UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON INTERNAL MANAGEMENT REVIEW OF NRC PROGRAM FOR MEDICAL USE OF BYPRODUCT MATERIAL

Location: ROCKVILLE, MARYLAND

Date: JUNE 24, 1993

Pages: 75 PAGES

SECRETARIAT RECORD COPY

NEAL R. GROSS AND CO., INC.

Doris Mossburg - Re: Mtg Transcript

From: Kathleen Ruhlman
To: Mossburg, Doris, Yeates, Elizabeth
Date: Tue, Aug 25, 1998 9:15 AM
Subject: Re: Mtg Transcript

Yes to both. The accession number for the transcript is 9307080025. The Taylor memo is attached. The memo also came through by itself and its accession number is 9308260103. Let me know if you need fiche addresses.

DISCLAIMER

This is an unofficial transcript of a meeting of the United States Nuclear Regulatory Commission held on June 24, 1993, in the Commission's office at One White Flint North, Rockville, Maryland. The meeting was open to public attendance and observation. This transcript has not been reviewed, corrected or edited, and it may contain inaccuracies.

The transcript is intended solely for general informational purposes. As provided by 10 CFR 9.103, it is not part of the formal or informal record of decision of the matters discussed. Expressions of opinion in this transcript do not necessarily reflect final determination or beliefs. No pleading or other paper may be filed with the Commission in any proceeding as the result of, or addressed to, any statement or argument contained herein, except as the Commission may authorize.

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

- - - -

BRIEFING ON INTERNAL MANAGEMENT REVIEW
OF NRC PROGRAM FOR MEDICAL USE
OF BYPRODUCT MATERIAL

- - - -

PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Thursday, June 24, 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
JAMES R. CURTISS, Commissioner
FORREST J. REMICK, Commissioner
E. GAIL de PLANQUE, Commissioner

STAFF SEATED AT THE COMMISSION TABLE:

JOHN HOYLE, Assistant Secretary

MARTIN MALSCH, Deputy General Counsel

JAMES TAYLOR, Executive Director for Operations

HUGH THOMPSON, Deputy Executive Director for Operations

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

MYRON POLLYCOVE, Visiting Medical Fellow

PATRICIA RATHBUN, Senior Risk Analyst, NMSS

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

2:00 p.m.

CHAIRMAN SELIN: Good afternoon, everybody.

The Commission is pleased to be meeting at this time to receive a briefing on the results of a senior management review on the regulatory program for medical use.

Last December, in response to the November 1992 therapy misadministration incident in Indiana, Pennsylvania and two other circumstances, the Commission requested the staff to undertake two reviews of the medical use program. The first of these reviews was to be performed by a senior NRC manager in which to focus on the implementation of NRC's current regulatory program. This review has now been completed and is the subject of today's briefing.

I guess if we like it, you stay a senior manager. Otherwise, it's just a matter --

The second review requested by the Commission is to be performed by an outside group and it will be much broader in scope. It's a longer term effort and will include an in-depth review of NRC's entire medical use regulatory program.

Today's briefing will be provided by

Doctor Carl Paperiello who, in fact, performed the internal review. His written report was just recently provided to the Commission and should be available here in the conference room.

Since the subject of the proper regulation of the medical use of radioactive byproduct material is not only of great importance but also great complexity, it is appropriate for us to allow Doctor Paperiello as much of our time as we can. The Commission is keenly interested in knowing what needs to be done to enhance the implementation of our current regulatory program for radiation medicine.

Commissioners, do you have any opening --

Mr. Taylor?

MR. TAYLOR: Good afternoon. With Doctor Paperiello are Pat Rathbun and Doctor Pollycove, who assisted him, and from my office Hugh Thompson.

I should note that the recommendations and various positions that have resulted from Doctor Paperiello's review would be incorporated into the staff's medical management plan, I believe a report of which is due by the end of July to the Commission. Some of what he recommends may indeed require some rule changes or certainly there are other changes and we intend to pull that into the medical management

plan which will be provided. So, today you will hear his positions, but they will be taken into account in this plan due to you the end of July.

With those opening thoughts, I'll ask Doctor Paperiello to continue.

DOCTOR PAPERIELLO: Good afternoon.

I was requested to conduct this review by the Commission and -- could I have the next slide?

(Slide) What I was directed to do was review the existing program, including agreement state oversight, to determine if it was effectively implemented and to coordinate this review with the medical management program and the IIT findings and make recommendations to correct deficiencies.

While conducting my review, much was happening, as you're all aware. In some cases I made a decision that the concentration of Agency resources reviewing a problem was so intensive that my limited time could be better spent elsewhere. And, of course, my review does not answer some of the more global questions that we expect the National Academy of Sciences to answer.

Therefore, this report is far from exhaustive. It represents what I was able to accomplish in three months, assisted by Doctor

Patricia Rathbun, who worked with our contractors at INEL and Lawrence Livermore and acts as a guide for me through most of the Headquarters maze here, and Doctor Myron Pollycove who provided much of the medical information used in the report.

(Slide) Can I have the next slide?

This is basically the outline of what I'm going to discuss today. As you can see, there's some still open issues.

(Slide) Next slide.

Today we're regulating what is a mature science. We've a large body of physicians and allied health personnel who are highly educated and trained. They have many subspecialties, numerous credentialing organizations, a substantial literature and a wide variety of radiation sources in routine use by technologists. Over time, radiation sources available to the medical practitioner changed. From radium and x-ray machines and small quantities of accelerator-produced isotopes, we went to reactor-produced isotopes for teletherapy, brachytherapy and radiopharmaceuticals. Now, we have linear accelerated teletherapy, isotope production cyclotrons and a number of other devices. The research instruments of one decade are the clinical instruments of the next

decade. All of this is supported by a cadre of individuals with professional and advanced degrees.

This technical growth is accompanied by two other changes. The delivery of medical services has grown very complex and I believe that the management control systems have not kept pace at all institutions. Secondly, complex medical devices, particularly computer-driven devices, are susceptible to failures that may not be readily apparent to the user.

(Slide) Next slide.

Where does this leave the NRC? The NRC mandate is broad. Theoretically the NRC has considerable authority, but only for byproduct material in medicine. There's small amounts of SNM and source material used, but basically for shielding and batteries in pacemakers. But we're talking about byproduct material by and large in nuclear medicine.

All other sources of ionizing radiation used in medicine are regulated by someone else, usually the state, and the 29 agreement states' state authority over medical uses of ionizing radiation is complete.

Coupled with this, the NRC has limited medical expertise. Except for visiting medical

fellows, we employ no physicians, no nuclear pharmacists and only a handful of medical physicists. We need to be prudent in how we regulate in this area. It makes no sense to have a regulatory position so draconian that the medical community is driven to choose radiation modalities primarily to avoid NRC jurisdiction, since some of these modalities require more expertise than the modalities using NRC regulated material. This could have an adverse effect on the public health and safety.

Then what should be our role? The NRC should maintain its leadership role in the regulation of radiation safety in the use of radioactive material. Management of radiation safety programs is where our expertise lies. The NRC's radiation protection standards and basic licensing regulations serve as a focus for numerous consensus standards and secondary radiation protection supporting criteria. We also have to recognize that we regulate a broad spectrum of licensees. Some licensees may over extend themselves and perform procedures for which they are not qualified and, unfortunately, an advanced degree does not preclude ethical weaknesses.

(Slide) Next slide.

CHAIRMAN SELIN: You're not looking at the

Commission?

MR. TAYLOR: You say no.

DOCTOR PAPERIELLO: Let's talk about misadministration.

Recent events brought to all of our -- to the forefront the problems concerning misadministrations. We've also identified problems with reporting and follow-up of these misadministrations. Implementation of our misadministration requirements by licensees has been questioned and individual commissioners have questioned a lack of precise statistical information on misadministrations.

I've looked at some data on misadministration rate. Doctor Pollycove has developed an estimate of about one misadministration in 4,000. I calculated a diagnostic rate of about one in 5,200 using an NCRP report and making an assumption that there's no probably much difference between diagnostic misadministrations and therapeutic misadministrations, at least grossly.

If you look at data on human error rates, it is reasonable to accept that the misadministration rate, if there is such a thing as a true rate, will range from somewhere in one in 1,000 and one in

10,000.

It's going to be difficult to develop a precise misadministration rate. Some misadministrations are not reported because they're not recognized. Some more fundamental problem is defining a denominator. In part, we don't know how many procedures are performed as noted in the Commission's testimony of Senator Glenn's hearing. It's also not clear how we ought to define a denominator and I'll give an example.

If I'm a patient and I'm going to get 4500 rads from brachytherapy, I may have the option of receiving 4500 rads from one low dose rate brachytherapy treatment. I will have one encounter with the physician, it will last three days. On the other hand, if I receive the dose in three 1500 rad fractions from high dose rate brachytherapy over three separate days, I will have three encounters with the physician. In this case, should we put three in the denominator or should we put one in the denominator? From my viewpoint of a patient, I just want to get through this procedure without being injured. So, that's a problem.

What we also need to understand, that not all misadministrations have severe or fatal outcomes.

Many are under doses. Doctor Pollycove estimates the serious misadministrations amount to about ten percent of all misadministrations. I looked at 51 patients receiving -- in 35 reports of misadministrations that we received in 1992.. I could only identify two severe misadministrations. One was the Indiana, Pennsylvania event that I investigated and one involved the loss of a normal thyroid due to an iodine 131 misadministration in Region III.

CHAIRMAN SELIN: This was a diagnostic --

DOCTOR PAPERIELLO: It was a confusion of a diagnostic and therapeutic and the man received, instead of microcuries, ten millicuries and he had a normal thyroid and it destroyed it.

It is likely that each treatment modality, HDR, teletherapy, low dose rate radioiodine and so forth, has its own fault tree in the language of PRA and different outcomes if you run into a failure. So, there is likely to be a different misadministration rate for each treatment modality. But we can still put the whole thing in global perspective in terms of relative risk for the patient. For few exceptions, radiation therapy is used in the treatment of cancer. Untreated, cancer is almost always fatal. With treatment, half the patients survive. So, out of

about -- to put it in perspective, out of 20,000 patients with cancer, all will die with no treatment, 10,000 will die in spite of the treatment, approximately 200 or more will die from the treatment if delivered as planned, and probably no more than one will die or be severely injured due to a radiological medical misadministration. Therefore, the relative risk is low.

As I intended to discuss later, most misadministrations are preventable. Radioiodine is a special case for two reasons. Misadministrations associated with diagnostic tests can cause an individual with a perfectly healthy thyroid to lose all thyroid function. I consider that a severe outcome. Second, loss of thyroid function in a fetus or a neonate can cause mental retardation and developmental handicaps.

(Slide) Could I have the next slide?

Misadministrations are preventable if licensees effectively implement the existing quality management rule. My report summarizes the findings of our contractors as well as my own observations. Misadministrations are caused primarily by errors that are not unique to the practice of medicine. Effective implementation of the current NRC quality management

requirements could have prevented and will prevent most of the misadministrations of the type currently being reported. However, we still have inadequate procedures, untrained staff and RSOs at facilities who are not doing their job.

(Slide) Next slide.

Misadministration follow-up. There has been a lack of consistent NRC follow-up of reported misadministrations. Why? There's several reasons. First, there's no clear management direction to the regional material staff on the totality of actions to be taken upon receipt of an information concerning a medical misadministration. The materials program is an incredibly busy program with far less redundancy and oversight relative to per licensee than a reactor program. Given the fact that people make errors and that the probability of error increases with absence of procedures and training, it's not surprising that errors are made.

Furthermore, on the average, the licensees that we regulate in the materials program are not as knowledgeable as reactor licensees and as a consequence communication errors lead to a lack of Agency response. People call in, they report events, they're not quite sure who they ought to call. They

look through their papers and call somebody's name who is on an inspection report or on a license that they received. That person is not there, the call gets passed around. I've experienced as Deputy Regional Administrator numerous times, people tell me things in the hall that should have been reported and were never reported and I have to act on them.

The other finding I have is we have an incomplete misadministration database.

(Slide) Next slide.

How can we fix it? I recommend the issuance of an NRC management directive that will describe all NRC actions to be taken for medical misadministrations and therapeutic events involving high doses. Appendix A to my report proposes an outline of such a procedure. I recommend that an inspection procedure be developed to prescribe all the information an inspector is required to gather and evaluate it. We expect the reported event, not just misadministrations. It's evident in misadministration reports, but I've been reviewing reports for the last several months and they're just incomplete.

I have recently seen reports that are just recitations of violations. They lack an analysis of root causes. They provide no information on the

consequences and present no information on licensee action. Incidentally, when I did the regulatory impact survey, I had the same complaint from licensees. You send inspectors here to follow-up on an event, they look for violations. When they find them, that's it, they're happy and they leave.

I also recommend that we find some way to give our inspectors formal training on inspecting allegations. Not all misadministrations are come in as allegations and, of course, not all allegations are misadministrations. But there is a problem that's recognized in the Agency in following up allegations and problems with the adequacy of that follow-up. But if you look at our program, we only give inspectors approximately two hours of classroom training and it's primarily on the allegation policy, doing fundamentals of inspection. Refresher training covers the same material. Almost all our inspector training is technical and inspectors handle technical issues very well. Some inspectors, with time, develop a sense when they're having smoke blown in their face by a licensee. We need to provide our inspectors with some procedures and training on how to follow-up an investigation, a misadministration.

When I was a material section chief in

Region III in the late '70s, materials allegations were rare. Now they account for almost 34 percent of the allegations received in Region III and approximately across the Agency about 30 percent of all allegations involve materials.

When you consider the human performance error rate for an activity like investigating an allegation, the availability of training and procedures has to have a significant impact. And, of course, when the inspectors make a mistake in handling an allegation, we have investigations and the Agency pays a high price in credibility and resources. Only a few allegations, of course as I mentioned, involve misadministration.

I've had a discussion with the IG's office on this issue to find out how do we train our investigators. They receive over a half a year of formal training in Georgia at a place called Glenco. It's a federal investigation institute. There is a two week course there for individuals who are inspectors and auditors in federal agencies, but not criminal investigators, to sort of get them used to dealing with the kind of behavior they run into. I don't know if this is the way to go. It's just something like that does exist.

With respect to the database, AEOD has the best misadministration database, but it needs augmentation. It should be supported as the basis of a potential national database and NMSS and AEOD need to develop a smooth interface to make sure this happens.

(Slide) Can I have the next slide?

COMMISSIONER REMICK: Excuse me, Carl, while you're catching your breath. When you say AEOD has the best database, the best in the Agency or --

DOCTOR PAPERIELLO: They have the best in the Agency that I can find. I mean it's not complete, but it's better than anybody else has.

I have proposed and attached an outline for a misadministration follow-up management directive. It defines what has to be done. It defines minimum qualifications for the inspector doing the inspection. It requires that we use a medical consultant in all cases. The medical consultant report, among other things, will provide information with respect to the probable consequence of the event. I propose to attach the consultants report to the inspector's report.

COMMISSIONER REMICK: Excuse me. You said you'd have a consultant in every case --

DOCTOR PAPERIELLO: In every case of a reported therapeutic misadministration.

COMMISSIONER REMICK: Therapeutic misadministration.

DOCTOR PAPERIELLO: So, we're talking about roughly in 1992 we had 35 reports, although not all the events occurred in 1992. I know some of them occurred in '90 and '91. Licensees, while doing their periodic reviews of their programs, came across misadministrations that occurred in other years.

COMMISSIONER REMICK: Would that be less than prescribed dose also?

DOCTOR PAPERIELLO: Commissioner, I haven't thought of that.

COMMISSIONER REMICK: Okay.

MR. TAYLOR: That's a reasonable question

DOCTOR PAPERIELLO: That's a reasonable question.

In any case, the consultant's report, if we had one, would be attached to the inspector's report. I am proposing, and I will admit this would be controversial, that the report would be distributed to the referring physician, the licensee and the patient. I discussed with OGC attorney who tells me, which I expected, that the report is a public

document. If the patient wanted the report, the report could be provided under a FOIA and I'm proposing, because of all the arguments about whether or not patients are being notified, to send a patient a copy of the report. If the patient hasn't been notified, we're going to hear pretty soon, unless the referring physician gives us a good reason why the patient shouldn't receive the report.

(Slide) Next slide.

The procedure would require all cases to receive a review for enforcement by regional and headquarters management and the procedure would also provide a patient follow-up policy.

(Slide) Next slide.

COMMISSIONER de PLANQUE: Carl, would you apply this to others, other than patients who might have also been exposed?

DOCTOR PAPERIELLO: In this procedure, no. We should have a procedure that addresses that question. I will note that a new Part 20 and a new Part 19, licensees will have to report to us all overexposures. That would include members of the public getting more than 100 millirem in a given year. Part 19, the new Part 19 requires that when you send a report to us, you send it to the affected

individual. So, in terms of what licensees have to do, the answer is they do have to make the notification. We ourselves are developing a procedure to do the same thing and I think it will have comparable -- it should have comparable words.

Part of our procedure and the problems are is how hard do you look? Where do you truncate and where do you stop because in principle everybody in Indiana, Pennsylvania received some dose from the source.

Let's talk about the follow-up policy and this is what I propose. We will always identify patients -- we will make best efforts, I should say, to identify patients receiving misadministrations. So, this will cover the case of Riverside Methodist where when do we stop. We should identify to the best we can who received a misadministration if the licensee tells us somehow between this month and this month there were misadministrations.

CHAIRMAN SELIN: Just to go back to what we were talking about, therapeutic misadministrations --

DOCTOR PAPERIELLO: Therapeutic.

CHAIRMAN SELIN: -- and radioactive iodine for diagnosis?

DOCTOR PAPERIELLO: Yes. Misadministrations as defined by the QM rule.

The medical consultant will determine the probable consequences as required by Section 208 of the Atomic Energy Act. Patients will be offered an opportunity to join DOE's voluntary long-term medical study. There are approximately 2700 people in that study. I don't think they're all medical misadministrations. I suspect they're people who have received over exposures. I didn't get into that.

COMMISSIONER REMICK: I hate to interrupt you when you're on such a roll, but what is that program? Could you tell us a little bit more about it?

DOCTOR PAPERIELLO: No, I can't. I don't know the details of what they're doing, but they are following people over a long-term who have received radiation exposures. I don't know if there's somebody in here who can.

COMMISSIONER REMICK: Are they following from the standpoint that they get reports of deaths or do they occasionally have examinations or we just don't know that?

DOCTOR PAPERIELLO: Cindy Jones?

COMMISSIONER REMICK: Okay. Fine.

MS. JONES: It's operated by REACTS. They have two different studies, the one of which is the voluntary program. Anyone who receives an over exposure can get into their program as a result of an over exposure anywhere around the world. So, for the most part, it has radiography, people who happen to lose a limb or have a serious over exposure. There's only very few in medical misadministration area, according to Doctor Shirley Frye at REACTS.

COMMISSIONER REMICK: What do they do in this program? Do they occasionally do physical exams of the people?

MS. JONES: No, they just make a note of it. They keep it on the database. If for some reason in the future someone wanted to contact that person to get follow-up, they have the address and phone number of that individual they can contact, but it is not an active database.

COMMISSIONER REMICK: I see. It's a registry kind of thing.

MS. JONES: Exactly.

COMMISSIONER REMICK: I see. Okay.

DOCTOR PAPERIELLO: Usually --

COMMISSIONER REMICK: Excuse me. I'm sorry.

DOCTOR PAPERIELLO: I'm sorry.

COMMISSIONER REMICK: Before we leave that, do we know of any alternatives other than DOE's that might be somewhat similar or --

DOCTOR PAPERIELLO: I don't, and that is the program that is currently referenced in Manual Chapter 1360 on medical consultants and scientific consultants and follow-up. Usually, patient follow-up will end upon completion of enforcement. The procedure will provide an option for NRC management to seek longer term follow-up. There may be cases where we may want to know what happens and we will make a decision to follow the patient longer. I don't anticipate that we will do it in most cases. Again, if you look at what's happening to patients, you have the under exposures and over half the individuals exposed in 1992 or reported were under exposures. Then you have individuals that received, although iodine misadministrations, that were small. In other words, they were supposed to get ten or 15 microcuries and they got 85 or 90 microcuries. Years ago, the normal diagnostic dose of iodine was 100 microcuries. So, they're not very significant.

You have patients who received dose fractions from teletherapy in which case the wrong

part of the body was irradiated, but it was caught after one or two fractions. Then you have brachytherapy events where patients pull sources out of their body, sources are left out and even though the brachytherapy events, roughly half of them represented under doses too. So, most of them are not -- they meet the definition of a mis-administration, they are preventable, but it's very apparent that there aren't very significant consequences.

The procedure will provide that where a patient has died or we find out that there could be an error in the death certificate that this information will be provided to the appropriate legal authorities in the state. We had a conversation with the ACMUI about this and the states have very stringent regulations and doctors can lose their licenses over misrepresenting the cause of death on a death certificate. So, this is something doctors are sensitive to. But the procedure will ensure that where there could be an error that the information we have is passed on to the appropriate legal authorities.

(Slide) Next slide?

Let's talk about material licensing.

Materials licensing guidance is in sad disarray. There are 20 licensing guides. Twelve were issued in draft form in 1985 and almost all are inaccurate due to being out of date. Revision of licensing guide has always been planned, but dropped due to the press of more immediate problems. Policy guidance and directive memos have been used in place of licensing guides, as was in the case of the high dose rate brachytherapy. I received many complaints about this situation during the regulatory impact survey. License reviewer training is not at the level of inspector training and the lack of codification of all of the licensing guidance hampers systematic training of license reviewers. The system of issuing individual regulatory guides hampers their maintainability because many of these things are related.

(Slide) Next slide.

We have to revise all of the guides, starting with the three medical guides. This needs to be done in a structured fashion to ensure maintainability and all guides should be placed in a periodic review cycle. I'm also proposing that unique licensing reviews be done here in Headquarters. If a licensing application isn't covered by a guidance

document, it should be done here. This will do two things. It will ensure that the regions cannot commit the Agency to an activity never before reviewed and it will also encourage the Headquarters staff to promptly issue new guidance.

For long-term licensing guidance we should plan to put licensing guidance on a bulletin board accessible to anyone and in Appendix B I describe the concept of such a system. Many of the pieces of these guides are the same. They'll deal with calibrating instruments or they deal with how to do surveys or the like. If you could create a system where the computer would generate the guide by pulling up the different modules, it would make it easier to maintain the guides.

Secondly, we expect licensees to know what we put in information notices and generic correspondence ten years ago. At power plants that works, but that doesn't work for material licensees. What I'm proposing is on a periodic basis you would review a licensing guide, you would gather all the generic correspondence issued that's relevant to that guide, any of the various individual guidances that we issued to the regions, and you would codify it into an updated licensing guide and then licensees would not

have to worry about any earlier guidance. If they went to that licensing guide, they would know everything they need to know.

COMMISSIONER REMICK: Have we thought about possibly putting those on a ROM disk that people could get and have it all on one nice little disk?

DOCTOR PAPERIELLO: Oh, yes. Yes.

COMMISSIONER REMICK: Wouldn't that be nice?

DOCTOR PAPERIELLO: You know, the interesting thing is, Commissioner, there are people around here who will turn around and -- if there was a big enough market, who would do it for you. We wouldn't even have to get involved.

COMMISSIONER REMICK: I agree.

COMMISSIONER de PLANQUE: Carl, before you go ahead, on the unique license reviews, do we make that service available now to agreement states or would you envision doing that for agreement states?

DOCTOR PAPERIELLO: Only if we're requested that I'm aware of. If a state has a problem, they'll call. What I'm thinking of right now is the radiolabeled biologics. This is something I just learned about in the last week. I understand FDA approved two more of them and now they are approving

ones that we license. And I asked who is licensing it and people looked at me and I said, "I want to know who has the licensing actin on it."

(Slide) Could I have the next slide?

Inspection program. Reactive inspections in the materials area are not always well done. Improperly done reactive inspections can cause the Agency significant problems. However, the prime performance indicator in the inspection program is total numbers of inspections. And inspection of a gas chromatograph source has an equal weight to either a misadministration or an allegation inspection which can be done a lot faster. The materials inspector is budgeted to do about 70 inspections a year.

Again, when I was in the region and the section chiefs saw me coming down the hall and asking about an event, I could always see their eyes glaze over because I know they were just thinking, "Paperiello is going to send me out to look into this thing and I'm going to have to cancel a trip and I'm going to lose five inspections next week." Well, that's just the way it is.

I want to change the program to ensure that reactive inspections are done and not to punish people because they don't meet the numbers because

we're dealing with these things.

The routine program is unresponsive to licensee performance. We inspect people on the same frequency whether or not they are good performers or poor performers.

CHAIRMAN SELIN: Do we in any sense rate the performances different or performers?

DOCTOR PAPERIELLO: Pardon?

CHAIRMAN SELIN: Do we rate performers different?

DOCTOR PAPERIELLO: No, but materials are different than a reactor. In a reactor, you need the rating because you have a lot of different specialists and a lot of different people. But if I walk into a hospital where essentially work is being done in this room and next room and I have a clear inspection and I pull the file and the last three inspections have been clear, I think we can think about extending the frequency of -- extending the interval between the inspections. That's what I'm proposing to do. And where the record is poor, shorten the interval.

Our program provides for that now, but what you find out is the people will shorten it, but it's almost impossible to get anybody to extend it. The risks are not completely reflected in inspection

procedure. We do a pretty good job in reflecting risk, but in the medical area there has been until recently too much emphasis on the size. So, a big hospital gets inspected more frequently than a small clinic, but the clinic may be doing therapy and a hospital may only be doing diagnosis. So, we need to adjust the frequency based on risk, not necessarily the number of people involved in the program.

Initial inspections. I propose that we will always do initial inspections, and the initial inspection will be didactic. Again I've spoken to OGC about this and they tell me whether or not the licensee possesses material, if the licensee has a license we have a legal right to conduct an inspection. But I do want this initial inspection to be didactic.

COMMISSIONER REMICK: Initial inspection before the person receives the license or after he receives the license? It seems to me we've had a couple of occasions recently on -- that showed the prudence perhaps before we actually issue a license to go verify that the person has the facilities and equipment that --

DOCTOR PAPERIELLO: I understand.

COMMISSIONER REMICK: I want to make sure

I understand what you're saying.

DOCTOR PAPERIELLO: When I'm proposing it would be afterwards, unless we had done a prelicensing visit, which we will do in the case of a broad scope license. The idea for this comes from my discussions with the agreement states. In some agreement states, when they issue the license, they have an inspector hand deliver the license. I would like to do that, but I'm concerned with the resource implications. We have a bigger program than the agreement states have. It's spread over a larger geographic area. I wouldn't want to hold up issuing a license to have somebody hand deliver it, and to me the best compromise is at least to do an initial within six months.

But I'm aware of the other issue. I'm meeting with somebody next week to talk about that one and maybe there will be even an adjustment in what I'm proposing. But I think we ought to do them, always do initial inspections.

(Slide) Next slide.

The procedure will also provide for when there was major program changes we would conduct -- we would put the program -- would treat it like a new license. It would get an initial inspection. There's been too much emphasis on record review and not enough

attention on licensee management and RSO responsibility and, of course, we've heard that team inspection places a fairly heavy burden on broad scope licensees. I have that feedback during the regulatory impact survey.

(Slide) Next slide.

I am proposing to completely revise Manual Chapter 2800, which orchestrates the materials inspection program. Priority given to reactive inspections, inspection frequency based on risk. I would adjust base frequency for performance by as much 50 percent and I proposed to review -- what I'd like to do in the broad scope inspection program is to do something that we do in reactors with area of emphasis and fragment the program over several years. You would still do an annual inspection like we do now and certain things you would look at every year, like exposures and incidents. But in different years, we would look at different things in depth. What I'm thinking of, of course, in '94 is to do effluence. With all the concern over sewerage reconcentration and EPA Clean Air Act, it would seem to me with the revision of Part 20 and the change in the effluent requirements in Part 20, that would be an area to concentrate on. But over about a period of three or

four years, you would cover the entire program in-depth. You would not need a team inspection. This, by the way, has been suggested and recommended by some of the broad scope licensees that I just talked to during the regulatory impact survey.

(Slide) Next slide.

COMMISSIONER REMICK: Carl, along that line, certainly with some of the broad scope licensees there would be many, many laboratories, many, many fume hoods and so forth. Would your approach be to go to the RSO and see what sampling they've done, what analysis they've done and then perhaps audit a couple of them? Or would you see going in and actually trying to sample all the fume hood effluents and --

DOCTOR PAPERIELLO: Commissioner, I don't know.

COMMISSIONER REMICK: Yes.

DOCTOR PAPERIELLO: At this point I'm just looking at what things we ought to do first. I don't know. That is a problem and I don't know.

COMMISSIONER REMICK: Yes.

DOCTOR PAPERIELLO: I'd like to reduce the emphasis on total numbers of inspections or at least use some kind of weighting factor to basically discourage people from doing large numbers of trivial

inspections at the end of the year just to keep the numbers up. I wish to revise the medical inspection field notes and I've talked to Doctor Pollycove about that who has agreed to assist us so we can concentrate on program management as opposed to just looking at records. We may have to consider doing announced medical inspections to do this. This would not be announced significantly advanced, but at least announced several days in advance so we could assure the availability of the physicians and the hospital administrators that we want to talk to.

(Slide) Next.

COMMISSIONER REMICK: To what extent do our inspectors in general, when they've conducted an inspection, indicate that they would like to see senior management in an exit mode?

DOCTOR PAPERIELLO: Not always, and I don't have a -- I can't give you a statistic, but I reviewed -- I would review at random inspection reports in Region I or in Region III and I would look in field notes and inspectors did not always exit with senior management, but I don't have a good sampling. What I would propose is to require that to be done.

COMMISSIONER REMICK: Just based on my past experience, that's certainly one way to get the

senior management aware of what is the NRC and what are the requirements, get some feedback --

DOCTOR PAPERIELLO: Well, that's exactly what I want to do, Commissioner.

COMMISSIONER REMICK: -- on how the RSO is doing and so forth. Otherwise, sometimes they don't hear, don't even hear of the inspections and if there are any problems and so forth. Just based on my personal experience, limited, that was welcome. People wanted to know.

DOCTOR PAPERIELLO: But, see, I also want them to talk to the physician who's responsible, who's RSO, and find out "what do you do?"

COMMISSIONER REMICK: No, I understand. I'm not limiting it to medical here. I'm talking about--

DOCTOR PAPERIELLO: Well, let's get to my next slide.

COMMISSIONER REMICK: Okay.

DOCTOR PAPERIELLO: (Slide) Licensee management and RSO responsibility. A review of the misadministration issues that have come before the Quality Management Panel since I've been here reveals that most problems are caused by poor management of the licensed program and RSOs who are unwilling or

unable to meet responsibilities.

We have licensees today in 1993 who are unaware of the Quality Management Rule. And when I asked the inspectors, "Did the physician have a current copy of Part 35?" the answer was "Yes." I said, "Did the physician read it?" and the answer was "The physician said he was too busy."

Now, this is not everybody. We have to put this all in perspective, but the point is we have that. The ACMUI at their last meeting, we discussed this issue and agreed that there are some physician RSOs who are unwilling volunteers. Somebody's name needed to go on the license and so his name goes on the license.

I will also point out that the radiation safety officer, we talk about radiation safety officers, but that position is only identified in 10 CFR, Part 33 and Part 35. In Part 35, there's fairly elaborate job description. But in Part 33, your broad scope, the RSO is really a consultant. He's involved along with the Radiation Safety Council or Committee on the approval of authorized users, but he's there for consultation. We expect the person to literally rule the campus or to control the program, but that's not what we have in Part 33.

In discussions with the ACMUI, it was decided that Board certification of medical users does not necessarily insure that they are qualified to be RSOs without some further training.

(Slide) Can I have the next slide?

How can we address some of these issues? And I am aware of a recent SRM on the subject. I recommend that the task force that NMSS already has underway to develop a NUREG defining management of the Medical Radiation Safety Program including RSO responsibility continue, but I think we need a parallel effort to determine generically RSO responsibility.

What I recommend is that eventually we have some kind of performance-based regulation defining RSO responsibility in Parts 30, 40, and 70, and I would like us to develop a performance-based regulation, but the regulated community to develop some kind of consensus standard on how to implement the performance-based requirements that we would put.

I'm not very comfortable in us defining, describing how an RSO should do his job in terms of a day to day basis when most of us here have not held that responsibility and I think the industry can do a better job there, but I think we can define the

performance objectives that we want met.

I have proposed an attachment, what I call an "RSO Certification Certificate." It's a pet idea of mine. The ACMUI, I have to be honest, was split on it. They thought it was just another damn piece of paper, at least some of them. But, what I'm trying to do is shake RSOs. When somebody puts his name on a form and says he will be RSO, I want the individual to realize that there are responsibilities and you are not just somebody on a form to keep the NRC happy. But anyway, it might be one approach.

(Slide) Can I have the next slide?

COMMISSIONER REMICK: Carl, if I may, is there a way of knowing -- the problem you're talking about with RSO, is it primarily in the medical area where you have this -- the major area where you have the conflict between the physician and the role of the RSO or is that true in --

DOCTOR PAPERIELLO: No.

COMMISSIONER REMICK: -- other major material licensees?

DOCTOR PAPERIELLO: I don't think it's a problem in major -- things like vendors where you have dedicated RSOs. The problem is wherever you have a part-time or ancillary duty. I have seen this happen

in the early days with nuclear pharmacy where the manager of the pharmacy was also the radiation safety officer and there was a conflict. You know, he was really being evaluated on how much product he was selling and the like and not on radiation safety and we had problems with nuclear pharmacies in the early '80s. I've seen the same thing happen with gauge licensees where an engineer had an ancillary duty and the company grew and opened branch offices and the person couldn't handle it and the job was just ignored. The program got too big for the person doing the job.

COMMISSIONER REMICK: That I can understand, but how about the -- we must have a number of broad scope licensees that are non-medical --

DOCTOR PAPERIELLO: That's true.

COMMISSIONER REMICK: -- and I'm wondering in that situation. Do you find the same things? I realize in some specialized cases you would.

DOCTOR PAPERIELLO: In recent years --

COMMISSIONER REMICK: I'm thinking that sometimes faculty take the same approach as physicians, but --

DOCTOR PAPERIELLO: Yes and no. Let me tell you what you find.

In the big -- well, I'm going to talk about now the Midwest where I'm from. The large land grant universities today do a good job and by and large what you find is these universities have large environmental services departments and the NRC and radiation is only a small piece of the action. They have to deal with all the chemical waste. They have to deal with biohazards in a fairly elaborate program.

You still come across some mid-size schools where you have a prof in a department somewhere where it's an ancillary duty and when you start pulling the string you find out the job is not being done. Some of that was a problem -- well, it was a different problem.

When I was a section chief, you had cases where the radiation safety officer was buried in a large department and his boss was the chairman of the radiation safety committee. The way I put it, the RSO didn't run into his boss' department and that was usually the largest material user on campus and that's where the violations were, but you don't see that anymore.

So it's not a massive problem. It's the part-time RSO that's the problem.

Let's talk about the master medical

agenda. When I started this thing there were 71 items. That was in the paper that went up to you in mid-May. I think they did a good job in defining all the issues, but my finding is it is a flat database. There were some priorities, but it lacks what I call "hierarchy." If you're going to change certain things, the orchestrating procedures should be changed first.

From my viewpoint, if you're going to do anything with the inspection program, you should first change Manual Chapter 2800. Once you do that, all of the reference procedures then can be changed.

The other issue that I have is Part 35. There are several references in there to revising, upgrading or changing Part 35. I think Part 35 needs to be structured to be easily changed. The medical area is the fastest changing area that we currently regulate and we need some way to change it easily every time the MDs develop another way to use radiation in medicine. There needs to be some structure.

It occurred to me again actually when I was writing my presentation here today that the approach that we use for dry cask storage might work where we would license a medical institution either

for diagnostic work only or for therapy, in which case they would need a QM rule, and then we would license the technology. And so a medical institution that was licensed for therapy could use any licensed technology in the medical area and of course associated with the licensing of the technology would be all the conditions that a licensee would have to meet. At least then you could modularize the thing and when somebody came up with a new technology you wouldn't have to tear apart 35 and glue it back together again.

(Slide) Next slide.

CHAIRMAN SELIN: Is this a good time to ask you the question I was waiting for? Of the things you went through, how many are compatibility issues? In other words, as you redo some of these guides, how many of them inconvenience people beyond the NRC itself?

DOCTOR PAPERIELLO: I haven't counted all of them. Clearly, if we change the inspection program and we require the states to have the same inspection frequency we have, it certainly would impact them.

It was interesting. When I discussed the idea of frequency as a function of performance, one state told me they tried that but the NRC stopped them.

We may have to stop and think about what we consider matters of compatibility and how and which and what we don't. Clearly, if we change the regulations, that can affect the states. If we change our licensing guides, whether it's a matter of compatibility or not, it will affect the states.

I did discuss -- is my agreement state slide up there?

(Slide) I did meet at the annual meeting of the Conference of State Radiation Control Program Directors in May. I did meet with all of the agreement states that were there, separate meeting with them, and discussed a number of these ideas.

The states depend very much on our regulations and they depend a lot on our regulatory guides. They either use them directly or they cut and paste and issue their own based on ours. They don't use our inspection procedures very much, according to them, but, Commissioner, I have not tried to count how this would affect the states other than that.

CHAIRMAN SELIN: There is a tendency -- I don't want to call it a movement, but a tendency in our agreement state program to try to identify places where there's no reason that we should be different as opposed to places where we do consciously do want to

give people quite a bit of flexibility, and as we go through that we want to make sure that we don't just capriciously --

DOCTOR PAPERIELLO: I understand and I do believe, and I think I mentioned in my report, I think we ought to -- and I'm going to get into it now -- I think we ought to allow the states in certain things a fair amount of flexibility and I think inspection, even though it's the easiest thing to count, it's one of the areas where flexibility ought to be allowed. The states might have a better idea and I think we ought to learn from them, which is getting into my next topic is the agreement states.

I didn't do nearly as much in here as I wanted to do and it looks like this is just an enormous area that could be mined, but I'd like to reflect on the fact there are 15,000 material licensees in the agreement states just for byproduct material or the stuff we regulate. We only have 7,000 licensees.

There is considerable support of the agreement states both directly and indirectly by the NRC, however the agreement states regulate a greater variety of radiation sources than the NRC. We don't get a lot in return and I believe it's our fault. Let

me say what I mean about "in return." They do inspect and do regulate 15,000 licensees. You can't regulate 15,000 licensees and not learn something and the office I represent, NMSS, needs to have greater cognizance of agreement states' activities in order to learn from state experience. Again, as an example, before we revise Part 35, I'd like to review four or five state regulations in the medical area to see if there are some innovative approaches to medical regulation and we can learn something.

I'd also like to note that in most states radiation protection responsibilities are usually located in state health departments. In conversations with state officials concerning the use of medical consultants, they look at me and say "I just go down the hall and find a doctor to talk to." And so I think that when we look at our own medical rules I think we have a source of assistance out there on practicality in the agreement states.

I note the ACMUI told you several months ago that you need to recognize there's a certain amount of conflict of interest here because we're part of the regulated community. Well, the agreement states really aren't and they are co-regulators and they may have something that they can help us with.

And the last observation -- and I think, Mr. Chairman, you raised the issue -- I don't know how we're eventually going to resolve it with respect to sealed source and devices, but I would recommend that the state approval of sealed source and devices be at least a level 2 matter of compatibility rather than three, and this area needs to receive close attention during state program reviews.

(Slide) Last slide.

There are several issues that I call "open." I think they're worthy of study or are being studied and I lack the time to resolve them.

First is enforcement. Enforcement is important, but it's expensive. My regulatory impact survey, the civil penalties got licensees' attention, but the subtleties of the enforcement policy was lost on them. The way it was generally put to me, "We understand a civil penalty. We understand a violation and we understand a clear inspection." People really didn't appreciate the different between a four and a five and they understood the differences between the threes and fours because they got a civil penalty, but when we start getting into adjustments for performance and identification they didn't understand it. And when I pressed them, "Well, has anybody read the

policy," very few people really read the policy and understood it.

Furthermore, and I know I've discussed this with Jim Lieberman and he thinks I over estimated, but my back of the envelope calculations indicate that the average material civil penalty cost on the order of a half an FTE to issue. This is based on the 10 FTE. The OE says they expend a year in civil penalties. My own knowledge of what the regions spend at least twice as much as they expand and the fact that we issue on the average of 60 material civil penalties a year, if you work out 30 FTE and 60 civil penalties, that's half an FTE. Granted, the people in OE do some other things in the materials area, and even if it's a quarter of an FTE we're talking about the cost of imposing a 500 or a 5,000 fine. Something needs to be looked at in that area.

For some time I've wanted regional assessments to be more objective. We need better performance indicator data systems than we now have and I believe efforts to put the agreement state and regional assessments on a comparative objective basis is certainly the right direction to go.

I believe there's safety merit in third party inspections. The American College of Nuclear

Physicians has a nuclear medicine practice audit program which covers many areas important to patient well being that are not covered in NRC inspections. In particular, the quality of diagnostic imaging. After all, there's very little difference in wasted patient dose from a diagnostic misadministration or a scan whose image is so useless the study has to be repeated. If a poor scan results in a diagnostic error, the results could be worse. This is an idea that needs to be explored. The issue of quality assurance in imaging is part of the American College of Nuclear Physician audit program. When broached, the agreement states don't like this idea.

Another idea agreement states didn't like is a ten year license. However, I found that states issued licenses for terms from two years to at least seven years. One NRC licensee told me his institution already had a ten year license. When questioned, he said, well, it was give years on a license and five years on timely renewal. Lack of timely renewal, as I discussed in my regulatory impact survey, is a burden on licensees. If we had ten year licenses, I would couple it with a requirement to require renewal six months before expiration so we would rarely have a license under timely renewal.

When I was in Region III, I did implement for my staff the six month prior to expiration of a license a broad scope license. We would call them and offer them a meeting to discuss the renewal and my understanding, at least from the statistics I was given, Region III looks pretty good on broad scope, actually all license renewals in terms of timeliness. Coupled with this is the fact that the -- I was surprised, at least in Region III when I looked into it, half of the renewals, and we're talking about somebody who already has a license. Half of the renewal applications had a deficiency letter and that was the largest percentage of the actions that got a deficiency letter. Some of the letters that would come across my desk for so long and I'd ask -- you're telling me the application is worthless. I mean it's a 20 page letter and the answer was yes. Well, part of that was, in fact, when people sat on these things and you pull an application off the shelf that's three years old, no wonder it's useless.

So, I think we can save everybody's resources if we did things on a more timely basis. But I think it's a matter worth looking into.

COMMISSIONER REMICK: Carl, there is another side of that. I mean it's easy to think,

well, if the person has the continuing license on a timely renewal basis that he's okay, but that's not necessarily the case because I know of some specific examples where people had applied in a timely manner. It's been five years. They haven't gotten a license renewal. They want to solve some of their residual waste problems and they've sought approval to do that, but we tell them, "Well, that's all tied up in the license renewal." So they sit waiting for us to get around to do the license renewal. They want to solve some problems, but that requires NRC approval, but we're saying you've got to wait until we're going to wrap this all together.

So, many times it's not to the licensee's benefit to sit there and not get --

DOCTOR PAPERIELLO: Well, it really isn't. There's other problems too. I'm a licensee. I file a renewal. In the meantime, I have ongoing activities. So, I file amendments. But as I file an amendment, my renewal and my license diverge. So, what I've been told by licensees, "We have to maintain two applications." Now, it is a burden on licensees and it's not a good thing.

How does all this fit together? We owe you in about another month, as Jim Taylor said, an

overview of the medical management program along with resources. I am working with the staff to accomplish that. What I'm trying to do is get everybody to put all the activities -- consolidate activities, create a hierarchy and put together Gantt charts which would describe how each of these things would be done and what the cost would be in terms of resources. So, right now, I don't know what the resource cost will be. I believe there's a lot of efficiency that can be obtained by consolidating things, but I should know better in another few weeks.

MR. TAYLOR: Is that it?

That concludes the presentation.

CHAIRMAN SELIN: Commissioner Curtiss?

COMMISSIONER CURTISS: I don't have any specific questions. I would like to commend you and your team for the work that you did. I thought the report contained a lot of thought provoking suggestions. It's a useful exercise, I think, to have somebody come in, Carl, with your background with the Agency, but not with an extensive involvement in this particular area here at Headquarters and to look at the situation from your perspective with an eye toward saying, "Why have we done things the way we've done them? Have we done them effectively? Are there gaps

in the regulatory coverage or are there things that we ought to look at doing differently?"

If there's a single thread that I thought ran throughout all of your report it was that you brought a new perspective and in several instances that you've discussed in some detail today I think have tabled some most thought provoking suggestions. I think there are some areas that I think struck a responsive chord with me in particular. I know we've talked around this table about the key role that RSOs play in an organization and recognizing the limited resources that we have to do inspections and audits and the like. I guess my experience is I've gone to many of these facilities and talked to many of the people who carry out these activities. The RSO is a key function, a key role in that organization and I guess I'd commend that area to you in particular as one I would hope would gain a high priority.

I guess the only challenge I see here is what lies ahead of you, and that is to take this very comprehensive and I think, as I say, very thought provoking report and translate it into a document that can be used to move the Agency in the direction of addressing the problems, maybe adopting some of the solutions that you suggest here. And importantly, to

obtain the necessary resources to carry out this effort with priority attached as the staff deems appropriate to the various suggestions you have made.

We had a similar briefing several weeks ago in the context of the regulation of large fuel cycle licensees where a similar comprehensive effort was undertaken and again there I saw the central challenge as being one of moving forward with what I thought was a very effective and thorough report, but with limited resources that are going to be competed for, if you will, in a whole range of activities that NMSS and the agency as a whole is undertaking, from enrichment to medical activities to large fuel cycle licensees and so forth.

So, although I won't be here at that time, when you get to the point of taking what you have here and coming back to the Commission in the next month or so with a more thoroughly integrated approach to -- a game plan, if you will, to how to proceed, I think that's really a key step in the process.

But at this point I guess I would commend all of you who have been involved in this effort. I thought it was really top drawer in its comprehensiveness, but more importantly in its thought provoking character solutions that you have suggested,

the ideas that you've put on the table I thought were most welcome.

DOCTOR PAPERIELLO: Thank you.

CHAIRMAN SELIN: Commissioner Remick?

COMMISSIONER REMICK: Yes. I certainly associate myself with Commissioner Curtiss' comments about the importance of the RSO and the person having authority and management realization how important that person is to them. There is one comment I would make though. There are licensees out there that aren't just Part 35 licensees or people who have -- the RSO has safety responsibilities for source material, byproduct material, special nuclear material, reactor activities and so forth. This starts to get over into other offices. So, what we do in the RSO, the other office should be at least aware so we don't do something that's inconsistent with the person's overall responsibilities in a number of our licensing areas.

DOCTOR PAPERIELLO: I'm well aware of that.

COMMISSIONER REMICK: Yes.

DOCTOR PAPERIELLO: In Part 50 licensees, at least at power reactors, through the tech specs the RSO -- we call them there the radiation protection

manager's job is described in ANSI standards and regulatory guides. That's tied there. My proposal is -- again has to be done in conjunction with the other offices. It's 30, 40 and 70 would have some kind of generic responsibility defined for the RSO. I'm well aware of that, yes.

COMMISSIONER REMICK: But Part 52, there are such things as non-power reactors out there and many times the RSO --

DOCTOR PAPERIELLO: I did not look at the non-power reactor.

COMMISSIONER REMICK: Sometimes that RSO has very, very broad and multiple license responsibility and hundreds of laboratories and so forth. It's kind of unique.

I do have a couple of questions. I didn't want to interrupt because you're doing such a fine job on the presentation. But has NMSS given any thought to whether there should be a medical safety goal? In other words, how do we know what's reasonable risk?

DOCTOR PAPERIELLO: I'm not aware that NMSS has defined that. I have thought about whether or not we could do some kind of PRA in the medical area for these things, but I think it would be incredibly complicated because so little is hardware

and so much is human and there's so much uncertainty in the human error rate numbers you use. And I also think the empirical evidence is better. In other words, we have a lot of data on misadministration. So, we know what the failures are, what people are doing. So, I think --

COMMISSIONER REMICK: I would not propose a PRA. I was just wondering how do we know when we're doing an okay job or the licensees are doing an okay job?

DOCTOR PAPERIELLO: I don't know.

COMMISSIONER REMICK: Yes. Okay. Now, I found the Enclosure 3. I think your consultant had an interesting table in there, figure in there about estimates of human performance error rates and the range of average operability for reactors. But also something very interesting. A 10^{-5} they called an upper limit of credibility. Did the staff give any thought to whether -- that kind of appeals to me, but I wonder if the staff has given any thought to that.

MR. TAYLOR: Go ahead, Carl, you're up.

COMMISSIONER REMICK: I don't want to put you on the spot, but if that's the case we ought to pass that on to NRR. When we start talking about core damage frequencies, 10^{-6}, 10^{-7} --

DOCTOR PAPERIELLO: I like this because I had it when I took a course in MORT about ten or 11 years ago and I remembered it and I retrieved it. This deals with people doing certain operations. If you want to avoid the consequences of errors, you need what the human factors people tell me is redundancy and diversity. So, there may be, and I understand this 10^{-5} number and the kind of two man team they talk about is used in the assembly of nuclear weapons. I'm depending on memory from ten or 11 years ago. And I don't know how good -- that's why I have the letter in here. This is the best I can say about how good this data is.

What you would have in a case like a nuclear power plant, of course, is if you're talking about somebody working on a HPCI system, but in addition to the HPCI you have low pressure injection, you have RCIC, you have a number of the other systems, so even if people do something bad on one system you have another hardware system to add redundancy. That's all I can say for this.

I don't want to -- this is what I use this thing for, the recognition that as you go from just popping somebody with a problem, being completely unprepared, air crew reaction during an air disaster where there

are no procedures and an air crew is faced with a disaster, what I recall being told is they do the wrong thing one-third of the time. Well, they kill themselves. You have somebody who has a good motivation, yet with no preparation and no procedures they get into trouble and are faced with a big problem.

I use this to emphasize the need, whether it's for our own people or licensees to have preparation and planning and training to deal with situations. I've been involved in incident response in this agency for now 13 years. I need to be trained. I need drills and things like that to keep my performance up because what I find is in an emergency I can only make so many decisions an hour, a handful. The more planning there is and the more preparation you have, the fewer mistakes you're going to make because many of the things that you do you've practiced. That's all I use it for.

COMMISSIONER REMICK: No, I find it very interesting. I thought it could be useful if it was true.

DOCTOR PAPERIELLO: I don't believe the data is very precise.

MR. TAYLOR: I don't either.

DOCTOR PAPERIELLO: I look at the relativeness of the whole thing.

COMMISSIONER REMICK: Now, that same contractor apparently pointed out that if people properly implemented the quality management rule of 94 percent of the misadministrations --

DOCTOR PAPERIELLO: It's a different --

COMMISSIONER REMICK: Oh, it's a different vendor.

DOCTOR PAPERIELLO: It's a different contractor, yes.

COMMISSIONER REMICK: Okay. Another contractor indicated that proper implementation of the quality management rule we could get rid of 94 percent of the misadministrations.

DOCTOR PAPERIELLO: Yes, I'm aware of that.

COMMISSIONER REMICK: It seems somewhat inconsistent with the other that level of credibility is 10^{-5}. People, no matter if they have procedures or not, still make mistakes. All of us do.

DOCTOR PAPERIELLO: And that 94 percent that he gives doesn't even include that. If you start looking at -- you back out the fact of that, you start getting the more like 70 or 75 percent.

COMMISSIONER REMICK: I see.

DOCTOR PAPERIELLO: It depends how you mean the quality management rule. What you're saying is if you've verified it and you didn't catch the error, you didn't do it right. All the numbers should be looked at in a relative sense and not an absolute sense.

COMMISSIONER REMICK: I thought if that was the case all we need is just emphasis on the quality management rule. We could back off from databases and all those things, if that's certainly true. We can certainly bring the risk level down exceedingly low. In fact, to the point of being credible or incredible.

DOCTOR PAPERIELLO: I would agree with you. I do believe that if we implement and have licensees implement the quality management rule, we will make a substantial reduction in misadministrations. But we still need the database. Why? We need to understand why things happen, even if there might be hardware failures we have to answer. And frankly, we need it purely for a lot of political purposes. I couldn't retrieve data. I went looking for answers and I couldn't find it. What did you do in a case like this? We don't know. I went through

the data. We had misadministrations five years ago. Did this misadministration have a significant consequence? It's not there. That's why we need a database, because we don't know what questions we're going to have to answer five years from now. The data is just not retrievable.

COMMISSIONER REMICK: Another question. Has the staff given consideration on what you think is the proper role of the NRC medical consultant? Should he be providing direct assistance to the primary physician, for example?

DOCTOR PAPERIELLO: The procedure on the role of the medical consultant, as Manual Chapter 1360, the revised manual chapter is in -- the proposed revised is what I included in my report. That is now circulating for office reviews and I know Bob Bernero sent it to OGC with a number of questions just addressing that question.

COMMISSIONER REMICK: Okay. So the staff hadn't come to a position on that.

DOCTOR PAPERIELLO: What the physicians tell us is there's nothing wrong -- and they are not violating practicing medicine -- if the physician in one state discusses the case with another physician. They tell me that goes on all the time. You have much

more of a problem if a physician starts providing advice to a patient, and I guess it depends how you do it. It's almost like an NRC inspector talking to a licensee, when are you being a consultant and the like, and I would have to leave it to their judgement on when they're crossing that line. But, again, there's issues on what's our liability and things like that and those questions have been asked of OGC.

COMMISSIONER REMICK: How about in the case of autopsy? Has the staff taken a position on whether they should observe, participate or await the report? Are those --

DOCTOR PAPERIELLO: I don't have an answer to that particular question, but I would suggest the other issue in Indiana, Pennsylvania. If that coroner had decided not to do the autopsy, there would be no way we could have made it happen.

COMMISSIONER REMICK: But you haven't looked at what our role should be in autopsy --

DOCTOR PAPERIELLO: No.

COMMISSIONER REMICK: -- as far as the guidance that you're developing?

One other question having to do with the medical consultant. Has thought been given on whether they should be prohibited to participating in any

subsequent litigation that might occur like the -- I think the NTSB people are precluded from what they found being -- that information be used in future litigation?

DOCTOR PAPERIELLO: I'm not even aware of that question.

MR. TAYLOR: We'll think about that.

DOCTOR PAPERIELLO: Think about that.

MR. MALSCH: Commissioner Remick, there is a provision of the Atomic Energy Act which basically says reports from licensees required by NRC are inadmissible in litigation against the licensee.

COMMISSIONER REMICK: Reports from, you say, are -- from --

MR. MALSCH: Reports required of NRC from licensees --

COMMISSIONER REMICK: Of NRC.

MR. MALSCH: -- are not admissible in litigation against the licensee.

COMMISSIONER REMICK: As a general matter, I wasn't aware of that. So that would apply here, you feel?

MR. MALSCH: In that area they would apply. Now, that doesn't go to the extent of NRC providing witnesses.

COMMISSIONER REMICK: Okay. Any thought been given to that?

MR. MALSCH: Only to the extent that, you know, we have an existing regulation in practice, the so-called "2(e)" regulations in practice whereby we carefully review all requests for NRC expert witnesses and generally our practice is to discourage that sort of thing, to provide information but try to limit the amount of NRC involvement in actual proceedings.

CHAIRMAN SELIN: That's a resource issue more than --

MR. MALSCH: It's a resource issue.

COMMISSIONER REMICK: You indicate that the license reviewer training is inadequate. Is there anything specific that has been developed on how we're going to go about changing that situation?

DOCTOR PAPERIELLO: I propose that we're going to change -- I'm going to change Manual Chapter 1245, which deals with the training of the inspectors, and just expand it to include the license reviewers. But it will also require the license reviewers, just like the inspectors, to go through a certification board, which is not now done.

I do have some concerns because I found in one case in -- when I did the Indiana IIT, I did refer

a matter to the IG. I didn't find what I was looking at had a consequence in the accident, but I found what I perceived to be irregularities. What I found out is that license reviewers were not even aware of the policy directive and guidance. I found that it was inadequate and I found -- the IG found it wasn't even used by two separate reviewers.

Now, the IG didn't pursue the reason why, but, when I started looking following that, it appears that the training of the reviewers was inadequate and didn't force them to review all of these things. On the other hand, there's a certain jumble in all these directives that the training -- it's a combination. You have to have training, but you also have to give them something that they can learn from. I mean, that's why you write a textbook, so you don't have to go through all these publications and try to figure out what's going on.

So, if we codify the guidance documents and then turn around and create a training program that has them systematically read all these things and understand them and then we test them, then we're going to have well-trained reviewers. Some of the regions do it, but, again, the region has to create this.

Why are we doing -- why do five regions create -- I've talked to different regions and where you have long-time experienced reviewers you're all right, because a lot of them what they've done is they've put together their own system, but there are different systems out there. But as a manager, I have to make sure that everybody's trained and everybody is trained the same way, but, no, it's going to be done through changing Manual Chapter 1245.

COMMISSIONER REMICK: Some of the things sound -- has a little bit of resemblance to a systematic approach to training. I'm not proposing that that's what's needed, but it has some of the elements.

Right, Hugh?

MR. THOMPSON: Yes.

COMMISSIONER REMICK: Okay. I infer from your several comments during your presentation and mentioning in the report that the regulatory impact survey for a small number of large material licensees and a couple of fuel cycle facilities was helpful. A number of these observations, concerns and recommendations are directly out of that report or at least --

DOCTOR PAPERIELLO: Well, as integrated

into it. I mean, it's all part of the program. Again, what I'm trying to do is I want to change 2800, but I only want to do it once. You know, I don't want to do it once to address broad scope problems and then do it two months from now to address medical problems. We can't afford it. We don't have the resources to do it.

COMMISSIONER REMICK: Let me ask my question. I assume that you found the results of that survey and the participation helpful to you?

DOCTOR PAPERIELLO: Yes.

COMMISSIONER REMICK: Now the question is, that's a small group of licensees. Would a sampling of some small licensees with diverse activities be useful also, do you think?

DOCTOR PAPERIELLO: Probably.

COMMISSIONER REMICK: Okay. Thank you. That's all I have.

CHAIRMAN SELIN: Commissioner de Planque?

COMMISSIONER de PLANQUE: Yes. Carl, you raised an issue earlier, and I didn't want to interrupt you at the time either because you were on a roll, about the situation of image quality and I thought I heard you say that the states were somewhat resistant to having programs in that area. Did I

understand that correctly?

DOCTOR PAPERIELLO: Pardon?

COMMISSIONER de PLANQUE: Image quality.

DOCTOR PAPERIELLO: Yes.

COMMISSIONER de PLANQUE: And you were talking to the agreement states at the CRCPD meeting.

DOCTOR PAPERIELLO: Yes.

COMMISSIONER de PLANQUE: And you mentioned the reaction of the states on this issue.

DOCTOR PAPERIELLO: I barely mentioned the issue of third party inspections. I had like 30 states there and it was overwhelming.

COMMISSIONER de PLANQUE: Right.

DOCTOR PAPERIELLO: Pushed me back. I didn't even have a chance to discuss the reasons why you might want to do that. It was just such an overwhelming negative reaction to the idea. I know there has been some discussion, and again I don't know how much, with OGC. I don't know legally what we're allowed to do. I will recognize in the reactor side of the house we do rely to a certain extent on authorized nuclear inspectors on the insurance side of the house. I don't know to what degree.

It's just that when I read the program that the American College of Nuclear Physicians laid

out, I think I could beef it up on the safety side of the house and meet our needs. They dealt with a lot of issues that dealt with image quality and making sure you got the results you wanted to do from the test. And I don't know about you, but I've been to the doctor for x-rays and the technologist says, "Hey, do you mind if I take another shot?"

COMMISSIONER de PLANQUE: Yes.

DOCTOR PAPERIELLO: It's not the thing.

Let's suppose the statistic that I have from the NCRP report is right, roughly one in 5,000 diagnostic misadministrations is a -- you get one misadministration in 5,000 diagnostic administrations. That's not a very big number. I don't know what -- I couldn't find -- I looked through NCRP. I couldn't find anything on image quality. They discussed it and there's a whole publication on image quality, but they don't tell you how many are bad. But if you have a bad image, it's wasted dose.

COMMISSIONER de PLANQUE: It's worthless.

DOCTOR PAPERIELLO: It has to be repeated and, even more, if the doctor would draw a bad diagnosis out of that, that could be very severe to the patient. And we don't inspect it. We don't have people qualified to do it. And if I have somebody out

there, when I take a look at the overall well-being of the patient, we might be doing more for public health and safety by endorsing and giving some encouragement to the licensees.

COMMISSIONER de PLANQUE: I would guess, this is not in our bailiwick, but the incident in New York on the mammography units was an excellent recent example of just that case.

Okay. I have no further questions, but I really want to congratulate you on an excellent report.

DOCTOR PAPERIELLO: Thank you.

COMMISSIONER de PLANQUE: I think it was first class and I really want to commend and thank you for your analysis and characterization of the misadministration problem. It was very nice to see it put in those terms and I think it puts it in an excellent perspective.

I'm also very pleased to hear you say that we should try to take more advantage of the expertise that's out there in the agreement states, because, indeed, in some of these areas their expertise is much more extensive and their experience is much greater than ours and I think we should take advantage of that.

The one think I would encourage you to do, you have obviously enormous plans here, very ambitious plans and very welcome plans as far as I'm concerned, but it will be resource intensive and I would encourage you to be as realistic as possible in terms of assessing what your resource needs would be.

Overall, super job.

CHAIRMAN SELIN: I have one question for you, Doctor Paperiello. I have the impression that, looking at the same chart that Commissioner Remick was looking at, the upper limit of confidence, one which nobody I know has ever remotely approached, but you were talking there about ability to do repetitive tasks, not more than one in a couple of -- I mean, not being able to reduce the error rate below more than one in a couple of thousand. Would you suggest that people are getting close to a kind of an asymptotic limit in misadministrations without having extraordinary complicated defenses in depth or doubling up?

DOCTOR PAPERIELLO: I really don't know. I didn't look at it in a quantitative way. I was looking more in a relative way. All I know is, when I look at real -- the actual events that are reported, some of these things are incredibly stupid. And I

don't mean human errors. I'm talking about preventable human errors. The technologist -- the doctor did not even recall. "I don't think I have QM procedures." We found them. He signed them, but the consultant wrote them. I mean, that's the kind of thing, when we have events that occur because somebody didn't read the procedures or somebody wasn't trained in the procedures. And this is happening.

The individual in Michigan that lost his thyroid, if there had been a written directive which was required by their procedures, it would not have occurred. The technologist didn't know that there were written procedures, because he wasn't trained. The physician who was the RSO had had a consultant write the procedures for him. I mean, this is preventable.

Somewhere we all know that there's going to be some ultimate limit unless we spend a tremendous amount of money. You'd have to go to a two person rule where you would have two doctors and medical and that would be -- you know, nobody could afford it. I would rather take the approach that, look, the risk is small relative to the horrible risk that cancer and its treatment present.

On the other hand, we can do better and it

doesn't take a whole lot to do better. Now quantitatively I don't know quite how to do it, but I certainly know qualitatively that somewhere in the order of two-thirds to three-quarters of the misadministrations that have been reported in the immediate past were avoidable if people had followed the QM rule, implemented it. And I don't mean people making mistakes, which they will make. I'm talking about systemic errors. The management didn't promulgate the rules, didn't ensure people were trained across the whole institution. Nobody at the institution was trained.

CHAIRMAN SELIN: Okay. As attractive as the concept of a safety goal would be, I just don't think we can. This is -- when people are hurt with radiation, it's too spectacular. If you can look at a case and you say "that one was preventable," to say that it was only one in 10,000 just doesn't carry much weight.

But I would also commend you for the work. I just have three sort of things to bear in mind.

One is make sure that you don't make all of the additional things additive as opposed to replacing other less productive things along the way.

The second is you look for frequencies.

The total burden on the licensees should not necessarily go up unless we really believe that we're going to improve --

DOCTOR PAPERIELLO: I understand that.

CHAIRMAN SELIN: -- the product.

Actually, there's a fourth thing.

The third is there are general trends to try to make our programs across the board more compatible with the state programs unless there's a good reason that it shouldn't be. I don't mean tying into states and how they do enforcement or how they do inspection, but not just be casually different and don't run afoul on that trend. Anytime you say "we ought to look at differences in training," we should at least say "does that mean that either we're going to go away from the states or we're going to pull the states in our direction and can we justify it?"

And then the fourth is the other point that Commissioner Remick made, which is we have a lot of licensees and a lot of inspectors in a lot of related areas and you have to do stuff that makes sense, but how does that affect people in other materials areas is a clear question.

It's a breath of fresh air. Just remember the old saying, you know, "We have met the maze and it

is us." So, you're now part of the Headquarters --

DOCTOR PAPERIELLO: Yes, I'm well aware of that. When I left Region III, they made that point.

CHAIRMAN SELIN: Thank you very much.

(Whereupon, at 3:41 p.m., the above-entitled matter was adjourned.)

CERTIFICATE OF TRANSCRIBER

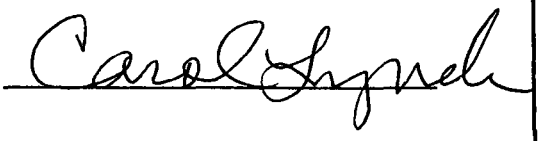
This is to certify that the attached events of a meeting of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON INTERNAL MANAGEMENT REVIEW OF NRC PROGRAM FOR MEDICAL USE OF BYPRODUCT MATERIAL

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: JUNE 24, 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

REPORT ON INTERNAL REVIEW OF NRC MEDICAL REGULATORY PROGRAM

JUNE 24, 1993

CARL J. PAPERIELLO

INDEPENDENT REVIEW

- REVIEW EXISTING PROGRAM
- AGREEMENT STATE OVERSIGHT
- COORDINATE WITH MEDICAL MANAGEMENT PLAN
- COORDINATE WITH IIT FINDINGS
- ADDITIONS

OUTLINE

- STATUS
- CONCERNS AND RECOMMENDATIONS
  - MISADMINISTRATIONS
  - MISADMINISTRATION FOLLOWUP
  - MATERIAL LICENSING
  - INSPECTION PROGRAM
  - LICENSEE MANAGEMENT AND RADIATION SAFETY OFFICERS
  - MASTER MEDICAL AGENDA
- AGREEMENT STATES
- OPEN ISSUES

STATUS OF RADIATION MEDICINE

- MATURE SCIENCE
- VARIOUS RADIATION SOURCES
- ALLIED HEALTH PERSONNEL

NRC REGULATORY ROLE

- BROAD REGULATORY ROLE
- LIMITED MEDICAL EXPERTISE
- STATE ROLE
- AGREEMENT STATE
- SPECTRUM OF LICENSEES

MISADMINISTRATIONS

- CONCERNS:
  - GROSS RATE
  - UNDERREPORTING LIKELY ESPECIALLY FOR EVENTS NOT RECOGNIZED
  - PRECISE RATE LIKELY TO BE INDETERMINATE
  - RELATIVE PATIENT RISK
  - RADIOIODINE SPECIAL SITUATION

MISADMINISTRATIONS (cont'd)

- CAUSES - GENERALLY MANAGEMENT RELATED AND NOT UNIQUE TO MEDICINE

- RECOMMENDATION:

  - IMPLEMENT QUALITY MANAGEMENT RULE

MISADMINISTRATION FOLLOWUP

- CONCERNS:
  - LACK OF CONSISTENT NRC FOLLOWUP
  - INCOMPLETE MISADMINISTRATION DATABASE

MISADMINISTRATION FOLLOWUP (cont'd)

- RECOMMENDATIONS
  - NRC MANAGEMENT DIRECTIVE ON MISADMINISTRATIONS
  - FORMAL EVENT FOLLOWUP PROCEDURE
  - ALLEGATION INVESTIGATION PROCEDURE AND TRAINING
  - AUGMENTATION OF AEOD MISADMINISTRATION DATABASE

MISADMINISTRATION FOLLOWUP MANAGEMENT DIRECTIVE

- DEFINES INVESTIGATIVE TASKS AND REPORT CONTENT
- DEFINES QUALIFICATIONS OF INSPECTOR
- MEDICAL CONSULTANT ROLE
  - MC 1360
  - PROBABLE CONSEQUENCE OF EVENT
- CONSULTANT'S REPORT ATTACHMENT TO INSPECTOR'S REPORT

MISADMINISTRATION FOLLOWUP MANAGEMENT DIRECTIVE
(cont'd)

- REPORT DISTRIBUTION:
  - LICENSEE, REFERRING PHYSICIAN, PATIENT, NMSS COORDINATOR, ACMUI
- ENFORCEMENT REVIEW BY REGIONAL AND HEADQUARTERS MANAGEMENT
- FOLLOWUP POLICY

PROPOSED FOLLOWUP POLICY

- IDENTIFY PATIENTS RECEIVING MISADMINISTRATIONS
- MEDICAL CONSULTANT DETERMINES PROBABLE CONSEQUENCES
- DOE'S VOLUNTARY LONG-TERM MEDICAL STUDY PROGRAM
- USUALLY FOLLOWUP WILL END UPON COMPLETION OF ENFORCEMENT
- OPTION FOR NRC MANAGEMENT TO SEEK LONGER TERM FOLLOWUP
- CONSIDER INFORMING APPROPRIATE LEGAL AUTHORITIES OF PROBABLE DEATH OR SEVERE INJURY

MATERIAL LICENSING

- CONCERNS:
  - LICENSING GUIDES OUT OF DATE
  - DRAFT LICENSING GUIDES NEVER COMPLETED
  - POLICY GUIDANCE AND DIRECTIVES USED IN LIEU OF GUIDES
  - LICENSE REVIEWER TRAINING
  - MAINTAINABILITY

MATERIAL LICENSING (cont'd)

- RECOMMENDATIONS:
  - REVISE ALL LICENSING GUIDES
  - GIVE PRIORITY TO THREE MEDICAL GUIDES
  - STRUCTURE FOR EASY REVISION
  - PERIODIC REVIEW CYCLE
  - UNIQUE LICENSE REVIEWS IN HEADQUARTERS
  - LONG TERM - LICENSING GUIDE BULLETIN BOARD

INSPECTION PROGRAM

- CONCERNS:
  - POORLY DONE REACTIVE INSPECTIONS
  - ROUTINE PROGRAM UNRESPONSIVE TO LICENSEE PERFORMANCE
  - RISKS NOT COMPLETELY REFLECTED IN INSPECTION FREQUENCY
  - INITIAL INSPECTIONS

INSPECTION PROGRAM (cont'd)

- CONCERNS: (cont'd)
  - MAJOR PROGRAM CHANGES
  - TOO MUCH EMPHASIS ON RECORD REVIEW
  - LICENSEE MANAGEMENT AND RSO RESPONSIBILITY
  - TEAM INSPECTION BURDEN ON BROADSCOPE LICENSEE

INSPECTION PROGRAM (cont'd)

- RECOMMENDATIONS:
  - REVISE INSPECTION MANUAL CHAPTER 2800
  - PRIORITY TO REACTIVE INSPECTIONS
  - INSPECTION FREQUENCY BASED ON RISK
  - ADJUST BASE FREQUENCY FOR PERFORMANCE
  - ALWAYS CONDUCT INITIAL INSPECTIONS
  - MAJOR AMENDMENTS TRIGGER EARLY REINSPECTION
  - REVISE BROADSCOPE INSPECTION PROGRAM

INSPECTION PROGRAM
(cont'd)

- RECOMMENDATIONS: (cont'd)
  - REDUCE EMPHASIS ON TOTAL NUMBERS OF INSPECTIONS - WEIGHTING
  - REVISE MEDICAL INSPECTION FIELD NOTES
    - CONCENTRATE ON PROGRAM MANAGEMENT
    - CONSIDER ANNOUNCED MEDICAL INSPECTIONS

LICENSEE MANAGEMENT AND RSO RESPONSIBILITY

- CONCERNS:
  - PROBLEMS CAUSED BY LICENSEE MANAGEMENT AND RSO PERFORMANCE
  - RSO IDENTIFIED ONLY IN 10 CFR PART 33 AND PART 35
  - BOARD CERTIFICATION OF MEDICAL USERS DOES NOT ENSURE RSO QUALIFICATION

LICENSEE MANAGEMENT AND RSO RESPONSIBILITY
(cont'd)

- RECOMMENDATIONS:
  - CONTINUE NUREG TASK FORCE
  - CONSIDER GENERIC DEFINITION OF RSO RESPONSIBILITY
  - CONSIDER RSO CERTIFICATION

MASTER MEDICAL AGENDA

- CONCERNS:
  - SEVENTY-ONE-ITEMS
  - LACK OF HIERARCHY
  - PART 35 STRUCTURE
- RECOMMENDATIONS:
  - INTEGRATION OF ISSUES AND RESOURCES
  - STRUCTURED MEDICAL REGULATIONS AND GUIDANCE

AGREEMENT STATE ISSUES

- AGREEMENT STATES - 15,000 LICENSES
- NRC - 7000 LICENSES
- CONSIDERABLE NRC SUPPORT OF AGREEMENT STATES
- STATE EXPERIENCE - NMSS COGNIZANCE
- MEDICAL EXPERTISE
- SEALED SOURCES AND DEVICES

OPEN ISSUES

- ENFORCEMENT COSTS
- COMPARISON OF NRC REGIONAL ASSESSMENTS AND AGREEMENT STATE ASSESSMENTS
- THIRD PARTY INSPECTIONS
- LENGTH OF LICENSE - 10 YEARS

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

June 16, 1993

MEMORANDUM FOR: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: MANAGEMENT REVIEW OF EXISTING MEDICAL USE REGULATORY PROGRAM (COMIS-92-026)

In COMIS-92-026, The Commission requested that a senior NRC manager be nominated to perform a management review of the existing medical use regulatory program. The Commission specified three areas of interest in performing the review: 1) determining whether the existing program, including oversight of the Agreement state program, is being effectively implemented; 2) coordinating the review with the management plan which is under development, and with any recommendations from the Incident Investigation Team (IIT) for the Indiana, Pennsylvania brachytherapy misadministration, and 3) identifying any recommendations to correct deficiencies in implementation of our existing program.

In COMSECY-93-004, the Commission approved the nomination of Dr. Carl J. Paperiello as the senior NRC manager to conduct this review. Dr. Paperiello performed this review during March, April, May and June of 1993. The work was carried out using a combination of interviews with NRC staff and management, contractor analyses, staff analyses and review of relevant documents. Some issues were discussed with the ACMUI and with Agreement States. The enclosed report contains the results of his review, highlights of which are also enclosed (Enclosure 1).

Dr. Paperiello, who will become the Director of the Division of Industrial and Medical Nuclear Safety in July, will be working with the staff to integrate the recommendations of his report into the report on the final Medical Management Plan due to the Commission by July 30, 1993. That report will provide resource estimates and projected completion dates.

A Commission Briefing by Dr. Paperiello is scheduled for June 24, 1993 at 2:00 p.m.

Original signed by
James L. Blaha for

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Highlights of Internal Management Review
2. Internal Management Review

cc: SECY
OGC
OPA
OCA

DISTRIBUTION
EDO R/F
DEDS R/F (2)
KStablein
KSchneider
JMTaylor
RBernero
KAmmerer
CPaperiello
GArlotto
PRathbun
E. Beckjord

*See previous concurrences

*IMAB	*NMSS	*NMSS:D	DEDS	EDO
PRathbun	CPapperiello	RBernero	HLThompson	JMTaylor
06/98/93	06/08/93	06/11/93	6/ /93	6/16/93

ENCLOSURE 1

Highlights of Report on
Internal Management Review of the U.S. Nuclear Regulatory Commission's
Program for the Medical use of Byproduct Material

The review was performed with the following major assumptions guiding the work:

1. The science of radiation medicine has undergone major technological change and development since the 1950's resulting in a mature technology with a large number of qualified radiation practitioners

2. The responsibility for radiation safety lies primarily with the possessor and user of byproduct material, and

3. The NRC should minimize its impact on licensees who are operating safely and who maintain compliance.

A major issue considered in the review was the regulatory role of the NRC. It is recommended that the NRC has and should keep its leadership role in the regulation of radiation safety in the planned use of radioactive material. For those licensees directly regulated by the NRC, regulations and requirements should be clear, reasonable and understandable, the licensing process should be efficient and timely, inspections should enhance safety and promote performance and enforcement should encourage licensee responsibility. The NRC needs to be alert to potential wrongdoing.

Misadministrations - The report provides a perspective on a number of issues surrounding the handling of misadministrations by the NRC, and proposes a number of practices and procedures which should improve the overall handling of misadministrations and other events.

Misadministration rate is estimated to be 2E-04. This figure is based on staff analyses, human factors studies, and NCRP Commentary No. 7. It should be considered an order of magnitude estimate only. It is likely that misadministrations have been under-reported. However, determination of the actual misadministration rate, while statistically feasible, would be highly time consuming, expensive, and will only provide a best case approximation of the actual rate of misadministrations. If the misadministration rate were to be determined with a greater degree of accuracy, it would be necessary to distinguish the rate between different treatment modalities.

The study concludes that the root causes of misadministrations are few in number, primarily managerial, and similar to those in non-medical accidents. Vigorous implementation of existing NRC requirements, especially the Quality Management Program (10 CFR 35.32), should significantly reduce the number of misadministrations. A major factor involved in preventing misadministrations is the provision of an adequate managerial climate by the licensee which fosters a climate of radiation safety. The Radiation Safety Officer (RSO) plays an essential role in the process.

Proposed Misadministration Followup Actions - Based on the results of the analysis of the NRC's processes for handling of misadministrations, three areas are recommended for followup actions.

First, recognizing that medical misadministrations and events involving high doses require prompt followup, the report recommends that the extent and depth of this followup be available in one NRC Management Directive. This procedure will ensure the inspector assigned is properly qualified and trained, will ensure consistent inspection extent and depth across the agency, and ensure the involvement of a medical consultant, the Offices of the General Counsel, Nuclear Material Safety and Safeguards, and Enforcement. The procedure provides that the NRC will make reasonable attempts to identify all patients who have received therapeutic misadministrations and ensures notifications are made, as required, by the regulations. It provides for long-term followup of patients through the voluntary participation of the patient in DOE's Office of Epidemiology and Health Surveillance Long-Term Medical Study Program. It provides for notification of appropriate local authorities for cases in which death occurs.

Secondly, the report proposes followup actions to improve allegation investigation procedures and train inspectors investigating allegations. Finally, the report indicates a need for a formal event followup procedure including documentation standards for those events which do not warrant an IIT or AIT.

Medical Licensing and Inspection Programs - The management review of the medical use program focused on determining needed improvements in medical licensing and inspection programs.

A majority of the materials licensing guides are out of date and do not provide sufficient guidance for licensees. Twelve guides, issued in 1985, are still in draft form for comment. Internal Division Policy and Guidance Directives have been used in place of licensing guides. Some licensing guidance is found in NMSS responses to regional Technical Assistance Requests (TARs). Training and qualification for license reviewers is far less developed than for inspectors, and when combined with the current lack of codification in licensing guidance results in serious problems in training new licensing staff.

The report recommends updating all licensing guides with priority given to the three medical guides, consolidation of all licensing guidance into licensing guides, and the updating of licensing guides to incorporate generic correspondence and NMSS positions subsequently issued as responses to regional requests for guidance.

The report notes that adjustments to the inspection program are needed. Too much emphasis is placed on completing the total number of budgeted inspections. Inspection Manual Chapter (IMC) 2800 places greater emphasis on the routine inspection program than on reactive inspections. However, in many cases, it is failure to handle reactive events, misadministrations,

allegations and poorly performing licensees that causes the Agency to expend considerable resources responding to Congressional inquiries, Inspector General investigations, and press criticism. Different types of inspections need to be given different weights in the evaluation of Regional and NRC performance.

The report recommends revision of IMC 2800 and the Regional Operating Plans to give top priority to reactive inspections. In addition, IMC 2800 specified inspection frequency should be revised to more accurately reflect risk and license performance. Finally, IMC 2800 needs modification so the license is treated as a new license for inspection purposes for certain major amendments.

New licensees would always receive initial inspections regardless of possession of material. The report recommends that NRC Form 591 be changed to provide for a licensee declaration in cases where the licensee asserts that it has not possessed licensed material or engaged in licensed activities.

Licensee Management and Radiation Safety Office Responsibility - Many of the significant problems identified in medical programs are a consequence of licensee management and RSO failure. NMSS has established a task force to draft a NUREG on Management of Radiation Safety Programs at Licensed Medical Facilities. The report recommends that the task force continue its efforts, however, it notes that a parallel effort should be established to examine current NRC requirements and guidance on the responsibilities of RSO's at all facilities. Consideration should be given to a performance based rule for all licensees, not just medical licensees. In addition, the revision of the inspection program in IMC 2800 discussed above, should include increased emphasis on management control and RSO responsibility. Although receiving mixed comment from the ACMUI, use of a certification of ability, willingness, and support by an RSO and the licensee's management either on the license application or as a separate form should be considered.

Agreement States - The NRC expends considerable resources supporting the Agreement States program, however, Agreement States can be an important resource to the NRC. State health departments can be a medical information source independent of the regulated community. Their regulatory experiences could be used in solving materials control problems. NMSS could benefit from greater cognizance of Agreement States activities.

Agreement States approve sealed sources and devices for interstate distribution. This area should be at least a level 2 matter of compatibility and should receive close attention during state program reviews.

Medical Action Plan/Medical Action Item - The report concludes that many of the issues sent to the Commission in the Agenda for Medical Program Improvements can be unified under a few major programmatic areas. In addition to priority, the action plan needs hierarchy so the upper level procedures or policies are changed first, or at least their content is known, before lower tier procedures are developed. In the language of computer programming a structured approach is needed. As discussed below, this hierarchial structuring of the action plan will be presented to the Commission in combination with an estimate of needed resources.

Information Management Systems - The major recommendation in this area relates to the AEOD misadministration event data base. The AEOD data base should be enhanced and supported with additional data fields. In addition, consideration should be directed to creation of a national data base consisting of both NRC and Agreement States event information. In addition, the computerized systems which provide information on aspects of the materials program such as inspections, and allegations were reviewed. These were found cumbersome and inadequate to provide the information needed in recent inquiries.

ENCLOSURE 2

Internal Management Review of the U.S. Nuclear Regulatory Commission's Program for the Medical Use of Byproduct Material

Findings and Recommendations

Carl J. Paperiello

June 1993

TABLE OF CONTENTS

INTRODUCTION

This report responds to the Commission's request to perform a management review of the existing medical use regulatory program (COMIS-92-026), Enclosure 1. The review was conducted from March through June 1993. During this period, there were several events which influenced this report and the subsequent direction of the medical use regulatory program. These included preparation for the Glenn and Synar Hearings, and the agreement by Chairman Ivan Selin to provide options for the regulation of medical radiation to Senator Glenn by August 1993. In addition, NMSS continued to assemble various issues and requests into an "Agenda for Improvements in the Medical Use Program" (Enclosure 8) which was sent to the Commission on May 19, 1993.

The current status of radiation medicine is another factor considered in this report. As will be discussed below, the science of radiation medicine has undergone major technological change and development since the 1950's when the Atomic Energy Act was written. The use of radiation and radioactive material in medicine and medical research is expected to continue to evolve and change rapidly. It is unlikely that these innovations will cease. This review was conducted with these developments in mind. Two other principles underlie this review:

1. The responsibility for radiation safety lies primarily with the possessor and user of byproduct material, and

2. The NRC should minimize its impact on licensees who are operating safely and who maintain compliance.

The review was carried out using a combination of interviews with NRC staff and management, contractor analyses, staff analyses, and review of relevant documents. Some issues were discussed with the Advisory Committee on Medical Uses of Isotopes (ACMUI) during its May 1993 meeting. Discussions were also held with Agreement State representatives during the week of May 16, 1993, at the annual meeting of the Conference of Radiation Control Program Directors. Due to time constraints, neither of these groups has had an opportunity to review this report. The author also had the benefit of information from the NMSS Regulatory Impact Survey that he conducted.

The issues covered in this report were subject to time and resource constraints. Furthermore, some problems in the inspection and licensing area go beyond the medical use portion of the materials program. As the review progressed, it became apparent that the best course of action was to begin to implement some of the more pressing of the identified tasks, rather to attempt an exhaustive analysis of all possible issues. Furthermore, as the review progressed, the staff continued to modify its regulatory program.

1.0 CURRENT STATUS OF RADIATION MEDICINE

Radiation medicine is a mature science comprised of: a large number of physicians and other allied health personnel who are highly educated and trained in various sub-specialties; numerous credentialing organizations; a substantial literature; and a variety of radiation sources in routine use by technologists. Research laboratory instruments of the 1950s and the 1960s, when the byproduct material medical use regulations and programs were being developed, are now routinely used in community hospitals and clinics. The physical, chemical and biological properties of radioactive material and ionizing radiation are relatively well-known, and probably known better than most other toxic substances. With tens of thousands of users, in principle, there is a large body of experience from which we can draw statistically valid conclusions concerning events that impact public health and safety.

The first isotopes used in research and medicine were accelerator produced and very scarce. After the nuclear reactor was created, isotopes from fission and neutron activation became available in large quantities. These radioisotopes quickly dominated the fields of research and medicine. Cobalt-60 (Co-60) provided a convenient source of photons with higher energies than the orthovoltage x-ray machines (up to 500 KeV) that were in use for radiation therapy. Reactor-produced isotopes displaced radium-226 for brachytherapy. Although charged particle reactions, using a variety of particles and targets, can produce a greater variety of isotopes than fission or neutron activation, research accelerators at that time, designed for purposes other than mass radioisotope production, were limited by their beam currents in the quantities of radioisotopes they could produce.

Since that time, there has been substantial technological growth on several fronts. Sophisticated radiation detection and measurement systems have dropped in cost due to advances in electronics and computers. Advances in accelerator design and the presence of commercial vendors in the marketplace have led to the commercial availability of production cyclotrons with very high beam currents. Similarly, compact linear electron accelerators with energies and outputs higher than Co-60 devices and comparable in cost are dominating the field of radiation therapy. Equally important is the growth in the number of medical and allied health personnel in the field. These individuals with professional and advanced degrees have the required skills to operate and maintain this sophisticated equipment. This is an important point. Without these highly educated and skilled people, this new equipment would be useless. In fact, much of the used Co-60 equipment is being sold to third-world countries because it does not require the technical infrastructure required by this newer equipment.

Paralleling these developments, has been the growth of two complex systems. The medical services delivery system has grown large and

complex due to the increased specialization of physicians and the incorporation of a large number of allied health and clerical personnel into the system. In some cases, command, control and communications do not appear to have kept pace with this growth. Secondly, medical diagnosis and treatment systems involving computer driven electro-mechanical systems are susceptible to failures that are not immediately apparent to the user and which frequently require complex analytical procedures beyond the capabilities of the user to detect.

2.0 REGULATORY ENVIRONMENT AND ROLE OF THE NRC

The Atomic Energy Act (AEA) of 1954, as amended, authorizes the Commission to issue general or specific licenses to applicants seeking to use byproduct material ... for medical diagnosis and therapy ... or such other useful applications as may be developed. All other medical uses and sources of ionizing radiation, except for the direct use of radiation from a nuclear reactor, are regulated by other entities, generally the States. For the most part, these uses and sources of ionizing radiation differ little in risk and characteristics from byproduct material regulated under the AEA. The one major exception to this generality is that intense, relatively long-lived radioactive sources are almost always reactor-produced.

As authorized by Section 274 of the Atomic Energy Act, the Commission has entered into agreements with 29 States to relinquish its regulatory authority over byproduct and other material. Therefore, in these States the State theoretically has authority over all medical uses and sources of ionizing radiation. In the remaining 21 States, the NRC regulates the medical use of byproduct material, while the State either licenses or registers other sources of ionizing radiation. A few States do very little at all.

Section 274 of the Act is intended to create an environment of cooperation with the States and, which the States improve their capabilities to regulate material under this Section. The Commission is also authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation and to ensure that State and Commission programs for protection against the hazards of radiation are coordinated and compatible. This Section also provides the Commission with the ability, upon its own initiative after reasonable notice and opportunity for hearing to the State with which an agreement has been entered, or upon the request of the Governor of such State, to terminate or suspend all or part of its agreement with the State and reassert the licensing and regulatory authority vested in it under the Act, if the Commission finds that (1) such termination is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of this Section.

The NRC theoretically has very broad authority under the Act to regulate medical uses of byproduct material (use of source and SNM in the medical area is limited to shielding and cardiac pacemakers).

However, there are practical limits on NRC authority associated with staff expertise and variations among licensees. The NRC staff expertise in the medical area is limited. Although radiation medical professionals include medical physicists, physicians certified in nuclear medicine, radiology, and radiopharmacists, with the exception of consultants and visiting medical fellows, the NRC employs approximately eight medical physicists, but no physicians or licensed nuclear pharmacists. Furthermore, it makes little sense to have a regulatory posture so draconian that the medical community is driven to choose radiation modalities primarily to avoid NRC jurisdiction. This is particularly true since some of these modalities require greater user sophistication than modalities using NRC regulated material. Thus, imprudent regulation could have an adverse impact on public health and safety.

What should the role of the NRC be? The NRC has, and should improve, its leadership role in the regulation of radiation safety in the planned use of radioactive material. In addition to those activities which the NRC directly regulates, the NRC provides significant resources both directly and indirectly to the States. The NRC's primary radiation protection standards and basic licensing regulations serve as a focus for numerous consensus standards and secondary radiation safety supporting criteria. For those licensees directly regulated by the NRC, regulations and requirements should be reasonable, succinct, and understandable; the licensing process should be efficient and timely; inspections should enhance safety and promote performance; and enforcement should encourage licensee responsibility.

Finally, the NRC regulates a broad spectrum of medical licensees. There is a wide variation in size from large teaching hospitals and medical centers to stand-alone diagnostic and therapy clinics with single physicians or partnerships. As in all fields of endeavor, there is a variation in talent among the practitioners. In spite of a tough credentialling process in the medical area, it appears possible that a physician may perform a procedure for which the individual is not fully qualified. Lastly, advanced education does not make an individual immune to ethical failures and NRC needs to be alert to potential wrongdoing.

3.0 MISADMINISTRATIONS

Recent events have brought NRC regulations concerning radiation therapy misadministrations and the reporting and followup of these misadministrations to public, Commission, and Congressional attention. In several memoranda dated early February, 1993, the Office of the General Counsel questioned the NRC's implementation of current

misadministration requirements. Individual Commissioners have questioned the lack of accurate statistical information and the desirability of a national database for therapeutic misadministrations.

Sections 3 and 4 of this report examine a number of issues surrounding misadministrations and their review by the NRC, and proposes a number of practices and procedures which should improve the overall handling of misadministrations and other similar events.

3.1 Rate of Misadministrations

Although accurate statistical data are not available, there are several sources that permit order of magnitude estimates of therapeutic misadministration rate, assuming reasonable detection and reporting probability. Dr. Myron Pollycove, Visiting Medical Fellow, in a memorandum (Enclosure 2) dated March 8, 1993, to John Glenn, provided an estimate of the radiopharmaceutical therapy misadministrations based on (1) the total administrations received from the American College of Radiology and Radiopharmaceutical Manufacturers and Distributors, and (2) misadministrations obtained by scaling the number of misadministrations reported in the 21 NRC States to the entire United States, based on population ratio. There is no *a priori* basis to assume a difference between Agreement States and NRC States. Dr. Pollycove estimates the annual radiation misadministration rate from sealed and unsealed radioactive sources to be 2.6E-04.

NCRP Commentary No. 7, Misadministration of Radioactive Material in Medicine - Scientific Background, dated October 1, 1991, provides information that permits an estimate of diagnostic misadministrations. There are an estimated 1300 misadministrations per 7 million diagnostic examinations each year. This results in a misadministration rate of 1.9E-04. If we assume that the therapeutic misadministration rate is comparable to the diagnostic misadministration rate, this result is consistent with Dr. Pollycove's estimates.

Human factors studies provide insights into human error rates for relatively simple processes (i.e., misreading labels, switch selection, etc). As shown in Enclosure 3, typical error rates for activities controlled by procedures range from 1E-3 to 1E-4 depending on the degree of control over the process. Although not all misadministrations are caused by human errors, errors of commission or omission contribute to most. Furthermore, some human errors as well as mechanical failures are caught by redundancy in the therapy delivery system. Therefore, an order of magnitude estimate of 2E-4 rate for misadministrations is consistent with our knowledge of the error rates which contribute to the events.

Furthermore, there are uncertainties in both the numerator and the denominator. As discussed below, there is reason to believe that some

misadministrations are not recognized and reported. The Commissioners' testimony at Senator Glenn's hearing illustrated the difficulty in defining the denominator because we do not know for sure how many procedures are performed. Actually, the problem is made more difficult due to differences in treatment modalities. For example, consider a condition for which a patient may receive high dose rate or low dose rate brachytherapy. The low dose rate treatment will generally be given in one treatment of several days. The high dose rate treatment will generally be given as several fractions over a period of several days or weeks. In one case, we have one treatment; in the other case we have several treatments. Should we count the number of misadministrations per patient, per treatment, or per billable procedure?

Not all misadministrations have severe or fatal outcomes. Many are underdoses; some are errors in the treatment fraction that are correctable by adjustments in future fractions, and some involve one or two fractions delivered to an unintended portion of the body. Dr. Pollycove estimates that serious misadministrations are about 10 percent of all misadministrations. My review of an Office for Analysis and Evaluation of Operational Data (AEOD) file of 35 misadministration reports for 1992 involving 51 patients shows 31 to be underdoses. Of the 20 overdoses or doses to the wrong body part, one resulted in a fatality, the Oncology Services HDR event, and one resulted in the loss of a normal thyroid.

3.2 Underreporting of Misadministrations

It is likely that misadministrations have been underreported. The misadministration discussed above that resulted in the loss of a normal thyroid was not reported until the licensee read of a similar misadministration in the NMSS Newsletter. On occasion, an inspector has identified a misadministration. It is also likely that the increase in therapeutic misadministration reports in the past few years is due to greater licensee awareness. In addition, "bugs" in computer software could cause multiple misadministrations that would go undetected and unrecognized, particularly if significant clinical manifestations were absent. Quantifying this problem is difficult.

One way to determine quantitatively the degree of underreporting as well as determining a "true" misadministration rate might be to sample a sufficiently large number of patient records. This would probably require the examination of thousands of patient files. The number reviewed would depend on the accuracy desired. Since this examination would require skills and familiarity with medical records that most inspectors do not have, this review would have to be performed by contractors. A survey of 5,000 patient files is estimated to cost about $300,000 and have a significant impact on several dozen licensees chosen for the review. Depending on the results, this sample may still be too small. A sample large enough to give a

statistically better estimate than now available may require approximately 50,000 patient files. Even this process would not identify the software induced misadministrations that have not been identified.

This report does not recommend expending significant resources trying to identify a "true" misadministration rate. It is likely that there are sufficiently different failure trees for each treatment modality such that each has its own "true" misadministration rate. Furthermore, each modality has a different probability of causing serious harm given the fact that a misadministration has occurred.

3.3 Relative Patient Risk of Therapeutic Misadministrations

Evaluation of the patient risk from therapeutic misadministrations must take into account the underlying reason for performing the procedures. Today, except for hyperthyroidism and arteriovenous malformations, radiation therapy is used for treatment of cancer, a generally fatal category of diseases if left untreated. Furthermore, alternative cancer treatments involve significant patient risk even if the treatment is delivered as planned.

In a memorandum to John Glenn dated February 1, 1993 (Enclosure 4), Dr. Myron Pollycove presented the relative risks of radiation therapy, general anesthesia, surgery, and chemotherapy in the treatment of five common malignancies that respond relatively well to treatment.

Dr. Pollycove's data show that mortality risks are in the order of 1E-2 or greater for surgery, (1E-3 for general anesthesia, 2E-3 for chemotherapy, 1E-2 for radiation therapy, <u>if delivered as prescribed</u>, in the case of cervical cancer, colorectal cancer and Hodgkin's disease, 7E-4 for radiation therapy in the case of prostatic cancer, and 6E-6 for radiation therapy misadministration. The morbidity risk is one to two orders of magnitude greater.

Untreated cancer is almost always fatal and treated cancer is fatal in about 50 percent of the cases. The accepted radiation treatment protocols involve a patient fatality risk of several percent and much higher morbidity risks. Therefore, the overall contribution of misadministration risk to total risk for cancer patients undergoing radiation therapy is very small. If the "true" misadministration rate is two or three times higher than current estimates, this conclusions is unchanged.

3.4 Misadministrations Involving Radioiodine

Radioactive iodine, usually iodine-131, is a special case for several reasons. It is used therapeutically to treat hyperthyroidism, a non-malignant condition but a disease with potentially fatal consequences if left untreated. Misadministrations during diagnostic studies can result in a loss of thyroid function in a previously normal thyroid. Iodine-131 is the most likely radiopharmaceutical currently used that,

if given unknowingly to a pregnant or nursing female, will affect the fetus or infant.

For the long-term control of hyperthyroidism, radioiodine therapy is the treatment of choice. Although misadministrations have occurred, the currently accepted treatment protocol is to render the thyroid hypothyroid and place the patient on long term synthetic thyroid replacement therapy. Therefore, the ultimate outcome of an overdose misadministration in this case is rarely different from the long-term desired outcome.

Other misadministrations of radioiodine are, in a relative sense, much more serious. A diagnostic procedure may be ordered to rule out a problem. In this case a misadministration which results in a normal thyroid becoming hypothyroid is a relatively severe outcome. This can also be the likely outcome to an infant if a pregnant or nursing female inadvertently receives a high dose. Untreated hypothyroidism in an infant will result in mental retardation and other developmental handicaps and impose serious burdens, both financial and otherwise, on the family and society.

3.5 Causes of Misadministrations

This section summarizes the findings of three separate reviews of misadministrations: the draft NUREG/CR, Summary of 1991 and 1992 Misadministration Event Investigations, presenting the results of contract work by the Idaho National Engineering Laboratory (INEL) to investigate seven misadministrations in depth; a special review of NRC data on other misadministrations by the same INEL group in support of this report; and a somewhat subjective review by this author of cases examined by the Quality Management (QM) Panel for enforcement action. In this latter review, all of the cases involved potential violations of the QM rule (10 CFR 35.32), but not all were misadministrations.

Enclosure 5 presents the Executive Summary from the INEL draft NUREG/CR. That report concludes:

- Many misadministrations occur primarily due to a lack of rigorous procedures intended to ensure patient and staff safety;
- While the QM rule has the potential to prevent many misadministrations, a number of licensees have not effectively implemented their QM program;
- A lack of substantive, direct involvement on the part of Radiation Safety Officers and Authorized Users is often a factor in misadministrations;
- Hardware failures occur very infrequently but can lead to severe consequences, particularly when operating procedures, staff training, or other factors are not well implemented;

- Changes in routine and unique conditions are factors which often predispose misadministrations.

INEL also conducted a special review of events using the existing NRC database of Abnormal Occurrence events reported in NUREG-0900 for the years 1987 through 1991 and misadministration events contained in the AEOD database for 1992. INEL was requested to identify common causes of misadministrations, identify correlations between direct causes and severity of misadministrations, determine if proper implementation of the QM rule could have prevented these events, and analyze the causes of multiple misadministrations and adequacy of licensee corrective actions to prevent multiple events. INEL's report is contained in Enclosure 6. The report finds:

1) Proper implementation of a QM plan could have prevented as many as 94 percent of the patient misadministrations included in the database.

2) A relatively small number of licensees (11) have experienced multiple misadministrations due to common cause failures. These multiple misadministrations, however, involved 60 percent of the patients in the database.

3) Errors in entering data into computer programs or computer programming errors are the dominant area in which direct causes result in multiple misadministrations.

4) In descending order, inadequate procedures or failure to follow procedures, professional errors (what INEL calls random errors made by an individual), and communication problems are the most significant direct causes of single misadministration events.

5) Inadequate procedures or failure to follow procedures and communication problems are most correlated with misadministration severity.

A review, by this author, of the misadministrations that occurred since the QM rule became effective shows that most would not have occurred if an adequate QM program had been effectively implemented. Most failures were systemic; procedures were lacking; procedures failed to address all the requirements of the QM rule and some individuals were not trained in the procedures. In some cases, the training was so poor that licensee personnel were unaware of the QM implementing procedures. In addition, during routine regional inspections, inspectors identified licensees that were required to have QM programs but were unaware of the requirements. Frequently, RSOs and authorized users named on the license exercised very little oversight over licensed activities.

3.6 Prevention of Misadministrations

Vigorous implementation of the existing NRC requirements, especially the QM Program (10 CFR 35.32), should significantly reduce the number of misadministrations currently being identified.
Most misadministrations are preventable.

In 10 CFR Part 35.32 f(2), each licensee who was required to have a QM Program, was required to submit a copy of the program to the appropriate region by January 27, 1992. NMSS planned to hire a contractor to review these plans because it was believed that the Regions lacked the resources to properly review them. However, for a variety of reasons, a contractor has only recently been selected. The contractor will review approximately 1600 plans. Review of these plans is important.

Although inspectors are finding problems with implementation of the QM rule, most of these problems are obvious, as noted in Section 3.5. After a contractor reviews approximately 100 of the plans, NMSS will evaluate the findings and determine whether additional actions by Headquarters or the Regions are needed. Findings may show that the problems are so obvious they can easily be identified by an inspector while preparing for an inspection. On the other hand, generic problems may be identified that warrant a generic solution.

4.0 MISADMINISTRATION FOLLOWUP

4.1 Potential Followup Problems

Fundamentally, NRC inspectors are technical individuals who are well qualified to identify and resolve technical issues. Most of the training provided by the NRC to new inspectors is technical (i.e., Manual Chapter 1245). Generally, inspectors are poorly equipped by training and temperament to deal with problems involving deliberate deception, or to identify ineffective licensee management without readily identifiable violations.

The NRC has detailed inspection procedures for technical inspections and provides comparable training. There are no equivalent procedures for misadministration followup, allegation followup, or similar reactive inspections; nor is there substantial training in these areas. Some relevant training is provided by AEOD for "big ticket" reactive inspections, such as Incident Investigation Teams (IITs) and Augmented Inspection Teams (AITs). Furthermore, these types of inspections have substantial management involvement by Headquarters and Regional managers and redundancy in reviewing the findings. In the case of nuclear reactors, the level of management review by NRR and Regional managers per site is also substantial.

According to the Office of Enforcement (OE), in FY 90 through FY 92

there have been 184 power reactor civil penalties and 179 material civil penalties. In the same period there have been 21 completed Office of Investigations investigations at power reactors and 52 completed investigations at materials facilities. During the same period about 30 percent of all allegations involved materials. These data reflect the reactive work load in these areas. However, on a national and regional basis, there is substantially less managerial and supervisory oversight per materials licensee, event, or case, than for power reactors. Given the human error rates shown in Enclosure 3 and the number of opportunities for error, additional procedures, guidance, and oversight is needed to ensure appropriate agency followup of materials events, including misadministrations.

Furthermore, most materials licensees are far less knowledgeable than reactor licensees. Frequently, materials events are reported to the wrong place in the NRC, the last inspector to visit the licensee, or a license reviewer. Licensees do not always provide the needed information about an event and frequently do not know, with certainty, if an event is reportable. Consequently, garbled information gets to an individual who may not have the experience and knowledge to ensure an appropriate agency response.

Followup to determine if deleterious effects result from misadministrations is not simple. Some serious deterministic effects may not manifest themselves for months. Furthermore, a cancer patient's reaction to a given radiation dose may be affected by the disease itself or additional treatment by chemotherapy. The NRC lacks in-house medical expertise and must rely on consultants to evaluate this information. When a patient dies, the NRC lacks the legal authority to make a final determination of the cause of death, which might require an autopsy. This authority and responsibility usually resides with the attending physician, a coroner, or medical examiner. This process is prescribed by State law.

However, determination of the possible consequences of a misadministration should be within the skills of the medical consultant. Textbooks provide tables of thresholds for organ doses in which radiation lesions are fatal or result in severe morbidity. The NRC has previously used this type of data in development of NUREG/CR-4214, Health Effects Models for Nuclear Power Plant Accident Consequence Analysis. The problem is more difficult than a mere inspection of reference tables. Adjustments have to be made for fraction effects and dose rate. There are models and generally accepted textbook techniques for doing most of these calculations. With the proper knowledge and experience, an expert can determine the probable consequences of a given dose (dose distribution) to a patient.

4.2 Proposed Followup Actions

4.2.1 Medical Misadministrations and Therapeutic Events

Medical misadministrations and events involving high doses require prompt followup. Appendix A provides an outline of a procedure for misadministration followup that permits the determination of the extent and depth of followup needed for each situation. This procedure will ensure the inspector assigned is properly qualified and trained, will ensure consistent inspection extent and depth, and ensure the involvement of a medical consultant, the Office of the General Counsel (OGC), the Office of Nuclear Material Safety and Safeguards (NMSS), and of the Office of Enforcement (OE). It will ensure patient notification since the patient will be sent a copy of all information available to the NRC unless the referring physician provides the NRC with a valid reason why it should not be sent to the patient. It provides for an NMSS misadministration coordinator to ensure that retrievable records are maintained and information is disseminated.

The procedure provides that the NRC will make reasonable attempts to identify all patients who have received therapeutic misadministrations and ensure that notifications required by the regulations are made. It provides for long-term followup of patients through the voluntary participation of the patient in the Department of Energy's (DOE's) Office of Epidemiology and Health Surveillance Long-Term Medical Study Program. This program currently has about 2700 individuals enrolled. Inclusion in DOE's program appears to be the best way to obtain any information of scientific value that might be derived from such an event.

Normally, enforcement actions are not completed for several months after an event. While enforcement actions are pending, NRC is normally kept informed of any significant patient complications known to the licensee. As a practical matter, the NRC usually obtains a level of knowledge of the consequences of the event proportional to its likely severity. Most of the therapeutic misadministrations reviewed for 1992 had minor or no observable deterministic effects, or were underdoses. In serious cases the NRC was deeply involved. Practically, the NRC cannot compel patient cooperation in long-term followup.

With the proposed procedures in Appendix A, NRC management will have sufficient information to make a stronger response, including a decision for longer term involvement in those cases where severe morbidity or mortality is a likely outcome. The procedure proposes to accomplish this to the extent practicable through issuance of an Order to the licensee.

In cases in which the NRC believes that death has occurred or is a likely outcome of a misadministration, the procedure provides for the NRC to give this information to the appropriate local legal authorities.

4.2.2 Allegation Investigation Procedure and Training

Inspectors are not trained in what constitutes legal evidence. There are no procedures to assist them in determining what constitutes adequate information to establish the validity or falsity of an allegation when there is the potential for tampering with data. With time, most inspectors gradually develop a sense of when something is wrong. However, this cannot be left to chance. The NRC needs an allegation inspection procedure; allegation followup should be restricted to senior inspectors; and these inspectors need additional training in investigative techniques.

This training could be provided by the Federal Law Enforcement Training Center in Glynco, Georgia. This Center offers a two week course, "Introduction to Criminal Investigations Training Program," to acquaint non-investigator personnel with the procedures, techniques, concerns, and problems associated with criminal investigation. The target group includes regulatory inspectors, paralegals, auditors, technical personnel, and others who might assist in a criminal investigation, or be required to testify in a criminal matter.

4.2.3 Formal Event Followup Procedure

A prescriptive event-followup procedure is needed for those events which do not warrant an IIT or AIT. During the Regulatory Impact Survey, some licensees complained that, when inspectors respond to a reported event, they concentrate solely on violations. Many of the recent inspection reports reviewed by the QM Panel show the same characteristics. Although AEOD provides training on root cause analysis, it is rarely found in these reports. A prescriptive procedure would require the inspector to document the sequence of events, the immediate causes, the root causes, the consequences of the event, the licensees' proposed remediation and then describe the regulatory violations. This procedure would be used for any materials event, and not just medical events.

4.3 Misadministration Tracking and a National Database

Currently, the best database of misadministration events is being maintained by AEOD, but it is incomplete. Older data is not as complete as recent data. However, the NRC has not defined what information should be placed in the database.

Since AEOD already has a system in place that can track medical events

and is responsible for the Abnormal Occurrence Report to Congress, the AEOD system should be enhanced and supported to meet NRC's needs. NRC should not create a new system. The fields to be placed in the database need to be enhanced to make a database search more useful. Suggested fields, in addition to the usual date, time and location, might include: treatment modality, consequences to the patient, immediate cause, root cause, enforcement action, and especially the relevant inspection report numbers where the details of the event and the consultant's report can be found.

Discussions with Agreement States at the 1993 Annual Meeting of the Conference of Radiation Control Programs Directors showed general support for a national database. Discussions centered on a system the States could access both for input and output by E-mail. The States, in general, are very receptive to some type of E-mail link to the NRC.

However, a State of New York representative stated that New York was forbidden by State law from revealing the identity of the institution responsible for a misadministration. Consequently, the State would provide the NRC with misadministration information, but not the identity of the institution, if the information could be released under the Freedom of Information Act.

5.0 MEDICAL LICENSING AND INSPECTION PROGRAMS

5.1 Size and Scope of Licensing and Inspection Program

Overall, the nuclear materials safety program involves about 24 million dollars and 220 FTE (Enclosure 7). Of these, 9.6 million dollars and 112 FTE are in the Regions. The Regions are responsible for the completion of about 5200 licensing actions and 2600 inspections a year. Additionally, about 320 licensing actions are the responsibility of NMSS. The budget allows an average of about 20 hours per inspection including preparation, performance of the inspection, documentation of the inspection, and completion of the enforcement action. Resources are also provided separately for escalated enforcement actions and response to events. However, expenditures on these activities have historically exceeded budget. This is particularly evident in Regions I and III, which have the largest materials programs.

Similarly, the budget provides about 4.5 hours for a license amendment, 8-9 hours for review and issuance of a new license and about 12 hours for a license renewal. These data reflect historical expenditure data. There is no explanation of why renewals take longer to process than new applications. However, license renewal has historically had the lowest priority due to the belief that delays in license renewal have little or no impact on licensees. Currently, there is a significant backlog (i.e., several years) in old renewal applications. Age adds to the length of time needed to complete an

action because, with time and changes in requirements, the likelihood of an application becoming deficient increases. The individual submitting the application also may no longer be employed in the same position as when the application was submitted.

There is generally no special provision in the budget for new staff. If there is a high staff turnover, backlogs in inspection and licensing can quickly grow. The materials licensing and inspection program is very production-oriented. The ability to train new staff quickly and to have clear, easily-retrievable procedures and guidance is essential.

5.2 Licensing Guidance

Licensing Guidance exists both as Regulatory Guides and Industrial and Medical Nuclear Safety Division Policy and Guidance Directives, and NMSS Responses to Regional Technical Assistance Requests.

Currently 12 of 20 materials licensing guides were issued as a draft "FOR COMMENT" and have not been issued in final form. Most of these were issued in 1985 when materials licensing was regionalized. Three of these relate directly to medical use, and all three are out of date with respect to 10 CFR Part 35, issued in 1986. Many are out of date due to other changes in regulations. With the revised 10 CFR Part 20 becoming effective in 1994, all will be significantly in error. In addition, a considerable amount of licensing guidance, including information needed by a licensee to properly prepare a license application, exists in the form of Industrial and Medical Nuclear Safety (IMNS) Division Policy and Guidance Directives. These documents are essentially internal NRC guidance documents. It is unlikely that a licensee can prepare an acceptable license application without a copy of the appropriate guidance document. Some of these documents are also out of date.

During the NMSS Regulatory Impact Survey, licensees complained about this situation. They complained that draft Regulatory Guides were not being issued in final form and, therefore, their comments were not being considered. They complained that they did not have a chance to review and comment on the licensing guidance being used by license reviewers and contained in the Policy and Guidance Directives.

Regional NRC licensing staffs have complained about this problem for at least the last three years during National Program Reviews and at other times. NMSS staff stated that resource constraints have resulted in this situation and other work has kept guidance revision at a low priority. However, NMSS receives several hundred Technical Assistance Requests (TARs) per year from the Regions. These generally ask for interpretations of regulations or for specific licensing guidance, and represent a resource burden on NMSS that might be avoided if licensing guidance were updated. It should also be noted that the Office of the Inspector General (OIG) (Case 93-29A) found that there was no effective system within NMSS for the tracking of

requests from NRC Regions for policy guidance or technical assistance. Some requests have been pending since 1990. There is significant disagreement between the Regions and NMSS about which TARs are pending.

The IIT Report, NUREG-1480, identified the fact that the licensing guidance in Policy and Guidance Directive (P&GD) FC 86-4 for HDR Brachytherapy was out of date and that Regulatory Guide 10.8, Guide for the Preparation of Applications for Medical Use, Revision 2, did not address HDR brachytherapy. An OIG Investigation (Case 93-a) revealed that two license reviewers who acted on the original Oncology Services Corporation license application and an amendment were not even aware of P&GD FC 86-4 when they processed the licensing action.

This is a major problem area that must be corrected. Without clear and current licensing guidance, licensees cannot submit applications with reasonable assurance they have provided the information required for licensing. This creates an expense, and results in a delay for the licensee in responding to deficiency letters and deficiency phone calls. It creates an expense for the regional staff because they have to issue deficiency letters and may have to send a TAR to NMSS for additional policy guidance. NMSS incurs the expense in responding to the region's request for guidance. Finally, the hundreds of policy decisions made by NMSS in the form of TAR responses, while being sent to all the regions, are never consolidated into easily retrievable form.

All licensing guides must be updated and issued in final form. Any guidance needed by licensees to properly submit an application must be included in the licensing guides and not in Policy and Guidance Directives. A program is needed to periodically review each licensing guide to incorporate all outstanding TARs and generic correspondence relevant to that type of license.

Appendix B presents a goal for accomplishing this task. This would result in all licensing guides becoming available to everyone on a bulletin board. The guides would exist in a modular form so that changes would be easy to make. Revision of licensing guides has been discussed with the Office of Nuclear Regulatory Research which has stated that it can only support this effort with technical editors. The use of Automated Data Processing systems to modularize the licensing guides has been discussed with the Office of Information Management Systems, but not in depth.

5.2.1 License Reviewer Training and Qualification

Lastly, a fairly elaborate training and qualification program for regional inspectors is prescribed in Inspection Manual Chapter (MC) 1245. No similar program was prescribed for regional license reviewers until September 1991 when certain criteria were prescribed in P&GD FC 91-4. However, these criteria are not as rigorous as those for inspectors. Furthermore, with the current lack of codification in

licensing guidance, systematic training of new licensing staff is very difficult.

5.2.2 Medical Licensing Actions Reserved for NMSS Headquarters

Currently, the Regions issue all medical licenses and license amendments. When unique devices or uses appear, the Regions usually request technical assistance from NMSS. This practice needs to be reviewed and revised. When a Region receives a request for a unique medical device or use, or an activity significantly different than one covered by NMSS generic guidance, procedures should permit a management decision to transfer the licensing review to Headquarters.

5.3 Inspection Program

The materials inspection program, including that for medical licensees, is established in NRC Inspection MC 2800. This procedure categorizes licenses by program codes and establishes inspection priority and inspection frequency. It also provides guidance on initial inspections, unannounced inspections, changes in inspection priority, scheduling of inspections, and adjustments in frequency based on performance. It specifies the inspection procedures to be used in conducting materials inspections.

Generally, inspection frequency is based upon risk. The need for a QM Program does not affect inspection frequency. Teletherapy, radiography, broad medical, and large manufacturing and distribution licensees are inspected annually. Small academic, fixed gauges, in vitro testing laboratories, small research and development licensees are inspected every five years. Priority 7 licensees, like gas chromatographs, are usually only inspected for cause. The procedure provides for telephone contacts with general and priority 7 licensees on a generally random basis. Depending on licensee responses, a site inspection may be performed.

There are adjustments needed in the medical area. Teletherapy and broad medical licensees are inspected annually. Most community hospitals are inspected every three years, but small institutions and private practice facilities, including therapeutic licensees, are inspected every four years. Recently, a new program code for High Dose Rate Brachytherapy has been established with an annual inspection frequency.

The regions tend to use discretion in reducing the inspection interval for poor performers, but not to extend inspection intervals for good performers. Representatives of several Regions gave no particular reason for this. It is likely that an absence of guidance, other than the need to justify exemplary performance, makes the staff reticent to take this step. Examination of the Licensing Management System, also used to track materials inspection, suggests extension occurs in only 1-2 percent of the cases.

Although MC 2800 addresses special inspections, this comes near the end of the chapter. This section includes responses to reported incidents, follow-up on escalated actions, and allegations. Except for incidents, little additional guidance is provided. Detailed guidance for incident follow-up is provided in NRC Inspection MC 1301. This manual chapter provides good, generally detailed guidance for a wide variety of events, including misadministrations, exposures of workers and the public, and loss of control of material.

The inspection program needs revision and reformation. Too much emphasis is placed on completing the total number of budgeted inspections. The Regional Administrator's performance contract and Regional Operating Plan are strongly driven by numbers of inspections and licensing actions derived from the budgeting process. Inspections of gauge licensees and amendments to add authorized users count as much as a misadministration inspection or a broadscope license renewal. MC 2800 places greater emphasis on the routine inspection program than on reactive inspections.

However, in most cases it is failure to handle reactive events, misadministrations, allegations, and poorly performing licensees that causes the Agency to expend considerable resources responding to Congressional inquiries, IG investigations, and press criticism.

MC 2800 and the Regional Operating Plans must be revised to give top priority to reactive inspections. In the past several years, Operating Plan revisions have given greater emphasis to inspections of priority 1, 2, and 3 licenses over lower priority licenses. However, program audits continue to emphasize numbers. The budget numbers should not divert resources into low priority work for the purpose of making the number of completions look good, when higher priority work is left undone or is poorly done.

MC 2800 should be revised to more accurately reflect risk and licensee performance. For medical licensees, the inspection frequency should reflect the need for correct implementation of a QM Program. Licensee performance should have a greater effect on inspection frequency than is now the case. Resources saved from reduced inspection frequency for good performance can be applied to weaker licensees. In the case of broadscope licensees, the inspection program could be adjusted two different ways. First, the inspection program can be planned with different areas of emphasis. Completion of all areas would take place over a cycle of several years in order to cover the program in greater depth than is now the case. This was suggested during the regulatory impact survey. Second, the depth and length of the inspection would then be altered by licensee performance.

The subject of initial inspections and deferral of initial inspections was discussed in OIG audit report 92A-17. This resulted because MC 2800 lacked guidance on deferring inspections when the licensee stated that it did not possess licensed material or engage in licensed activities. This situation would usually occur during an

attempt to perform an initial inspection. The same audit report discussed an inspector's verification of licensee assertions.

Some Agreement States make it a practice to have an inspector hand carry the license to a new licensee and explain to the new licensee its duties and responsibilities. MC 2800 should be revised to require the performance of the initial inspection regardless of whether the licensee possesses material. The initial inspection, however, should be modified to be didactic in nature. The inspector should ensure the licensee has copies of the appropriate regulations, Regulatory Guides, and generic correspondence. Also, the inspector should ensure that the licensee understands its duties and responsibilities. NRC Form 591 should be modified so that in cases where the licensee states that licensed material has not been possessed or used, the licensee will sign a certification to that effect on the Form 591.

Finally, there are changes in licenses through amendments that significantly increase the scope of licensed activities. MC 2800 needs modification so that for certain major changes, the license is treated as a new license for inspection purposes.

The actual conduct of medical inspections should be changed. Currently, inspectors appear unannounced at a hospital, usually in the morning. The physician may not be at the hospital. The technologist is usually preparing doses, giving doses to patients, or scanning patients. Inspectors are usually very sensitive to patient care. To avoid impacting patient care, inspectors may concentrate on record review. The thrust of medical licensee inspections, at least for the next several years, should focus on program management. Medical inspection procedures need to be changed to decrease record review, increase assurance that the RSO and Radiation Safety Committees are managing the program, and ensure licensee management is aware of, and supports, the radiation safety program. This may require some inspections to be announced and scheduled in order to ensure the availability of appropriate licensee staff.

6.0 LICENSEE MANAGEMENT ACCOUNTABILITY AND RADIATION SAFETY OFFICER RESPONSIBILITY

The NRC should concentrate its efforts on ensuring that licensees manage their radiation safety programs and that RSOs and Radiation Safety Committees carry out their responsibilities. The clinical competence of physician users and other allied medical professionals, to the extent practicable, should be left to the medical community and State medical licensing authorities. This will allow the NRC to concentrate its expertise in the area in which it is best qualified, radiation safety management. Current NRC qualification standards in the medical area need to be radiation safety performance based.

Licensees bear the fundamental responsibility for the safe use of

medical radiation. Title 10, Code of Federal Regulations, Part 35, Sections 35.21, 35.22, 35.23 and 35.25 identify individuals within a licensee's organization who have special responsibilities for radiation safety in the use of licensed material. These sections establish responsibilities and authorities for the RSO, the Radiation Safety Committee, and authorized users.

However, many of the significant problems identified in medical programs are a consequence of licensee management and RSO failure. The Commission, in a memorandum dated March 31, 1993, requested a review of this matter (Enclosure 9). The IIT in the Indiana, Pennsylvania, event identified in NUREG-1480, the failure of the licensee's management and the RSO to properly implement a radiation safety program as a major cause of the incident. A review of seven misadministrations by a team directed by the Idaho National Engineering Laboratory (Enclosure 5) found that weakness in organizational policy and procedures directly contributed to all seven misadministrations. Lack of RSO oversight was a significant direct cause in five of the seven misadministrations. The reviews by the QM Committee in NMSS reveal numerous examples of weak to almost non-existent radiation safety programs. Although not resulting in misadministrations, in the past half-year inspectors have found licensees and RSOs that were not even aware of the QM rule. This is over a year after the rule went into effect.

In some institutions that have hired consultants to assist user RSOs, the RSO has essentially delegated the RSO role to the part-time consultant, losing redundancy and day-to-day oversight that is not being provided by the consultant.

The ACMUI discussed the role and training of the Radiation Safety Officer and physician users at its meeting on May 3 and 4, 1993. It was acknowledged that some individuals named as RSOs unwilling physician volunteers, that an individual RSO's job frequently required management skills, and that board certification may not automatically qualify an individual to be an RSO. The panel noted that some training, perhaps only on-the-job training for some programs, was needed beyond board certification to be an RSO. The degree of training was a function of the complexity of the program. An RSO for a facility, solely doing thyroid therapy, would not necessarily be qualified to be RSO for a large facility doing external beam therapy and brachytherapy. There was discussion of how one might test potential RSOs.

NMSS has a task force to draft a NUREG on "Management of Radiation Safety Programs at Licensed Medical Facilities." This task force includes representatives from NMSS, the Regions, and Agreement States. A manager in one Region suggested third party certification of RSOs. This would be similar to the "check pilot" used by the Federal Aviation Association. This will not solve all the problems, however, because many problems are caused by technically capable individuals being either incapable managers or unwilling RSOs. For many RSOs,

their duties are ancillary assignments. A proposal to require all RSOs and a corporate official to sign a certification (Appendix C) that the RSO understood his/her responsibilities, was capable of executing them, had the time and resources to perform them, and would be supported by management in the performance of the duties, received a mixed reception from the ACMUI. About half the committee felt that Part 35 established the same requirements and it would just be another piece of paper to sign that would be ignored just as easy as the rule.

Problems due to RSOs' failure to perform is not limited to the medical area. Part 35 provides the most extensive written description of requirements for the RSO and the Radiation Safety Committee. Part 33 has requirements for broadscope licensees, but they are not as strong or detailed as those in Part 35. There are no general requirements for RSOs in Parts 30, 40 or 70. Proposed revisions in 10 CFR Part 34 will define RSO duties for radiographers.

Reactor Radiation Protection Managers are usually required to meet certain American National Standards Institute (ANSI) qualification standards (ANSI 3.1) with certain additions specified in Regulatory Guide 1.8. The reactor approach of using a consensus standard should be encouraged in the materials area. During the Regulatory Impact Survey, a licensee noted that the NRC was capable of identifying programmatic failure but not capable of understanding the root cause of the problem and fixing it. This is likely to be true in many cases. Peer developed RSO qualification standards incorporated into consensus standards are more likely to be successful and practical than those developed by an NRC staffer without recent practical radiation safety management experience.

The NMSS task force should continue its efforts. A parallel effort should be established to examine current NRC requirements and guidance on the responsibilities of RSOs at all facilities. Consideration should be given to a performance-based rule for all licensees, not just medical licensees. Professional societies should be contacted to discuss the development of model Radiation Safety Officer qualification standards. In addition, the revision of the inspection program in MC 2800 should include increased emphasis on management control and RSO responsibility. Inspection Procedure 87101 already includes a Performance Evaluation Factor program to assess management performance. These factors should be reviewed based on recent findings of problems resulting in medical misadministrations. Although receiving mixed comment from the ACMUI, use of a certification by an RSO and corporate official either on the license application or as a separate form should be considered. It would make some reluctant individuals refuse the position and give the NRC greater leverage if a program was found ineffective or grossly deficient.

7.0 MEDICAL ACTION PLAN/MEDICAL ACTION ITEMS

The staff has received numerous directions from the Commission in addition to is own proposals to improve regulations in the medical area. In his memorandum (Enclosure 8) of May 19, 1993, Mr. James M. Taylor, Executive Director for Operations, sent to the Commission the staff's Agenda For Improvements in the Medical Use Program. This report summarized and set priorities for all the issues identified to date in the medical area. This agenda was examined during the current review. In addition, the Commission presented ten other issues to be considered in an SRM (Enclosure 9) dated March 31, 1993. These issues are listed below in Section 7.1.

7.1 Specific Commission Issues

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

  This is discussed in Section 4.3. The existing AEOD database of misadministrations can be expanded to accomplish this. A set of essential data elements needs to be defined.

- Consider the potential for underreporting of misadministrations.

  This is discussed in Section 3.2. Underreporting is most likely if a misadministration is not recognized as such.

- Consider possible NRC policies on patient followup.

  A policy on patient followup is proposed in Section 4.2.1 and Appendix A.

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

  The role of the NRC medical consultant has been defined in a proposed update of Inspection MC 1360 (Appendix D). This document is presently circulating for Office and OGC review. The attached procedure on misadministrations (Appendix A) will be made consistent with the final MC 1360.

- Consider NRC's role and scope of responsibilities versus that of the Food and Drug Administration (FDA) and Agreement States in the review and approval of sealed sources and devices.

  This item was not reviewed in depth in this report. A Memorandum of Understanding with the FDA is currently being developed. In addition, the Office of Policy Planning is defining a number of options in response to Senator Glenn. If the current framework of regulation remains, NRC oversight of Agreement State reviews

needs to be strengthened as discussed in Section 8.2. The results of NRC Human Factors Research on Brachytherapy should be provided to the FDA because current findings show weaknesses in computer controlled devices and control software.

- Consider the regulatory actions that may be appropriate to better define responsibilities and role of a radiation safety officer (RSO) at medical institutions.

  This is discussed in-depth in Section 6.0.

- Proceed with clarifying amendments to 10 CFR Part 35, Regulatory Guide 10.8, and internal staff guidance memoranda to clarify the radiation safety requirements applicable to high dose rate remote afterloaders.

  This is in progress. Draft internal licensing and inspection guidance has been completed and is being circulated for comment.

- 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.

  This issue is under consideration by the Office of Enforcement staff.

- Consider the potential mechanisms for tracking and notifying Agreement States and appropriate licensing/credentialing authorities of problem authorized users, including chronically careless practitioners as well as wrongdoers.

  A memorandum from the OGC dated May 27, 1993 (Enclosure 10) describes the current system. NRC currently does about as much as it can legally do without additional rulemaking. Information concerning individuals against whom the NRC has taken an action and given due process of law is being provided to Agreement States. The creation of additional categories would require rulemaking and some provision to offer hearing rights to an affected individual.

- Consider the need to establish procedures under which local authorities including the coroner or medical examiner would be notified of misadministrations or other serious events including potentially significant exposures to radiation or radioactive materials.

  The misadministration procedure outlined in Appendix A would provide for this notification to ensure the accuracy of death certificates.

7.2 Agenda for Medical Program Improvements

A review of the Agenda for Medical Program Improvements (Enclosure 8) indicates that a number of the 71 issues can be unified under major areas of program revision discussed earlier in this report. There is a need to consolidate these issues under the major areas of program revision and create a hierarchy among them since many of the items are interrelated. Twenty issues relate to a general revision of either the inspection program (Section 5.3) or the misadministration followup procedure (Appendix A). Ten issues relate to revisions in licensing guidance (Section 5.2) and related rulemaking (i.e., Revision of Part 35 to incorporate High Dose Rate Brachytherapy and Gamma Stereotactic surgery, Record Retention, etc.). Ten issues relate to licensee management of radiation use programs and Radiation Safety Officer responsibilities (Section 6.0).

Several of the issues involve either ongoing or potential rulemaking. The major rulemaking issues are: Use and Preparation of Radiopharmaceuticals For Diagnosis, Therapy, or Medical Research; The Administration of Byproduct Material or Radiation From Byproduct Material to Patients Who May be Pregnant or Nursing; and Release of Patients Administered Radioactive Material. Several other of the Agenda items may involve revision to 10 CFR Part 35.

The three rulemaking issues above need prompt attention. Time did not permit a detailed review of the three rules for this report. However, consequences of the inadvertent exposure of fetal or neonatal thyroids to radioiodine (see Section 3.4) is suffciently severe to warrant additional regulatory efforts to protect them. With respect to further revisions of 10 CFR Part 35, consideration should be given to changing its structure to more readily accommodate technological changes in medical practice, such as occurred with the introduction of the gamma knife and the high dose rate afterloader.

8.0 AGREEMENT STATE ISSUES

8.1 Status

There are 29 Agreement States that regulate approximately 15,000 materials licensees. The NRC regulates about 7,000 licensees of which approximately 2,000 are medical licensees. In addition to byproduct material, Agreement States regulate other sources of ionizing radiation in generally a similar fashion to byproduct material. In most States, radiation control programs are located within State health departments which also regulate the practice of medical arts. The size of the staff with expertise in the materials radiation protection area may be small (two to three persons), in some states, but can be comparable to the materials staff in an NRC region in larger states. Generally, states do not have the specialists, particularly engineering and dose modeling specialists, available to

the NRC. They may have physicians and allied health professionals in other sections of the health department that are not on the NRC staff.

The NRC provides considerable assistance to the Agreement States both directly and indirectly. Direct assistance includes training for State regulatory staff provided by both the NRC using NRC staff and contractors paid for by the NRC. For some of this training, the NRC pays State travel and per diem costs. Other direct assistance includes rotations between State and NRC staff for training purposes, consulting activities and, in some circumstances, the use of NRC inspectors and license reviewers from the Regions to assist in State inspection and licensing activities. The NRC provides indirect assistance through its rulemaking activities, regulatory guides, research program, and NUREG publications.

The Agreement States provide support to the Office of State Programs (OSP) through training efforts, by furnishing some instructors and, in some cases, providing the training facility. Most of the contractor provided training is similar to the technical training provided to the NRC materials inspection and licensing staff. OSP offers "How to Inspect" and "How to License" training which is very practical and includes role playing. Instructors include individuals from OSP, NRC regions, and Agreement States. New NRC inspectors and license reviewers sometimes attend the courses.

OSP also conducts workshops on special topics (e.g., High Dose Rate Brachytherapy) for Agreement State personnel. NRC personnel may also participate in training at these workshops.

Agreement State Programs are expected to be adequate and compatible. In the medical area (10 CFR Part 35) only the definitions, and the misadministration and QM rules are matters of compatibility. Product evaluations, i.e., evaluations of sealed sources and devices, are Category I indicators. These bear directly on health and safety, but are not matters of compatibility. This area is generally not evaluated in-depth during Agreement State Radiation Control Program reviews.

8.2 Observations and Suggestions

The appropriateness of the Agreement States' approving sealed sources and devices for distribution in interstate commerce has been questioned. Section 274 of the Atomic Energy Act states that notwithstanding an agreement, the Commission could require the manufacturer of a device containing byproduct material to have a Commission license. This is a policy decision that needs further evaluation not only for medical devices, but also for both specifically licensed and generally licensed devices. However, if Agreement States are going to approve sealed sources and devices for interstate commerce, their requirements should be a matter of level 2 compatibility. This area also needs greater attention during the State program review. NMSS would need more resources to support OSP

in this effort. This would still require fewer NRC resources than would assumption of all distribution licensing by the NRC.

At a meeting with Agreement States representatives to discuss this medical review, strong support was received for updating licensing guidance. NRC licensing guides are used by the States in varying degrees. Some States have formally modified them for their own use. NRC inspection procedures do not appear to be used as directly by the States.

Agreement States currently regulate a larger number of radiation users, and more diverse radiation sources than the NRC. The States regulation, licensing, and inspection activities are different from the NRC. The concept of federalism, in part, envisions the States as laboratories for innovation. The NRC should avail itself of the States' experiences. NMSS needs to maintain greater cognizance of Agreement State regulatory activities and utilize the benefit of State experience. OSP needs to be cognizant of NMSS activities that would be relevant to the States.

The Agreement States have considerable expertise regulating the medical arts and the use of ionizing radiation in the medical arts. Caution should be used in making all of 10 CFR Part 35 a matter of compatibility. Agreement State views on changes in medical or pharmacy regulations can provide information useful to the Commission and, coming from a co-regulator, be independent of the regulated community.

9.0 INFORMATION MANAGEMENT SYSTEMS

In addition to the AEOD database discussed in Section 4.3, there are a variety of computerized systems which provide information for use by the NMSS and Regional materials staff. These are: the License Management System (LMS), the Inspection Followup System (IFS), and its predecessor, the 766 database.

In addition, there are two tracking systems currently in use in IMNS for tracking work items related to the medical program. The first of these is "BRAT", the Medical, Academic and Commercial Use Safety Branch's (IMAB's) Ticket Tracking Program; and the second is the newly created Medical Program Actions System database used to track items which have resulted from the Commission Staff Requirements Memorandum of March 31, 1993.

The current review revealed that these systems as a whole are cumbersome and inadequate to provide the management reports necessary to respond to the serious questions raised recently in Inspector General investigations, in response to the Cleveland Plain Dealer articles, in preparation for Congressional testimony, and in response to the General Accounting Office. Even routine information requests

take weeks to process, due to the current format and structure of the information retrieval systems. This led to an inability of the staff to produce timely and accurate responses to questions about incidents such as the Riverside Hospital event; led to confusion with respect to the scope of patient notification; and makes it difficult or impossible to provide accurate statistical information regarding the frequency and rate of misadministrations. A similar situation exists with respect to tracking allegations. An attempt to determine the percentage of allegations existing in the materials area revealed that the allegations management system does not lend itself to producing direct reports; rather, information must be disaggregated from reactor specific data, thereby greatly reducing its reliability and utility. Information management systems in the materials area need to be reviewed and updated. The Division of Industrial and Medical Nuclear Safety needs: 1) a Division-level database for work items such as Technical Assistance Requests, to track not only completion, but to evaluate submittal and processing quality; and 2) a database that will permit the tracking of the materials program performance indicators in NMSS and the Regions.

10.0 SUMMARY OF RECOMMENDED ACTIONS

10.1 Ensure the Quality Management Program is Implemented by Licensees

Quality management programs submitted by licensees must be reviewed for adequacy. Weak procedures and programs must be upgraded.

Inspection emphasis must be placed on medical program management and RSO performance.

10.2 Misadministration Followup

An NRC Management Directive is needed to define the totality of the agency's response to a misadministration. The procedure outlined in Appendix A is recommended.

10.3 Revise Inspection Manual Chapter 2800

10.3.1 Reexamine Inspection Program Priorities in Manual Chapter 2800

Revise Inspection Manual Chapter 2800 to more accurately reflect risk and licensee performance. The frequency of inspecting medical programs should be based on the need for a quality management program and should be adjusted for performance.

For broadscope licensees, in general, including medical broadscope licensees, the depth of the inspection should be based on performance. Furthermore, in consideration of licensee concerns over the impact of team inspections and in order to ensure all areas are eventually covered in depth, the inspection program for all broadscope licensees should be segmented. In this way, certain areas will be inspected in depth each year, so

that over a period of several years the entire program is covered in depth.

Top priority must be given to reactive inspections including misadministrations, allegations, unanticipated radiation exposures and loss of control over material. The total number of inspections should no longer be used as a primary performance indicator in evaluating NRC or Regional performance.

Initial inspections should always be performed even if the licensee does not possess material. Initial inspections should be didactic in nature. NRC Form 591 should be modified so that licensees are required to certify any claim that they do not/have not possessed licensed material nor are they engaged in licensed activities.

Add guidance that puts reinspection on the same schedule as initial inspections after an amendment is issued which substantially increases the licensees' program.

10.3.2 Add Reactive Inspection Procedures

Issue a special event response inspection procedure to ensure that management can adequately evaluate events with respect to cause and consequences.

Issue an allegation followup inspection procedure and provide investigatory training for inspectors, to improve the quality of allegation responses.

10.3.3 Revise Routine Medical Inspection Procedures

Revise inspection procedure and field notes for HDR and the Gamma Stereotactic Device (Gamma Knife).

Revise general medical inspection procedure and field notes to reduce the depth of record review, emphasize determination of RSO and authorized user management of program and inspector communication with hospital administration.

10.4 Revise Licensing Practices and Guidance

Licensing guidance must be updated, consolidated into one set of documents, and put on a mandated periodic review cycle. Give priority to revision of three medical guides. End the practice of putting licensing guidance in internal NRC documents.

Complete all licensing actions in a timely manner.

Revise Inspection MC 1245 to establish a license reviewer training program as comprehensive as that for inspectors, including certifying boards.

Ensure Regional TARs are tracked by the Division of Industrial and Medical Nuclear Safety (IMNS).

10.5 Licensee Management Accountability

Continue task force efforts to develop a NUREG on Management of Medical Radiation Safety programs.

Consider modification of regulations to address authorized physician user radiation safety training and experience and generically address radiation safety program management and RSO responsibility.

Consider use of the Radiation Safety Officer Certification Form in Appendix C.

10.6 Tracking

Maintain and upgrade AEOD's current system for tracking misadministrations. Determine the information fields needed in the system, including reference to inspection number(s) misadministrations.

Consider providing staff and Agreement States with computer terminal access to the database. Provide the staff and Agreement States a buffered way to enter data into the system.

Enhance and upgrade current information management systems providing information on materials issues.

10.7 Agreement State Issues

Agreement State reviews of sealed sources and devices should be a level 2 compatibility matter.

The NRC and NMSS need greater knowledge of Agreement State activities to make use of State experience and innovative ideas.

Ensure the NRC benefits from the fact that in most Agreement States, Radiation Control Programs are in Health Departments with extensive experience regulating medicine and the allied health professions.

11.0 OPEN ISSUES

Due to time constraints, several issues more remote from the medical area than the issues discussed here, were not reviewed with sufficient depth to make recommendations. Only observations are provided.

11.1 Enforcement Costs

Materials escalated enforcement is resource intensive. Enclosure 7 shows that OE expends 10 FTE on materials enforcement including Headquarters and regional OE FTE. A certain fraction of the 20 FTE expended by OGC is on enforcement. This author's experience is that the Regional technical staff spends at least twice the resources on a materials civil penalty case as the regional and Headquarters OE staff. These individuals must document the inspection, write the violations, write at least a portion of the initial version of the enforcement letter, arrange the enforcement meeting with the licensee, conduct the enforcement meeting, document the enforcement meeting, develop a regional position using all the enforcement policy factors and provide, in most cases, all the information OE and OGC need to independently evaluate the region's recommendation.

Since the NRC issues about 60 materials civil penalties a year, it would appear that the NRC's cost of issuing civil penalties, ranging from several hundred to several thousand dollars, is about 0.5 FTE. This may have recently been somewhat reduced with the increased Regional delegation changes that occurred early in 1993. The costs of enforcement are billed to the good as well as the poor licensees.

Expenditures of Regional resources on enforcement in excess of resources provided by headquarters forces a reduction in inspections and licensing activities.

11.2 National Program Review/Agreement State Radiation Control Program Review

There is currently a Task Force headed by Guy A. Arlotto, Deputy Director of NMSS, reviewing the NRC's Evaluation of the Regional Materials Program and Agreement State Radiation Control Program. As an observation, 8 of the 10 Category I Indicators and 11 of the 19 Category II Indicators used to evaluate Agreement States are applicable, at least in a relative fashion, to evaluation of NRC regional programs. For example, the indicators, Status of Inspection Program and Frequency of Inspection, are directly comparable. The indicator, Inspection Procedures, could become compliant with adequacy of use of Manual Chapter inspection procedures in the case of Regional evaluations.

11.3 Third Party Certification

Third party inspections could be of some value and augment NRC resources. The American College of Nuclear Physicians (ACNP) presented to the ACMUI a description of its Nuclear Medicine Practice Audit Program. This program reviews aspects of the licensee's Quality Assurance program not inspected by the NRC. NCRP Publication No. 99, Quality Assurance for Diagnostic Imaging Equipment, describes steps to be taken to ensure that diagnostic nuclear medicine scans are of the highest possible quality. The NRC does not inspect in this area, but

the ACNP program does. It would appear that, for the overall well-being of the patient it is as important that a prescribed scan yields useful information for the radiation dose received as it is to avoid a misadministered dose.

Although not discussed in depth, the Agreement States indicated opposition to third party inspections.

11.4 Length of License

Currently, materials licenses are issued for five years. Practically, since some licenses are under timely renewal for five years or longer, due to lack of NRC resources, one can ask why licenses are not issued for ten years to begin with. This would reduce the renewal burden on the NRC and the licensee. One could also require that renewals be submitted earlier than the 30 days now required. This would assure licenses are renewed before they expire. During the Regulatory Impact Survey, licensees complained about the added cost to them of the NRC not promptly reviewing license renewals.

The Agreement States are generally against ten-year licenses. This may be due to their preference for regulation by license condition, rather than by rule. However, there appears to be a diversity in license length in Agreement States. One state issues seven-year licenses. Another state issues initial licensees for two years, but renewals are longer.

Appendix A

FOLLOWUP ON THERAPEUTIC MISADMINISTRATION REPORTS

SCOPE: Applies to all events resulting from therapy misadministrations or any other medical event including fetal or infant exposures resulting in an unplanned or unexpected dose to the patient in excess of Revised Part 20 incident limits. (25 rem effective whole body, 75 rem eye, 250 rads to the skin or an organ.)

I. INVESTIGATION TASKS

A. Determine sequence of events.

B. Determine immediate and root causes.

C. Determine compliance with quality management rule.

D. Determine compliance with misadministration rule.

1. Notification of NRC - 24 hours.

2. Notification of NRC - 15 days.

3. Notification of referring physician and patient - 24 hours.

4. Written notification of patient - 15 days.

E. Review by NRC medical consultant.

F. Review of enforcement options by NMSS, OE, and Region.

II. STAFFING

A. Inspector qualifications.

1. Senior GG-14 or above.

2. Training in teletherapy, brachytherapy, nuclear medicine.

3. Accident investigation training.

B. Medical consultant.

C. NMSS coordinator.

1. Same qualifications as A. above.

2. Capable of performing dose calculations and evaluations.

3. Maintains file of all medical investigation reports.

4. Coordinates review of event by OGC for final determination of status as misadministration.

III. MEDICAL CONSULTANT ROLE

A. Review event.

B. Independent analysis of cause.

C. Determine dose to patient.

D. Determine likely medical consequences.

E. Determine adequacy of licensee report to the NRC and the patient.

F. Determine likely medical followup needed.

G. If the patient was not notified, determine the validity of the justification.

H. Provide Medical support to licensee and referring physician if requested and consistent with the NRC's role as a regulator.

IV. REPORTS

A. The investigation report package will include the inspector(s)' report, the medical consultant's report and the Licensee's report to the NRC. Final report is due 15 days after receipt of licensee's and consultant's report.

B. NRC investigation report distribution

1. Licensee

2. Referring Physician

3. Patient or whomever notified by referring physician

4. ACMUI

5. NMSS medical event coordinator

V. FOLLOWUP POLICY

A. When misadministrations have occurred the NRC will make reasonable efforts to ensure the patient or an appropriate relative of the patient is informed of the event and the probable consequence of the event.

B. Where the misadministration has recently occurred and what the NRC's role will be in

1. Providing the information from the NRC's inspection and the consultant's report to the patient and the referring physician.

2. Ensuring the licensee's written report has been provided to the patient and the referring physician.

3. Providing whatever additional medical advice is requested by the patient or the patient's physician and consistent with the NRC's role as a regulatory.

4. Informing patient of DOE's voluntary long-term medical study program.

C. When the event indicates that there has been or may have been misadministrations in the past, the NRC will make a reasonable effort to

1. Identify all patients that received a misadministered dose.

2. Inform all patients or their survivors, if the patient is deceased, of the information available to the NRC.

3. For patients who have died, provide the facts as known to the NRC to the appropriate authorities to ensure the accuracy of death certificates.

D. Upon completion of the above, any enforcement action and followup on licensee corrective actions, NRC involvement will normally cease.

E. In certain cases NRC management may decide that further followup is appropriate, in these cases the NRC will issue Order(s) to the licensee to specify the followup information required. These cases are likely to be situations in which death or severe morbidity are expected by the NRC medical consultant. Since the legal authority for determination of cause of death is usually prescribed by State law, the NRC will bring its information to the appropriate local legal officials charged with this responsibility.

F. Followup reports will receive the same distribution as the original investigation report.

Appendix B

LICENSING GUIDE BULLETIN BOARD

Statement of the Problem:

Licensing Regulatory Guides (RGs) are obsolescent and getting worse every day. Furthermore, numerous RGs were issues in draft form for comment and never revised or issued in final form. The new Part 20 will ensure every licensing RG will need revision. Because of the time it takes to issue guides, guidance including information needed by licensees to prepare license applications is frequently issued as Policy Guidance and Directive. However, even these are out of date. Frequently regulatory policies including interpretations of regulations are issued as Information Notices and never issued in a more durable form. Regions ask specific questions on licensing and inspection matters but the answers have not always been widely disseminated not have the licensing guides been revised to incorporate specific guidance. Currently in Region III, about 20% of all license amendment applications, 30% of all new license applications and 50% of all license renewal applications receive deficiency letters. In Region I, the percentage is significantly greater. This results in a loss of efficiency for applicants as well as license reviewers. Hopefully clearer guidance will increase everyone's efficiency. Clear and complete guidance is needed to ensure consistency among the Regions and even among license reviewers within a Region considering the degree of staff turnover.

System Design:

1. Computer Based System with the ability to make global changes. When Part 20 changes, references to sections of the old Part 20 could be quickly changed to the new sections in all documents.

2. Modular construction. Many regulatory guides contain the same material. Calibration of instruments, components of the radiation safety program, identification of contacts, etc. When called up each licensing guide would be created automatically from its modular components. This would also make revision easier because (1) computerized text is much easier to revise and (2) a component would be revised and not a whole guide.

3. The system would include all relevant material also needed by licensees and license reviewers. This would include relevant Information notices, Bulletins, and responses to Task Action Requests. These documents would be included in modules that would be linked to the relevant licensing guide. When an individual pulled up a guide they would have the option to pull up all relevant related documents.

4. There would be a three year review cycle for each licensing guide in which all regulatory changes, relevant information in IN's, Bulletins, and TAR's would be incorporated into the Licensing Guide so the staff and licensees would not have to be aware of informal guidance documents issued 10 years ago.

5. I envision this system to be initially available to the NRC staff over the LAN. However, I want it designed so that licensee and the public can access it like a bulletin board. In this case, some components might only be accessible to the staff (i.e., responses to some TARs). In this latter case I envision including the NMSS Newsletter on the bulletin

board.

6. The system must be user friendly, menu driven (preferably with a mouse), provide for read-only access, and include a help menu.

7. I expect to have Regional staff contribute to the establishment and maintenance of the modules in the system. I also expect to put revised inspection procedures in this system under each licensing guide so that licensees can conduct self inspections using our procedures.

8. A contractor is needed to set up this system, to disassemble the existing documents into modular form and to load existing documents into the system. NRC resources are needed to modify those modules which currently contain erroneous information.

Appendix C

RADIATION SAFETY OFFICER CERTIFICATION

RADIATION SAFETY OFFICER CERTIFICATION

We certify that the individual to be named on this license to perform the function of Radiation Safety Officer as defined in 10 CFR Part 35.21:

1. Has read and understands the NRC regulations applicable to this license and the specific conditions in the license,

2. Has sufficient technical knowledge to perform the duties of a Radiation Safety Officer,

3. Has and will continue to have sufficient time to perform the duties of the Radiation Safety Officer,

4. Has and will continue to get sufficient resources to accomplish the tasks of the Radiation Safety Officer,

5. Is completely willing to perform the functions of the Radiation Safety Officer, and

6. Has and will continue to receive the support of the management of this licensee in ensuring that all licensed activities will be conducted in accordance with NRC regulations and the specific terms of the license.

Radiation Safety Officer Applicant_____

Date_____

Corporate Officer/Proprietor_____

Date_____