in terms of frequent and intimate contact with the programs? We might at some point take a review of the enforcement policy. We're already doing that on the reactor side. But that's a tough -- it's just hard to say how would you analyze that question.

COMMISSIONER REMICK: My personal views are of course we have to have enforcement because there are some people who intentionally violate. But I do agree with you that I think most people want to do what is right. The important thing is when they're made aware of a problem, they want to modify it or change it, mitigate it. If they don't, then I think enforcement is more important.

DOCTOR PAPERIELLO: That's right.

COMMISSIONER REMICK: But I think in this agency we tend to go the civil penalty almost regardless of the circumstances. That's not quite true. That's perhaps an overstatement, but the tendency is to fine, fine, fine. I think the publicity, getting proper attention and so forth, the importance of those things are lost and we think that a fine will accomplish what we're trying to accomplish. Personal view, long felt.

DOCTOR PAPERIELLO: (Slide) Could I have the next slide?

The Commission raised an issue in one of the SRMs on the role of the RSO. This is also an issue the staff had begun to focus on independently on a somewhat different path. The current issues focus on medical RSOs, but it probably goes to all licensees.

If you look at our regulations, there is no across-the-board recognition of the role of the radiation safety officer. We have a relatively week radiation safety officer in Part 33, that's an older regulation, a somewhat stronger RSO in Part 35 and I've seen a draft proposed revision of Part 34 on radiographers which was a still stronger requirement. Power reactors, I've mentioned this before, have RPMs and requirements for management control procedures and audits.

We have several things we're doing. We're working on a NUREG that will basically describe radiation safety programs at medical facilities with different sizes. In other words, this is no requirement, this is just ways it can be done. We're looking at the training and experience criteria for physicians, physicists and RSOs for the medical

facilities. We're looking at a goal of a -- a regulation in Part 30, 40, 70, wherever we need it, essentially to address the major source material, byproduct material. I would like to have a performance based regulation for RSO and management duties. My goal is to tie in existing regulations. The new Part 20 requires at least an annual program review. Part 35 requires annual reviews of the QM program, and then looking for the industry to develop guidance, how management can best assure itself that its program and RSO are functioning properly. To me that's the root of the problem.

I think this will address the concerns that have been raised in this area. But I think it's an across-the-board thing. We again propose to do this through the rulemaking process which will include advanced notice of proposed rulemaking and get a lot of the affected people on board to give us ideas on the best way we can accomplish this.

(Slide) Next slide.

We have research and information management. We have a number of research activities between us and the Office of Research into human factors and risk assessment. We are also working with AEOD to expand their materials and misadministration

database and tracking system. I have initiated a computer-based tracking system for work activities in my division. This did not exist before I came here. There's a lot more that can be done on management of information. I have a meeting in a week with IRM to deal with how we can use computers more effectively.

In the area of risk analysis, it's interesting. About two weeks ago, Lawrence Livermore gave a contract report here on risk analysis as applied to the gamma knife. They identified treatment planning as the greatest risk path. In particular, going from the diagnostic imaging of the brain and translating the parameters into the gamma knife. Three days later, I heard of a misadministration with a gamma knife in Colorado caused by the identical problem that Lawrence Livermore in their study has identified as the most significant source of misadministrations for that device. I think that's a technology that they are working on that we want to develop because I'd like to apply it to other devices to try to identify what are the critical things that ought to be looked at.

(Slide) Next slide.

Just a brief update. We are actively implementing the QM rule. We have an enforcement

panel that reviews cases. Enforcement probably, although that's what they call it, is really to look at what the regions are finding, have consistency in application of violations and applying the enforcement policy and these people involve NMSS, OGC, OE and regional representatives as well as Doctor Polycove. In addition, we have contractor review has been initiated of plans and we are following up these plans and routine inspections.

(Slide) Next slide.

The staff is looking for your endorsement or some sort of approval of what we're proposing. As I noted earlier, there are ongoing efforts to address many of the actions in here because we received these as action items from either the IIT or in Commission SRMs. The management plan is a portion of the whole medical use program. We have a lot of activities that are already ongoing in this area.

Nominally we're planning on implementing this for budget purposes as of the beginning of the next fiscal '94. Just like anything else, if this thing takes several years to do, we have the National Academy study which may cause some type of mid-term correction. Events may cause changes. Obviously congressional hearings and the like. So, I anticipate

that some things will change. I think some of the more immediate tasks will get done before there are any changes, I expect.

CHAIRMAN SELIN: Other than the really large question about how much does it pay to do on AEA radiation when you have such unequal programs for linear accelerators, let's set that aside. If we do all these things, are we 80 percent towards having a predictable and reasonably secure program or is it just the tip of the -- well, the tip of 90 icebergs? What's your assessment of how effective these steps will be?

DOCTOR PAPERIELLO: I believe in the things that we regulate that we will be in reasonably good shape. But it's hard to quantify the things. We don't have a lot of --

CHAIRMAN SELIN: Incidents.

DOCTOR PAPERIELLO: You know, I don't believe -- it's not clear that we have a lot of big problems out there. They're infrequent. I'm working in an area where nobody has said, "This is a risk number that I want you to work to." It's sort of, "Fix things and I'll tell you when they're fixed." There's some issues that are efficiency. I mean let's put aside this program. We have in our inspection and

licensing program when I talk about the guidance not being clear and things like that, there are things that just as a manager bother me because they're inefficient and we're spending a lot of time doing things that we shouldn't be doing. So, whether or not we have this plan or not, I would -- in this role, in my job now, I would feel an obligation to fix them.

CHAIRMAN SELIN: But we have at least three things. We have an obligation which is not a risk number but it's a patient interaction number that misadministrations should be treated in a consistent fashion and patients should get a certain amount of information. We have the feeling that there's an occasional really awful incident --

DOCTOR PAPERIELLO: That's right.

CHAIRMAN SELIN: -- and that without being able to prove things, that with replicable management and a lot of self-checking in there, the chances of such a terrible incident as opposed to a miscalibration that one or two people slip in can be stopped. And the third thing is we know that we don't know frequency figures. We're not even confident that we have good misadministration data and we're very confident that we don't have good administration data. Those would be three reasonable program objectives.

The third I don't think is address in your program, is it, collecting --

MR. BERNERO: The administration data?

CHAIRMAN SELIN: The administration data.

MR. BERNERO: No, it's not addressed in this program.

CHAIRMAN SELIN: But the other two and in the misadministration rate you have the programs that seem to be designed to attack them.

DOCTOR PAPERIELLO: We have a -- when we look at changing Part 35, we may consider establishing a requirement. Now, this is separate -- this is sort of slightly. We have had a recent correspondence with the IG on this topic and that deals with collecting administration data. I believe to collect data like that we're going to have to have a requirement the licensees keep it. I'm aware of some large institutions where several hospitals are covered by one license. There are a lot of departments, in other words there are separate therapy and nuclear medicine and radiation oncology are separate departments. In other words, I think the IG believes our inspectors can go out and look in a book and there's a number. The point is, I don't believe -- we're going to check that, but I don't believe there's a book that we can

look for a number in that somehow we can compile. I really believe if we want the information we're going to have to have licensees maintain it. We're going to have to tell them what we maintained because I think there is a distinction in terms of problems between, say, teletherapy and brachytherapy and pharmacy therapy and then the information might be retrievable. But I don't think it's being maintained out there in a form which is readily collectable.

CHAIRMAN SELIN: What I hear you saying, which you didn't really say, but I was hoping you meant these things when you said them, first of all you've got a whole lot of management fixes. Either they're better management or they're efficiencies and as long as we're going to run the program we might as well run it a little more elegantly and a lot more efficiency.

DOCTOR PAPERIELLO: Right.

CHAIRMAN SELIN: We have, as I said, at least these three major areas. If we do these things right in terms of patient relationships, in terms of avoiding -- you know, little problems growing into big problems and just getting good misadministration data, clearly you have some steps going here and there may be a couple of others. In other words, it probably is

your opinion that you're not going to come back to us in five years with a similar program for the next set of things.

I will say one thing that I think you ought to seriously consider. I think it's important to collect administration data, but I also think it's important that we look at things from the physician's and the facility's point of view and say, "What are they reporting to different organizations? Do we really need an NRC administration data? Is there something that the Centers for Disease Control or some other group could expand? Does it have to be done on a comprehensive basis or are there surveys that could do this?" We shouldn't just say, "Let's write something into the Part 35."

DOCTOR PAPERIELLO: I would hope some of this information light might be shed by the National Academy study.

CHAIRMAN SELIN: Very good point. Very good.

MR. BERNERO: And also, if we pursue this as we have in the past run into it, for us to put a unilateral requirement on licensees would immediately raise hackles at OMB and it would be a major burden --

CHAIRMAN SELIN: Oh, you didn't read the

Vice President's report. It's okay now, as long as it's voluntary.

MR. BERNERO: Yes, an offer they can't refuse.

CHAIRMAN SELIN: Right.

Commissioner Rogers?

COMMISSIONER ROGERS: Yes. I wondered if you could say a little bit about how you prioritized the 90 items on your program. They seem to have come from all kinds of sources, SRMs. I looked through them to see what the origin of them was and it seems to be a very mixed collection of --

DOCTOR PAPERIELLO: Well, by and large, some things were prioritized primarily on what things were relatively simple to do and we could do. We merged a lot of things and I don't see a real distinction of saying one thing as -- I don't know how to weight whether or not a misadministration management directive is more important than a rule. I think there's equivalency there, except I can get a management directive done in the next three to six months and have somebody look at it, where rulemaking has a real long time constant.

So, I'm afraid there is not a very rigorous prioritization in these things. A lot deals

with what is relatively -- you can get a lot done over a short period of time versus things where to do it it's going to take a lot longer time to do.

COMMISSIONER ROGERS: Well, I was impressed with your little computer program for attracting things. It looks like a nice little program to keep track of things in the way it's been set up, this time line chart and the software, I suppose, that goes along with it.

And in looking through the SRM of March 31st on these matters, there were a couple of items that it wasn't clear to me immediately where they were in your program, but I picked them up as various tracks in the system.

DOCTOR PAPERIELLO: Okay.

COMMISSIONER ROGERS: In particular, track 78 was one -- 76 and 78 I had a little trouble finding, but I did find them and saw that 76 had already been taken care of. That was consider NRC's role and scope of responsibilities versus that of FDA and agreement states in the review and approval of sealed sources. I think you've said that was completed. I think 76 was labeled as completed in here.

DOCTOR PAPERIELLO: We do have an MOU now

with the --

COMMISSIONER ROGERS: Right.

DOCTOR PAPERIELLO: With FDA.

COMMISSIONER ROGERS: Right. But item 78, which -- item 8 in the SRM which was track 78 was really notifying hospital boards where escalated enforcement is undertaken by NRC. In looking at your GANTT charts under enforcement, I see that the single item that's there, revision of the enforcement policy, doesn't start until the middle of '95. I was just curious as to why if you're going to do that kind of notification you have to wait until the beginning of '95 to start doing it.

DOCTOR PAPERIELLO: Well, when we discussed this with OE, they kind of -- this was their input on the project. Up to now we can handle things like that on a case by case basis. I would raise an associated issue, although it's not a new issue. In the last several weeks we have had several escalated enforcement cases involving VA hospitals. I don't know what to do about VA hospitals. You know, several years ago I met -- came into Washington and with some Headquarters people met with the VA to see if they could do something about bringing -- you know, could they self-regulate.

CHAIRMAN SELIN: You enforce until they come to us with a plan to avoid the enforcements, not the other way around? I mean sooner or later you'll get their attention and then they'll pay some attention to responding.

DOCTOR PAPERIELLO: Commissioner, I wish I had a board there to go to. If there was a case where that idea is a good idea --

CHAIRMAN SELIN: There's a board. There's a secretary.

MR. BERNERO: Yes, they have a secretariat--

CHAIRMAN SELIN: And an assistant secretary for medical.

MR. BERNERO: -- and about two years ago I think you're referring to the -- from time to time we have met with VA Washington and we have enforced -- and typically, of course, it's VA in some city like Houston or somewhere that we've got a major case, and we're enforcing strongly against them and they come up with some kind of proposal and --

CHAIRMAN SELIN: You've got to treat them the way we treat TVA. We forget that they're federally owned and they're an organization we're dealing with. That means public meetings, et cetera.

MR. BERNERO: We've done it before and we have to do it again.

DOCTOR GLENN: I will mention that the VA has taken some actions in response to our meeting a couple of years ago.

CHAIRMAN SELIN: Well, this is not a VA meeting. I didn't mean to get off on that.

DOCTOR PAPERIELLO: Commissioner, I understand --

COMMISSIONER ROGERS: The issue is why we're waiting until the middle of '95 to start this consistent --

DOCTOR PAPERIELLO: And the reason is OE went and told me, "This is when we're going to do the next iteration of the policy and we'll put it in then." That's a very --

MR. BERNERO: But that's not to say we aren't doing it --

COMMISSIONER ROGERS: On a case by case basis.

MR. BERNERO: -- in ad hoc fashion, case by case.

COMMISSIONER ROGERS: Yes. Right.

Well, I was just curious as to why it wound up so late in the program.

But I want to commend you for the basic structure of the program. It looks like it's a very well thought through organization of the 90 items. I can't comment on the individual items particularly, but it does seem to me that the approach that you're taking here is a systematic one that allows you to track things pretty well. So, I'd like to compliment you on that.

CHAIRMAN SELIN: Commissioner Remick?

COMMISSIONER REMICK: On the question of the RSO, the qualifications or responsibility and authority they have are important issues. One thing I don't understand, do we have different written expectations for RSO for medical broad scope licenses than we do for RSOs in broad byproduct material broad scope licenses in other areas like in the academic research area, or are we lacking in both areas guidance or expectations and so forth?

DOCTOR PAPERIELLO: Things are scattered. The regulations -- again, it depends on the age of the regulation. The RSO requirements for broad scope, which is Part 33, has a requirement in Part 33 is the person is there for advice. There is no discipline that the individual exerts over the program. When you get into Part 35, there are stronger responsibilities,

but it's not clear, it's not quite clear how firm the person -- the person has to have procedures, the person has to follow the program and do things like that, but you don't talk about authority. You know, in a reactor, the radiation protection manager has the absolute authority to stop a job. I mean that's -- we don't have that quite anywhere for material licensees. Now, they may do it in the program that we license through their own procedures, but it's not a definitive thing there.

Now, we always have requirements that you as a licensee are responsible for your program and you appoint an RSO, but the problem you have is let's take a community hospital. We want a nuclear medicine program. We hire a physician to run the program and in some cases the administration just defaults to the physician. You know what has to be done. The physician will hire a consultant. They'll submit the license application and it's not clear that the administration in a hospital has any interaction with the program beyond that. Of course, it even gets worse if you find out an inspector has done an inspection and when they exit they exit with a physician and don't exit even with the hospital administrator. Now, we've tried to stop that, but

that's --

MR. BERNERO: I'd just like to add a point of concern on that. It's almost in contrast. If you look at an RSO in an institutional education industrial thing and then go to Part 35, I'm troubled that the Part 35 basically says it's a worker safety RSO. Part 35 is essentially silent on patient safety and RSO responsibilities related thereto. That, I think, is what leads to the tendency, especially in smaller institutions, that the doctor is in full control and the RSO is almost an afterthought. That causes me more concern than the medical area.

COMMISSIONER REMICK: The reason I ask the question, I come from a background where the RSO that I had involvement with had a lot of responsibility, but he also had a lot of authority which was backed up by a safety committee and by the administration, that he had authority to assure safety. But I must admit I don't know if that's because that's in compliance with an NRC regulation or it just so happens historically that's true how it was set up. So, I didn't know if there was a different regulation in that other arena than there is from the medical or just happenstance.

DOCTOR PAPERIELLO: The regulation is

relatively weak. The licensing policy is stronger and my experience in the Midwest, having been there for a number of years, at the major land grant universities in the Midwest, the RSO is strong, but considerably stronger than the person was 15 years ago. So, it's been a movement and in part, at least my observation is that all of the universities have become more environmentally conscious. It's not just radiation safety, but it deals with biological safety and chemical safety and OSHA requirements. So, they have major departments to deal with that and the radiation safety officer is part of a department of environmental affairs or something like that to deal with all the hazards that appear on campus.

So, that is a practical thing. But you still get some smaller schools and smaller -- it's the smaller -- mid-size and small institutions where the disconnects. The major institutions are doing by and large a good job and I don't want to mess that up either. That's the other thing. You don't want to put a lot of more burdens on them when they're already doing a good job.

COMMISSIONER REMICK: One other question. In the IIT report, in Indiana, Pennsylvania, there was a finding in there that there was some confusion of

our own inspectors about what was meant in Part 35 by doing a survey of the patient. Some people thought that the area radiation monitor was adequate. I look at the attachment 4 to the SECY document, and you don't have to refer to it, but it says, "A temporary instruction has been drafted to provide guidance on routine inspection of high dose rate afterloaders." Is clarification of what is meant by Part 35 included in that or is that being covered under some other instruction or some other --

DOCTOR PAPERIELLO: Well, it's in the TI. We have also prepared a -- you know, we sent the bulletin out to all HDR users on the --

COMMISSIONER REMICK: Well, this was a question about our own inspectors.

DOCTOR PAPERIELLO: Well, it's clear with our own inspectors now, but as recently as two or three weeks ago somebody on my staff, who I won't name, came to me and said, "Well, we don't license HDR units under Part 35." I mean this is a year later and I said, "If I read Part 35, you cannot use radiation on a human being in medicine unless you're in compliance with Part 35. Read the statement of intent."

COMMISSIONER REMICK: But clarification to

our inspectors is being taken care of by that technical --

DOCTOR PAPERIELLO: Yes, at this point the inspectors that are in the field today. This person wasn't an inspector. But anyway --

COMMISSIONER REMICK: Okay. By joining Commissioner Rogers in his comments on the report, I found it very concise and I thought a very thorough and good job and I thank you.

COMMISSIONER de PLANQUE: Yes, just a couple of questions.

Carl, a very general one. Are there any FACA constraints that you're facing in terms of carrying out any of this if you want to get task groups together or bring in people from the outside? Do you have this problem at all?

DOCTOR PAPERIELLO: In what?

COMMISSIONER de PLANQUE: The FACA constraints.

MR. TAYLOR: FACA, the Federal Advisory Committee Act.

COMMISSIONER de PLANQUE: Is that hampering you in any way?

DOCTOR PAPERIELLO: I was told -- I just received information that we may have -- we have to

consider that with the task group that we have on the NUREG on RSO and managerial responsibility. We have been using -- we have agreement state regulators as part of that and I think the initial view was if we had other state regulators we didn't come under that act. But we have just received information from the Office of General Counsel that we have to -- you know, it depends how we use them. If we use them for advice, then we're all right. Well, I guess we're all right. It depends how you handle the law and whether your meetings are open and noticed and all that. If we expect them to agree, a consensus, then we do.

MR. TAYLOR: And that's a FACA.

COMMISSIONER de PLANQUE: Okay.

DOCTOR PAPERIELLO: So, I'm working with our attorneys. Whatever we do, we are legal.

COMMISSIONER de PLANQUE: Well, I would hope that we can interpret things in a way that will not constrain you anymore than is necessary.

DOCTOR PAPERIELLO: Yes.

MR. TAYLOR: We've learned how to do that in the agency in a couple of ways.

COMMISSIONER de PLANQUE: Okay. All right.

MR. BERNERO: You'll have to speak to my

attorney.

COMMISSIONER de PLANQUE: Yes, right.

A question on the human factors research part of it, looking at your GANTT chart again.

DOCTOR PAPERIELLO: Right.

COMMISSIONER de PLANQUE: In so many of these cases it seems like human error is involved in the misadministrations, yet I see that's not coming in until '96. Are we expecting any interim progress on that?

DOCTOR PAPERIELLO: We have interim reports. I have a report coming in on -- Research has a report that is -- they may have received, I've seen early drafts of it, on HDR. I have a report that I have a draft report from Lawrence Livermore on the gamma knife. They're my contractor. The others are Research. So, this is a combination. We are going to be looking at some of the other technologies. I'm very much interested in Lawrence Livermore's technology because basically what they've developed is a process and a computer code that ought to be applicable to devices in general and different technologies. We need to know what is the weak point in a given technology. In other words, a patient getting stuck in the gamma knife is not a source of

misadministration. That's some things you don't have to worry about.

COMMISSIONER de PLANQUE: Okay. And just a general comment. There's always a concern with moving resources into an area if you haven't really established there's a real problem and a real need, as the Chairman was alluding to before. We've got to keep in mind that the resources are spent with the ultimate goal of adequate protection, health and safety.

But that gets me to your comments about efficiency. I would applaud your efforts in making things more efficient for the staff but also for the licensees because indirectly if you free up resources that are spent unnecessarily on unnecessary rules and regulations and paperwork, then you're freeing up those resources for presumably time and effort on the real health and safety issues.

DOCTOR PAPERIELLO: I understand. In the ideal world, I would like to have a licensing guide like a driver's license manual. I mean I come into Maryland, I have to get a Maryland driver's license. But I go to the license bureau, they give me a booklet and it tells me what I have to do as a passenger car driver in the State of Maryland. I don't have to go

through the code and take out truck drivers and livery and all that.

In the ideal world, if I'm a radiographer, I ought to be able to go a licensing guide that tells me how to apply for a license and I would like to have a checklist in the back that they can go down. You want to know whether you're in compliance? Here's a self-checklist. Did you do this, this, this, and would walk you through that and therefore the -- again, I say ideal. If the radiographer knows what's in that manual and does it, they're okay and that way they don't have to -- right now there's a certain amount of spaghetti logic that you have to go -- the computerese is spaghetti logic in 10 CFR trying to figure out if I'm a small entity what I have to do to stay in compliance.

So, therefore, it will help us, but it will also help the licensees and save them money and help keep them in compliance. Like I said, most licensees, I believe, want to do the right thing. It's just they have to know what to do.

COMMISSIONER de PLANQUE: Yes. And I would just join my colleagues in saying it's an extremely well done report. Thank you.

DOCTOR PAPERIELLO: Thank you.

COMMISSIONER REMICK: Carl, excuse me just a minute. When you get all those guides done, would you please put it in CD ROM and then the Commissioners can see what our expectations are on our licensees?

DOCTOR PAPERIELLO: More than that, and this is what I want to talk to IRM. We ought to have a bulletin board that a licensee can call in and download it. That makes it easier for us to maintain on the thing. So, yes.

COMMISSIONER de PLANQUE: I forgot one more item. On the enforcement issue, if you haven't seen a letter in the Health Physics Newsletter last month on this issue, you ought to take a look at it.

DOCTOR PAPERIELLO: I know. I have it myself.

CHAIRMAN SELIN: Has this program been presented to our Advisory Committee on the Medical Use of Isotopes?

DOCTOR PAPERIELLO: As this, no.

CHAIRMAN SELIN: Do you plan to do --

DOCTOR PAPERIELLO: We do.

CHAIRMAN SELIN: I think it's a terrific job. It seems to be responsive but not foolishly so to the various amount of conflicting guidance that you've gotten in the past and at least that the first

cut does seem to coincide with some priorities.

I would just like to emphasize the three points that have come up.

Number one, please think about agreement state implications of these pieces. Number two, take a look at some point, different points, and see how much of the stuff, other than the efficiency pieces, attack real problems as opposed to fill out logical, concise pieces. Then the third point, if you do decide to try to tackle the question of total numbers of administrations head on -- well, first of all, I would suggest that that's a proper topic for the National Academy review to look at. I think you suggested that anyway. But we are not the only players in the field --

DOCTOR PAPERIELLO: I know.

CHAIRMAN SELIN: -- and at some point we have to put ourselves in the shoes of the licensed community and the different people that are asking them for comparable information. But it is something we're going to have to get sooner or later. There's just no question at all. It may not be efficient from a health and safety point of view, but we're going to be on the Hill all the time saying, "Sorry, sir, we don't know the answer to that question." That's also

a legitimate objective of any program, is to give us a good answer when we get the same question three years in a row.

So, thank you very much for an excellent presentation.

DOCTOR PAPERIELLO: Thank you.

(Whereupon, at 3:21 p.m., the above-entitled matter was concluded.)

CERTIFICATE OF TRANSCRIBER

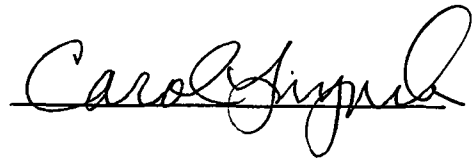
This is to certify that the attached events of a meeting of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON MANAGEMENT PLAN FOR REGULATING MEDICAL USE OF BYPRODUCT MATERIAL

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: SEPTEMBER 10, 1993

were transcribed by me. I further certify that said transcription is accurate and complete, to the best of my ability, and that the transcript is a true and accurate record of the foregoing events.



Reporter's name: Peter Lynch

MEDICAL MANAGEMENT PLAN

COMMISSION BRIEF by
CARL PAPERIELLO, Ph.D.

September 10, 1993

BACKGROUND

- NMSS Senior Management Conference (8/92).
- Medical Issues Paper (9/92).
- Indiana, Pennsylvania Therapy Misadministration and IIT Findings (11/92).
- Master Agenda for Improvement to the Regulatory Program (5/93).
- NRC Senior Manager Review

DEVELOPMENT OF PLAN

- Each of the 90 Action Items were Reviewed. Some Consolidated, Some Completed.

- Priority assigned, Lead & Support Offices, Resources, and Time Frame Identified for Each Action Item.

DEVELOPMENT OF PLAN cont.

- Action Items Categorized into 9 Major Regulatory Program Areas. Direction of Program Area Determined.

- TIMELINE CHART: Identifies Program Areas and Projected Time Frame for the Action Items.

RESOURCES

- Total: 50 direct FTE and $4.25M from FY 94 - 1st qtr. FY 98.

- All Resources Budgeted Except for $1.25M in FY 94 for NMSS. Includes $800K for NAS study and an additional $450K for QM reviews. Funds will be obtained through available or redirected NMSS or Agency Funds.

RESOURCES cont.

- Affected Offices: NMSS, RES, OGC, AEOD, OE, OSP, and the Regions.

- Rotation of Regional Personnel.

PROGRAM AREA #1

ISSUE: MEDICAL POLICY AND COORDINATION

- National Academy of Science Review
- Implement MOU with FDA
- Time Frame: Present - 1/96
  Resources: ~ 3 FTE Total

PROGRAM AREA #2

ISSUE: MISADMINISTRATION & PATIENT FOLLOWUP

- 3 step approach: 1) Draft Management Directive; 2) Ensure Adequate Implementation of QM Rule; 3) Evaluate Effectiveness of QM rule.

- Time Frame: At Present - 12/94 (Mgt. Directive - Contractor Review of QM plans); Resources: ~ 4 FTE Total

PROGRAM AREA #3

ISSUE: MEDICAL RULEMAKING

- Comprehensive, to include provision for changing technology and patterns of use.

- Complete ongoing actions related to: release of patients, radiopharmacy and radiation exposure to embryo/fetus or nursing infants.

- Time Frame: Present - 6/97
  Resources: ~ 12 FTE Total

PROGRAM AREAS #4, #5 & #6

ISSUE: REVIEW OF LICENSING AND INSPECTION GUIDANCE AND ENFORCEMENT POLICY

- Licensing guidance out of date and incomplete.

- Inspection guidance to focus on management and effectiveness of Radiation Safety Programs. Provide additional guidance on response to events, including misadministrations.

PROGRAM AREAS #4, #5, & #6 cont.

- Examine ways of providing greater incentive for compliance by medical use licensees.

- Time Frame: Present - 12/97
  Resources: ~ 14 FTE Total

PROGRAM AREA #7

ISSUE: LICENSEE MGT. & RSO RESPONSIBILITIES FOR LICENSED ACTIVITIES

- 3 step approach: 1) NUREG on Radiation Safety Program Mgt.; 2) Evaluate Training & Experience Criteria for Physicians, Physicists, and RSOs; 3) Revise Parts 30, 35, 40, & 70.

- Time Frame: At Present - 12/97 (NUREG - Revision of Parts 30, 35, 40, 50 & 70); Resources: ~ 12 FTE Total

PROGRAM AREAS #8 & #9

ISSUES: RESEARCH AND INFORMATION MANAGEMENT

- Human Factors and relative risk assessment.
- Expand database and tracking systems.
- Time Frame: Present and Ongoing
  Resources: ~ 5 FTE Total

QM IMPLEMENTATION

- QM Enforcement Panel Reviews Cases Weekly to Interpret & Apply Enforcement Policy.

- Panel Participants: NMSS, OE, OGC, Regional Representatives and Medical Visiting Fellow.

- Contractor Review of Plans and Followup During Routine Inspection or Review During Reactive Inspection.

SUMMARY

- Staff Seeks Commission Approval of Proposed Plan.
- Ongoing efforts to address some action items identified in plan.
- Management Plan is a Portion of the Entire Medical Use Regulatory Program.

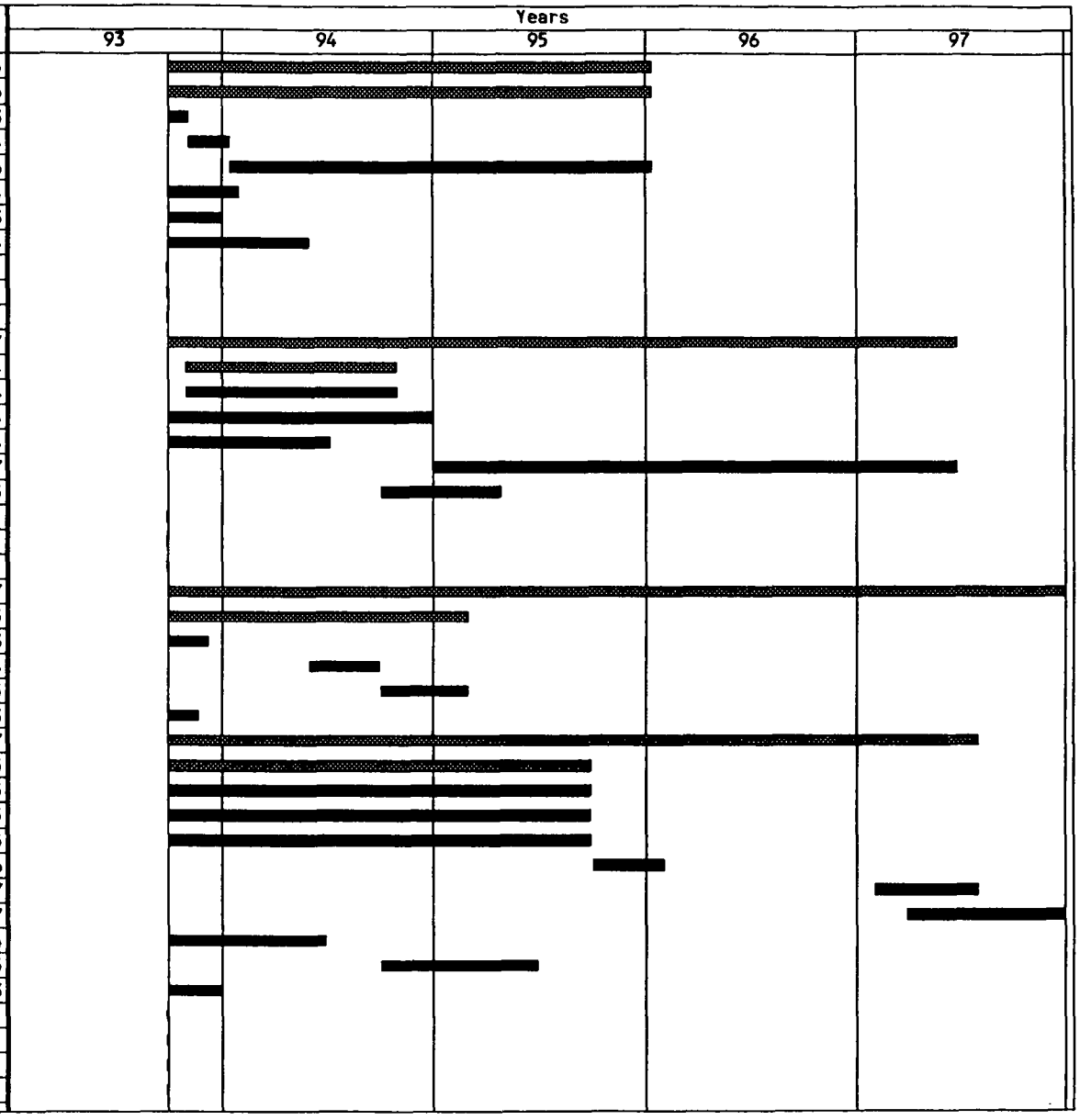
SUMMARY cont.

- Implementation of the plan is scheduled to begin on 10/1/93.

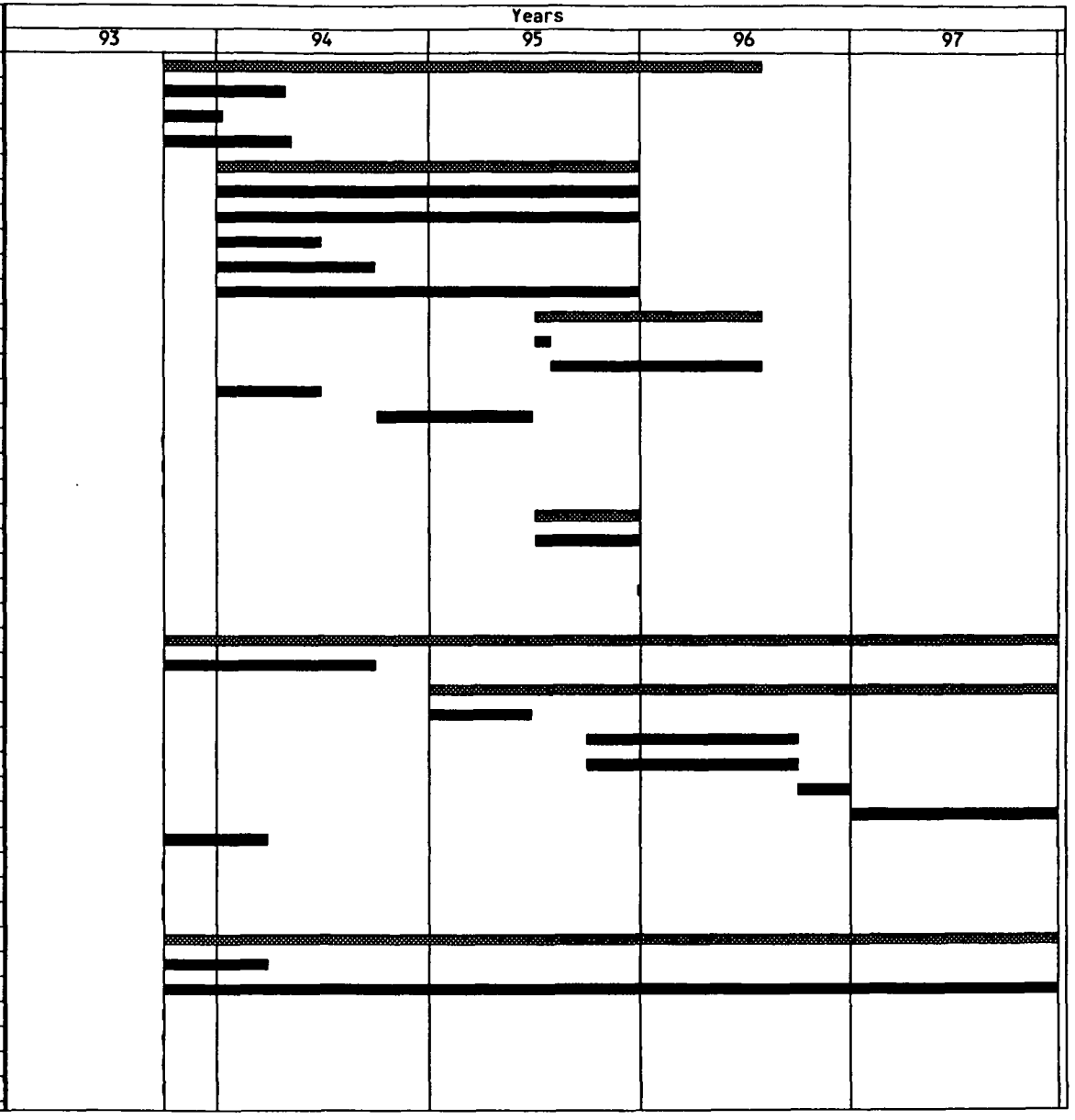
- Implementation will require full management attention and dedication of resources.

- Periodically review and adjust based on new information such as the report of the National Academy of Sciences.

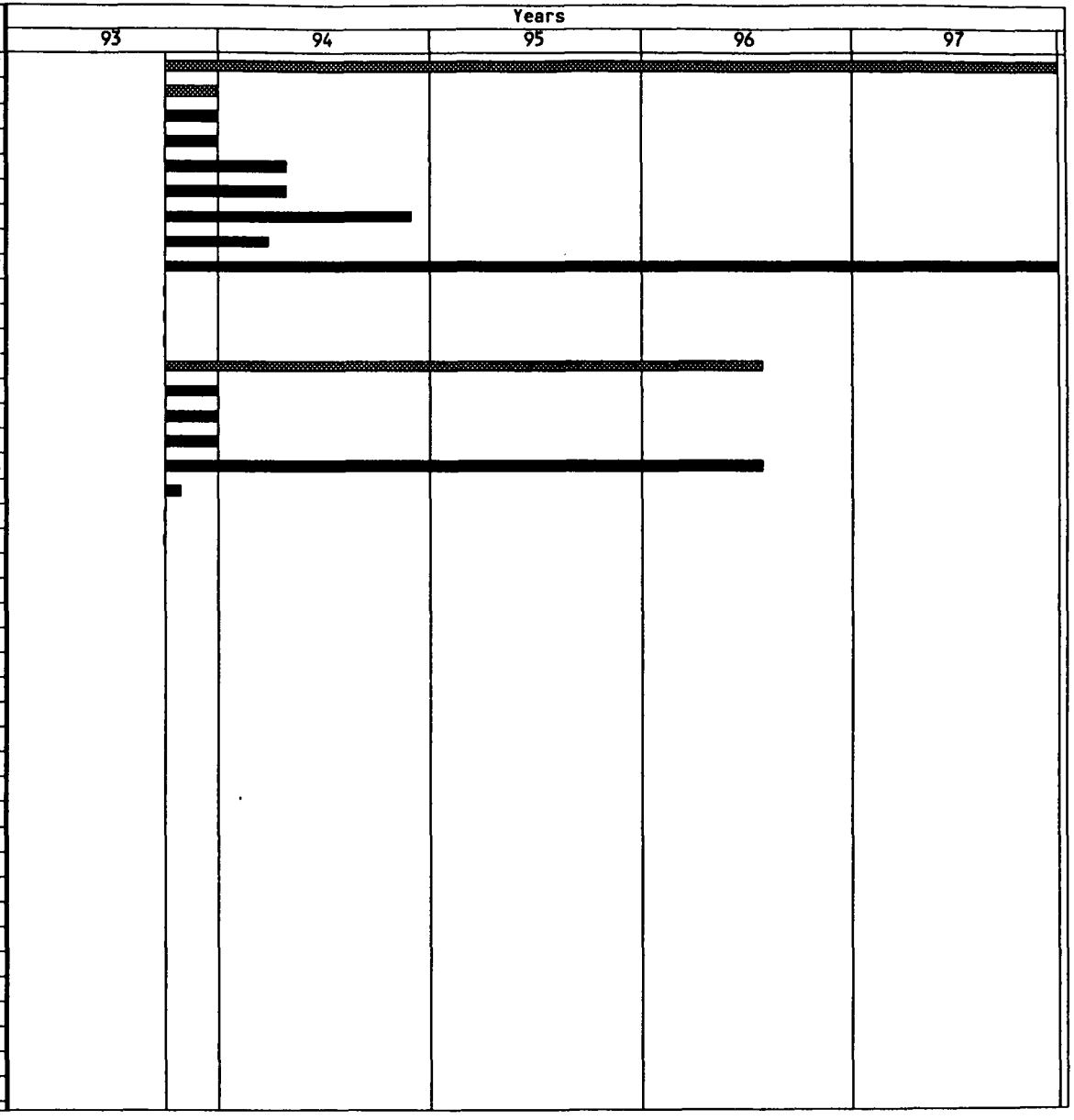
Task Name	Start	End
POLICY ISSUES	Oct/01/93	Jan/12/96
National Academy of Science Study	Oct/01/93	Jan/12/96
Proposed SOW to NAS	Oct/01/93	Nov/04/93
Let Contract	Nov/04/93	Jan/14/94
Contract Work and Final Report	Jan/14/94	Jan/12/96
Waste Processor Guidance	Oct/01/93	Jan/31/94
RES-1979 Med Policy	Oct/01/93	Dec/31/93
NRC/Agreement State Device Jurisdiction	Oct/01/93	Jun/01/94
RULEMAKING	Oct/01/93	Jun/27/97
Pharmacy Rule	Nov/01/93	Nov/01/94
Final Rule	Nov/01/93	Nov/01/94
Embryo/Neo-nate Protection	Oct/01/93	Dec/30/94
Part 20/Part 35 Patient Release	Oct/01/93	Jul/07/94
Part 35 Revision (HDR & Other Issues)	Jan/03/95	Jun/27/97
Review QM Rule Progress	Oct/03/94	Apr/28/95
LICENSING GUIDANCE	Oct/01/93	Dec/31/97
RG 10.5 Broadscope	Oct/01/93	Mar/01/95
Draft to RES	Oct/01/93	Dec/09/93
Draft for comment	Jun/01/94	Sep/30/94
Final Reg Guide	Oct/03/94	Mar/01/95
Submit Revised FC 86-4 to OGC	Oct/01/93	Nov/23/93
Add Appendices to RG 10.8	Oct/01/93	Aug/01/97
Draft to RES	Oct/01/93	Sep/29/95
Therapy Included	Oct/01/93	Sep/29/95
Physician Training	Oct/01/93	Sep/29/95
Relation to QM	Oct/01/93	Sep/29/95
Draft for comment	Oct/03/95	Feb/01/96
Final Reg Guide	Feb/03/97	Aug/01/97
Revise Reg Guide 8.33	Apr/01/97	Dec/31/97
Revise License Reviewer Training	Oct/01/93	Jun/30/94
Issue MC on Materials Enforcement Discreti	Oct/03/94	Jun/30/95
Issue Guidance for Master Material Program	Oct/01/93	Dec/31/93



Task Name	Start	End
INSPECTION GUIDANCE	Oct/01/93	Jul/31/96
Prime Alert-10	Oct/01/93	Apr/29/94
MC - Assessing Public Exposure & Notificat	Oct/01/93	Jan/13/94
TI on Significant Licensee Changes	Oct/01/93	May/09/94
Revise MC 2800	Jan/03/94	Dec/29/95
Program Expansion	Jan/03/94	Dec/29/95
Performance Adjustment	Jan/03/94	Dec/29/95
Medical Field Notes	Jan/03/94	Jun/30/94
QM Inspection Procedure	Jan/03/94	Sep/30/94
Satellite, Field, Temporary	Jan/03/94	Dec/29/95
Third Party Inspection	Jul/03/95	Jul/31/96
Memorandum to OGC	Jul/03/95	Jul/31/95
Evaluation	Aug/01/95	Jul/31/96
Event Response Procedure	Jan/03/94	Jun/30/94
Allegation Follow-up Procedure	Oct/03/94	Jun/30/95
ENFORCEMENT	Jul/03/95	Dec/29/95
Revision of the Enforcement Policy	Jul/03/95	Dec/29/95
MANAGEMENT AND RSO RESPONSIBILITY	Oct/01/93	Dec/31/97
NUREG-MAN/RSO	Oct/01/93	Sep/30/94
Rulemaking	Jan/02/95	Dec/31/97
Adv. Notice of Proposed Rulemaking	Jan/02/95	Jun/28/95
Industry Workshops	Oct/02/95	Oct/01/96
Guidance Documents	Oct/02/95	Oct/01/96
Proposed Rule	Oct/01/96	Dec/31/96
Final Rule	Jan/02/97	Dec/31/97
RSO Certification Form	Oct/01/93	Mar/31/94
INFORMATION MANAGEMENT SYSTEMS	Oct/01/93	Dec/31/97
Licensee Events - Support to AEOD	Oct/01/93	Mar/31/94
Division Action Items	Oct/01/93	Dec/31/97



Task Name	Start	End
MISADMINISTRATION	Oct/01/93	Dec/31/97
Management Directive	Oct/01/93	Dec/31/93
Patient Follow-up Policy	Oct/01/93	Dec/31/93
Notification of Local Authorities	Oct/01/93	Dec/31/93
AIT/IIT Guidance	Oct/01/93	Apr/29/94
Medical Consultant Policy	Oct/01/93	Apr/29/94
Review all QM Plans	Oct/01/93	Dec/01/94
TI-QM Inspection	Oct/01/93	Mar/31/94
Misadministration Coordinator	Oct/01/93	Dec/31/97
RESEARCH	Oct/01/93	Jul/31/96
QA/QC & Risk for Gamma Knife	Oct/01/93	Dec/31/93
QA/QC & Risk for HDR Afterloaders	Oct/01/93	Dec/31/93
Misadministration Events Analysis	Oct/01/93	Dec/31/93
Human Factors Studies	Oct/01/93	Jul/31/96
Southwest Research Source-Wire Evaluation	Oct/01/93	Oct/29/93



POLICY ISSUE
(Notation Vote)

August 31, 1993

SECY-93-244

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: PROPOSED STAFF MANAGEMENT PLAN FOR NRC's MEDICAL USE REGULATORY PROGRAM

PURPOSE:

To request Commission approval of a proposed plan for management of the medical use regulatory program to address major policy issues associated with the current program. The medical management plan identifies major program areas and reflects the current management direction for the medical use regulatory program.

SUMMARY:

This paper provides the Commission with the proposed staff management plan for the medical use regulatory program. It incorporates action items previously identified in the master agenda transmitted to the Commission in a memorandum dated May 19, 1993, and others resulting from the senior manager review of the medical use program submitted in June 1993 by Dr. Carl Paperiello. The plan includes a combination of one-time initiatives and ongoing projects.

Resources to implement the management plan are included in the FY 1994-1998 Internal Program/Budget Review document except $1.25M in FY 1994. This funding shortfall includes $800K for the National Academy of Science study and $450K for the medical quality management program contract. The shortfall will be funded by reprogramming funds within NMSS or the agency. The resources

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504-2659

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NOTE: TO BE MADE PUBLICLY AVAILABLE AT COMMISSION BRIEFING ON SEPTEMBER 10, 1993

for each office are identified in a Table on page 8. Implementation of the medical management plan is scheduled to begin on October 1, 1993; however, there are current efforts to address some of the action items previously identified by the staff and included in the management plan. The projected completion date for plan action items is December 31, 1997.

BACKGROUND:

During the NMSS Senior Management Conference held on August 3 and 4, 1992, senior management decided to prepare a medical management plan to guide the conduct of the medical use regulatory program. In a memorandum dated September 8, 1992, from Robert M. Bernero, the staff described its efforts to develop this plan and anticipated submitting it to the Commission in January 1993.

In September 1992, the staff identified a number of actions to address the more pressing problems associated with the regulatory program and developed a medical issues paper that identified certain program areas to be reviewed to determine if modifications were necessary for improvement. Subsequently, the medical issues paper was discussed during meetings with representatives from the Agreement States, the U.S. Nuclear Regulatory Commission's Advisory Committee on the Medical Uses of Isotopes (ACMUI) and NRC regional management. However, these efforts were delayed as a result of staff actions in response to the November 1992 radiation therapy misadministration and associated patient fatality in Indiana, Pennsylvania, and the Cleveland Plain Dealer series of articles published December 13-17, 1992.

In a Staff Requirements Memorandum (SRM) dated March 31, 1993, the Commission directed the staff to continue with development of the medical management plan, the internal management review of current practices for implementing the medical use regulatory program and the external review of the program. In recent months, the staff developed a master agenda for improvement of the regulatory program. The master agenda identified 71 action items to address the issues raised as a result of the Incident Investigation Team (IIT) report associated with the Indiana, Pennsylvania incident, and others previously identified in the medical issues paper. It was submitted to the Commission in a memorandum dated May 19, 1993. Since that time, the staff identified 19 other action items resulting from the senior manager review of the medical use program submitted in June 1993 by Dr. Carl Paperiello. These additional 19 action items were combined with the 71 master agenda items and considered during development of the medical management plan described below. The development of this plan was influenced by key meetings with the ACMUI, representatives from Agreement States, professional organizations, other regulatory agencies, the medical community, and NRC senior management.

DISCUSSION:

Each of the 90 action items was analyzed to determine the: scope of the required work to complete all tasks associated with the action item; lead and support Offices for completion of the tasks; priority of each item so that an interrelationship of tasks could be identified; projected time frame for completion of each action item; and estimated resources for completion of the action item. In some cases, action items were consolidated to coordinate work efforts and increase efficiency, and in some cases, action has been completed or will be completed before October 1, 1993. The staff reviewed the action items and grouped them into nine program areas, which are discussed below. The projected time line associated with a specific action item can be found in the enclosed Gantt chart (see enclosure 1). The 90 individual action items are also referred to as "tracks" and are found in Enclosure 2. It should be noted that the number assigned to an action item or track is for accounting purposes and does not reflect its priority.

PROGRAM AREA #1
Policy Issues

In February 1979, NRC issued a medical policy statement to guide its regulatory program. A key issue in the policy statement is the commitment to patient safety without intrusion into the practice of medicine. Since then, there have been a number of key regulatory initiatives to address medical use issues, some of which have been opposed by members of the regulated industry and representatives of Agreement States. Reexamination of broad policy issues regarding NRC's role in the regulation of the medical use of byproduct material will include an analysis of the policy statement, and NRC's current regulatory relationships with the Food and Drug Administration (FDA) and Agreement States. NRC and FDA representatives recently signed a Memorandum of Understanding for medical use to further clarify their respective roles.

In accordance with the SRM dated June 23, 1992, and December 21, 1992, the staff is in the final stages of securing contract support for the conduct of an external review of the medical use program composed of several tasks. These include: an analysis of whether the evolution of NRC's medical use program has been consistent with the medical policy statement and whether any changes to the policy are warranted; whether NRC's current framework is appropriate to fulfill its statutory responsibilities for public health and safety; and the appropriateness of the regulatory relationships that exist among NRC, the Agreement States, FDA and various State boards.

PROGRAM AREA #2
Misadministrations and Patient Followup

There is lack of a clear policy on the staff actions required to respond to a misadministration report and lack of agreement among Offices on the appropriate level of patient followup. The ongoing effort to resolve these issues, on a case-by-case basis, diverts significant resources from day-to-day management of other safety-significant issues associated with the regulatory

program and long-term improvements, as shown in the medical management plan. Consequently, resolving misadministration followup issues is a high priority item in the medical management plan. Therefore, the staff plans the following: 1) develop an NRC Management Directive to provide specific inspection guidance and procedures for misadministration followup to permit the determination of the extent and depth of followup needed in each case; 2) ensure adequate implementation of the 1992 Quality Management Program and Misadministrations (QM) rule; and 3) once the QM rule has been in effect for some time, evaluate whether modifications to the rule are necessary to provide clarification of requirements to reduce the likelihood of errors during patient administration of byproduct material. The staff is scheduled to brief the Commission in January 1995 to review the progress made with the QM rule, and determine whether further or alternate direction is needed.

The staff has identified a number of specific questions about NRC's legal responsibilities related to patient followup and is currently formulating answers to these questions to develop the policy basis for the Management Directive mentioned above. These questions involve complex legal matters and require coordination with and review by the Office of the General Counsel (OGC) staff. Therefore, concurrent with its effort to develop the patient followup policy, the staff has provided these questions to OGC which OGC has responded to, or is in the process of responding to. Additionally, the staff has provided OGC with the draft Management Directive and the presumptions made by the staff in developing the policy. OGC has provided comments on the draft Management Directive.

The NRC Management Directive will specifically provide: 1) guidance on use of a medical consultant in misadministration cases to assist NRC staff in evaluating the medical consequences of the radiation exposure and licensee compliance with reporting and notification requirements; 2) an NMSS misadministration coordinator to follow up with the regions on each misadministration, monitor patient followup activities, maintain complete records of misadministrations, and coordinate data collection with the Office for the Analysis and Evaluation of Operational Data (AEOD) and the Office of State Programs (OSP); 3) inspection procedures to ensure that inspectors properly emphasize to licensees their duty to meet all reporting and notification requirements associated with misadministrations; and 4) guidance for notification of local authorities for more serious misadministrations, so that actions by NRC and local authorities can be coordinated. The Draft Management Directive is scheduled for Office review by December 31, 1993.

PROGRAM AREA #3
Rulemaking

Currently, there are three medical use proposed rulemaking actions in progress: 1) draft revision of the patient release criteria described in section 10 CFR 35.75 and possibly, conforming changes to 10 CFR Part 20; 2) revision of requirements for radiopharmacy (published as a Proposed Rule in June 1993); and 3) development of a draft proposed rule to reduce the likelihood of an unintended radiation exposure to an embryo/fetus or nursing infant.

A comprehensive revision to Part 35 is planned to address a wide variety of issues. The staff is considering a major modification to the format of Part 35 and associated licensing and inspection guidance to more easily accommodate changes in the current technology and patterns of medical use. Specifically, Part 35 would incorporate "general" modules, containing appropriate safety standards applicable to all authorized types of medical use, to allow greater licensee flexibility, and "specific" modules, to address radiation safety requirements specific to each type of use. These specific modules would also be discussed in supporting regulatory guides. The staff will also evaluate the feasibility of incorporating existing national technical standards into regulatory guides for the conduct of specific quality control tests on required equipment. Specific regulatory issues to be addressed in the major revision include: requirements for the safe use of remote afterloading brachytherapy and gamma stereotactic radiosurgery devices; modification of existing training and experience criteria; lessons learned as a result of inspection, licensing and enforcement activities since the last revision of Part 35 in April 1987; and minor revisions to clarify existing requirements. As part of the management plan, there are several related tasks on supervision, and training and experience related to radiation safety, that must be completed and the results evaluated, before the staff can make any recommendations in this area. This issue is discussed further in program area 7, "Management and Radiation Safety Officer Responsibilities." The staff anticipates that final action to revise Part 35 may not be completed until the end of calendar year 1997.

In the interim, there is a need to develop and provide specific licensing and inspection guidance. This issue is described in more detail in program area 4, "Licensing Guidance," and program area 5, "Inspection Guidance."

PROGRAM AREA #4
Licensing Guidance

Comprehensive licensing and inspection guidance is a high priority item and focus of the medical management plan. Adequate information is needed by NRC regional staff, licensees, and applicants. The staff proposes two steps: 1) revising current guidance that is outdated because of evolving medical technology and practice; and 2) issuing new guidance to address each type of medical use currently authorized. Existing guidance for licensing radiopharmacies will be updated to incorporate current requirements, and the staff has begun updating current guidance for licensing the medical use of teletherapy devices. Existing guidance in various documents for licensing manual brachytherapy applications, including Strontium-90, and radiopharmaceutical therapy will be consolidated. Additionally, new guidance for the medical use of remote afterloading devices is in its final stages of development, and new guidance will be developed for gamma stereotactic radiosurgery.

The issuance of comprehensive, up-to-date guidance should result in fewer requests by the regions for technical assistance. In addition, it is likely that licensees will submit more complete license applications, thus reducing NRC resources spent on licensing actions.

PROGRAM AREA #5
Inspection Guidance

Current inspection guidance needs to be revised to focus more attention on the management and effectiveness of radiation safety programs and the performance of key personnel such as the Radiation Safety Officer (RSO), responsible managers, and members of the Radiation Safety Committee (RSC). In addition, the inspectors need additional guidance on: 1) misadministration followup; 2) new authorized types of medical use such as remote afterloading and gamma stereotactic radiosurgery; and 3) reactive inspections and allegation followup at licensed facilities, including medical facilities. The staff will also develop criteria for when an inspection for misadministration followup warrants an Augmented or Incident Investigation Team.

Recently developed inspection procedures for the review of licensee Quality Management (QM) Programs will be evaluated based on the findings of a pilot program to be conducted in the near future. A contractor who reviews the QM programs submitted by licensees will assist NMSS and regional staff in conducting the pilot program, using the QM inspection procedures to evaluate the utility of the procedures. The staff will consider the contractor's findings in the issuance of final QM inspection procedures.

As a partial alternative or augmentation of routine NRC inspection efforts, the staff will continue to explore the issue of third-party audits of medical use programs conducted by professional organizations such as the American College of Nuclear Physicians and the American College of Radiology. The staff will consult with the OGC on the legal questions surrounding this issue. The staff will solicit additional information from interested professional organizations to determine whether certain components of audit programs meet the needs of NRC's regulatory program and would be used to enhance or substitute for routine inspections conducted by NRC staff.

PROGRAM AREA #6
Enforcement

The current materials escalated enforcement process may need modification to increase incentive for larger licensees to assure compliance. The staff is reviewing the amount of base civil penalties for various categories of licensees or facilities, and is proposing to evaluate other potential sanctions, such as probation for medical licensees, as suggested at a meeting of the NRC's ACMUI. By FY96, Office of Enforcement (OE) staff will complete a proposed revision to the current enforcement policy on base civil penalties and will have considered other ways of providing greater incentive for compliance by medical use licensees. In addition, the staff is currently tracking identified wrongdoers and has notified the appropriate State, and will notify the appropriate professional bodies.

PROGRAM AREA #7
Management and Radiation Safety Officer Responsibilities

NRC requires a radiation safety program at a licensed medical use facility to

include appropriate management direction and supervision. Key components include: executive management of the licensed facility, the RSO, and RSC. Responsible individuals are expected to take an aggressive approach to ensure that adequate resources are available, that the program adequately ensures public health and safety, and that procedures are fully implemented. Inspection activities at medical facilities indicate that individuals do not always fulfill their roles to ensure effective management of the radiation safety program. This problem is not unique to medical licensees, and will be addressed through rulemaking for all materials licensees.

The staff proposes a three-step approach. First, Parts 30, 40, and 70 will be revised to emphasize the commitment by licensee management, and clarify management's responsibility, to ensure that adequate resources are provided for effective radiation safety management. Licensees must ensure that all responsible parties fulfill their respective roles and are knowledgeable of appropriate regulatory requirements. The rule would reflect materials licensing and inspection guidance directed at significant management involvement in the radiation safety program. Secondly, NMSS staff has initiated a task force to develop a NUREG entitled, "Management of Radioactive Materials Safety Programs at Medical Facilities." The NUREG, a practical guide for NRC staff and licensees, will clarify the role of licensee management, the RSO and RSC to effectively manage the radiation safety program at licensed medical use facilities. Task force participants for development of the NUREG include Headquarters and regional staff and two representatives from Agreement States. The task force is also seeking input from professional organizations and conducting an extensive literature search on related issues. Thirdly, NRC staff will evaluate current training and experience requirements for physician authorized users and RSOs and will secure contract support to evaluate a broad scope of related issues. These include: 1) the adequacy of the radiation safety requirements, including the didactic, laboratory, and clinical components, of the accreditation programs offered by medical professional boards; 2) the preceptor process currently used by NRC for documentation of training and experience obtained outside of an accredited program; the feasibility of a testing process for authorized users and RSOs in lieu of recognition of other training paths; and 3) the need for training and experience criteria for supervised individuals. As part of this contract, other board certification programs, not currently recognized in Part 35, may be evaluated for demonstration of adequacy to meet the required training and experience criteria. The results of this study will be considered during the major revision of Part 35 discussed in program area 3.

PROGRAM AREA #8
Research

NRC has ongoing contracts in place to evaluate the risks associated with therapy procedures and the human error component of misadministrations. These include: 1) a contract for the investigation of certain therapy misadministrations, including root cause; 2) contracts to evaluate the contribution of the human factors in brachytherapy and teletherapy performance errors; and 3) contracts to evaluate quality assurance and risk associated with brachytherapy procedures and devices, and gamma stereotactic

radiosurgery. The findings of these studies could result in revised equipment specifications and operating procedures and form the basis for revised regulations and inspection guidance. Contract work is in the final stages for item 1, and has yet to be completed for items 2 and 3.

PROGRAM AREA #9
Information Management Systems

NMSS and AEOD staff will expand the current NRC database for tracking and evaluation of medical events within the NRC and Agreement State jurisdiction. Currently, the staff is working to identify a set of essential data elements to meet the needs of NRC and enhance the current system. Additionally, NMSS staff will expand the current medical use program tracking system to accommodate action items identified in the management plan.

RESOURCES:

In FY 1994 through FY 1998, the staff estimates approximately 50 direct Full Time Equivalents (FTE) and $4.25M will be required to implement the medical management plan by the Offices of NMSS, OGC, OE, AEOD, Nuclear Regulatory Research (RES), and the Regions. A chart with resources by Office and fiscal year is shown below. All resources are currently within budget, except $1.25M in FY 1994. This shortfall will be funded by NMSS if funds are available, or additional funding will be provided during mid-year or as necessary.

*BUDGETED RESOURCES PER FISCAL YEAR BY OFFICE

OFFICE	FY94 FTE $K	FY95 FTE $K	FY96 FTE $K	FY97 FTE $K	FY98 FTE $K
AEOD	0.8	0.0	0.0	0.0	0.0
OGC	0.8	0.8	0.8	0.8	0.8
OE	0.3	0.3	0.3	0.3	0.3
RES	2.5/350	2.5/100	2.5	2.5	2.5
NMSS/REGIONS	5.6/308	6.6/1200	6.1/500	6.1/500	6.1/500
TOTAL	**10.0/658**	**10.2/1300**	**9.7/500**	**9.7/500**	**9.7/500**

* Direct Staff FTE

The resources for AEOD in FY 1994 are for development of an expanded non-reactor event database. Beginning in FY 1995, AEOD resources for maintenance and operation of the database, and other efforts in implementing the management plan, are considered part of their normal responsibilities.

The table reflects expenditure of FTEs at a constant rate. Inherently, implementation of the management plan will require changes and adjustments. The enclosed Gantt chart contains the projected time frame associated with

completion of action items, and thus, does not reflect a constant rate of resource expenditure. It is expected that more FTEs may be required in FY 1994 for initiating implementation of the management plan and less in FY 1998, if the plan is completed on schedule. NMSS will internally reprogram any FTEs necessary in FY 1994 from lower priority efforts.

The resource estimates presented do not include OSP. OSP's role in this plan is limited to support in coordinating review of rulemakings by the Agreement States, which is part of its normal, ongoing efforts to involve the Agreement States in an early and substantive fashion in changes to NRC regulations that may affect them. Many of the medical use program areas will have a significant impact on Agreement State programs. Early and substantive interaction with Agreement States could involve workshops and meetings in which OSP would normally provide travel and per diem expenses, as well as make arrangements for such workshops. If such workshops were to be held, it is estimated that each workshop would cost approximately $25K for a two and a half day meeting. The staff believes that it would be prudent to have approximately one workshop per year. OSP staff resources for arranging such a meeting are estimated to be less than 0.1 FTE per year.

OBSERVATIONS AND CONCLUSIONS:

1. The staff anticipates that the medical management plan will be dynamic and will require periodic review and modification to adjust for new initiatives resulting from periodic reassessments, unforeseen events, and changes to projected completion dates, particularly, when the outcome or completion date of one task affects another. It should be recognized that the assignment of additional action items or tasks could have a significant impact on implementation and completion of all tasks associated with the medical management plan. Each new action item must be carefully evaluated to determine its priority, and associated resource implications and time frame, so that the impact on the plan can be estimated and priorities adjusted.

2. In addition to implementing the management plan, the eight member technical staff dedicated to the medical use regulatory program will continue to manage a wide variety of program issues that typically ranges from 160-190 action items, at any one time (see Enclosure 3 for a categoric description of these issues and tasks). Most of these items are not included in the management plan because they represent routine tasks associated with program management.

3. NMSS plans to rotate regional personnel to NMSS for some period of time to accomplish specific goals, whereas, some work by regional personnel will be coordinated with NMSS, while remaining in the region. Regional personnel will assist NMSS staff on various action items and related issues, and be focused primarily on rulemaking and the development of new and revised licensing and inspection guidance.

4. NMSS will sustain or increase the level of effort to support the ACMUI. The expertise it represents is a valuable asset to the staff in its

effort to more fully understand current and future medical use and technology. The staff will continue to consult with the ACMUI, particularly in view of the number of issues identified in the management plan to be addressed by the Commission over the next few years.

5. As part of its integration of tasks, NMSS staff has identified difficulties or inefficiencies in meeting some IIT due dates. The staff has incorporated changes in these due dates into the medical management plan. Enclosure 4 provides an update on, and current due date for, IIT action items. (EDO WITS 9300046).

RECOMMENDATION:

That the Commission:

1) Approve the staff's proposed management plan for the medical use regulatory program as presented.

2) Note that the staff plans to provide an annual briefing on the status of implementation of the management plan, beginning 1 year from Commission approval of the plan.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Gantt chart
2. Maps to Tracks & Indiv. Trkng. Sheets
3. Routine tasks assoc. with Prog. Mgt.
4. IIT Item Dates

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Thursday, September 16, 1993.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Thursday, September 9, 1993, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

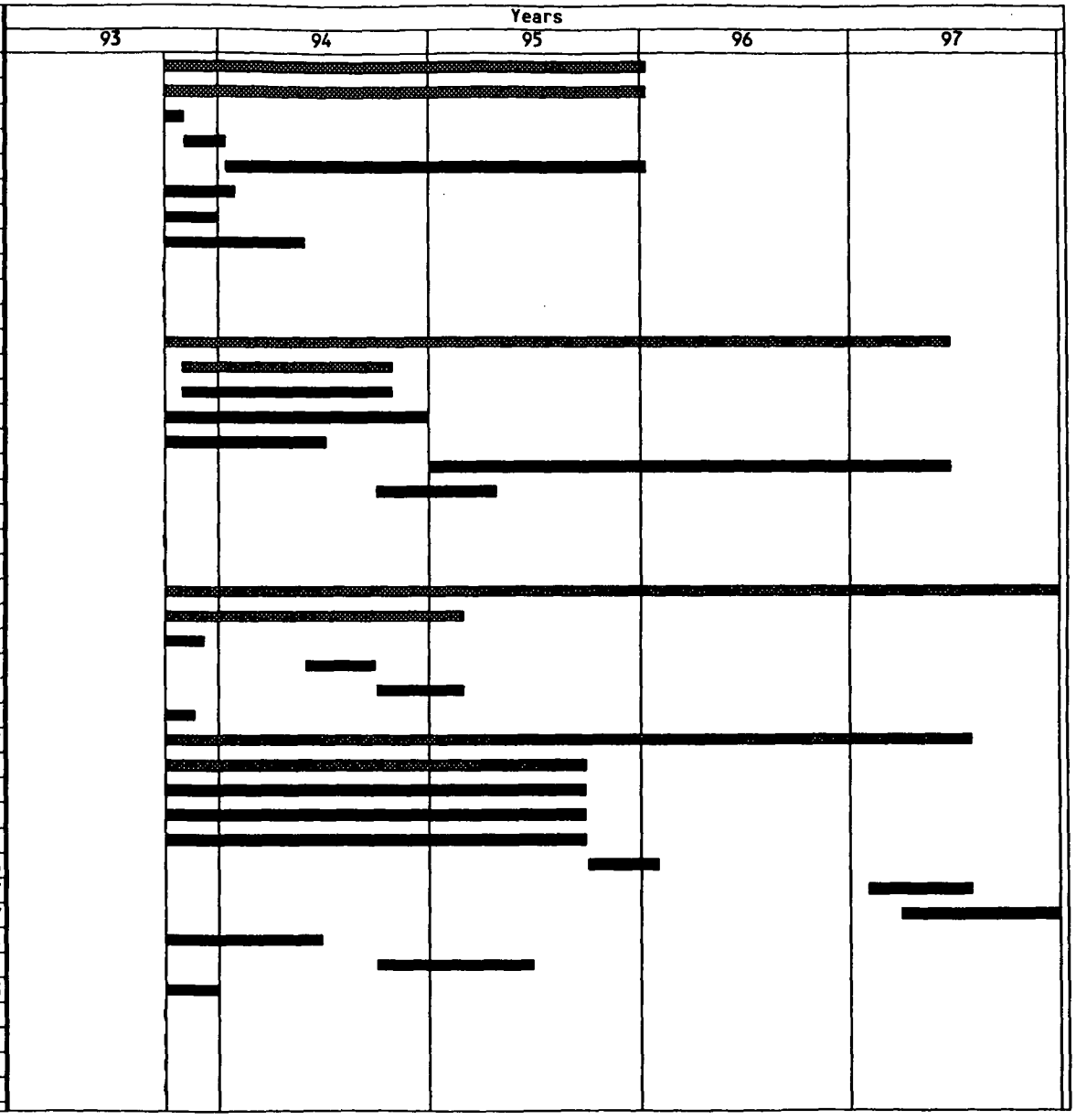
DISTRIBUTION:

Commissioners	OPA
OGC	OCA
OCAA	OPP
OIG	EDO
	SECY

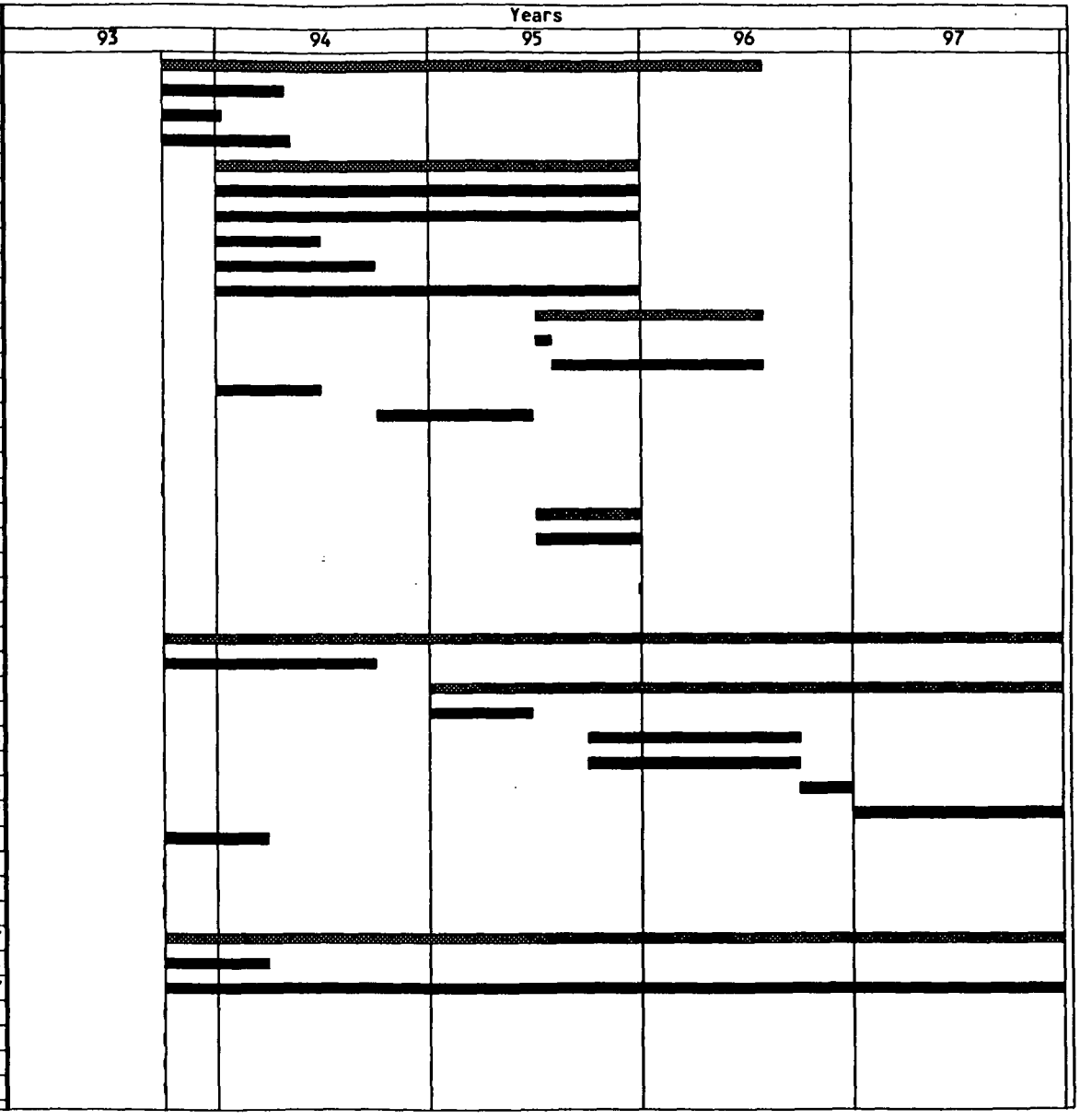
ENCLOSURE 1

Gantt Chart
for NMSS resources

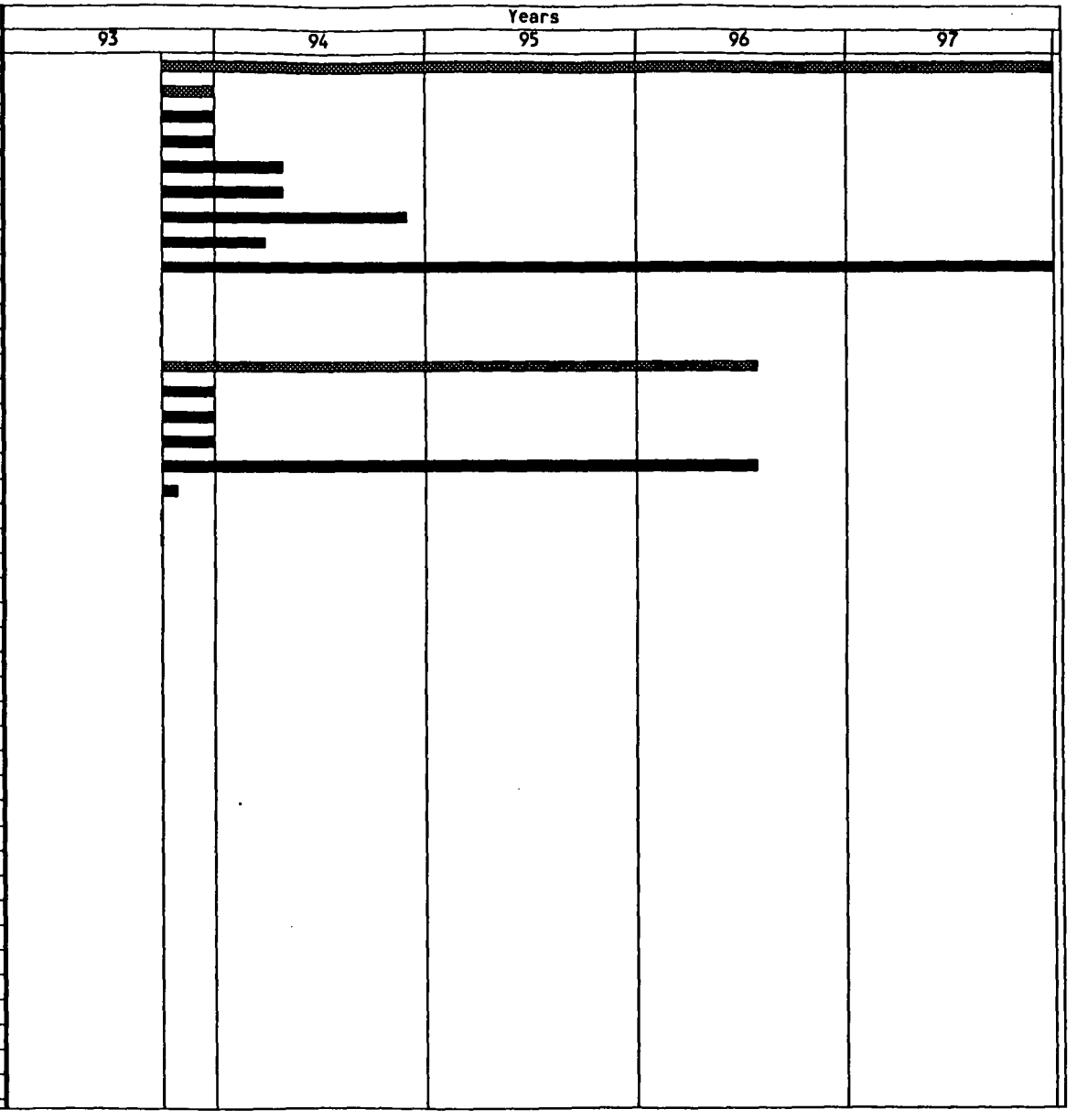
Task Name	Start	End
POLICY ISSUES	Oct/01/93	Jan/12/96
National Academy of Science Study	Oct/01/93	Jan/12/96
Proposed SOW to NAS	Oct/01/93	Nov/04/93
Let Contract	Nov/04/93	Jan/14/94
Contract Work and Final Report	Jan/14/94	Jan/12/96
Waste Processor Guidance	Oct/01/93	Jan/31/94
RES-1979 Med Policy	Oct/01/93	Dec/31/93
NRC/Agreement State Device Jurisdiction	Oct/01/93	Jun/01/94
RULEMAKING	Oct/01/93	Jun/27/97
Pharmacy Rule	Nov/01/93	Nov/01/94
Final Rule	Nov/01/93	Nov/01/94
Embryo/Neo-nate Protection	Oct/01/93	Dec/30/94
Part 20/Part 35 Patient Release	Oct/01/93	Jul/07/94
Part 35 Revision (HDR & Other Issues)	Jan/03/95	Jun/27/97
Review QM Rule Progress	Oct/03/94	Apr/28/95
LICENSING GUIDANCE	Oct/01/93	Dec/31/97
RG 10.5 Broadscope	Oct/01/93	Mar/01/95
Draft to RES	Oct/01/93	Dec/09/93
Draft for comment	Jun/01/94	Sep/30/94
Final Reg Guide	Oct/03/94	Mar/01/95
Submit Revised FC 86-4 to OGC	Oct/01/93	Nov/23/93
Add Appendices to RG 10.8	Oct/01/93	Aug/01/97
Draft to RES	Oct/01/93	Sep/29/95
Therapy Included	Oct/01/93	Sep/29/95
Physician Training	Oct/01/93	Sep/29/95
Relation to QM	Oct/01/93	Sep/29/95
Draft for comment	Oct/03/95	Feb/01/96
Final Reg Guide	Feb/03/97	Aug/01/97
Revise Reg Guide 8.33	Apr/01/97	Dec/31/97
Revise License Reviewer Training	Oct/01/93	Jun/30/94
Issue MC on Materials Enforcement Discreti	Oct/03/94	Jun/30/95
Issue Guidance for Master Material Program	Oct/01/93	Dec/31/93



Task Name	Start	End
INSPECTION GUIDANCE	Oct/01/93	Jul/31/96
Prime Alert-10	Oct/01/93	Apr/29/94
MC - Assessing Public Exposure & Notificat	Oct/01/93	Jan/13/94
TI on Significant Licensee Changes	Oct/01/93	May/09/94
Revise MC 2800	Jan/03/94	Dec/29/95
Program Expansion	Jan/03/94	Dec/29/95
Performance Adjustment	Jan/03/94	Dec/29/95
Medical Field Notes	Jan/03/94	Jun/30/94
QM Inspection Procedure	Jan/03/94	Sep/30/94
Satellite, Field, Temporary	Jan/03/94	Dec/29/95
Third Party Inspection	Jul/03/95	Jul/31/96
Memorandum to OGC	Jul/03/95	Jul/31/95
Evaluation	Aug/01/95	Jul/31/96
Event Response Procedure	Jan/03/94	Jun/30/94
Allegation Follow-up Procedure	Oct/03/94	Jun/30/95
ENFORCEMENT	Jul/03/95	Dec/29/95
Revision of the Enforcement Policy	Jul/03/95	Dec/29/95
MANAGEMENT AND RSO RESPONSIBILITY	Oct/01/93	Dec/31/97
NUREG-MAN/RSO	Oct/01/93	Sep/30/94
Rulemaking	Jan/02/95	Dec/31/97
Adv. Notice of Proposed Rulemaking	Jan/02/95	Jun/28/95
Industry Workshops	Oct/02/95	Oct/01/96
Guidance Documents	Oct/02/95	Oct/01/96
Proposed Rule	Oct/01/96	Dec/31/96
Final Rule	Jan/02/97	Dec/31/97
RSO Certification Form	Oct/01/93	Mar/31/94
INFORMATION MANAGEMENT SYSTEMS	Oct/01/93	Dec/31/97
Licensee Events - Support to AEOD	Oct/01/93	Mar/31/94
Division Action Items	Oct/01/93	Dec/31/97



Task Name	Start	End
MISADMINISTRATION	Oct/01/93	Dec/31/97
Management Directive	Oct/01/93	Dec/31/93
Patient Follow-up Policy	Oct/01/93	Dec/31/93
Notification of Local Authorities	Oct/01/93	Dec/31/93
AIT/IIT Guidance	Oct/01/93	Apr/29/94
Medical Consultant Policy	Oct/01/93	Apr/29/94
Review all QM Plans	Oct/01/93	Dec/01/94
TI-QM Inspection	Oct/01/93	Mar/31/94
Misadministration Coordinator	Oct/01/93	Dec/31/97
RESEARCH	Oct/01/93	Jul/31/96
QA/QC & Risk for Gamma Knife	Oct/01/93	Dec/31/93
QA/QC & Risk for HDR Afterloaders	Oct/01/93	Dec/31/93
Misadministration Events Analysis	Oct/01/93	Dec/31/93
Human Factors Studies	Oct/01/93	Jul/31/96
Southwest Research Source-Wire Evaluation	Oct/01/93	Oct/29/93



ENCLOSURE 2

Guide to Maps;
Maps to Track Sheets; &
Individual Track Sheets

DIRECTIONS FOR REVIEWING MAPS TO TRACKS AND INDIVIDUAL TRACK SHEETS

Attached you will find three documents to guide you through review of the 90 track sheets on action items considered in development of the medical management plan. They are:

1) a list of the tracks by topic bin that will enable you to identify which tracks were included for each line item in each topic bin;

2) a numerical list of the tracks that indicates whether the track (action item) is categorized into a topic bin on the Gantt chart and where it can be located; and

3) individual track sheets for all 90 action items that provide specific information on the topic bin, brief description of item, source of the action item, action needed, end date, support Offices, and contract costs, where applicable.

General comments:

- The topic bins identified on the Gantt chart are:

  1- Policy Issues
  2- Rulemaking
  3- Licensing Guidance
  4- Inspection Guidance
  5- Enforcement
  6- Management and RSO Responsibility
  7- Information Management Systems
  8- Misadministrations
  9- Research

  The individual tracks (90) were categorized into topic bins and assigned the appropriate topic bin number as indicated above.

- The following abbreviations were used on the individual track sheets to indicate the resource support provided by other Offices:

  C- Commission
  R- Regions
  I- IIT
  A- ACMUI
  O- Other
  E- EDO
  X- Research
  P- State Programs
  M- Medical industry
  F- Enforcement
  N- NMSS
  D- AEOD
  S- Agreement States
  G- OGC

- The start date of 10/1/93 was chosen for certain items because it is impractical to indicate a date prior to submittal or Commission approval of the medical management plan. However, there are on-going efforts to address several of the action items identified in the plan, including IIT items.

Enclosure 2

MASTER TRACK LIST
(BY BIN)

TOPIC BIN AND TASK NAME	TRACKS
1 POLICY ISSUES	
National Academy of Science Study	14, 22, 31
Proposed SOW to NAS	-----
Let Contract	-----
Contract work and final report	-----
Waste Processor Guidance	60
RES-1979 Med Policy	90
NRC/Agreement State Device Jurisdiction	57
2 RULEMAKING	
Pharmacy Rule	-----
Final Rule	64
Embryo/Neo-nate Protection	12
Part 20/Part 35 Patient Release	62
Part 35 Revision (HDR & Other Issues)	7, 26, 47, 55, 89
QM Rule Commission Briefing	67
3 LICENSING GUIDANCE	
Regulatory Guide 10.5 Broadscope	10
Draft to RES	-----
Draft for Comment	-----
Final Reg Guide	-----
Submit Revised FC 86-4 to OGC	45
Add Appendices to Reg Guide 10.8	-----
Draft to RES	-----
Therapy Included	48
Physician Training	65
Relation to QM	-----
Draft for Comment	-----
Final Reg Guide	-----
Revise Reg Guide 8.33	81
Revise License Reviewer Training	86
Issue MC on Materials Enforcement Discretion	68
Issue Guidance for Master Materials Programs	69

Enclosure 2
Attachment 1

BIN AND TASK NAME	TRACKS
4 INSPECTION GUIDANCE	
Revise MC 2800	50
Program Expansion	58
Performance Adjustment	83
Medical Field Notes	66
QM Inspection Procedure	9, 34
Satellite, Field, Temporary	-----
Prime Alert-10	52
MC - Assessing Pub. Exposure & Notification	53
TI on Significant Licensee Changes	59
Third Party Inspection	15, 23, 24
Memorandum to OGC	-----
Evaluation	-----
Event Response Procedure	84
Allegation Follow-up Procedure	85
5 ENFORCEMENT	
Revision of the Enforcement Policy	30, 78, 79
6 MANAGEMENT & RSO RESPONSIBILITY	
NUREG-MAN/RSO	33, 77
Rulemaking	6, 8, 13, 16, 17, 18, 51, 56
Advance Notice of Proposed Rulemaking	-----
Industry Workshops	-----
Guidance Documents	-----
Proposed Rule	-----
Final Rule	-----
RSO Certification Form	88
7 INFORMATION MANAGEMENT SYSTEMS	
Licensee Events - Support to AEOD	72
Division Action Items	87

BIN AND TASK NAME	TRACKS
8 MISADMINISTRATION	
Management Directive	40, 49
Patient Follow-up Policy	28, 39, 74
Notification of Local Authorities	80
Medical Consultant Policy	41, 75
AIT/IIT Guidance	37
Review all QM Plans	21
TI - QM Inspection	25
Misadministration Coordinator	82
9 RESEARCH	
QA/QC & Risk for Gamma Knife	2
QA/QC & Risk for HDR Afterloaders	3
Misadministration Events Analysis	4
Human Factors Studies	5
SW source-wire evaluation	61

COMPLETED:

11, 20, 27, 29, 32, 35, 36, 38, 42, 43, 44, 46, 54, 63, 70, 71, 76

DELETED:

19, 73

1 - Task for development of the Medical Management Plan

MASTER TRACK LIST
(BY TRACK)

TRACK #	COVERED ON GANTT	BIN
1	N/A	N/A
2	Y	9
3	Y	9
4	Y	9
5	Y	9
6	Y	6
7	Y	2
8	Y	6
9	Y	4
10	Y	3
11	Done	
12	Y	2
13	Y	6
14	Y	1
15	Y	4
16	Y	6
17	Y	6
18	Y	6
19	Deleted	
20	Done	
21	Y	8
22	Y	1
23	Y	4
24	Y	4
25	Y	8
26	Y	2
27	Done	
28	Y	8
29	Done	
30	Y	5
31	Y	1
32	Done	
33	Y	6
34	Y	4
35	Done	
36	Done	
37	Y	8
38	Done	
39	Y	8
40	Y	8
41	Y	8
42	Done	
43	Done	
44	Done	
45	Y	3
46	Done	
47	Y	2
48	Y	3
49	Y	8

BIN TITLES

1 = POLICY ISSUES
2 = RULEMAKING
3 = LICENSING GUIDANCE
4 = INSPECTION GUIDANCE
5 = ENFORCEMENT
6 = MANAGEMENT & RSO RESPONSIBILITY
7 = INFORMATION MANAGEMENT SYSTEMS
8 = MISADMINISTRATION
9 = RESEARCH

Enclosure 2
Attachment 2

TRACK #	COVERED ON GANTT	BIN
50	Y	4
51	Y	6
52	Y	4
53	Y	4
54	Done	
55	Y	2
56	Y	6
57	Y	1
58	Y	4
59	Y	4
60	Y	1
61	Y	9
62	Y	2
63	Done	
64	Y	2
65	Y	3
66	Y	4
67	Y	2
68	Y	3
69	Y	3
70	Done	
71	Done	
72	Y	7
73	Deleted	
74	Y	8
75	Y	8
76	Done	
77	Y	6
78	Y	5
79	Y	5
80	Y	8
81	Y	3
82	Y	8
83	Y	4
84	Y	4
85	Y	4
86	Y	3
87	Y	7
88	Y	6
89	Y	2
90	Y	1

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 01

Source Code: N **Document No.:**001 **Doc. Date:** 09/08/92

DOCUMENT: Memo on Medical Management Plan

DESCRIPTION: Develop medical mgt. plan to include long term objectives, umbrella policy, strategy for achieving those objectives, & provision for annual update. Coordinate with ACMUI and Agreement States.

ACTION: Prepare management plan.
Incorporate Commission direction regarding evolution of program and consistency with policy statement.

STATUS: In progress.

NOTES: Action incorporates Commission direction in SRM of 6/23/92 (Item #31).

PRIORITY: H
LEAD: Glenn
SUPPORT: X,R,G,F,D

Category 1: PO
Category 2: O
Category 3:

Due Date: 08/30/93

Due Date:

Due Date:

Enclosure 2
Attachment 3

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 09

TRACK NUMBER: 02

Source Code: N **Document No.:**001 **Doc. Date:** 09/08/92

DOCUMENT: Memo on Medical Management Plan

DESCRIPTION: Develop a methodology for assessing risk significance of use of medical devices & examine QA issues for gamma knife.

ACTION: Develop NUREG on Methodology and QA issues.

STATUS:

NOTES: Livermore

PRIORITY: M
LEAD: Cunningham/G
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date: 12/30/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 09

TRACK NUMBER: 03

Source Code: N **Document No.:**001 **Doc. Date:** 09/08/92

DOCUMENT: Memo on Medical Management Plan

DESCRIPTION: QA Plan for HDR Afterloaders.
Contract to examine requirements, QA procedures, devise critical components & risk of high dose rate devices & provide model QA/QC program.

ACTION: Develop QA/QC plan for HDR Afterloaders.

STATUS:

NOTES: Find out real due dates from Serig/Rathbun.

PRIORITY: H
LEAD: Glenn
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date: 12/30/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 09

TRACK NUMBER: 04

Source Code: N **Document No.:**001 **Doc. Date:** 09/08/92

DOCUMENT: Memo on Medical Management Plan

DESCRIPTION: Conduct misadministration events analysis & summarize root causes & corrective actions.

ACTION: Publish NUREG summarizing results.

STATUS:

NOTES:

PRIORITY: H
LEAD: Rathbun
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date: 12/30/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/19/93

TOPIC # 09

TRACK NUMBER: 05

Source Code: N **Document No.:**001 **Doc. Date:** 09/08/92

DOCUMENT: Memo on Medical Management Plan

DESCRIPTION: Human Factors studies
Teletherapy, Brachytherapy, remote afterloaders.
Conduct human factors study.
Manual brachytherapy study to follow remote aft'ldr study.

ACTION: Issue NUREG/CRs summarizing results of HF studies of teletherapy and remote afterloading brachytherapy.

STATUS: Comments on initial draft of Vol. I of HF Evaluation of Remote Afterloading Brachytherapy provided to contractor; final version of Vol I due 9/30/93. Initial draft of HF Eval of teletherapy in preparation by contractor; final version of Vol I due 12/31/93.

NOTES: Manual brachytherapy study to begin approximately 7/94 and be completed 7/96.

PRIORITY: H
LEAD: Serig/Coffma
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date: 09/30/93

Due Date: 12/31/93

Due Date: 07/31/96

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 06

Source Code: A **Document No.:**001 **Doc. Date:** 09/08/92

DOCUMENT: Memo on Medical Management Plan

DESCRIPTION: Reassessment of training & experience criteria and preceptoring process for physician authorized users by Visiting Medical Fellow.

ACTION: Evaluate need to revise training & experience criteria in Part 35 & need to revise preceptoring process.

STATUS:

NOTES: Action incorporates recommendations from ACMUI (Item #18) to revise 35.920 & 35.930 and to revise preceptor process. Contract dollar figure and resource considerations are also for related Items #08, 13, 16, 17, 18, & 56. All Items are being consolidated for these purposes.

PRIORITY: M
LEAD: Glenn with P
SUPPORT: X,G,P,S,M,A

Category 1: O
Category 2: RM
Category 3: RG

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 07

Source Code: N **Document No.:**002 **Doc. Date:**

DOCUMENT: Medical Issues Paper (MIP)

DESCRIPTION: Adequacy of Part 35

ACTION: Review lessons learned since 1986 revision & include changes in the user need memo. See Item #26, if appropriate.

STATUS:

NOTES: See related Items #26, 47, 55 & 89.

PRIORITY: L
LEAD: Glenn
SUPPORT: R,A,S,P,M

Category 1: O
Category 2: RM
Category 3: LG

Due Date: 06/27/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 08

Source Code: N **Document No.:**002 **Doc. Date:**

DOCUMENT: Medical Issues Paper (MIP)

DESCRIPTION: Part 35
Evaluate need for training & experience requirements for supervised individuals.

ACTION: Evaluate Part 35 requirements for supervision, training, & experience. Determine if revision is necessary.

STATUS:

NOTES: Resource and contract considerations were made in Item #06 for this and Items #13, 16, 17, 18 and 56.

PRIORITY: L
LEAD: Glenn
SUPPORT: S,A,X,G,P,M

Category 1: O
Category 2: RM
Category 3: PO

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 09

Source Code: N **Document No.:**002 **Doc. Date:**

DOCUMENT: Medical Issues Paper (MIP)

DESCRIPTION: Inspection/Enforcement guidance for QM Rule.
Issue guidance for performance-based inspections of QM programs.

ACTION: Issue revised TI & field notes for QM program inspections.
Issue Enforcement Guidance Memorandum.

STATUS: Combined with Item #34. See related #66 (Final TI). Rsrcs considered in #34. COMPLETED: Enforcement Guidance Memo issued 4/30/93. Draft TI issued to Regions. Final TI (Item #66) will be based on Livermore contract, to be done after 12/93.

NOTES: See followup items #34 and #66.

PRIORITY: H
LEAD: Glenn
SUPPORT: F,R

Category 1: IG
Category 2: PO
Category 3: EG

Due Date: 09/30/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 03

TRACK NUMBER: 10

Source Code: N **Document No.:**002 **Doc. Date:**

DOCUMENT: Medical Issues Paper (MIP)

DESCRIPTION: Licensing Guidance
Complete SRP for Type A Broad Scope (updating P&GD).
Submit revision to RG 10.5 for Broad Scope to Research.

ACTION: Complete SRP & submit revised Reg Guide for Broad Scope to Research.

STATUS:

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT: X, R, A

Category 1: LG
Category 2: RG
Category 3:

Due Date: 03/01/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 11

Source Code: N **Document No.:**002 **Doc. Date:**

DOCUMENT: Medical Issues Paper (MIP)

DESCRIPTION: Abnormal Occurrence (AO) Reporting Criteria
Review and revise AO reporting criteria.

ACTION: Prepare Commission Paper on revision of AO reporting criteria to specifically address misadministrations.

STATUS: COMPLETED: Staff has prepared a Commission Paper recommending AO Reporting Criteria for misadministrations and this paper is currently with EDO for review.

NOTES: Incorporates OGC recommendation in Item #38.

PRIORITY: H
LEAD: Jordan
SUPPORT: N, R, P

Category 1: PO
Category 2: RG
Category 3:

Due Date: 04/30/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 12

Source Code: N **Document No.:**002 **Doc. Date:**

DOCUMENT: Medical Issues Paper (MIP)

DESCRIPTION: Part 35 Rulemaking on Admin of Byproduct Material to Pregnant and Breastfeeding Women.

ACTION: Revise Part 35 to address need for licensees to determine pregnancy status of patients prior to administration to EDO.
Prepare licensing and inspection guidance.

STATUS:

NOTES: Proposed rulemaking due to EDO 11/30/93.
Final rule 12/31/94.

PRIORITY: H
LEAD: Bahadur
SUPPORT: N,G,P,S,A

Category 1: RM
Category 2:
Category 3:

Due Date: 11/30/93

Due Date: 12/30/94

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 13

Source Code: A **Document No.:**007 **Doc. Date:** 07/13/92

DOCUMENT: ACMUI Minutes

DESCRIPTION: NRC should prepare syllabus that can serve as basis for didactic basic radiation safety training of physicians for licensure.

ACTION: Evaluate need for syllabus.

STATUS:

NOTES: Resource and contract considerations were made in Item #06 for this Item and Items #08, 16, 17, 18 and 56.

PRIORITY: L
LEAD: Glenn
SUPPORT: X,G,P,S,M,A

Category 1: RG
Category 2:
Category 3:

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 01

TRACK NUMBER: 14

Source Code: A **Document No.:**009 **Doc. Date:** 11/05/92

DOCUMENT: ACMUI Minutes

DESCRIPTION: NRC should fund a national study of the impact of regulation on all uses of byproduct material in medicine. Study should be conducted by a University of neutral professional group.

ACTION: Evaluate for inclusion in Regulatory Impact Survey.
Award contract by 10/01/93.
Complete Action by 01/12/96.

STATUS:

NOTES: Award & monitor contract.
Award 10/01/93; complete 01/12/96.

PRIORITY: M
LEAD: Paperiello
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date: 10/01/93

Due Date: 01/12/96

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 15

Source Code: A **Document No.:**009 **Doc. Date:** 11/05/92

DOCUMENT: ACMUI Minutes

DESCRIPTION: NRC should explore substitution of voluntary accreditation by professional organizations for some of the NRC inspection processes.

ACTION: Request OGC to prepare legal analysis of substitution. Staff will evaluate feasibility of substitution of ACNP, ACR processes in Commission paper with recommendations.

STATUS:

NOTES: Incorporates ACNP recommendation (Item #23) and ACR recommendation (Item #24).
Projected resources are based upon the development of the Commission paper and include consideration of resources for Items #23 and #24.

PRIORITY: M
LEAD: Glenn
SUPPORT: G,S,P,F,A

Category 1: O
Category 2: PO
Category 3:

Due Date: 07/31/96

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 16

Source Code: A **Document No.:**009 **Doc. Date:** 11/05/92

DOCUMENT: ACMUI Minutes

DESCRIPTION: NRC should establish testing process for physicians & RSOs to evaluate competence.

ACTION: Evaluate feasibility of developing testing process.

STATUS:

NOTES: Resource and contract considerations were made in Item #06 for this Item and Items #08, 13, 17, 18 and 56.

PRIORITY: M
LEAD: Glenn
SUPPORT: G,P,S,X,M,A

Category 1: PO
Category 2:
Category 3:

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 17

Source Code: A **Document No.:**009 **Doc. Date:** 11/05/92

DOCUMENT: ACMUI Minutes

DESCRIPTION: NRC should monitor adequacy of radiation safety component of consultant rad. safety courses, residency programs, & board certification courses.

ACTION: Evaluate adequacy of radiation safety component of programs.

STATUS:

NOTES: Resource and contract considerations were made in Item #06 for this Item and Items #08, 13, 16, 18, and 56.

PRIORITY: M
LEAD: Glenn
SUPPORT: G,P,X,M,S,A

Category 1: O
Category 2:
Category 3:

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 18

Source Code: A **Document No.:**009 **Doc. Date:** 11/05/92

DOCUMENT: ACMUI Minutes

DESCRIPTION: NRC should revise 10 CFR 35.920 (Training for Imaging and Localization) & 10 CFR 35.930 (Training for Therapeutic Use of Radiopharmaceuticals) to more appropriately reflect knowledge base.

ACTION: Incorporated into action for Item #6.

STATUS:

NOTES: Resource and contract considerations were made in Item #06 for this Item and Items #08, 13, 16, 17 and 56.

PRIORITY:
LEAD: Glenn
SUPPORT: X,G,P,M,S,A

Category 1: O
Category 2: RM
Category 3:

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 19

Source Code: A **Document No.:**009 **Doc. Date:** 11/05/92

DOCUMENT: ACMUI Minutes

DESCRIPTION: NRC should expand address list for mailings to include not only licensee mgt. but also RSO & Chief of Service for each authorized user. And use newsletters of professional societies for informing users.

ACTION: Evaluate feasibility and cost of expanding LTS and mailing lists.

STATUS: Deleted.

NOTES:

PRIORITY: L
LEAD: Combs
SUPPORT: O

Category 1: O
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 20

Source Code: N **Document No.:**011 **Doc. Date:** 03/10/93

DOCUMENT: SOW QM Plan Review

DESCRIPTION: Contractor to review QM plans for adequacy & develop tracking system showing status of reviews.

ACTION: Award Contract.

STATUS: COMPLETED.

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 21

Source Code: N **Document No.:**011 **Doc. Date:** 03/10/93

DOCUMENT: SOW QM Plan Review

DESCRIPTION: Contractor to review QM plans for adequacy & develop tracking system showing status of reviews.

ACTION: Complete review of all QM plans and issue final report.

STATUS:

NOTES: Related to Item #25.

PRIORITY: H
LEAD: Glenn
SUPPORT: R

Category 1: O
Category 2:
Category 3:

Due Date: 12/01/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 01

TRACK NUMBER: 22

Source Code: N **Document No.:**013 **Doc. Date:** 03/12/93

DOCUMENT: Response to COMSECY-93-004

DESCRIPTION: Upon Commission approval of SOW, prepare proposal package for National Academy of Sciences' Review of Medical Program.

ACTION: Prepare proposal package for NAS Review of Medical Program.

STATUS: COMBINED WITH ITEM #14.

NOTES: Contract and resource figures are considered in Item #14. Consolidated with Items #14 and 31.

PRIORITY: H
LEAD: Paperiello
SUPPORT:

Category 1: O
Category 2: PO
Category 3:

Due Date: 10/01/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 23

Source Code: N **Document No.:**017 **Doc. Date:** 11/09/92

DOCUMENT: Summ. Public Meeting on QM

DESCRIPTION: ACNP expressed a desire to explore possibility of NRC recognition of its Practice Audit Program as alternative to inspection of the audit program.

ACTION: Incorporated into Item #15. Resources considered there. Item #24 was also incorporated into #15.

STATUS:

NOTES:

PRIORITY: L
LEAD: Glenn
SUPPORT: G,S,P,F,A

Category 1: O
Category 2:
Category 3:

Due Date: 07/31/96

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 24

Source Code: O **Document No.:**018 **Doc. Date:**

DOCUMENT: Comm Paper QM/Misadministration

DESCRIPTION: American College of Radiology (ACR) expressed interest in discussions w/ NRC re: acceptance of a voluntary QA program.

ACTION: Incorporated into action for Item #15. Resources considered there. Item #23 was also incorporated into #15.

STATUS:

NOTES:

PRIORITY: L
LEAD: Glenn
SUPPORT: G,S,P,F,A

Category 1: O
Category 2:
Category 3:

Due Date: 07/31/96

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 25

Source Code: N **Document No.:**020 **Doc. Date:** 05/13/92

DOCUMENT: SECY 92-175: Annual Report

DESCRIPTION: Provide training to Regions on QM field notes & temporary instruction. (Sept/Oct timeframe)

ACTION: Followup training for Regions on interim final field notes & temporary instruction for QM rule.

STATUS:

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT: R

Category 1: IG
Category 2:
Category 3:

Due Date: 03/31/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 26

Source Code: N **Document No.:**020 **Doc. Date:** 05/13/92

DOCUMENT: SECY 92-175: Annual Report

DESCRIPTION: User need memo to revise Part 35 and Reg Guide 10.8 to address remote afterloader brachtherapy and gamma stereotactic surgery.

ACTION: Issue user need memo to RES following completion of Item #48 to revise Part 35 and Reg Guide 10.8.

STATUS:

NOTES: See related Items #7, 47, 55 and 89. Also considers resources for #47 and 55.

PRIORITY: H
LEAD: Glenn
SUPPORT:

Category 1: RM
Category 2: RG
Category 3:

Due Date: 06/27/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 27

Source Code: M **Document No.:**020 **Doc. Date:** 05/13/92

DOCUMENT: SECY 92-175: Annual Report

DESCRIPTION: ACNP/SNM petition of 2/10/92 contends current fee schedule adversely impacts medical licensees.

ACTION: Prepare comments for LFMB.

STATUS: COMPLETED 4/9/93

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 28

Source Code: N **Document No.:**021 **Doc. Date:** 01/19/93

DOCUMENT: SECY 93-007: Aspects of Med. Prog. RE: Misad.

DESCRIPTION: Consider issue of expanded NRC followup of patients subject to misadministrations; also refer to external group for consideration.

ACTION: Issue comprehensive Management Directive. Review findings of NAS when completed in 1/96.

STATUS:

NOTES: Resource consideration encompasses the following related Items: #39, 40, 49, 74, 80; which are all related to Dr. Paperiello's Management Directive.

PRIORITY: H
LEAD: Glenn/Combs
SUPPORT: G,R

Category 1: PO
Category 2: O
Category 3: RM

Due Date: 12/31/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 01

TRACK NUMBER: 29

Source Code: N **Document No.:**021 **Doc. Date:** 01/19/93

DOCUMENT: SECY 93-007: Aspects of Med. Prog. re: Misad.

DESCRIPTION: Conduct analysis of adequacy of NRC & FDA review of medical devices.

ACTION: Develop MOU with FDA on medical devices. See related Items #57 and 76.

STATUS: To be completed by 10/01/93.

NOTES:

PRIORITY: H
LEAD: Paperiello
SUPPORT: P, S, G

Category 1: O
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 05

TRACK NUMBER: 30

Source Code: N **Document No.:**021 **Doc. Date:** 01/19/93

DOCUMENT: SECY 93-007: Aspects of Med. Prog. re: Misad.

DESCRIPTION: Reassess materials civil penalties policy.

ACTION: Reassess materials civil penalty policy.

STATUS:

NOTES: Probation/higher

PRIORITY: M
LEAD: Lieberman
SUPPORT: N, A, S, P

Category 1: O
Category 2: PO
Category 3: EG

Due Date: 12/29/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 01

TRACK NUMBER: 31

Source Code: C **Document No.:**022 **Doc. Date:** 06/23/92

DOCUMENT: SRM: Annual Medical Briefing

DESCRIPTION: Analysis on whether the evolution of the NRC's medical use program has been consistent with the 1979 statement of Comm. policy & whether any changes to the policy are warranted.

ACTION: Incorporate into medical management plan; also refer to external group. Work into all rulemakings a statement of consistency. Add to NAS.

STATUS: COMBINED WITH ITEM #14 (AND #22).

NOTES: Incorporate into Item #14, (consequently #22).
See related Item #90.
(still have a question re: source document)

PRIORITY: M
LEAD: Glenn
SUPPORT: X

Category 1: O
Category 2:
Category 3:

Due Date: 01/12/96

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 32

Source Code: C **Document No.:**023 **Doc. Date:** 12/21/92

DOCUMENT: COMIS-92-026: Review of Medical Program

DESCRIPTION: Nominate senior NRC manager to perform mgt. review of existing medical program. Coordinate review with med. management plan & focus on whether program is being efficiently implemented.

ACTION: Perform management review of existing medical program.

STATUS: COMPLETED 6/15/93

NOTES:

PRIORITY: H
LEAD: Paperiello
SUPPORT: N, P

Category 1: O
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 33

Source Code: N **Document No.:**024 **Doc. Date:** 08/10/92

DOCUMENT: Memo on Developing NUREG for RSOs

DESCRIPTION: Role of licensee management radiation safety committee & RSO in the effective management of the rad safety program at a medical use facility.

ACTION: Develop and publish NUREG.

STATUS:

NOTES: See related IIT Item #51.
Contract and resource considerations for this and Item #77.
Resource considerations do not include time expended with Agreement States.

PRIORITY: M
LEAD: Glenn
SUPPORT: R,S

Category 1: RG
Category 2:
Category 3:

Due Date: 09/30/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 34

Source Code: N **Document No.:**028 **Doc. Date:** 02/09/92

DOCUMENT: P&G Directive on Supervision

DESCRIPTION: Formal guidance will be developed for routine and reactive inspections re: QM Rule.

ACTION: Finalize field notes & inspection procedure after completion of pilot program.

STATUS:

NOTES: Followup action to complete Item #9. Consolidate with #66. Resource consideration for Item #66 is included here.

PRIORITY: H
LEAD: Combs
SUPPORT: R

Category 1: IG
Category 2:
Category 3:

Due Date: 09/30/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 35

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Develop guidance document on licensee responsibilities in event of misadministration. Include reporting, patient notification and investigation of event.

ACTION: Develop Information Notice.

STATUS: COMPLETED 5/30/93

NOTES: Also see related IIT Item #55.

PRIORITY: H
LEAD: Glenn
SUPPORT: G

Category 1: RG
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 36

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Evaluate need for specific requirement, together with implementing guidance, imposing a duty on licensee to inform other persons exposed as a result of misadministration.

ACTION: Incorporate into action for IIT Item #54.

STATUS: COMPLETED

NOTES:

PRIORITY:
LEAD: Combs
SUPPORT:

Category 1: O
Category 2: LG
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 37

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Develop criteria for when a misadministration warrants an AIT or IIT.

ACTION: Revise directive 8.3, NRC Incident Investigation Program to include criteria that may warrant AIT or IIT for misadministrations.

STATUS:

NOTES: Will include examples.
Coordinate with AEOD.

PRIORITY: M
LEAD: Jordan
SUPPORT: N, O, R

Category 1: O
Category 2:
Category 3:

Due Date: 04/29/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 38

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Develop criteria for misadministrations that are abnormal occurrences, identifying what efforts NRC will use to meet its statutory reporting obligations under Section 208.

ACTION: Incorporate into action for Item #11.

STATUS: COMPLETED

NOTES:

PRIORITY:
LEAD: Jordan
SUPPORT: N

Category 1: O
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 39

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Develop criteria for following up with patients suffering acute present injury or possibility of radiation illness after misadministrations.

ACTION: Incorporate into revision to MC 1360 in Item #41.
Commission - Consider policies on patient followup.

STATUS: Consolidated into Item #28 - Management Directive. Resource considerations made there.

NOTES: Need response to OGC memo.

PRIORITY: H
LEAD: Combs/Glenn
SUPPORT: G

Category 1: IG
Category 2:
Category 3:

Due Date: 12/31/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 40

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Review draft & final guidance on QM Program to ensure inspectors properly emphasize licensee's duty to report misadministrations to patients & referring physicians.

ACTION: Incorporated into guidance development addressed in Items #09 and #34, and Management Directive (#28).

STATUS:

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT: R,G

Category 1: IG
Category 2:
Category 3:

Due Date: 12/31/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 41

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Review existing policies/requirements/guidance on proper role of medical consultants in assisting NRC.

ACTION: Revise MC 1360 to address issue and provide guidance to regional and HQ staff.

STATUS:

NOTES: Incorporates Item #75; resource consideration is made here.

PRIORITY: H
LEAD: Combs
SUPPORT: R

Category 1: IG
Category 2:
Category 3:

Due Date: 04/29/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 42

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Review existing policies/requirements on retention of records including what records must be retained and for how long.

ACTION: Meet with OGC and request legal analysis of basis for longer retention.

STATUS: Completed.

NOTES: Should be completed by 7/30 per Fred.
Feed into long term Rulemaking on Part 35.

PRIORITY: M
LEAD: Combs
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 43

Source Code: G **Document No.:**029 **Doc. Date:** 02/12/93

DOCUMENT: OGC Memo on Misadministrations

DESCRIPTION: Staff may wish to review for each misadministration classified as an AO, licensee's written reports to patients versus those submitted to NRC.

ACTION: Prepare memo based on meeting with OGC & OI to discuss feasibility.

STATUS: COMPLETED by memo of 4/19/93; see Item #70

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date: 04/15/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 44

Source Code: G **Document No.:**030 **Doc. Date:** 02/17/93

DOCUMENT: OGC Memo on IIT Report

DESCRIPTION: Review guidance & guides on Brachytherapy in light of IIT findings re: Indiana, PA incident.

ACTION: Issue bulletin to all HDR users;
consider longer term actions consistent with IIT memo.

STATUS: PARTIALLY CLOSED: Bulletin issued 4/20/93
COMPLETED

NOTES: See related actions under IIT Item #55.

PRIORITY: H
LEAD: Glenn
SUPPORT: G

Category 1: LG
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 03

TRACK NUMBER: 45

Source Code: G **Document No.:**030 **Doc. Date:** 02/17/93

DOCUMENT: OGC Memo on IIT Report

DESCRIPTION: Revise licensing guidance in FC 86-4 which appears to be outdated & not well integrated with NRC regulations.

ACTION: Submit revised FC 86-4 to OGC.

STATUS:

NOTES: See related actions under IIT Item #55.

PRIORITY: H
LEAD: Glenn
SUPPORT: R, G

Category 1: LG
Category 2: LG
Category 3:

Due Date: 11/23/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 46

Source Code: G **Document No.:**030 **Doc. Date:** 02/17/93

DOCUMENT: OGC Memo on IIT Report

DESCRIPTION: Revise insp. guidance to address HDR Brachytherapy & cover multiple places of use, situations where RSO can't promptly respond & license amendments greatly expanding licensee's operations scope.

ACTION: Issue TI for inspection of HDR afterloaders.

STATUS: To be completed by 9/30/93.

NOTES: See related IIT Item #59 for multiple locations & changes in scope.

PRIORITY: H
LEAD: Combs
SUPPORT: R, P

Category 1: IG
Category 2:
Category 3:

Due Date: 09/30/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 47

Source Code: G **Document No.:**030 **Doc. Date:** 02/17/93

DOCUMENT: OGC Memo on IIT Report

DESCRIPTION: Consider revisions to Part 35 to eliminate list of sources in 35.400; clarify which provisions apply to HDRs & to LDRs; & need for additional provisions for either.

ACTION: Incorporate into action for Item #26.

STATUS:

NOTES: Resources considered in Item #26. See related Items #7, 26, 55 & 89.

PRIORITY:
LEAD: Badahur
SUPPORT: G,N,S,P,M,A

Category 1: O
Category 2: RM
Category 3:

Due Date: 06/27/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 03

TRACK NUMBER: 48

Source Code: N **Document No.:**031 **Doc. Date:**

DOCUMENT: Outline for Paperiello Review

DESCRIPTION: Revise existing guidance & develop new guidance for all therapy other than HDRs.

ACTION: Revise, develop and issue licensing guidance for all therapy other than HDRs; including Regulatory Guides and Standard Review Plans.

STATUS:

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT: X

Category 1: LG
Category 2:
Category 3:

Due Date: 09/29/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 49

Source Code: N **Document No.:**031 **Doc. Date:**

DOCUMENT: Outline for Paperiello Review

DESCRIPTION: Regional inspectors need an inspection procedure for the followup of misadministration reports & other radiation therapy events.

ACTION: Incorporated into Item #28 - Management Directive.

STATUS:

NOTES: Resource considerations made in Item #28.

PRIORITY: H
LEAD: Combs
SUPPORT: R,G

Category 1: IG
Category 2:
Category 3:

Due Date: 12/31/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 50

Source Code: N **Document No.:**031 **Doc. Date:**

DOCUMENT: Outline for Paperiello Review

DESCRIPTION: Ensure availability of current inspection guidance for therapy programs other than HDR.

ACTION: See related IIT Item #55.
Brachytherapy, teletherapy, gamma stereotactic, radiopharmacy, strontium-90.

STATUS:

NOTES:

PRIORITY:
LEAD: Combs
SUPPORT: R

Category 1: IG
Category 2:
Category 3:

Due Date: 01/29/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 51

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Evaluate need to further define RSO & authorized user responsibilities. Issue new or revised guidance, as appropriate.

ACTION: Evaluate need for guidance for authorized users.

STATUS:

NOTES: Resources do not consider any action beyond evaluation. Revised guidance for RSOs will be developed under Item #33.

PRIORITY: M
LEAD: Glenn
SUPPORT: A,S,P,X,G,M

Category 1: O
Category 2: RG
Category 3:

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 52

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Evaluate performance & design of PrimAlert-10 ARMs. Take followup action as required to resolve issue of spurious alarms & need for confidence by users.

ACTION: 1) Write to manufacturer for evaluation of nonionizing RF's or EMF's re: Spurious alarms. 2) Issue TI to Regions to include in routine inspection program. 3) Issue IN

STATUS:

NOTES: If appropriate, issue Information Notice to licensees.

PRIORITY: M
LEAD: Combs
SUPPORT: R

Category 1: O
Category 2:
Category 3:

Due Date: 04/29/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 53

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Evaluate NRC's process for: a) assessing exposure & consequences, & b) notifying individuals & authorities following following elevated exposure to the public. Issue guidance as appropriate.

ACTION: Incorporate IIT lessons and issue Manual Chapter.

STATUS:

NOTES: Draft is currently in place.

PRIORITY: H
LEAD: Combs
SUPPORT: R,G

Category 1: IG
Category 2:
Category 3:

Due Date: 01/13/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 54

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Evaluate need to further define licensee responsibility for assessing radiation exposure & notifying members of public & authorities. Issue guidance as appropriate.

ACTION: Staff will evaluate need for rule change.

STATUS: COMPLETED (New Part 20 with 19.13(d) requires informing members of the public who receive >100 mrem.)

NOTES:

PRIORITY: H
LEAD: Combs
SUPPORT: R, G, NRR

Category 1: O
Category 2: RM
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 55

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Eval. need to update & integrate existing requirements. Guidance & inspection procedures for HDR Afterloaders. Issue new or revised requirements & guidance, as appropriate.

ACTION: Incorporate results of guidance & research into user need memo to RES to revise Part 35.

STATUS:

NOTES: Related actions include: Issue bulletin to Remote Afterloader users (4/30/93); Revise P&GD 86-4 (6/30/93); Issue TI for HDR inspections (7/30/93); Evaluate QA and HF studies (9/30/93). Refer also to Items #7, 26, 48 & 89. Resources considered in Item #26.

PRIORITY: H
LEAD: Badahur
SUPPORT: G,N,S,P,M,A

Category 1: LG
Category 2: IG
Category 3: RM

Due Date: 06/27/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 56

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Eval. performance based approach vs schooling or certifications to verify adequate rad. safety knowledge of HDR afterloader users. Issue new or revised requirements or guidance, as appropriate.

ACTION: Conduct evaluation, discuss with ACMUI and provide recommendations.

STATUS:

NOTES: IIT due date is 3/01/94. Can we change the date to 12/30/94 Need to seek contract dollars, estimate $5K-7K. Check with Pangburn to see what has been done in response to last SRM. Resource and contract considerations have been made in Item #06. Resources considered in #06 for this & 8,13,16,17,18.

PRIORITY: H
LEAD: Glenn
SUPPORT: X,G,P,S,M, A

Category 1: O
Category 2: RM
Category 3: LG

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 01

TRACK NUMBER: 57

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Eval licsng interface & juris. betw NRC/FDA & states/agreement states for sealed sources & devices including licensee requirements for design reviews & QA/QC. Execute new or revised agreements, as appropriate.

ACTION: Coordinate with FDA/Agreement States.
Prepare evaluation of interface & jurisdiction issues.
Develop Commission paper.

STATUS:

NOTES: Refer to Item #29 for FDA interface issue.
This action dependent on Commission response to Task Force.

PRIORITY: H
LEAD: Haughney
SUPPORT: P, S, G

Category 1: O
Category 2: PO
Category 3:

Due Date: 06/01/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 58

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Revise inspection guidance to include a provision to trigger consideration for licensees whose programs have significantly changed.

ACTION: Develop criteria and prepare P&G Directive.

STATUS:

NOTES:

PRIORITY: H
LEAD: Combs
SUPPORT: R

Category 1: LG
Category 2: IG
Category 3:

Due Date: 01/29/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 59

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: For near term & where indicated, conduct inspections of licensees whose programs have significantly expanded or changed since last routine inspection.

ACTION: 1) Issue TI to Regions to poll licensing staff; determine if any significant issues are found. 2) Complete inspections. 3) Followup .

STATUS:

NOTES:

PRIORITY: H
LEAD: Combs
SUPPORT: R

Category 1: IG
Category 2:
Category 3:

Due Date: 05/09/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 01

TRACK NUMBER: 60

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Eval need for assisting nonradioactive waste processing industry in establishing guidance for detecting & obtaining expert assistance for handling of radioactive materials. Assist in developing guidance.

ACTION: Develop guidance for non-radioactive waste processors on emergency response, incorporating IIT lessons.

STATUS:

NOTES:

PRIORITY: M
LEAD: Austin/Combs
SUPPORT: P, R

Category 1: O
Category 2:
Category 3:

Due Date: 01/31/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 09

TRACK NUMBER: 61

Source Code: I **Document No.:**032 **Doc. Date:** 03/12/93

DOCUMENT: IIT Action Memo

DESCRIPTION: Evaluate Southwest Research's final report on source wire failure and document findings.

ACTION: Evaluate and make recommendations to the Commission.

STATUS:

NOTES: Contract info reflects 200K; 180K spent thus far.

PRIORITY: H
LEAD: Haughney
SUPPORT:

Category 1: O
Category 2:
Category 3:

Due Date: 10/29/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 62

Source Code: M **Document No.:** **Doc. Date:** 06/01/91

DOCUMENT: Marcus Petition

DESCRIPTION: Inconsistency between revised Part 20 Public Dose limits & Patient release criteria in 35.75 should be clarified (incorporate ACNP petition).

ACTION: Issue final rule revising Parts 20 and 35 and prepare Reg. Guide. Modify licensing and inspection peocedures.

STATUS:

NOTES: Proposed rule due: 8/30/93
Final rulemaking due: 3/30/94

PRIORITY: H
LEAD: Cool
SUPPORT: N,P,G,S,A

Category 1: RM
Category 2: LG
Category 3: IG

Due Date: 07/07/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 63

Source Code: N **Document No.:** **Doc. Date:** 06/05/89

DOCUMENT: ACNP/SNM Petition

DESCRIPTION: Continue to allow physician-directed departures from package inserts: extension of time period under interim final rule.

ACTION: Issue final rule revising Part 35.

STATUS: Completed 7/22/93

NOTES:

PRIORITY: H
LEAD: Bahadur
SUPPORT: N,G,P,S,A

Category 1: RM
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 64

Source Code: M **Document No.:** **Doc. Date:** 06/05/89

DOCUMENT: ACNP/SNM Petition

DESCRIPTION: Revise Pt.35 to allow departures fr/pkg inserts create category of auth. nuc. pharm., allow physician authorized users & auth. nuc. pharm to compound radioactive drugs, allow research in human subjects...

ACTION: Issue final rule revising Parts 35, 32 and 30.
Revise current radiopharmacy guidance.
Modify licensing & inspection guidance.

STATUS:

NOTES:

PRIORITY: H
LEAD: Bahadur
SUPPORT: N,G,P,A,S

Category 1: RM
Category 2: LG
Category 3: IG

Due Date: 11/01/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 03

TRACK NUMBER: 65

Source Code: N **Document No.:** **Doc. Date:** 02/17/93

DOCUMENT:

DESCRIPTION: Prepare P&GD on acceptable training and experience for physician-authorized users.

ACTION: Develop P&GD.

STATUS:

NOTES:

PRIORITY: M
LEAD: Glenn
SUPPORT: P,S,G,A

Category 1: LG
Category 2: PO
Category 3:

Due Date: 09/29/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 66

Source Code: N **Document No.:** **Doc. Date:** 12/09/92

DOCUMENT:

DESCRIPTION: Review medical field notes, specifically Nuclear Medicine field notes (diagnostic component) to determine savings of time to divert to QM inspections. (IMAB 1149)

ACTION: Revise QM field notes & inspection guidance.

STATUS:

NOTES: Consolidated with Item #34, & resources considered there. See related Item #9. Revision to 87100. IMAB to provide user need memo to IMOB for that action.

PRIORITY: M
LEAD: Glenn/Combs
SUPPORT: R

Category 1: IG
Category 2: EG
Category 3:

Due Date: 06/30/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 67

Source Code: C **Document No.:** **Doc. Date:** 06/25/91

DOCUMENT: SRM Dated 06/19/91

DESCRIPTION: Provide Commission with assessment of the effectiveness of QM Rule at annual briefing 3 years after rule becomes effective.

ACTION: Gather data regarding implementation, monitor QM enforcement actions; evaluate need for comprehensive QM program.

STATUS:

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT: X,R,A,S,P

Category 1: RG
Category 2: IG
Category 3: EG

Due Date: 04/28/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 03

TRACK NUMBER: 68

Source Code: R **Document No.:**NA **Doc. Date:** 02/17/93

DOCUMENT: IMAB 974

DESCRIPTION: Prepare Policy & Guidance on Temporary exemptions for Emergency/Humanitarian Reasons.

ACTION: P&GD would provide Region with guidance on how to proceed in granting temporary exemptions from the regulations for emergency/humanitarian reasons, such as patient release outside of criteria in 35.75.

STATUS:

NOTES: Although this action was originally considered to be a licensing issue, the final action will be to provide guidance through the inspection manual on when & how to grant temporary waives as a matter of discretion.

PRIORITY: M
LEAD: Glenn
SUPPORT: R, G

Category 1: PO
Category 2:
Category 3:

Due Date: 06/30/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 03

TRACK NUMBER: 69

Source Code: N **Document No.:**NA **Doc. Date:** 12/19/91

DOCUMENT:

DESCRIPTION: Prepare Policy & Guidance directive for master materials licensing/inspection manuals (IMAB 731).

ACTION: Prepare P&G Directive.

STATUS:

NOTES:

PRIORITY: M
LEAD: Glenn, Smith
SUPPORT: R, O

Category 1: LG
Category 2: IG
Category 3:

Due Date: 12/30/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 70

Source Code: N **Document No.:**NA **Doc. Date:** 03/10/93

DOCUMENT:

DESCRIPTION: Need for clarification of apparent weaknesses in 10CFR 35.33 regarding patient notification.

ACTION: Prepare memo to OGC requesting clarification of current rule language & whether additional rulemaking is needed.

STATUS: COMPLETED 4/19/93

NOTES:

PRIORITY: H
LEAD: Glenn
SUPPORT: G, H

Category 1: O
Category 2: PO
Category 3: RM

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 71

Source Code: N **Document No.:**NA **Doc. Date:** 08/05/92

DOCUMENT:

DESCRIPTION: Develop inspection manual guidance regarding verification of newly-licensed activities & supervision under 35.25 guidance Coordinate with IMAB.

ACTION: Update inspection guidance in Manual Chapter 2800.

STATUS: Completed

NOTES:

PRIORITY: H
LEAD: Combs
SUPPORT: N, G, L

Category 1: IG
Category 2: LG
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 07

TRACK NUMBER: 72

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Consider the advisability of establishing a national data-base for tracking and evaluation of medical events within the NRC and Agreement State jurisdiction.

ACTION: NMSS issue user need memo to AEOD/
Expand existing AEOD data-base.

STATUS:

NOTES: Resource estimates are for preparation of user need memo.
AEOD resource estimates are for developing and maintaining the database.

PRIORITY: M
LEAD: AEOD
SUPPORT: N

Category 1:
Category 2:
Category 3:

Due Date: 03/31/94

Due Date: Ongoing

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # N/A

TRACK NUMBER: 73

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Consider the potential for underreporting of misadministrations.

ACTION: Include discussion in the Medical Management Plan.

STATUS: Deleted. Discussed in Dr. Paperiello's report.

NOTES:

PRIORITY: H
LEAD: State Progra
SUPPORT:

Category 1:
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 74

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Consider possible NRC policies on patient followup.

ACTION: Incorporate into Mgt. Directive on Misadministration follow-up.

STATUS:

NOTES: See related Items #28 & 39; part of Management Directive. Resources considered in Item #28.

PRIORITY: H
LEAD: N
SUPPORT: G

Category 1:
Category 2:
Category 3:

Due Date: 12/31/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 75

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Define the appropriate role and responsibilities of the medical consultant in NRC medical activities.

ACTION:

STATUS: MC 1360 is now in circulation for Office and OGC review. Procedures will be made consistent with the final MC 1360.

NOTES: See related Item #41; resources considered in Item #41.

PRIORITY: H
LEAD: Combs
SUPPORT: R

Category 1:
Category 2:
Category 3:

Due Date: 04/29/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 01

TRACK NUMBER: 76

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Consider NRC's role & scope of responsibilities vs. that of the FDA & Agreement States in the review & approval of SS&D.

ACTION:

STATUS: MOU with FDA is presently being developed. Office of Policy & Planning is defining options in response to Sen. Glenn. To be completed by 10-/01/93

NOTES: See related Items #29 (FDA) and #57 (Agreement States). Resources are considered in those Items.

PRIORITY: H
LEAD: Glenn
SUPPORT: G

Category 1:
Category 2:
Category 3:

Due Date:

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 77

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Clarify responsibilities & role of RSO at medical instits.

ACTION: Develop and publish NUREG.

STATUS:

NOTES: Contract and resource considerations for this Item are made in Item #33.

PRIORITY: M
LEAD: Glenn
SUPPORT: R,S

Category 1:
Category 2:
Category 3:

Due Date: 09/30/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 05

TRACK NUMBER: 78

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Consider the need for modifications or additions to the Enforcement Policy to provide for notifying licensee boards of Directors or Trustees in cases where escalated enforcement is undertaken by the NRC.

ACTION: Memo needed to Lieberman.

STATUS:

NOTES:

PRIORITY: L
LEAD: Lieberman
SUPPORT: N

Category 1: OE
Category 2:
Category 3:

Due Date: 12/30/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 05

TRACK NUMBER: 79

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Consider potential mechanisms for tracking & notifying Agreement States & appropriate licensing/credentialing authorities of problem auth. users/wrongdoers.

ACTION: Develop tracking system for wrongdoers; info to be available to license reviewers. Evaluate existing mechanisms to determine need for identifying physicians associated with mulitple misadministrations, and notifying appropriate authorities.

STATUS:

NOTES: May 27, 1993 memo from OGC describes current system. Creating additional categories would require rulemaking & some provision to offer hearing rights to an affected individual.

PRIORITY: M
LEAD: Lieberman/Co
SUPPORT: A,D,N

Category 1:
Category 2:
Category 3:

Due Date: 12/29/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 80

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Notify local authorities for serious misadministration or other serious events including potentially significant exposures to radiation or radioactive materials.

ACTION:

STATUS:

NOTES: Procedure outlined in Appendix A of Paperiello paper. Would ensure accuracy of death certificates. See related Items #28, 39, 40, 49, 74. Part of Management Directive.

PRIORITY: H
LEAD: N
SUPPORT: R,G

Category 1:
Category 2:
Category 3:

Due Date: 12/31/93

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 03

TRACK NUMBER: 81

Source Code: IG **Document No.:**033 **Doc. Date:**

DOCUMENT: Memo to Bernero from IG 3/93

DESCRIPTION: Revise guidance in RG 8.33 to clarify sampling & guidance for determination if other errors exist.

ACTION: Revise RG 8.33 to clarify sampling and incorpate findings from contractor review of QMPs, if warranted.

STATUS:

NOTES: Results from the IG audit.

PRIORITY:
LEAD: Bahadur
SUPPORT: G,R,A,S,P,N

Category 1:
Category 2:
Category 3:

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 08

TRACK NUMBER: 82

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: NMSS Misadministration Coordinator

ACTION: Coordinate response with Regions, monitor misadministrations and followup, and maintain complete records of misadministrations, and coordinate data collection with AEOD. Send memo to Agreement States informing of this action.

STATUS:

NOTES: Resources are considered on a per-year basis.

PRIORITY: M
LEAD: Combs
SUPPORT: R, D, P

Category 1:
Category 2:
Category 3:

Due Date: 12/31/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 83

Source Code: **Document No.:**033 **Doc. Date:**

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Inspection MC 2800 & inspection procedures should reflect risk & be based on the need for a QM program and be adjusted for performance.

ACTION: Revise MC 2800 and inspection procedures.

STATUS:

NOTES: Meetings to be held with License community, States, ACMUI, and Regional counterparts.
Resources being expended for Items #50, #34, and #71 will support this effort.

PRIORITY: M
LEAD: Combs
SUPPORT: S,A,R,F,P

Category 1:
Category 2:
Category 3:

Due Date: 01/29/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 84

Source Code: **Document No.:** **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Special event response procedure to ensure that management can adequately evaluate events with respect to cause and consequences.

ACTION: Issue reactive inspection procedure.

STATUS:

NOTES:

PRIORITY: H
LEAD: Combs
SUPPORT: R, D

Category 1:
Category 2:
Category 3:

Due Date: 06/30/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 04

TRACK NUMBER: 85

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Allegation followup.

ACTION: Issue allegation followup procedure.

STATUS:

NOTES:

PRIORITY: H
LEAD: Combs
SUPPORT: F,R,G,D

Category 1:
Category 2:
Category 3:

Due Date: 06/30/95

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 03

TRACK NUMBER: 86

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Revise MC 1245 to establish a license reviewer training program.

ACTION: Revise MC 1245.

STATUS:

NOTES: Already in P&GD form- needs to be formalized for this. Grandfather those who are qualified; provide for ongoing refresher training also.

PRIORITY:
LEAD: Combs
SUPPORT: R,S,P

Category 1:
Category 2:
Category 3:

Due Date: 06/30/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 07

TRACK NUMBER: 87

Source Code: N **Document No.:**033 **Doc. Date:**

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: Ensure Regional TARs and other ticketed action items are tracked by the Division.

ACTION: Establish Division tracking system.
Maintain the system on a daily basis.
Revise associated P&GD.

STATUS:

NOTES: FTE to be considered on a per-year basis.

PRIORITY: H
LEAD: Combs
SUPPORT:

Category 1:
Category 2:
Category 3:

Due Date: 03/31/98

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 06

TRACK NUMBER: 88

Source Code: **Document No.:**033 **Doc. Date:** 06/01/93

DOCUMENT: Paperiello Paper to Commission

DESCRIPTION: RSO certification form

ACTION: Determine method for implementing use of RSO certification form.

STATUS:

NOTES:

PRIORITY: M
LEAD: Glenn
SUPPORT:

Category 1:
Category 2:
Category 3:

Due Date: 03/31/94

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 02

TRACK NUMBER: 89

Source Code: **Document No.:** **Doc. Date:**

DOCUMENT:

DESCRIPTION: Revision of Part 35 & Reg Guide 10.8 to address remote afterloader brachytherapy, gamma stereotactic radiotherapy and other therapies.

ACTION: Support Research in revision of documents.

STATUS:

NOTES: See related Items # 7, 26, 47, 48, 55.
Begin in 1995 after compltetion of Items #48 and #26.

PRIORITY: H
LEAD: bahadur
SUPPORT: P,N,G,S,M,A

Category 1:
Category 2:
Category 3:

Due Date: 06/27/97

Due Date:

Due Date:

MASTER AGENDA: Medical Program Improvements
Printed on 08/05/93

TOPIC # 01

TRACK NUMBER: 90

Source Code: N **Document No.:** **Doc. Date:**

DOCUMENT: SRM on Annual Medical Brief

DESCRIPTION: Analysis of consistency with 1979 Medical Policy Statement. Compare all rulemakings for consistency with the above.

ACTION: Send memorandum to Office of Research requesting an analysis to be included in each rulemaking package.

STATUS:

NOTES:

PRIORITY: M
LEAD: Glenn
SUPPORT:

Category 1:
Category 2:
Category 3:

Due Date: 12/31/93

Due Date:

Due Date:

ENCLOSURE 3

Medical and Academic Section
Routine Work Items

ROUTINE MANAGEMENT OF MEDICAL USE REGULATORY PROGRAM

1. CATEGORIC LIST OF 180 TICKETED WORK ITEMS:

   - o Preparation of Commission Papers
   - o Assistance to other Offices, i.e., rulemaking efforts, guidance from OGC, data gathering, interact with OSP
   - o Technical Assistance Requests from the Regions
   - o Review of enforcement cases, particularly QM related issues
   - o Issuing inspection and licensing guidance
   - o Review of potential misadministrations
   - o Preparation of Information Notices, Bulletins, NMSS Newsletter articles, generic letters to licensees and other communications
   - o Environmental Assessments for the release of radioactive material from research studies at academic institutions
   - o Monitor and followup on incident response
   - o Freedom of Information Act Requests
   - o Coordination with other regulatory agencies and professional organizations
   - o Responses to members of the public and others

2. MANAGEMENT OF UNTICKETED BROAD PROGRAM ITEMS:

   - o Management of, and preparation for meetings of the ACMUI
   - o Contract management/Technical advisor duties
   - o Followup on regulatory issues associated with Indiana event
   - o Implementation of the QM rule
   - o Development of a NUREG on effective management of radioactive material safety programs at medical facilities
   - o Three current rulemaking efforts to revise Part 35
   - o Oversight of the broad materials licenses issued to the U.S. Departments of Army and Navy
   - o Coordination with the Veterans Affairs Central Office and the FDA
   - o Presentations at regional workshops and professional meetings
   - o Management of the Medical Visiting Fellows Program

ENCLOSURE 4

IIT Action Item Update

IIT ACTION ITEM UPDATE (8/93)

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 licensee committed to provide a written detailed response to the March 5, 1993, NRC deficiency letter to address weaknesses in radiation safety training, RSO oversight, normal emergency operating procedures, and internal and independent audit program. Region I received the licensee's submittal on April 8, 1993. Upon review, Region I issued a letter to OSC dated April 22, 1993, to acknowledge the submitted radiation safety program upgrades, inform OSC that the upgraded program appeared to meet NRC requirements, and inform OSC of planned future NRC inspections. Inspections were performed during the period of April 22 through May 5, 1993, and an inspection report was issued on May 28, 1993. The inspection findings confirmed that appropriate supervision was exercised by the Medical Director and authorized physician users, and the physicists were cognizant of and performed their duties in accordance with the applicable requirements. Additionally, the inspectors verified that the corporate oversight of licensed activities had improved. On June 3, 1993, NRC issued general relaxation Orders to OSC to resume brachytherapy procedures, without specific relaxation requests, at the Greater Harrisburg and Greater Pittsburgh Cancer Centers. A hearing by the Atomic Safety and Licensing Board (ASLB) to review NRC's suspension of licensed activities is pending.

STATUS:	Open
COMPLETION DATES:	Review findings of ASLB expected to be held no earlier than 10/93.
CONTACT:	RI/Cooper

Action 1b. Evaluate the need to further define RSO and Authorized User responsibilities.

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.

STATUS:	Open
COMPLETION DATES:	Draft NUREG for RSO's 6/30/94 (No change) Evaluate authorized users; Possible rulemaking 12/30/97
CONTACT:	NMSS/IMAB/Glenn

Action 1c. Evaluate performance and design of PrimAlert-10 Area Radiation Monitors (ARM's) and take appropriate followup action.

Action Plan:

The staff has written to the manufacturer (Victoreen) and requested an evaluation of the potential for nonionizing 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.

STATUS:	Open
COMPLETION DATES:	Letter to Victoreen 8/31/93
	Issue TI to Regions 12/31/93
	Decision on IN 4/29/94
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.

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.

STATUS:	Open
COMPLETION DATES:	Issue guidance 1/13/94
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.

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.

STATUS: Open
COMPLETION DATES: Memorandum to OGC: 9/30/93
Incorporate guidance: 2 months after receipt of OGC interpretation.
CONTACT: NMSS/IMOB/Combs

Action 3a. Evaluate the need to update licensing and inspection guidance and requirements for HDR afterloaders.

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.

STATUS: Open
COMPLETION DATES: Issue Bulletin 4/30/93
Revise P&GD 86-4:
Draft 8/30/93 Final 11/23/93
Issue TI:
Draft 7/29/93 Final 10/31/93
Evaluate QA studies 9/30/93
Evaluate HF studies 9/30/93
Issue user need memo 3/1/94
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.

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.

STATUS: Open
COMPLETION DATES: Discuss with ACMUI 11/93
Incorporate into user need memo, as appropriate 3/1/94 (No change)
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 an Memorandum of Understanding (MOU) with the FDA to further clarify respective roles.

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.

STATUS:	Open
COMPLETION DATES:	Establish MOU between NRC and FDA 10/30/93
	Discuss at All Agreement State Meeting 10/93
	Complete Commission paper 6/1/94 (No change)
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.

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.

STATUS:	Open
COMPLETION DATES:	Issue P&GD 1/29/95
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.

Action Plan:

The staff has 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.

STATUS:	Open
COMPLETION DATES:	Issue memorandum 7/9/93
	Proposed Regional schedule for conduct of inspections due to IMOB 9/30/93
	Complete inspections 5/9/94
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.

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.

STATUS:	Open
COMPLETION DATES:	Conduct meeting 6/29/93
	Publish final guidance 1/31/94
CONTACT:	NMSS/LLWM/Austin and IMOB/Combs

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

Action Plan:

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

STATUS:	Open
COMPLETION DATES:	Complete evaluation 10/30/93 (No change)
CONTACT:	NMSS/SCDB/Haughney