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T-1151

# OFFICIAL TRANSCRIPT
# PROCEEDINGS BEFORE

NUCLEAR REGULATORY COMMISSION

DKT/CASE NO.

TITLE ACRS/SUBCOMMITTEES ON REACTOR RADIOLOGICAL EFFECTS AND SITE EVALUATION

PLACE WASHINGTON, D. C.

DATE NOVEMBER 12, 1982

PAGES 1 - 295

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

SUBCOMMITTEES ON REACTOR RADIOLOGICAL EFFECTS

AND

SITE EVALUATION

Room 1046
1717 H Street, N.W.
Washington, D.C.

Friday, November 12, 1982

The Subcommittees on Reactor Radiological Effects and Site Evaluation met, pursuant to recess, at 8:30 a.m., Dade Moeller, Chairman, presiding.

ACRS MEMBERS PRESENT:

D. MOELLER
J. RAY
R. AXTMANN

ALSO PRESENT:

R. MULLER
R. KATHERN
J. SHAPIRO
H. PARKER

DESIGNATED FEDERAL EMPLOYEE:

J. MCKINLEY

P R O C E E D I N G S

MR. MOELLER: This is a meeting of the Advisory Committee on Reactor Safety Subcommittees on Radiological Effects and Site Evaluation. I am Dade Moeller, Chairman of the Subcommittee. We have one other ACRS member with us at the moment, Mr. Jerry Ray, sitting on my left, and we expect that Robert Axtmann will be joining us shortly.

We also have a team of ACRS consultants with us, naming, again beginning from my left, R. Muller, R. Kathern, Jacob Shapiro, and Herbert Parker.

The objectives of this meeting are several. This morning we will be, first of all, briefed on the current status of the NRC proposed revisions to 10 CFR 20, "Standards for Protection Against Radiation," and this will include, following that session, a briefing by DOE officials on their reactions and those of their national laboratory personnel on the proposed revisions. Then, we will follow that with a briefing by EPA officials on their proposed revisions to Federal Guidance on Occupational exposure.

We will then take a break for lunch. Then, this afternoon, we will begin with a discussion of a draft Federal policy statement on the distribution and use of potassium iodide for thyroid blocking in the

event of an accident at a nuclear power plant. That will be presented by an official or representative from FEMA. Then we will follow that with a briefing by a member of the NRC staff on this same subject.

Next, we will discuss a proposed revision to 10 CFR Part 140, criteria for extraordinary nuclear occurrences, and we will close out today with a discussion of the de minimis concept from a regulatory point of view, and that will include presentations by the NRC staff, by EPA as they are looking at this concept in terms of radioactive waste, and by representatives of, I believe, the Edison Electric Institute, and then a representative from the Oakridge National Laboratory.

We will then recess for the evening, and the subcommittee will resume its meeting tomorrow morning with a discussion of two items. First of all, a proposed amendment to 10 CFR Part 50 which is a proposed ALARA rule for operating nuclear power plant licensees, and then we will consider the possible impact of seismic events as they relate to emergency planning for accidents at nuclear power plants.

We have a variety of subjects that we are going to try to cover, and we have a rather lengthy agenda. But I hope we can move forward with it and

accomplish our objectives.

Our purposes are several. We are here to listen and to be brought up to date on each of these subjects, and in so doing we will seek also to foster communications and to promote interchange among the people involved in these issues, and that includes, of course, the public, as well as the various Federal agencies.

Where warranted, and where we believe we have something useful to say, tomorrow, following the formal portion of the meeting, we will consider the development of written recommendations for submission to the Advisory Committee on Reactor Safeguards for the consideration of the full committee in terms of possibly submitting written comments to either the NRC staff or the NRC Commissioners.

This meeting is being conducted in accordance with the provisions of the Federal Advisory Committee Act and the Government in the Sunshine Act. Ms. R. C. Tang, sitted on my right, is the Designated Federal Employee for the meeting. We also have with us Mr. John McKinley and Dr. Thomas McCone, Dr. McCone being an ACRS fellow.

The rules for participation in today's meeting have been announced as part of the notice previously

published in the Federal Register on October 25, 1982, and then amended on November 8, 1982.

A transcript of the meeting is being kept, and it is requested that each speaker first identify himself or herself and speak with sufficient clarity and volume so that he or she can be readily heard.

We have received one written statement relative to the subjects being covered at the meeting, and this written statement was submitted by Russell M. Bimber from Paynesville, Ohio.

Mr. Bimber has commented on three topics being covered at this meeting. First of all, the use of potassium iodide as a thyroid blocking agent. The second item is a comment on the revisions of 10 CFR 20. The third item is a comment on the subject of the extraordinary nuclear occurrence.

We are making copies of his written comments available to all of the members of the subcommittee and copies are additionally available for anyone who desires them.

We have not received any formal request for time from members of the public to make oral statements at this meeting. Why don't I ask at this time if there is anyone here who might desire a few minutes to make an oral statement at any time in the next two days, other

than the people, of course, who are on the agenda.

I see no response, so we will not allow time at the moment, but, again, if someone comes forward later, we will certainly accommodate them.

Let me ask at this time if any of the members of the subcommittee or our consultants have any questions on how we will proceed.

Since at least one member of our consulting staff is new, I will simply say that we will carry through in our discussion in the formal presentations of each of the comments of our various speakers. You are free to interrupt and ask questions either while they are speaking, or we can do that at the end.

We are here to become informed. We are here to solicit and encourage you to provide the subcommittee members with your thoughts, with your recommendations, with your suggestions, with your comments on each of these topics.

Tomorrow morning, as I said, following the last formal presentation, we will meet in open session, open to the public, but it will be an executive session where we will simply discuss among ourselves what our conclusions are and try to reach a consensus on each of the items in terms of what our recommendations will be that we will forward then to the full committee.

I see, after making that comment, that the DOE people have asked that they be permitted to proceed through their presentation and hold questions until the end. We can certainly accommodate you in that request.

MR. VALLARIO: Mr. Chairman, would it be possible to put EPA second on the list?

We have quite a bit of material to cover, and I think it would be more prudent to have us as anchor on the morning session, so that we could regulate ourselves knowing how much time it would take. Would it be possible to do that?

MR. MOELLER: We will certainly try to do that, Ed. We will go ahead with the NRC, and then if the EPA people are here, we will move forward with them.

MR. VALLARIO: Thank you.

MR. MOELLER: Any other comments or requests?

There being none, let's move forward with the initial presentation, which is the current status of the NRC proposed revision of 10 CFR Part 20, and I will call on William Mills.

MR. MILLS: Where would you like me to be?

MR. MOELLER: I think up here would help.

Let me repeat that although it is, in a sense, sort of a formal meeting, I want to get to the facts, I

want comments, I want us to really get into these subjects and discuss them. So don't stand on formality. Raise your hand, and I will recognize you.

We can have comments from the DOE people during the NRC presentation, and vice versa.

MR. MILLS: Thank you, Mr. Chairman, members of the subcommittee, and consultants.

What we would like to do today, as you have mentioned, is to give you a status report of where we are with the revision of Part 20, and to fill you in on some of the contacts that we have had since our previous meeting, and discussion on the issue.

We want to give you a feel for some of the significant changes that we have made in the draft rule, and then to tell you where we are relative to the status of the rule and the accompanying information that we must prepare to submit it as a proposed rule for consideration within the NRC.

Let me touch first on the kind of meetings that we have held since our last discussion.

We have met with the Edison Electric Institute in a meeting in Atlanta, in which we went over in detail the comments that they had, and some of the issues that they raised, and this will be reflected in the changes we have made.

We have met with the Atomic Industrial Forum on two occasions here in Washington. On one occasion, it a half-day meeting in which we discussed some of the general topics. Then for two days, we sat down with a ad hoc working group of the Atomic Industrial Forum in which we went through line by line down the rule, and heard their comments on the possibility of some the practical problems they had with the implementation of the rule.

We also participated in a conference sponsored by the Atomic Industrial Forum in which we presented three papers that dealt with the Part 20 issue in one way or another.

Mr. Minogue gave a paper on the general approach to 10 CFR Part 20 revision, as well as brief comments on the de minimis concept. He also talked about the source term research that is being undertaken relative to that problem.

Mr. Guy Cunningham, from the Executive Legal Office in NRC, gave a paper on de minimis, and you will be hearing from that paper this afternoon. We gave also a short presentation of the overall content of the revision of Part 20.

We have met with the NRC Regions I and II, and we had lengthy discussions in which we covered the focus

of the revision. This was particular important because one of the questions that come up repeatedly will be how we will translate the revision into the actual inspection procedures, and what steps will we take to inform the inspectors of what these changes are and some of the intent. They have raised questions which we have also fed into the revision.

We met with the Westinghouse people, I guess their collective health physics program. Particularly of interest to us, that we discussed in the earlier meeting, was the fuel fabrication. I think we have worked something out with these people.

As a follow up to a meeting in which Dr. Denny Ross met with Assistant Secretary Young in the Department of Energy, we met with the DOE staff, with Deputy Assistant Secretary, Mr. Bob Davies, and many of the people who will be giving a report from DOE this morning.

We have proposed to DOE, as a follow up to our discussion, to sit down with them and discuss where we are in agreement, where the major areas of disagreement remain. We have such a meeting scheduled now for the 22nd or the 23rd of this month.

I am sure you will hear some of the problems that DOE sees in the revision during the course of the

day, and that will be beneficial to us as well.

MR. MOELLER: There is a question, Bill.

MR. RAY: Excuse the interruption, please, but maybe you can fill in the gaps in my background, in my understanding of the procedures in the review of this proposed rule.

I gather from your narration that the review has been by organizations that have expertise and interest in the industy. Has there been any formal submission to the general public for comments, or will there be?

MR. MILLS: Yes, sir. There will have to be a formal proposal.

The intent, when we started out, in drawing up a rule, was to meet with the licensees and other interested parties. For example, we have met with the National Resources Defense Council. We have met with the hospital people. The idea was that we would develop a rule in which we got early input on the practicality and the problems that they saw in the revision of such a rule.

In doing so, with the full understanding that this was an evolutionary process in terms of revising the rule, and that we were not asking for formal review at this time. The formal review will of course occur

when we get the approval from the Commission, and then it would in fact be published in the Federal Register.

MR. RAY: Mr. Mills, if you have the time to do that, I think that it is a splendid idea myself, because the thing you show the public then has more support in the scientific area.

MR. MILLS: I guess it is not a unique approach in the NRC, but it is certainly one that we have found to be in the best interest of our work, not to go to a formal review process prior to getting those kinds of input.

I was going to cover some of this in the status, but let me just say that what you are hearing from us has not in fact received any formal review within the NRC itself.

My colleagues here, Mr. Cool and Mr. Baker, if you saw their version of the rule, you would see a document which is continuously being rewritten and significant changes are being made. So we are not at that point where we have even asked for a review within the NRC.

I must say that the sessions that we have had by talking to licensees and other interested individuals, we have in fact gotten significant changes in our thinking, and we think it is resulting in a rule

that is better focused on what it is supposed to do, and at the same time it meets the requirements that we see in NRC.

There hasn't been any formal blessing of any type. Of course that will be a long process, and we recognize that.

We, of course, have tried to sharpen the definitions. We have made a lot of editorial changes. One of the things as a result of the discussions that we have had, in the current version, probably the version that you have seen which was written in August, we continued to carry the SI units in the document, we now are dropping the SI units from all areas except in the definitions themselves.

It made the reporting requirements a little bit complex as to whether or not there would report the SI units or the conventional units that we have used up to date. So we don't ask that they make that they make that conversion. That was of particular concern to the unions people, because to try to explain to them a new system of units was a very difficult problem, and others as well.

One other thing that we changed is the photo conversion factors. We had in the table a long list of conversions from rads to rems as a function of energy.

The reason we changed it was that we never intended for the licensee to actually try to determine the small changes in the photo spectra. That was not the intent. The intent was to address the problem of calibration of his dosimeter, so that his dosimeter was responsive to the air filters.

What we have done, we have tried to simplify that. We never intended that the licensee have a continued spectrometer problem, so we dropped a lot of the conversion.

We modified the controls for the very high radiation areas. We had a lot of conditions in those requirements that the licensee would have to do three additional activities. We found that that constituted a lot of unnecessary redundance, and without jeopardizing the control on the high radiation areas, instead of making them "and" clauses, we have made them "or" clauses. We don't feel that this is in any respect going to jeopardize the control that the NRC will have over those radiation areas.

One of the things that, of course, is of major interest to us is the requirement for the summation of the internal and external exposure. After a lot of discussion on this issue, we have arrived at what we consider to be a tentative position that we find, at

least acceptable, and that is to allow the licensee to list his external exposures separate from his internal exposures.

This will also provide us some information relative to the summation. We will have a place on the form, the record that he submits as well as keeps on the workers, a place to sum these if, in fact, he would like to do so. In doing so, we think we have helped particularly the situation of those few licensees in which the requirement of two entries or the summated entry, it is new information for us as well as them. So we have allowed both the record of the internal and the external exposures.

Also relative to that issue, we allowed greater flexibility in how one addresses the problem of 50-year dose commitment. He can list it as a fraction of the annual dose limit, or he can list as a fraction of the annual limited intake. He can also list it as a fraction of the DAC, the derived air concentration, in a year of exposure.

The latter, of course, is the same requirement we now have relative to the reporting of the maximum permissible concentration per year. So there is really no change in the DAC in terms of the reporting than the present Part 20.

We think that this will add greater flexibility in the operation. This will be of particular value to the fuel fabrication industry, which is very much concerned about this problem.

We have also been discussing with the fuel fabrication. One of the problems they have, of course, is how to use individual data that they might have on a worker to correct the records. That is perhaps not the true recording of the worker exposure, and we ask that at the end of the year the record be submitted to us.

One of the things that they raised with us was whether or not some delay of that record could be allowed, so that if they were to gather two more quarters of data on an individual worker, they could, in fact, get a better feel for what the yearly component of the annual dose was, and not have to make an inappropriate correction in that.

We are still thinking about that, but we think that this is perhaps one way to accommodate him without sacrificing what our intent was relative to the 50-year dose commitment.

One of the changes we have made relative to the plant special exposures, and I might say that there was concern when we went to the regions as to the industry might view the plant special exposure. We have

taken that information from the regions. We have had discussions with the Atomic Industrial Forum. We think we have a plant special exposure requirement that is, in fact, implementable. The industry doesn't see any problem with it.

I might also say that they were very reluctant to use the plant special exposure, and that is what we were trying to get them to do. In the regions, they have expressed some concern that it might be misused. We as yet don't see that it will be particularly misused.

One of the questions that was raised to us relative to the plant special exposure was the reporting being to the regional office. Some concern was expressed as to what might be reported, if a journalist wished to make a big case on the plant special exposures. That was of some concern.

What we have said now is that the records on plant special exposures would be held within the facility and would be made available to the inspectors, so that we could get a feel for that. It might be that we will just require that a letter be sent with some details if, in fact, they have used the plant special exposure provision. But we didn't want to have a record submitted to each regional office in such a way that

they might be misused.

In thinking about the medical exposures, one of the concerns that we had was the number of areas in which it occurred to us that we were writing a broad radiation protection standard, but we were rather focusing down on the medical exposures in a way that was perhaps unnecessary, in appropriate, I should say, to the Part 20 revision.

So what we are now considering is that we would -- As some of you may or may not know, there is a revision of Part 35 underway to give the control of human exposures to byproduct materials. That revision is underway, and it is a little bit further along than Part 20. But it would seem to us to be more appropriate for that regulation to address this rather special requirement that we have put in relative to medical exposures.

For example, the control of high radiation areas associated with therapy patients, how to handle the sewage disposal of the patient excrement. We feel that these would be more appropriate if they were incorporated into Part 35. So we will be looking at ways to do that.

I will tell you a little bit about where we are going. The status of the rule is that we are still

working on it. It still has a long way to go. We are developing a viable alternative to the present Part 20, we think, which we described some of the problems.

We will, of course, have to address the overall question of the cost of implementing the rule. We are addressing that. I don't recall if I brought it up before, but we have amended or tied into an EPA contract that they have been looking at relative to their own proposals back early in 1981. But that particular study did not address some of the NRC proposals until we have been able to tie into that. I am not sure, but I think it is Cohen Associates, which is now part of another consulting firm.

We have gotten a lot of reports from Mr. Cohen in which he has gone to licensees and sit down with them and discussed at great length the cost of implementing the revision to Part 20, as written in the some earlier drafts and also in the August draft.

We have also contracted with Oakridge National Laboratories for the value impact statement which we will need when we go to the formal review process within the Commission. They will evaluate Mr. Cohen's analyses as well as the additional information that they have collected relative to the cost and the benefits of the revision as they see it.

We essentially have that part of the activity underway. We will not have that information except for Mr. Cohen's information. We will have not have a draft value impact statement when we start through the review within the NRC at the division level. After division review, at that time it is sent out by Mr. Arsenault, our division director, to other divisions at NRC to get their views.

I might say, within the NRC, we have met with NMSS and we have also met with NRR and discussed the intent of the revision, and we have gotten feedback from them. We did not ask them at that time for any type of commitment either for or against the rule, but we did get some valuable input from them.

I have sort of run through some of the highlights of where we are. My colleagues and I, if you have some questions, we will be glad to answer them. We are looking forward to hearing both the DOE presentation as well as EPA. We appreciate that it is one of your objectives to get the interested parties to talk because this is important.

Thank you.

MR. MOELLER: Thank you, Bill.

I have a couple of questions. You say that it has a long way to go, and you have also commented that

it has not been formally reviewed by the other components within NRC. Will it be reviewed totally within NRC before you would plan to publish it?

They will all have to review and sign off, in essence.

MR. MILLS: Yes. In the publishing of the rule, I am not sure if they necessarily have to concur in the content of the rule, but they would have to concur in the publishing of the rule. I know that in EPA, you could publish something with non-concurrence by the Administrator, but I am not sure that that is true in NRC.

MR. MOELLER: How long might that take?

MR. MILLS: We are shooting to get this division review underway, so that in the month of December, which is kind of a slack month, we hope to give the reviewers a chance to enjoy their holidays with our version of the revision.

We have discussed this already with many of these people, and we think we have reflected their comments already. I think that this next review will be more or less addressing the broader issues rather than the smaller details. I would not hazard a guess as to how long within NRC such a review would take place.

As far as us getting a package which we are

satisfied with within our branch, we hope to get that out, or we will ge it out before the end of this year.

Herb Parker.

MR. PARKER: Bill, let me say first that I come at this from a position of bias. I am a member of the NCRP Subcommittee No. 1, and I feel that that group very recently came to a solution which is far superior to the wholesale swallowing of the ICRP system. I realize that you cannot prepare a regulation on a system that has not been published. I would have hoped that you could wait about two years when it is available, but I also appreciate that you have pressures in the other direction.

So really the remaining question is, if we support your going through with this, how willing would you be to redo the whole thing to a far superior system two years from now?

MR. MILLS: I appreciate those remarks, Mr. Parker. I would hope that any time an improvement in the system of radiation protection occurs that the NRC would be flexible enough to recognize those changes and to implement them into the rule. I would guess that it is very likely that the hearing process for this revision is going to be a very long one. Therefore, some of the NCRP views have to be taken into

consideration for the scientific respect that they have.

As to whether or not we would change the rule, or how long it would take us to change after looking at the NRCP document, I would hope there would not be a situation where the NRC would not take it into serious consideration. If we have to go back to the drawing board to get a better system, I personally would be in favor of that.

The important thing, I think, at this stage of the game is that we had a system to us by the ICRP in 1977. It has problems. We think we have taken into account some of the problems. We feel that there are some revisions that we have to make in the current Part 20, and we need to move the process along. Hopefully by doing so, we might be able to step up the NRCP to get its report out.

MR. PARKER: Thank you.

MR. MOELLER: Any other questions? Jake Shapiro?

MR. SHAPIRO: For many decades, we lived with a cap of 15 rem as a single organ dose. Your revision essentially increases that cap to 50 rem in those cases where the statistic gives you a level above that. Have you, in addressing this, received any input from the

industry or from other sources that in fact the 15 rem was too low a limit to live with?

MR. MILLS: I will ask Bob and Walter to pipe in, as they have done most of the discussion.

We have not seen nor heard that that was a particular problem. I think what it amounts to is the fact that the 15 rems is calculated as an annual dose on the old ICRP-2 model, or perhaps the recent one. But, in essence, what it means is that with the ICRP 30 and 32 models, the doses would appear to be much larger. I have not looked at it in terms of what the overall risk differences are, if you look at the 15 rems under the old system.

We have not received any indications that the industry has any difficulty in meeting the 15 rems. But I am not so sure. For example, in the case of the fuel fabrication situation, they don't actually report to us, but they give us how many MPC hours during the year, and it would depend on how we calculated that MPC as to whether we use the new information or the old information. But I don't think that they raised it as a particular problem.

MR. SHAPIRO: As I read it, the shorter lived materials, whether it is a few months or a couple of years, your regulation would allow repeat a 50-year

working dose provided there as no external radiation.

MR. MILLS: Right.

MR. BAKER: To clarify that just a bit. The new system, of course, is based on what Herb would call a quasi-risk rationale, it is not a purist type system by any means, but nevertheless what we believe to what we believe to be very close to a risk system.

There are a number of changes. For example, we are now adding, if you will, the external doses plus the effective internal doses, I say effective because the dose which is the surrogate of this is based on a common risk internal and external.

So this is a whole new system. Some of the values have gone up, some are down, and some stay about the same. It is not as straightforward as comparing, let's say, the permissible dose on the present system for specific organs. In the new one, there is a cap, but there is also a multiplicity of internal organs for the doses which are weighted and summed.

So the two systems are so different that I don't think a simple comparison like 15 rems as compared to a 50 cap is truly valid. This probably doesn't clarify your question, but it is more complex than a comparison.

MR. SHAPIRO: What I am saying, as I read it,

though, it will result in higher organ doses than were allowed before, especially with nuclides that tend to concentrate in a single organ, perhaps the lung. What I am asking is, have you had indications, aside from any other changes, from any source whatsoever that a 15 rem cap is in fact too low? That is the only answer I am really interested in.

MR. BAKER: I don't know that that particular question has been raised. More nearly, one compares the MPCs in the current rule with the derived air concentrations in the old rule. As I said, some of these go up, some of them go down, and some stay about the same.

That is really the only significant comparison that has been made. One has not compared doses to a particular critical organ now in the present system, with the current analytical models, and so forth, that are used, with the new models and new limits. But rather it is one of comparing you recapitulations.

MR. MOELLER: Herb Parker, and then Jerry Ray.

MR. PARKER: Bob, I think you put words in my mouth when you say I have referred to the ICRP system as a quasi-risk system. I would call it strictly erroneous risk system based on what we had as knowledge in

approximately 1948, rather than the knowledge of 1982.

MR. MOELLER: Jerry Ray.

MR. RAY: Dr. Shapiro's question stimulates one in my own mind, and it reflects my ignorance. I think it was stated quite clearly.

Evidently you have increased some limits. Could you give me the bottom line in the exposure, say, to a worker over a 20-year career. When he walks away from the plant, will he have significantly higher biological damage incurred than under the new rules than he would have had under the old rules?

MR. MILLS: My impression is, if he is working in a situation where most of his exposure is due to external, there will be no change.

MR. RAY: Even though certain limits of exposure have been increased.

MR. MILLS: One could say that he will walk away with a lower dose because of the fact that we no longer rely, for example, on 12 rems as a year, which is an operating kind of thing, or 3 rems a quarter. So with the external, he probably walks away with a little bit less.

In terms of the internal exposures, it is hard to say because unfortunately we don't have a lot of good data. Except for the MPC value, we really don't know

what the dose has been to the worker from the internal emitter. It is highly variable with the individual.

What we are doing, I think, is giving more assurance that, in fact, the limits are being met for internal emitters.

MR. RAY: You mean that you are more prescriptive now in the controls?

MR. MILLS: Yes. The controls, by requiring a recording of the dose for the internal emitters in the consideration of the 50-year dose limit, we in fact require, I think, a much stronger requirement which we can relate to relative to the what the worker's history has been over 20 years. We think that that is where the importance lies.

MR. RAY: In your discussions with the various nuclear community organizations, do they reflect their concurrence with this philosophy or this conclusion?

MR. BAKER: I think that our interactions with the nuclear community have been pretty resolved the philosophical as well as the operational problems for the most part as they have existed.

I would like to say just a word on you other question. One of the big changes between the old Part 20 and the proposed revision has been a requirement for ALARA, that is sort of an admonission that it should be

as low as achievable.

Then in order to truly cause this to happen, you will find a series of requirements which would cause things to happen, cause actions, cause reports, cause different to happen below the limits. It might be an evaluation to see why certain doses have exceeded certain levels. These are not limits below the limits, but rather action points below the limits.

So we think that these progressive pressure points below the limits will indeed do what we wanted to do to indeed find the levels that are as low as reasonably achievable. This is done, as I said, with a series of reference levels that are action points, or reporting requirements, or whatever, that are below the limits.

What happens then is that the MPCs then become essentially conversion factors, and they should not be looked upon as speed limits where it is all right to go up to some point, as one could read in the current Part 20. Rather, indeed, the emphasis throughout is on doing things as far below those limits as is reasonably achievable, and we are trying to make that something meaningful rather than just a phrase, and we think we can do it.

MR. RAY: Let me see if I can say in words

that I understand, if I can indicate my comprehension of what you just told me.

I gather that what you are saying is that you are setting up a system such that you motivate the licensee to insure protection of the worker, or establish exposure conditions such that he would be below the maximums, and thereby improve the working conditions of the individual from the viewpoint of exposure. Is that what you are saying?

MR. BAKER: We sincerely believe that we can do that. We think that we can do it by setting these reference levels which are actions levels. For example, we will have levels where, if it is exceeded, the licensee would not be cited for exceeding a limit because it is not a limit, it is below the limits, but it is a level which is exceeded which would cause the licensee to [illegible], for example, why he is, what he is doing to keep things as low as is reasonably achievable.

He would have reporting things so that we could look over his shoulder, and it could be that he is perfectly justified in being at that point. But he has to look and verify this. We think that this is the proper route to go.

MR. MOELLER: We will take one more comment,

and then we will move on to the next presentation.

Jack Selby, did you have a comment?

MR. SELBY: Yes.

I think that it also should be noted that this discussion of the 50-rem cap, that not all limits have been raised. One very important one, that is to the extremities, has been lowered from 75 to 50. So it has not all gone in one direction.

MR. MOELLER: Thank you.

Ed, the EPA people, I rather, are not here, so if you don't mind.

Bill, excuse me, is this an okay place to move on?

MR. MILLS: It is up to you, Mr. Chairman.

MR. MOELLER: I would like to because I think many of the individual points to be raised will be raised as the discussion progresses this morning.

So, thank you very much.

You have had so many meetings, I wonder if you could meet with Herb's NRCP and pick their brains before they publish what they are going to publish, so that you know.

MR. MILLS: We have already met with NRCP once.

I have talked to Lawrence Sinclair since then,

and we are very much interested in NRCP's view. We appreciate your comment, and we certainly will continue to do that. We are very interested in their help.

MR. MOELLER: Thank you again, Bill.

All right, we will move on.

Let me repeat, while Ed comes up, I am sure the subcommittee members and consultants will have or do have a variety questions, but I do believe that most of these will come up during the course of our discussions.

MR. VALLARIO: Mr. Chairman, members of the panel, and members of the public.

My name is Edward Vallario, and I am the Department of Energy's Group Leader for health physics, and we represent some of the same views of the Department on the proposed change by NRC to 10 CFR Part 20.

I would like to note that the Department fully appreciates the opportunity to present these comments. We think that it is quite constructive to get into a forum like this and attempt, perhaps, to use it as an umbrella to resolve some issues that we find really quite significant.

We believe that there is a wealth of practical experience out in the universities and laboratories, and

we think that this is indeed needed to assess the technical adequacy of any basic emission detection standards. I say this in the context of the practical experience that people have in the laboratories, and so forth.

In this context, present here today are the principal health physics representatives from three major DOE laboratories. From Savannah River-Dupont, we have Mr. Rosco Hall. From Rockwell, International, Rocky Flats, we have Mr. Robert Yoder. From Battelle Laboratory, we have Mr. Corley, who will focus on the operational experience as regards the environment question.

Mr. Ken Heid is from Battelle also. Most of you know him, he has been a principal in the area of internal dose assessment. He will represent some views that were expressed at an IAEA subcommittee meeting, views reflecting the European concerns.

Finally, we have Mr. Selby, who most of you know, who has a very broad background in health physics.

These laboratory principals will provide the operational backup data in support of the Department's views. I will attempt to convey the concerns that we have, and then proceed to have the people from the

laboratories present the data that I think you would be interested in seeing.

First, to place our comments in proper perspective, we wish to commend the NRC staff for some very excellent features reflected in their revision. These are the presentations on the de minimis levels and the concept of setting both and internal and external exposures, both of these have been overlong in coming.

We woud note, however, that there are some features of the revision that present some very, very serious operational problems to the Department, which really don't have any gain in safety.

I plan to cover these areas. They depict the total position of the Department. In particular, the application of restrospective versus prospective dose limitation system, problems associated with the 50-year effective dose equivalent as it relates to the well-retained, long-lived nuclides, and any number of problems in applying these concepts in terms of radiation dose management.

We were a little surprised, and I will go into this in some detail, to hypothesize that under the proposed revision it is conceivable for the fetus to receive a 3 rem dose. I will get into that.

Then, of course, the individual monitoring

requirements appear to go in the opposite direction from where we feel monitoring requirements should be going, and I will get into details.

Then, of course, the bottom line, and I was pleased to note that Billy Mills said that one of the things they are going to consider is the cost associated with the system. We are here to convey to you that this is a rather serious matter, and we are talking about tens of millions of dollars. The operational people will convey this.

With that, I would like to begin, the department has a fundamental difference of opinion with respect to the application of ICRP 26 dose limitations. The stress appears to be on the work place rather, in my opinion, on the individual. In this sense, the proposed revision to 10 CFR Part 20 as an application of ICRP 26 is both a retrospective and prospective dose limitation system.

Members of the ICRP Committee have gone on record reinforcing the use of the ICRP 26 for planning purposes, for prospective application, and noting that the prospective dose limitation system is intended to provide guidance for the derivation of secondary standards, and the planning and control of work involving potential radiation exposure.

However, by proposing the use of ALIs to assess and record an individual's occupation exposure, the NRC, we feel, has inappropriately applied ICRP-26. In support of this, I would like to quote three references.

The first one relates to a statement from 26, which conveys the intent that air sampling as an integral part of this dose assessment system, and it has to be, and here ICRP 26 states: "Only in a few circumstances can the results of programs of monitoring of the workplace be used to estimate the dose equivalents or intakes of individual workers. The use of derived or authorized limits is essential in the interpretation of environmental monitoring programs."

I would like to refer to another reference from Dr. Bill Baer, whom all of you know, and this was at a recent meeting of the ACRS on June 23rd, in which the NRC discussed the 10 CFR Part 20 revision.

Dr. Moeller stated, "Let me put words in your mouth, and correct me if I am wrong, the DACs are simply a mechanism for controlling operation or looking at it in terms of --

"Dr. Baer: For planning purposes.

"Mr. Moeller: Planning and designing controlling operations.

"Dr. Baer; Exactly."

I would like to go further and refer to the statements that came out of the IAEA working group. This was a working group that was constructed to look into the implementation problems of ICRP 26. Ken Heid was the chairman of the working group of IAEA, and he is going to get into this in some detail. But at this point, I think it is sufficient to note that all members of the committee, except for the NRC member, voted against the use of the 50-year dose commitment.

I would like to get into the application of perspective versus retrospective. There is some decided advantage, as you all know, in the application of ICRP-26 as a perspective application, and one of the more significant things is that you can determine occupational risk. But we see some very serious problems associated with using this system for retrospective applications.

One of the important problems is that the ALIs are based on standard reference man, and as we know the distribution of radionuclides in the body is dependent on a number of individual parameters, such as age, size, sex, and metabolic patterns, occupational exposure, isthmus should be based on each individual's metabolism. When ALIs are used to assess an

individual's exposure, this is difficult, if not impossible.

In the case of long-lived, well retained nuclides, the development of an individual model may require years, and you may not be able to assign the committed dose in the year of intake.

The problems associated with the long-lived nuclides are related to the 50-year dose provision, which I will now discuss, and in this sense, we turn to the next viewgraph.

The 50-year dose commitment presents some obvious problems. Clearly the issues are the extrapolation of the 50-year dose to the first year, where we feel that affords no greater protection at all. What you are doing essentially is assigning for exposure to the first year of intake, an exposure that has not been received.

My comment related to the the 50-year committed effective dose equivalent is specific only to the long-lived nuclides. For the short-lived nuclides, the system works quite well.

There are some obvious measurement problems associated with this. Frankly, the measurement systems are inadequate. In this sense, let me talk to first the air sampling mode. There are two ways of doing this.

One is, of course, the continuous rapid response systems.

This is material that was prepared by Livermore. Lawrence Livermore conducted a study and they found that typically for plutonium, for example, the continuous air monitors are really quite inadequate. The integration time that is commonly used is five minutes.

If you will note the particle size in the respirable range from 0.6 micrometers to 2.4 micrometers, we are talking anywhere between 7.3 and to 95 MPC hours. So that is clearly not a system that could be used for purposes of monitoring in the sense of air.

With respect to the other mode of air sampling, you can achieved sensitivities of 0.10 of DAC, but here again you are talking about for over a week in the case of plutonium, for example.

If you take an eight-hour sample, you pull it, you count it, and you wait 24 hours for decay, and you count again, and then you wait another week and you count it again. so you are talking about assessments well after the fact.

Going back to my original point, if your focus is on the control of the workplace, the system works

fine. But if your concern is the individual worker, this system does not work at all. So that is the problem that we have there.

With respect to the next area, in vivo assessment, levels to which you have to conform are well below detection capability by a factor of ten or more, and you have similar problems with bioassay.

One of the very serious problems that we see, and Dr. Yoder and Rosco Hall will be focusing on this quite a bit from the operational experience point of view, so it is sufficient to say that the control treatment of low exposures is going to change dramatically with this system.

We can see that in cases where someone receives 200 millirem, and this is quite common when we are talking about intake, you may have some minor load breaches or things like that, what happens in this new system is that 200 millirem becomes 10 rem. So low exposures are now going to become technical over-exposures.

Then, of course, you have got the next problem, and that is the management of subsequent years exposure. This is a problem. You use, according to the Part 20 revision, the metabolic models, unless you have other means, and in the case of plutonium, as we all

know, it takes years before you can come up with accurate information. But the system that is being proposed dictates that you find some exposure in the first year of intake.

What do you do, years later you come up with another number, then you come back and you retrofit the exposure. I can't begin to tell you the problems that this represents.

What is the effect on health physics practices as we see it today. Clearly, we think there is going to an ineffective utilization of the workforce. The program today is based on true exposure, actual exposure.

The system that is being proposed, in the case of long-lived nuclides, in in-take you would be talking about a management system based upon exposures yet to be received, if you will. In the case of workers, some will have to be removed for the year.

So we end up with ineffective utilization of workers based on the system that we don't quite comprehend.

Of course, the credibility of detection control is the thing that bothers me. The current program is based on, as I said, actual exposures. In fact, there must be millions of dollars being spent in

enhancing accuracy of dosimetry. NRC is involved in a certification program, we are too, to try to refine our measurement system, to try to learn more about these low dose exposures, and so forth and so on. Then we come up with a system now where we are talking about holding the line, and maybe going a little higher in terms of monitoring requirements, and forgetting about data with reference to rem. We have a problem with that.

Of course, the net effect of the 50-year dose commitment, as I indicated before, our cost estimates are in the tens of billions of dollars, this is certainly not reasonable cost, and we don't believe there is any gains from the safety point of view.

The next area I want to talk to is radiotion dose management. I will not go through this again. I did talk to the problems of handling non-routine exposure data, which is a severe problem.

I believe the revision states that if you have a technical over-exposure, if you have 25-rem once in a lifetime dose, you charge it against. But in our exposure experience, we see where that would be wiped out immediately, and then where do you go. So the problem of technical over-exposure is a real one, and we don't know how to handle it under the new system.

The fetus dose thing is an interesting one,

very interesting. The monitoring requirements state that you monitor where the deep dose is greater than 500 millirem, and where your intake dose is greater than 1.5 rem. I can postulate a situation, when we are talking about a group of workers now, who will not be required to be monitored, and this group of workers will include women.

I could postulate a situation where clearly a female worker, who is pregnant, unaware of it for the first couple of months, working in a non-monitored environment based on the monitoring rule or the criterion in the proposed rule, could receive, where the age specific parameters are known, 0.49 and 1.0 rem, you could possibly come up with 1.49 exposure, and this is not known, but she is not monitored.

Then she declares herself, and based on the proposed revision, she is then restricted to 500 millirem during the period of gestation. So you are talking, in the case where age-specific parameters are known, conceivably a dose of 2.00 rem to the embryo.

In the case where the age parameters are unknown, as you indicated in the revision, the embryo is twice sensitive, so the effects on the embryo are twice, so you multiply the committed effective dose by two, and it is conceivable, in this particular case, where the

age-specific parameters are unknown, that the embryo would have received something on the order of 3 rems.

I submit that the control in the case of the gestation dose needs to be reassessed in this context.

Going back to radiation dose management, clearly another problem we can see is that the records will reflect the anomalies in data, with the 2.0 rem monitoring rule and the 500 deep dose, and the 1.5 intake dose. There will be a body of data that will be unreported, that will not be reflected in the exposure records of individuals.

Again, it is interesting, the revision states that if an individual, coming from one nuclear plant and going to another, and there is no exposure data, that individual will be charged 1.5 rem per year. So there is a tremendous inconsistency. Now we are face with the problem of a fellow being charged 1.5 rem, and we don't know what his exposure is.

So we see quite a disruption in the data that goes into the records, and this of course will impact on epidemiology. ALARA focusing has been in the area of less than 1.0 rem in the Department of Energy. If you have been observing our annual summary report, there was something like 98.6 percent of our radiation workers received less than 1.0 rem, and we are trying to improve

in that area.

The ALARA application is in the less than 1.0 rem region, and if we were to implement a system such as that proposed by the Nuclear Regulatory Commission, it would have a detrimental effect on ALARA, and they would no longer be focusing on an area in the low dose region.

Now to the individual monitoring requirements, these are the things that are presenting problems to us. There is a 30 percent monitoring criterion that we have problems with. Of course, the effect on the management requirements, and I will get into that in detail with the next slide, but the effect is, of course, in eliminating a lot of information and creating a lot of anomalies, exposure trend analysis is going to be impacted upon.

The Department at the present time does not have any such criterion. They record any positive exposure intake and we track this, and it becomes a part of the exposure status of the individual, and our control system is a positive one and reflects this type of practice. Of course, the impact on the monitoring requirements, as I indicated before, is the ALARA.

I am hoping that this is correct because we had a heck of a time trying to focus on the monitorig

requirements with the use of the various terms, and that is another problem.

In the case of the monitoring requirements, the problem here is that good practice, in our opinion, dictates that you report all measured exposures. The system doesn't require that. Implementing the 30 percent criteria and the 500 millirem deep dose criteria will effectively eliminate about 50 percent of the total man-rem estimates in current information.

I would like to tell you that the Department has been going in an entirely different direction. We do have this 10 percent limit, and Billie properly mentioned that the reporting requirements are not that much different from what they had in the past.

Now that may be true, but I think there is a need to reassess monitoring requirements in light of many things, the recent activity of the Office of Workmen's Compensation Program. the Hatch Act, the off-site litigation problem. There is a tremendous focusing on low dose, and the compensation cases are being litigated at levels below 1.0 rem.

We, in the Department, have been looking into this in connection with our RIRS upgrade program. This is the radiation information record system. One of the very important considerations in the Department that we

are looking at is lowering the monitoring requirements to 100 millirem per year.

It is true that we need to get away from monitoring everyone because of the cost associated with this. But, we believe we can effectively accomplish this end, not by raising the limits, but simply by lowering them from 10 percent of the limit to 100 millirem per year.

So we are going in an entirely different direction because we are interested, beyond the subject of data, in enhancement of data for epidemiology studies. We are interested in reflecting a more positive control in the workplace, and I believe when you do this and you record all positive exposures, you are effectively accomplishing this. I think when you rule out exposures less than 2.0 rem, you are not accomplishing this, and so forth.

We want to make you aware of the fact that our position on the monitoring has to do largely with the opinion that we feel that the monitoring requirement levels should be effectively lowered.

The bottom line of all this is that we are concerned about. Of course, there is programmatic cost and that has to do with the workers. In the case of the plutonium production facilities, you are talking about

curtailment, to a large extent, of operation, to go through some sort of transition period, to remote, or to modifying the remote systems to be able to comply with the 50-year dose commitment.

This is a very serious matter because you are talking about plants oriented toward defense programs and national security, and you are talking about retrofit costs on the order of tens of billions of dollars.

This is not an off-the-shelf number. We did look at this for the second time in connection with this NRGC petition. Here they are attempting to reduce the dose equivalent to 500 millirem, if you recall that business a couple of years ago. But a new assessment has been made and these are the dollars we are talking about. So the facility costs are quite high.

Let me get down to the litigations. I have an affection for the attorneys and the lawyers because this radiation business can get you into a lot of trouble. You always feel more comfortable when they are around.

This business of compensation, as I mentioned before, is a very serious matter. We can see, for instance, someone coming into court, alleging cancer, if you will, or some physical manifestation associated with radiation, and the judge says, "Can you produce the

records of the individual." We find that that individual, while he worked in a radiation area, he was not required to be monitored and there is no record associated with the individual. This problem could be a serious one.

The technical overexposure is again another problem. In the case of the long-lived, well-retained nuclides, when you make this extrapolation, you go from low exposure to something that is higher, and the fellow develops cancer. Incidentally, that technical overexposure becomes the dose record of the individual, as we understand, and that is the number you work with. We can conceive that that could be used in a court of law to litigate a claim, and it is not really reflecting the true exposure of the individual.

I have taken an awfully long amount of time to go through this. Let me now turn this over to Dr. Yoder, who will present some operational data.

MR. AXTMANN: I have a question, Mr. Chairman.

MR. MOELLER: Could we ask a few questions at this point?

MR. VALLARIO: Their data is in support of what I have been saying, so you may get the answers from these gentlemen, and it will save time.

MR. MOELLER: Are you willing to wait, Bob?

MR. AXTMANN: Sure.

MR. MOELLER: All right we will withhold.

MR. PARKER: Could we dispatch an emissary to battle with the vacuum cleaner.

MR. MOELLER: We have done that, Herb, and what we have been told is that the air conditioning system is on the fritz, and they are in there trying to correct it. We will try to obtain a projection as to how long it will take. I know it is disturbing, but I hope you will bear with us.

Roughly, how long will each person require?

MR. VALLARIO: About 15 minutes.

MR. MOELLER: That is for five people. You are talking then of another hour and 15 minutes.

MR. VALLARIO: Yes.

MR. MOELLER: Let's get started, but try to keep it as short as you can.

MR. VALLARIO: Alan Richardson said that we could have the time.

MR. YODER: Mr. Chairman, and members of the panel. I am pleased to be here. My name is Robert Yoder, and I am Director of Health Safety Environment for Rockwell International, the operating contractor for the Department of Energy's Rocky Flats site.

We will discuss with you this morning that some issues that have developed as we have reviewed the NRC's proposed 10 CFR 20 document dated in August. Because their thinking is continuing to evolve, so the comments that I may make may be changed or may have already changed. However, that is the last draft that we do have.

I would like to show you a few slides with regard to a comparison of the information regarding the ICRP 30 and the 10 CFR 20 document. The derivation of the information came from codes that at Oakridge which I presume are owned by the ICRP, and anyone can make calculations on them.

However, we noticed that due to the rounding factor there are changes with regard to the annual limiting intake, with regard to plutonium 239, based on our calculations. While that may not look too important for Class Y materials, which are the ones that are retained for a long time in the body, this represents about a 30 percent change or reduction in the limit.

When one takes this ALI and looks at the information which one can obtain from the calculation on the dose to the bone surface, one finds that ALI would have a committed dose of 32 rem to the bone, rather than the 50 rem that is actually stated in the limit, because

of the way the values are rounded and the way one actually can make the calculations.

If one looks at the whole body effective dose, and I apologize for the terminology in the sense of dose, this is the weighted annual dose for the Class Y materials, and the value would be about 2.9 rem for the soluble materials, and the value would be 2.2 rem per year for the total dose commitment for the ALI.

The amount of material in the lung from an acute ingestion -- I will restrict my remarks to acute ingestion, because most of the intake is from acute events rather than chronic exposures. These also are the ones that are the easiest to measure. If I had problems with these, the problems were more severe with the chronic measurements.

In terms of the initial long-term deposition, one is talking about for the Class Y material it is about 1.4 nanoCuries, and for the Class W material it is about 0.7 nanoCuries, and at the end of the year the amount of material that has already been transferred to the bone represents about 0.9 nanoCuries for the insoluble and about 0.5 nanoCuries for the soluble material. So the material is moving.

MR. PARKER: Bob, are these the new ICRP numbers you are talking about?

MR. YODER: Yes, these are the values that come out of ICRP 30, which is the calculation from ICRP-26.

MR. PARKER: 10 CFR 29, are those new numbers, too. those are not old numbers?

MR. YODER: Those are the numbers that are in the August draft.

If we look at our ability to measure plutonium in air, we find in the air of the MPCs, the DACs are approximately the same, in fact it is relaxed just a little bit for the insoluble material. The ability to detect this material in the air for long-term sampling is about one-tenth, roughly, of the DAC. So one can measure the material in the air.

As Ed mentioned, it takes perhaps a week in order to be able to analyze one of those samples to come back and determine what was the value at some previous point in time.

If we look at our experience, we take about 60,000 air samples per year in the work environment, and on a monthly average we have about 58 of those samples that would show -- 58 events, rather, that would have air samples associated with above the DAC or above the MPC level.

Of those, 46 are those that we have

anticipated at above level air samples, so we have taken precautions, we have provided air suits, or respiratory protection, or other requirements, to minimize or eliminate the possibility of intake. We are then left with 12 events per month in which we have to conduct an investigation in order to determine was there a potential exposure.

If we look at our ability to measure in vivo radioactive material, particularly plutonium, for of initial long lived activity in the lungs of about a one micron particle size, the 10 CFR 20 numbers that I referred to a moment ago are these. We can infer from our lung counting at Rocky Flats about 1.3 nanoCuries of plutonium. That is an inferred measurement based on our ability to measure amoritium which goes with plutonium in most cases, and if that amoritium is at a thousand part per million.

If the level is lower in amoritium, our ability to determine plutonium or inferred plutonium is less. If one has no amoritium in the exposure -- in the material, then we are well above 16 nanoCuries in order to measure plutonium in the lung, and that 16 nanoCuries is the present value for the lung burden to get 15 rem per year.

This problem is compounded somewhat if we say,

at previous burden, or no previous exposure, we can have a limited detection from 1.3 nanoCuries. If we have 10 percent or 25 percent of the existing values in the lung, our limited detection goes up because we are trying to measure a very small increment on a background that already exists. So one has the statistical problem of evaluating a true change in the deposition level.

We have, in this case, 10 percent of lung burden, and we have about 170 employees in that category, we have about 72 in the category of 25 percent.

If we look at our ability to use bioassay as a technique again these particular materials, the proposed ANSI standard has a minimum detectable performance of a minimum detectable activity of 0.16 deeper rem in a liter of urine in a 24-hour sample of urine. We find that for the class Y materials, at 90 days or 180 days following an ALI, this would assume you had an ALI and now know about it until your program caught up with that individual, and you would be unable to detect it from the class Y materials. You would be able to measure it for the class W materials, or the relatively soluble materials, up to about 180 days.

Again, for periods of time of one, two, or three years following the intake, one has an decrease in

sensitivity with regard to the ability to monitor that material that is there on top of an existing burden.

We do not have very good experience with regard to using bioassay, particularly urine samples for insoluble materials in terms of inferring how much material is in the body. Here we are showing the estimated urine analysis of how much plutonium was in an individual versus the extrapolated tissue analysis that was obtained through trans-uranium registry program for these individuals. Notice that our estimates, in every case, are higher than the actual material there, and in some cases, the deltas are quite large.

The impact to use these data that we may have with this type of an error, we would be assigning a committed dose quite a bit higher than that which may actually be the estimated dose to the individual.

With regard to the problems we are having in terms of our technical matters is that the detectability depends upon how much is already in an individual and what that level is in the individual. New uptakes will be very difficult to interpret and to get a good and accurate measure of the change in the system.

Urine measurements have not been successful to infer lung deposition, and we have some problem, but this is really an administrative problem, of trying to

figure our when you start and stop the year. You cannot handle 5,000 urine samples on January 1, and be able to maintain an operation. So there are some problems with that, but those are really administrative problems.

We believe that the sensitivity of measurement is not yet adequate to measure the very small increments of intake that are associated with the ALIs. The values here are calculated based upon acute exposures rather than a chronic exposures.

I would like to show you one viewgraph --

MR. AXTMANN: Before we go any further, I am not sure, after you compared urine samples with tissue analyses.

MR. YODER: Yes.

MR. AXTMANN: Analyses of what tissue?

MR. YODER: One was the data from the trans-uranium registry in which we estimated how much was in the body. This would be from the autopsy samples of lung, liver, and bone, where one determines from the urine sample how much is there. The question is, from autopsy what can you infer is there. So this is a composite for each individual of how much we thought was there.

MR. AXTMANN: There are that many autopsies every year?

MR. YODER: We have 50-some autopsies, and these are 12.

MR. MOELLER: This was representative sample, then, or is this all of your sample?

MR. YODER: We have 50-some samples, not all were exposed to soluble materials. Some were exposed to soluble, and some combination. What is tough is to get into the analysis of that data, this is trying to reflect some of the difficulties in inferring how much is in the individual by urine sample.

I am going to show you a curve that is in the ICRP 2 documents of a number of years ago, and I have put committed dose up here, which I really don't care whether the number is 50 or 30, it is the concept that I am looking at, for a short lived or for a material that assimilates fairly rapidly in the body, such as some of isotopes of calcium, for example, calcium-40. In a year or so, the committed dose that you are assigning is in fact the dose that the individual is receiving.

In this period, however, the dose that you are assigning has not been received. When one looks at plutonium as a material, the assigned dose, of course, goes on, and for every year we are assigning a 50-rem dose to the lung, when in fact the dose that is actually being received is represented by the small area located

right here, and after 50 years of exposure at the ALI, the dose does reach the 50 rem committed dose. After the individual leaves work, this curve should drop off as no more intake occurs.

The point I want to make is, with our difficulty in making measurements in this range, and our difficulty in making very small measurements of the change, we are assigning very large exposures to individuals that we have questions with. So we are forced to go back and ask the question, since I don't feel comfortable in assigning a dose that I don't know is there, what options does one have to deal with this particular issue.

Until we look at the operational impact of our environmental measurements, the room samples, our in vivo, our bioassays, I have not mentioned wounds, but the new document does at least give us some insight as to how one would handle events of that nature, we have some alternatives which improve the technology.

I was informed by a member of the NRC staff that we are going to have some major improvements in our urine bioassay measurement technique, which I look forward to seeing. However, they are still in the laboratory and have not been tried out in the field with regard to the applicability on a routine basis. We may

be able to improve that.

Our lung counting and measurements of materials on the lung, we are not seeing much opportunity in the next few years for major advancement in being able to reduce our MDA. Therefore, I have to look at the option of the modifications that can be done with regard to the activities we are now engaged in.

I do not feel it appropriate to assign a significant dose based on an air sample, taken several days before, with which we are kind of uncomfortable in terms of making a dose assignment. Therefore, we look to operations or activities in order to remote or automate those operations with which the employee is in close proximity to the radioactive material. We would, in effect, have to look at that option of removing the worker from the actual glove-box activity, free him in the control room or in more remote areas so that it can be separately contained and controlled.

Looking at the cost of these types of options, assuming we even know how to do the remoting of very complex activities, I estimate that at Rocky Flats we are talking in terms of $4 to $5 billion in order to achieve that. If I extrapolate that over the Department of Energy, to other plants that they may have which will require similar modifications, the costs will certainly

be in the neighborhood of $10 billion-plus, if one has to use that option.

Thank you very much.

MR. MOELLER: Thank you, Bob.

I think we will go ahead with the five individual presentations, and then we will have our general discussion session. So let's go ahead. We will have one more and then take a break.

MR. HEID: Mr. Chairman, members of the subcommittee, and consultants, I want to thank you for the opportunity to be here today to make a few comments.

Name is Ken Heid. I have 34 years of experience as a proffessional health physicist, all of which in the applied health physics end of the business. Included in that 34 years is 16 years as Manager of a Personnel Dosimetry Section. For the last two years, I have been Associate Director for the U.S. Trans-Uranium and Uranium Registries, responsible for the health physics aspects of these studies.

My comments today will be mine. I am not a spokesman for either Battelle nor the Department of Energy. Further my comments essentially will be aimed at the long-lived, well-retained radionuclides because, in my opinion, that is where the problem is, or one of

the main problems.

I will start out, I would like to read a quote from Dr. HUgh Dell, who is a member of the main ICRP Committee. In a recent publication, he stated: "In the practical application, release protection will be governed by national laws and regulations. There is a risk of confusion or conflict if those responsible for drafting or enforcing such laws and regulations are not fully aware of the original purpose of the basic recommendations, the assumptions behind them, and the significance of the concepts employed." I believe this statement is very prophetic.

Many groups have been involved in discussions and presentations or documents involving the ICRP 26 concepts that we are discussing -- No, we are discussing the 10 CFR 20 that uses as a basis, primarily, the ICRP 26 concepts.

I have two slides.

The proposed changes for internal dosimetry that have I have listed are 1977, when ICRP 26 came out, 1979 when ICRP 30 was published, and in 1980 IAEA convened a group of experts, so-called, to discuss this, and they formed Technical Committee 334 that talked about that.

In 1981, we discussed the EPA proposal. Now

we are talking about the NRC proposal for 10 CFR 20. In addition, we heard Dr. Parker mention the activities of the NCRP, and I am sure we are all looking forward to this, but so far they haven't published anything.

Shortly after the ICRP 26 concepts came out, they were mandatory in the European community, at least to the extent that they were told to begin the transition period. Each of them were given a date by which they had to comply.

During this transition period, the health physicists were desperately trying to figure out how they could implement these concepts. It was very easy to implement the concept on a prospective basis, but to try and come up with respective method for dose assessment, a meaningful and practical assessment, and one which they could compare with these requirements that were laid down on the 50-year dose commitment basis, was very difficult. They immediately set out a call for help, "Because we have to do it, now somebody tell us how we can?"

In response to their cry for help, the IAEA set up a committee in 1980. This panel was given the problem of trying to come up with some meaningful, factual, and reasonable method to measure or evaluate, assess the internal loads, and then compare with the

limits.

The group took the concepts of ICRP and found that they were acceptable for control purposes. I would like to elaborate a little bit on what Ed was saying earlier about the one negative vote. Everybody was in agreement that we could use it for control purposes, that is for management of the worker exposure.

As Jake Shapiro pointed out earlier -- I am sorry, I think it was Billie Mills pointed out earlier, there is basically little difference for control basis prospective use between the old system and the new system. We are still trying to divide up the permissible internal exposure and say, let's try not to get more than one-fiftith of that in any one year. That is what the MPCs did and that is what we are doing now. The numbers may vary a little bit, but the concept is not too dissimilar.

For dosimetry for short-lived emitters, the dose commitment and the annual dose are basically the same. There is very little difference. The real problem, and where everybody but the one agreed that it was totally unacceptable was for dosimetry for long-lived, well-retained radionuclides.

Here basically we are comparing a prospective limit with a dose assessment, and we are trying to

assess that dose at what it is going to be in 50 years, and this 50 rem for stochastic, which is really plutonium, is 50 rem over a 50-year period, or one rem per year as the limit. For the non-stochastic the high rem committed dose equivalent is 5 over a 50-year period, or one-tenth of a rem per year.

To further supplement the European picture, I might make a few comments about a meeting I attended just last week. Ron Kathren was there. There were three representatives from the UK, a representative for the Department of Defense, Ron and I, and then Bill Baer and Wright Thompson were in this meeting.

At that time, the UK representatives described their effort to try and make some progress. They had actually put lapel samplers on a few thousand people for a couple of year period and tried to see if there was any correlation between intakes as measured by the lapel samplers and uptakes based on measurements made for the individuals. They found absolutely no correlation, and I think that should not be surprising. Without a lot of additional data, intake does not relate to uptake.

MR. MOELLER: Excuse me on that. You are assuming that the lapel monitor did indicate intake, and you are saying that if it did, there was no correlation between the intake and the uptake.

MR. HEID: In some cases they did, and in some cases there was no activity there, but they did find some in fecal samples. They were collecting fecal as a primary means because that is a more sensitive measure for the bioassay.

MR. RAY: Why would it indicate positively in some cases and not in others? Do the different nuclides react differently?

MR. HEID: This was all plutonium work.

I think that probably the difference is particle size and ingestion. There are a lot of reasons you could have.

MR. RAY: The circumstances under which the ingestion took place.

MR. HEID: There are just a whole bunch of parameters that have to take to relate uptake to intake.

MR. MOELLER: Jack Selby.

MR. SELBY: I would like to respond a little bit more on that.

The lapel air samplers that we currently have available to us sample at the rate of one or two liters per minute, that is a very, very low flow rate.

There have been studies that have demonstrated that perhaps the lapel air sample is only looking at a

stagnant volume of air located near the surface of the protective clothing, and not the true air concentration that he is breathing.

MR. HEID: Their conclusion from the studies they ran was, they prepared lapel samplers and room samplers with the human data, worker data, was that air sampling was an excellent trigger for a diagnostic evaluation using in vivo and bioassay measurements for the individual, period. I totally concur with this conclusion.

When this was presented to the other members from ICRP, Bill Barren, Roy Thompson, their response was that ICRP had put out 26 as a prospective tool for management, for planning for design of new facilities, for planning and management of the worker exposure. It was not intended to be used on a retrospective basis. They were considering issuing a second document which would be for retrospective dose assessment.

They did not give us any indication of if or even when this might be published. They had run into problems, and we don't know where that stands. I hope that the NCRP will come through and give us some help.

The 10 CFR 20 proposal provides probably -- I think it does -- provides better capability for prospective control of worker exposure. However, again, I repeat it is not valid for dose assessme They are throwing out 40 years of experience where we use the critical organ dose concept. This has proven to be

effective in control, and I see no need to rush into this Why don't we wait until the experts come up with their findings and recommendations on how to do it on a retrospective basis?

The previous speaker went into the details, so I will just kind of recap the point I wanted to make. He was saying on his slides that an uptake of less than one nanocurie, I believe the number was .5, .6, in that range, nanocurie uptake, not intake but uptake, would result in a committed dose equivalent of 50 rem for bone. For plutonium, that is 50 rem for 50 years.

The committed effective dose equipment would be five rem. Both of these are from an uptake of less than one nanocurie of plutonium. The strict application of the 50 year committed dose will present the five health physicists with the following problems. These have been touched on, but I would like to repeat them for emphasis.

Often years are required to collect the data necessary for a meaningful dose assessment, especially when chelation therapy has been administered. This, if administered promptly, benefits the worker, but it sure is not a benefit to the health physicist trying to evaluate the deposition.

So, I can take one extreme case where the

treatment continued for several years, and we still don't have a meaningful measurement that we have been able to make through in vivo techniques.

Also, the chelation therapy will change the distribution throughout the body. What the chelation tends to do is remove -- still talking about plutonium, keep that in mind. It tends to remove the plutonium from the blood and the liver. It has very little impact or effect on the bone. It will block any additional deposition from going to the bone, but what already had been deposited there, most of it will stay there, so that now you end up with a case where the bone has a deposition, the liver doesn't.

When you try to apply this standard model to all of them, it is a very confusing result that you get. Also, the previous speaker mentioned that the state of the art does not permit assurance or detection at these reduced limits.

Just a few words on the impact on epidemiology studies, and I will broaden that out to include the impact on the U.S. transuranium industry, since I am involved in that. If we were to get health physics data expressed in committed effective dose equivalent for the internal exposure, forget it. There is no way we can try to compare the health phsyics data without working

backwards, making assumptions on what assumptions they used to arrive at that figure.

So, it is really going to cast doubt on the credibility that might be made in any such study as these.

One quick word on uranium. Basically, the same kinds of concepts would apply for uranium, but to a much lesser degree. Most of the uranium clears very rapidly from the body. Thus the annual dose and the 50-year committed dose are comparable. However, there appears to be a small fraction of the uranium that is well retained in the body. We have seen in vivo measurements for years after a person was removed. The clearance rate is much lower than anticipated.

In this particular fraction, it would fall into the same ball park as plutonium. The 50-year committed dose equivalent just does not apply.

In conclusion, let me just stress again that I would hope that we are not in such a big hurry to get this done that we don't wait for the experts to give us an answer that might end up with a much better product than what is proposed by the NRC in 10 CFR 20.

Thank you.

MR. MOELLER: Thank you.

Let's now take a break until a quarter of

11:00. And then we will resume.

(Whereupon, a brief recess was taken.)

MR. MOELLER: Let's resume the meeting, please.

For those who are wondering about the schedule, the people from EPA tell me that they will need roughly about a half-hour, so we are not as bad off as it might appear. Above all, though, when we have had people who have so obviously devoted a lot of time to preparation and who come here at great personal sacrifice to be with us today, my objective is to hear them out and to give them the time that they need.

So that will be the premise on which we will continue. We will move ahead then now.

MR. HALL: Mr. Chairman, members of the committee staff, consultants, I consider it an opportunity for me to come and express my views on the implementation of the proposed 10 CFR 20. I was with DuPont at the Savannah River plant during the startup of the production reactors, separation facilities, fuel fabrication facilities, the laboratories, and I have worked in those facilities protecting the health of DuPont employees and other DOE employees for the last 30 years.

I am currently the staff health physicist with

the primary responsibility for monitoring and determining the dosimetry or the dose equivalent received from radiation sources, both external and internal to the body, for approximately 10,000 employees at the Savannah River plant, the Savannah River laboratory, and other DOE facilities at the site.

This proposed revision to the 10 CFR Part 20 will certainly have a major impact on the Savannah River plant if an attempt is made to implement it in the form of the August, 1982, draft. Health protection for DOE contractors' employees can be improved significantly by the practical application of the prospective dose limitation system recommended by ICRP and Publication 26.

(Slide.)

MR. HALL: But, however, without some major changes in some of the proposed concepts and as 10 CFR Part 20 is currently drafted, it is unacceptable for the assessment of employee committed effective dose equivalent and the effective control of some of the significant occupational radiation exposures.

(Slide.)

MR. HALL: On this slide, I have listed some of the operational problems that Mr. Vallario has presented earlier, the plutonium intakes, air sampling,

bioassay, and 50-year dose commitments. I will briefly show some of the examples of how these are problems at the Savannah River plant operations.

The primary operational problems with the proposals are monitoring for the possible assimilations of radio nuclides into the body and the compliance with the dose limitation systems that are listed in Section 20.205.

(Slide.)

MR. HALL: We show here all of the confirmed assimilations of radio nuclides in the body of employees since 1972 at the Savannah River plant. These do not, except for the blue ones that indicate tritium, do not indicate any minimum amount. If we confirm an intake it is listed there, whether it be one millirem dose equivalent or ever how high.

Now, the blue ones indicate the tritium assimilations, and they indicate the ones that are above a limit, an administrative limit of 20 microcuries per liter, that would result in a total integrated dose to the whole body of approximately 100 m-rem.

The purple ones are for fission products. I guess the main reason our production reactors do not get any induced activity or fission products in the bodies of people is that our moderator is duterium that

contains tritium. When you project for tritium, there is no way to assimilate fission products.

By the same token, we have plutonium in our separations area, and the only way to keep plutonium out of the bodies of our employees is to keep the fission products that are associated with those. So, these uptakes result from accidents.

The green ones, for example, are for uranium, and it is primarily depleted uranium. These intakes are not necessarily above the TLV of the .2 milligrams per liter. In fact, if you expose the worker to one-tenth of 1 percent of that TLV for eight hours, he would exceed the ten micrograms per liter of uranium, which would be recorded on these incidents.

So the effective control that can be used and that is used is to preclude the intakes of radioactive materials into the body. However, you can see some worrisome red colors that have to do with plutonium and some orange colors that might have to do with the americium and curium. At least a couple of these orange curiums are californium 252 rather than curiums, but that is the same sort of transuranium nuclides involved in that particular case.

But all of the employees with potential intakes are investigated and the measured dose received

is placed in the employee's record. All radiation workers that are potentially exposed to radioactive airborne contamination are not only monitored, they are identified as radiation workers, and all radiation workers are monitored for both external and internal intakes into the body.

I think that the thing that may be shown is that with tritium, the DOE's guidance and requirements requires both the external and internal be added together, and we add the dose from all tritium assimilations. We detect tritium down to five-tenths of a microcurie per liter, which would be less than an m-rem or so exposure, but we take a sample of each day, some 60,000 a year, and if the dose is measured, it is added to the external exposure and placed in the employee's record so that we know either how much or how little exposure each employee has.

We figure that it is important to not only identify but to record what the individual exposure may be.

(Slide.)

MR. HALL: These are the confirmed tritium assimilations that have occurred during 1982. As you can see, the maximum approach is about .25 rem, the level at which the proposed 10 CFR 20 requires us to

begin monitoring, so I suppose from this, if we had been under this instead of those 60,000 samples, we would have had to monitor one employee if we could have identified him prospectively.

In the power reactors, the total exposure for some 1,000 employees during 1981 was 150 rem total collective dose equivalent to the whole body. Of that, about 60 rem was due to tritium assimilations, and of those tritium assimilations, most were below the required measuring level.

As a matter of fact, for this year, the total dose at the Savannah River plant, if we had neglected to measure and add in these tritium internal doses we are approaching the 100 rem collective dose equivalent to the whole body of the 10,000 employees that we monitor at Savannah River.

So, that just points out the salient importance of measuring what the employees get.

(Slide.)

MR. HALL: This shows a picture of where the 1,000 were. It says the plutonium assimilations can occur by inhalation and be deposited in the lung, the bones, or the liver. We also have ingestion. At least at the Savannah River plant, ingestion is not an occuptional hazard, but puncture wounds is an

occupational hazard.

If puncture wounds occur, there is some guidance in 10 CFR 20, but none of the ALI's or DLI's can be applied to a puncture wound. Those are applied only for inhalation or ingestion because they were not calculated to get the factors that would make them applicable for puncture wounds, and the concept for -- needs to include all routes of entry into the body.

(Slide.)

MR. HALL: What we are saying is that as far as inhalation of airborne contamination goes, we have much experience with monitoring airborne contamination in the form of tritium exposure which is a gaff. It may be in the workplace, and yes, at low levels we permit employees to breath tritium atmospheres if they will receive less total external exposure by picking up tritium without the respiratory protection.

We have thousands of people each day for the past 30 years where they have estimated their tritium assimilations from airborne samples that were taken at the time of their work. However, we found that it is necessary to collect samples daily if they work daily and three times a week if they work intermittently to correct those estimates.

The estimates for tritium assimilations are

usually on the conservative side, and the employees will estimate a factor of two or three higher than they actually receive. However, it is a different case on the unplanned exposure, where the person is involved in a protective equipment failure, where you have a torn plastic suit, or the loss of containment, or where there is a procedure violation, and the proper protective measures were not taken.

Estimates based on air sampling in those conditions are meaningless. You know, yes, they had one, you had better evaluate. They are immediately removed from work until -- of course, with tritium, there is no problem to evaluate. It reaches equilibrium in the body in two hours. Obtain a sample of body fluids, and you know the real answers that you can put in the employee's records.

(Slide.)

MR. HALL: As Dr. Yoder indicated earlier, that when he has an assimilation, and I at this point would like to indicate that I personally concur with the statements made earlier by Mr. Heid and Mr. Yoder, that if you have an assimilation or a potential assimilation from an unplanned incident, that these are the steps that are taken to evaluate that. Yes, first, you have to know how it occurred. Was it a puncture wound or was

it inhalation? Then you would need to know what radio nuclides were involved.

Now, we have no problem identifying small quantities of plutonium in our waste tank or in a waste farm where we are processing radioactive waste, because for every nanocurie of plutonium, there are hundreds of nanocuries of cesium 100 or other gamma-emitting radio nuclides emitting plutonium, so therefore from the air sample you can get the ratio of the two, and if you are counting in vivo immediately after the incident when he still contains all the fission products and the plutonium, you can assess updates down to the fraction of a nanocurie level.

And of course the airborne contamination is a consideration. It just gives you the extent of the release and how long the men were there, which is how worried you get, and then you look at the clothing contamiation, the skin contamination, was his hair contaminated, nasal contamination, the whole body in vivo count comes early.

However, those particular assessments are, as was pointed out, do not have the sensitivity needed, and you have urinalysis, fecal analysis, and for long-lived nuclides like plutonium, this has to occur by not only months but years after the intake. So, this

investigation must begin immediately when it occurs. There is no way to investigate this thing with a long chronic exposure with any success.

(Slide.)

MR. HALL: Both Mr. Vallario and Mr. Yoder have addressed air sampling to some degree. Here, I merely show a comparison between what the personal air samplers are. These are the operational state of the art air samplers that are available at the Savannah River plant, the normal room air sample, where we assess and compare them with the 10 CFR proposed Appendix B levels for ALI's.

As you can see, the amount that can be detected when you compare it with the amount of the DAC's, the methods are very marginal, if you only had a pure sample of plutonium 238 with only one plutonium isotope. Unfortunately, if you will read the proposed 10 CFR Part 20, and I think it is well that they recognized that you can have mixtures, with plutonium mixtures, the DAC is $3 \times 10^{-13}$th.

(Slide.)

MR. HALL: At Savannah River, our plutonium, except in the fuel fabrication facilities, where plutonium 238 is produced to provide power sources for satellites, it is a plutonium mixture. Here is a

typical mixture that we may encounter. You will notice that in this mixture, you have both beta-emitting isotopes, the plutonium 241, and alpha-emitting isotopes.

We normally just measure the alpha-emitting isotopes on air samples. In a reprocessing facility or in a laboratory, you can have separations of the americium 231 daughter from this mixture. Immediately after separation, the ingrowth of americium 231, I am sure that many of you are familiar with, changes hourly and daily and weekly by orders of magnitude.

Therefore, if the identity of each radio nuclide is known, but the concentration of one or more of the nuclides or the isotopes in the mixture is not known, the DAC is $3 \times 10^{-11}$ and the ALI is .7 nanocuries.

(Slide.)

MR. HALL: On that basis, a brief review of some of the data shown earlier as far as in vivo counting with the state of the art Foswick detectors. This shows that for plutonium 239, plutonium 238, you do not see a small fraction of what we consider the lung burden now, and these do not compare very favorably with the .7 for the annual assimilation, and in operational you would like to be able to measure a small fraction of

that.

(Slide.)

MR. HALL: I would like to use this assimilation of plutonium that occurred in the spring of 1982 to show you what effect the 50-year committed effective dose equivalent would have on this employee. The employee was working in a facility. He was protected with cabinet -- processed cabinet gloves.

During the work, inadvertently the glove failed at constant air monitor high volume sampling that 40 CFM alarmed immediately, and when he left the work location, we monitored him and did not detect any activity in the in vivo. The initial urinalysis, even though the man was treated with DPTA, that enhances a factor of 50 with only a fraction of a deep rem per day.

However, the nine fecal samples collected a week after the accident contained measurable quantities of plutonium and the assessment of his retained lung burden was 2.9 nanocuries. You can see that this represented about 2.3 rem, a 12-month committed dose equivalent to lung organ dose.

Now, if you evaluate this with -- you would have to look back and say, well, now, the intake was 19 nanocuries, and you would say, well, now, we are lucky, because 10 CFR Part 20 says the annual ALI is 20

nanocuries. We are home free.

However, with that typical plutonium isotope about 12 percent or 160 nanocuries of that was plutonium 241, so you have to add to that 4.8 rem that you would calculate 1.1 rem from the plutonium 241, and the americium 241 daughters, and immediately you have 5.8 rem, and we would have had to have gone to this employee, whose lung dose was not more than 15 percent, which is half the value that the new 10 CFR 20 says you would have to measure if it were the organ dose, it says 30 percent, if this was 15 percent of that organ dose. For some short-lived compound, it would be half of that.

Suddenly, we have to disrupt the individual and say, well, you are overexposed, we must remove you from work, we must upset your family, all other psychological impact that goes with this, and after several conferences, we may be able to look at the other socioeconomic problems.

(Slide.)

MR. HALL: In summary, we have identified some of the shortcomings and pitfalls that we have seen in the proposed monitoring and records system, and the problems associated with the 50-year committed dose equivalent are more severe for the Savannah River plant than they are -- than for what the licensees may

anticipate for themselves today.

However, in the future, many licensees will face the same problems that we have been facing because of prolonged storage of spent reactor fuel, reprocessing of fuel, and the breeder program.

I mentioned the isotopic content of my typical plutonium, breeder plutonium, power reactor plutonium. The dose from the plutonium 241 data that you are not measuring will probably be at least equal to that of the alpha.

Thank you.

MR. MOELLER: Thank you.

Let's see. Jack Selby is going to be the next presenter.

MR. MULLER: There were several of those slides that it would be nice to get copies of.

MR. MOELLER: I'm sure we will.

MR. SELBY: Mr. Chairman, members of the Subcommittee, and NRC Staff. I appreciate the opportunity to participate in your Subcommittee meeting on the proposed draft 10 CFR Part 20. I am Jack Selby, Manager of Health Physics Technology at Battelle Northwest.

For the past five years I have been the project manager of an extensive health physicist support and assistance program which we conduct for the Department of Energy at the headquarters level. It should be noted that my comments represent my opinions and not my employer nor DOE.

As an operational health physicist for 28 years, I share with you the dedication to the three basic principles governing radiation protection of workers, namely, occupational exposure should be: one, justified; it should be kept as low as reasonably achievable; and it should be subject to upper limits of individual risk.

However, these principles require careful balancing to ensure that no one segment of the worker population nor the public is required to bear a

disproportionate share of either the dose or the financial burden in order to satisfy a regulatory agency position which may have little or no justification.

There are several problems associated with the draft guidance that concern me. These include, but are not limited to: the apparent treatment in the recording and reporting of effective dose equivalent for radiation workers; number two, the implication and stigma that a worker has received an effective dose equivalent orders of magnitude greater than the annual limit of 5 rem by adopting the committed dose equivalent for 50 years. This can result from assigning all of the 50-year committed dose to the year the worker was exposed to a minute quantity much less than the long-lived emitters.

The alternate approach would be to assign to a particular year only the dose received during that year, regardless of when the intake occurred.

Finally, the continued emphasis on the measurement of percent, rather than the actual uptake in the individual, and the relative impact of identical acute deep dose equivalent external and committed effective dose equivalent internal exposures.

I will try to touch on all of these as we go along.

(Slide.)

I intend to touch briefly on three major points in my discussion: the Department of Energy experience, the impact on worker protection, and the apparent legal implications.

(Slide.)

A very useful document on occupational exposure to ionizing radiation in the United States, EPA 520/4-80-001, was produced by the EPA. This document illustrated what many of us have been aware of, namely that the nuclear industry, through its flexible radiation protection program with emphasis on ALARA, has been effective in lowering individual and collective doses, even though the jobs are becoming more complex and the worker population is increasing.

I would like to show a little bit of the experience we've had in the Department of Energy along this line.

(Slide.)

In this figure we have slotted for selected years the numbers of individuals in the various exposure ranges, zero to one, one to two, two to three, and so on. It should be noted that beyond 1968 any points that you see on this represent unplanned exposures, because the Department of Energy contractors and the Department of Energy adopted the philosophy that we would not use

the banking concept but we would limit our exposures to five rem.

If you will note, in 1976 we had approximately five people in the four to five rem range. Now, that is in a worker population of approximately 100,000 workers. In 1977 we had a few more. We had in the neighborhood of 20.

(Slide.)

To further characterize this, I would like to show the breakdown of the most recent year to illustrate a point that I want to touch on later. Here again, we have shown the ranges, zero to one, one to two, two to three, and we have plotted the collective dose equivalent that has been recorded for the radiation workers.

As you can see, the single greatest contributor to the collective dose equivalent in the Department of Energy and its contractor organization is in the zero to one rem range. If I further break that down and showed you the zero to .5 and the .5 to one, you would see that the majority of it was in the zero to .5, and therein lies one of the problems that we have with the current draft of 10 CFR 20, that is, to encourage not measuring exposure at .5 or less.

(Slide.)

Showing this in yet a different way, we believe that if you identify a worker to be monitored, a radiation worker, that you should record all measurements whether they are negative or positive. And in fact, some people feel perhaps the negative values are even more important. I know Ken would take exception with that, because he challenged me last night. But we certainly do not believe there should be holes in the occupational exposure record for values that are below a measurement level, and I'll get into that a little bit more.

Now, as you can see, last year in our radiation worker population, which was approximately 83,000 according to the statistics we received, 54 percent were less than measurable. That means that the dose recorded on the dosimeters was background. 44 percent were in that range that I pointed out, zero to one rem. Only 1.5 percent of that worker population was above one rem.

I would submit that we should concentrate a great deal of attention in this area and not throw the data out and not forget about that particular aspect of the worker population.

(Slide.)

Referring back again to the study that the EPA

did -- and it should be noted that the report failed, however, to present several important data points. These include the actual magnitude of workers' total exposure, external plus internal, and its relationship to a perceived limit of 250 rem dose equivalent for a worker employed for 50 years in the nuclear industry. It failed to identify the magnitude of internal exposure. It failed to identify the magnitude of forearm exposure.

And one additional one now that comes out as a result of one of the requirements in 10 CFR 20 -- and it may have been modified, as we heard this morning from Dr. Mills, but one would wonder how the application of the F conversion factors that are contained in Table 1 of the August draft will impact on the current reported deep dose equivalent, since these values vary from 1 to 1.5 depending on the energy of the photons.

I would like to note that for a plant such as Rocky Flats involving worker plutonium if you look at the levels we're talking about you would probably have to multiply the current reported doses by approximately 1.4, and that impact I do not believe has been reviewed.

(Slide.)

To further take a look at the internal part of

this, we have prepared a slide which represents 168 depositions, plutonium depositions that we currently have at Hanford. We have attempted to place these in the ranges based on the maximum permissible body burden. We have 114 workers with less than five percent of the maximum permissible body burden of plutonium-239. We have 4 in excess of 50.

Over here we have attempted to calculate the 50-year committed dose equivalent using the requirements of ICRP 26. It should be noted, however, that these numbers when we did it were based on the weighting factors in the EPA document, and therefore if we used the current numbers these would increase by approximately 25 percent.

(Slide.)

In order to make a point, I wanted to show a list of our highest external radiation exposures at Hanford. It should be noted that the first on the list is the separations operator with 144 rem of external exposure, and the majority of this was received during the Recouplex accident. We do not choose to take resort in the one-time accidental exposure and neglect it. So it has been included and he has been controlled accordingly.

Now, looking at the rest of the group, where

unplanned exposures exceeding limits have not occurred, you will see the average age is -- I'm sorry, the average length of service is somewhere around 25 to 30 years, and the average annual exposure is someplace in the 2 rem range. Now, in this particular group there are four individuals who are also deposition cases.

(Slide.)

Again, looking just at their external exposure situation, we have three separations operators and a reactor operator who are in the highest exposure group at Hanford and who have also plutonium depositions. As you can see again, the average service is somewhere in excess of 30 years and their average annual exposure is approximately 2 rem.

(Slide.)

Now, looking at that group and calculating for the 50-year committed dose, this is what their total whole body risk would be assumed, based on the ICRP 26 model. Again, it should be noted that these numbers are 25 percent low because they were based on the weighting factors in the EPA document and not on the current guidance.

So you can see that for worker A, with 68 rem external exposure, with a deposition of less than 50 percent of the body burden, he's now set it at

approximately 25 rem.

MR. KATHERN: Jack, can you put that up again?

MR. SELBY: I should mention, this should be A, B, C, D. Was that what you were catching on?

MR. KATHERN: Yes, that was the question.

MR. MOELLER: And you're also going to show us, Jack, what their actual dose has been up to this time?

MR. SELBY: No, I didn't.

MR. MOELLER: It's much less?

MR. SELBY: It's much, much less, yes.

(Slide.)

For the sake of time, I'm throwing out a few of these things here.

MR. DAVIES: Jack, would you mind putting that slide back that you just took off, the one with the two C's? Did you get the total accumulated dose?

MR. SELBY: This one right here or the second column?

MR. DAVIES: The second column.

MR. SELBY: That is their external dose.

MR. DAVIES: Okay.

MR. SELBY: This is what you would calculate using the 50-year calculated dose equivalent, and this

then would be the calculated effective dose equivalent (Indicating).

MR. MULLER: That's the sum of the two.

MR. KATHEEN: Yes.

(Slide.)

MR. SELBY: Quickly, I would like to hit a few points that Ed Vallario has already hit, but I just would like to hit them once more. I have five concerns. I had four when I made this slide and I came up with a fifth one, which is design of the radiation protection program.

The occupational exposure history we feel is extremely important in not only protection of the individual, but also in the protection of the company and any organization that is associated with that history. I think we are seeing now efforts to try to go back, for example, and to calculate or estimate exposures to military personnel who are involved in test site shots, who worked at plants where there was radioactive material, and their records were either not kept or they were lost or what have you.

So we feel that occupational exposure history is extremely important. If you review ANSI N.13.6, I'll admit it's out of date, but it does have a message. That message is that you should use good business

practices and all actions should be auditable. All actions should be auditable.

That is, you shouldn't be throwing out data. You should be putting in whatever you measure. You should be justifying what you measure. And if you will refer to 20.1103 in the draft standard, it says that if you are exposed to two DAC hours in eight hours, to ten DAC hours in a week, you can go ahead and escalate that out to a year, you're talking about 25 percent that you do not have to record. So you could in effect, one day because you are above that two DAC hours in eight hours you record it, the next day you're below it and you don't.

If you're going to use that concept, you should be recording everything you measure or estimate. That same point goes to an incomplete data base. You've got holes in your records. If you're monitoring for the individual, report what you're monitoring. If you're not going to monitor, then don't play games of that sort.

However, when you go on down to the next point, calculation of assumed exposure, if you read the guidance, you do not have to monitor for an individual if you assume that he is going to receive less than half a rem per year or he is going to be exposed to less than

30 percent of an ALI in a year. So you do not have -- it's a perfectly good judgment.

However, when you come to Form 4 and the instructions as to how you fill that out and each employer, when he hires somebody who has worked at another facility that involved radiation exposure, has to fill this Form 4 out, and he is required to fill in any gaps where the exposure has not been measured with 1.5 effective dose equivalent rem.

So therefore the exposure, as we have seen on the earlier charts with the DOE experience, much of our exposure is down in the zero to one rem range. In fact, it's down in the zero to a half a rem range. And all of a sudden we're going to start putting in exposure that doesn't exist. I think that's going to raise a lot of questions on the part of the individuals and on the part of the legal records, et cetera.

ALARA, the exposure records, serve another purpose. That is that they are very, very useful in comparing results of the radiation protection program within facilities in a given plant, between plants having similar operations. It provides an important base to look at worker group problems and to look at important exposure categories.

We feel that when you have a set of data that

you are accumulating, that it should not be added together in one final number. That is, the relationship to the effective dose equivalent of five rem per year. You should maintain all of the parts so that you can continue to do the comparison of the results and look at important worker groups and important exposure categories.

That encouragement has to come out of organizations like the Department of Energy and the Nuclear Regulatory Commission.

(Slide.)

I mentioned that I had one other point I wanted to make or put on this graph. That's design of the radiation protection program. We feel that continued emphasis on total dependence on air sampling, rather than encouragement to involve good internal dose measurement programs, is not a good service to the radiation worker.

That is something that is not new. It was in the existing 10 CFR 20, and we would hope that when a change is made in 10 CFR 20 and we talk about improving worker protection that a strong consideration would be given to encouraging the development of a good internal dosimetry program.

Now, it turns out that that requirement in 10

CFR 20 seems to be counterproductive with what is going on in other parts of the Nuclear Regulatory Commission and also in the Department of Energy. As was mentioned earlier this morning, there is a great deal of effort going on to improve the quality of the measurement program.

The Nuclear Regulatory Commission sponsored the study by the University of Michigan, which should lead to the certification of dosimetry processing. I think that is a very, very valuable exercise that they have supported and I think it is very useful to all of the industry.

The Nuclear Regulatory Commission and the Department of Energy jointly are looking at a certification program for bioassay, again to improve the quality of the measurement program, and I think that's the way we should be going. We have heard that we have a great deal of problems in terms of sensitivity -- or perhaps I shouldn't say sensitivity, but minimum detection levels -- in our current measurement program, and we should be attempting to take care of that.

At the same time, we should be encouraging the use of good internal dosimetry programs.

(Slide.)

My last slide, I'm not going to belabor this

since Ed has covered it so well already. We feel that many aspects in the draft that we reviewed, the office draft of 10 CFR 20, carry legal implications. To name three of them: the 50-year committed dose; the implication of technical overexposures, applying this concept; and the encouragement of an incomplete data base.

Again, let me thank you for allowing me to appear here today. I'd be happy to answer any questions when we get to the question period.

MR. MOELLER: Thank you, Jack.

Let's see. We'll finish up then with the DOE presentations, presented by Jack Corley.

MR. CORLEY: I suppose I could almost save everybody a little bit of time by just reading my introduction and my summary and let us get to lunch a little bit earlier.

I am John or Jack Corley and a staff engineer with the Radiological Science Department of, in spite of what's on the program, Battelle's Pacific Northwest Laboratory. I've been a health physicist for 35 years for 8 of which I was in charge of the Environmental Surveillance Program at the Hanford site. For the past eight years I've been responsible for the technical assistance project in the area of environmental

radiological protection for first the AEC and now the Department of Energy, and as such I've had primary responsibility for the preparation of guides of good practice for radiological environmental surveillance and effluent monitoring.

Like my cohorts, I have to make it clear that I am going to give you my views and not DOE's or Battelle's position.

Practical application of the ICRP recommendations to population groups introduces different problems and constraints than it does for occupational exposure. In large part, it's due to the lack of specific identification of the exposed individuals in the environment, the fact that those individuals are a mixed heterogeneous group and continually changing, and because we don't really have the ability to control as individuals future exposures to those same population groups. We do of course have control by remedial actions at the source or by intervention in exposure pathways for groups as such.

Several aspects of the proposed 10 CFR 20 regulations then generate similar concerns for environmental surveillance as for occupational protection responsibilities. Others engender some different responses and I'll try to point this out.

It is noted that several of the concerns that we are addressing are inherent in the adoption of ICRP Publication 26 recommendations, for example the assignment of a 50-year dose commitment to the year of intake and the use of weighting factors to calculate an effective whole body dose equivalent.

But others have been introduced in the NRC drafting process: the use of factored ALI's for population dose estimates and a directed ALARA emphasis. In principle, the use of 50-year committed dose equivalence from radionuclides with long biological half-lifes seems more appropriate for assessment of population exposures than for occupational doses. The latter capability will exist to substantiate a priori estimates through external and internal monitoring procedures, however sensitive they might be.

For members of the public, use of the committed dose equivalence may be necessary to demonstrate compliance as well as for predictive purposes. As a matter of fact, a number of our DOE sites are currently calculating 50-year committed dose equivalence for plutonium.

As noted earlier, however, the acceptance of the principle of calculating committed dose equivalence does not necessarily imply, and in fact in my view does

definitely not imply, acceptance of the principle of calculating and basing our controls strictly on effective committed dose equivalence. And even the acceptance of the 50-year dose equivalent requires an additional caveat or two: The conversion of health effects to individual --the conversion of risk health effects to individual body organs to an equivalent body risk and control purposes certainly is just as valid for uncontrolled area populations as for occupational exposures.

The practice may indeed be even more useful for comparison of collective health risk as an aid in design analysis, or even to provide a trend indicator for a given facility or for a group of similar facilities.

However, loss of the pertinent individual body organ dose estimates, whether it's for epidemiological purposes or for potential legal protection, inevitably will occur if no other record is maintained than the effective collective committed dose equivalent. Especially where nuclide pathways population exposures are limited, one wonders if this is really the right way to go.

The masking of probable risk of health effects to specific body organs especially, as well as the

actual genetic risk is especially questionable where specific nuclides are highly concentrated in one body organ. And of course, you've already been given examples, I believe, by Jack Healy of plutonium bone doses and the other obvious example is thyroid doses where the only releases are radioiodines.

One would find it difficult to evaluate a claim of excess cancer incidence solely on the basis of effective dose equivalence. The weighting factors recommended by the ICRP and incorporated by the NRC in proposed 10 CFR 20 involve so many assumptions as to physiological parameters and relative risks which for a diverse population group, I would certainly expect to see large deviations from standard values for which adequate data is almost always lacking to some extent.

Perhaps no ready alternative is available if a single coefficient of risk must be derived for assessment of total public health risk. However, determination of an effective committed whole body dose equivalent may well involve increases in effluent and environmental monitoring programs. Unfortunately, the potential need for and cost of extending specific radionuclide measurements and accumulating other necessary components of the data base has not really been evaluated for the broad variety of licensees, nor

even all the variety of DOE facilities.

I would in addition raise one additional point of concern about potentially misplaced emphasis in an effluent reduction program or an ALARA application program if we were looking only at effective committed dose equivalent rather than specific nuclide releases. Of greatest concern, however, to me and I think to others concerned with evaluating population doses is the proposed use of the proposed ICRP's ALI and DAC tables with constant factors to adjust for lower limits, different exposure periods, and an assumed age distribution.

Aside from the the fact that the ICRP specifically warns against this practice, application of the standard factors for all nuclides and for all the diverse critical groups to be found at the various licensee facilities will largely negate any claim to more precise controlled population exposures. If all such calculated annual intakes were equivalent to less than the de minimis values, obviously one could ignore the weakness of the assumptions used. I am not confident that that is the case.

As one example only, I will flash on one flip chart here.

(Slide.)

This I stole from Roy Thompson, who all of you know. It was in a paper given at a meeting, and it simply demonstrates the range, some of which are orders of magnitude, for two age groups only, the adult and the infant. Now, the factors for the infants, of course, apply presumably for only one or at most two years of life. Then we get into childhood for which we have still different ratios.

Then the teenage years, which at least in our current dose models we are using still different factors, and then finally into the adult years. So the period of time over which the different factors apply continues to change as the exposed population ages change.

I suggest that the ability to adjust ALI's for all nuclides and all factors of that kind -- and that is by no means all -- is some years away. I understand in fact that the Committee too, the ICRP has been struggling with the problem for some time without success to date. Maybe Herb has indicated the NCRP may now have some solutions to some of these problems. I'm not sure.

In the interim, I suggest the ICRP in its more recent publications has certainly provided some guidance as to calculating some specific organ doses for some

specific nuclides, without recourse to ALIs and the DAC tables. To the extent these models can be realistically adapted to the different age groups and the mixtures of age groups and exposure patterns, I suggest that that could at least be attempted.

This Committee and the other people here in this room are probably aware of the considerable uncertainty that now exists as to the adequacy of the data base for doing so, however, and at least for many of the radionuclides and certainly to the extent that any better precision of dose and risk calculations can realistically be claimed.

Let me say a word about ALARA prioritization, which is of some concern to me. Section 20.102 of the proposed regulations addresses this prioritization of ALARA effort. With due respect to my colleagues primarily concerned with occupational doses and occupational worker protection, I submit that the general public in no way would accept in an either-or situation a principle of minimizing occupational doses at the expense of greater public exposures. This I do not think has been addressed in the proposed regulations.

As a matter of fact, the members of the public most apt to be affected by releases from any of the

licensee facilities and to which your population dose limits are addressed, the maximally exposed individual or critical group, is not even mentioned in terms of ALARA.

Proper implementation of this principle then requires consideration of all categories of exposure and indeed involves some social and political judgments which presumably the NRC has to take. But I hope that if they do take them they will consider both collective and individual doses, and also to the worker and to the public.

I have to say something about proliferational limits and I'll wrap this up just as fast as I can. The use of reference levels or action levels for special reporting for initiating the investigative action is basically sound and generally accepted as good radiation protection practice. We can all agree to that.

For those responsible for reporting to the public, we must be concerned with the continuing proliferation of such levels, which leads only to additional public confusion and misunderstanding as to the differences between reference levels, ALARA values, and limits. As a matter of fact, I'm not sure it's only the public that gets confused on this at times. But this is just a few I pulled out, and I'll put up my

single chart if you can all see those.

(Slide.)

I would warn you at the outset, I think you recognize these are not necessarily the same base, but here if we look here at the whole body dose equivalent or committed whole body dose equivalent, as the case may be, in several of these limits but not in others, then we have the stated 10 CFR 20 limit of 500 millirem per year.

We have a reference reaction level at 100, which is relatively new. At 25 we have the light water reactor uranium fuel cycle, the limit proposed by EPA CFR 190. Down here we have the EPA Safe Drinking Water Act limit, on drinking water supplies now not on releases, of 40 CFR 141, at 4 millirem per year. We have a range of 3 to 15 from 10 CFR 50, Appendix I, depending on the nuclide and the pathway. And then down here -- and thank you, gentlemen -- we have a proposed de minimis level.

Anywhere from the 500 to one, as we all recognize, we say is ALARA. We have some design objectives. Now, we have in some cases attempted, and that of course is what 10 CFR 50 is all about, we have attempted to apply numerical values to define ALARA. At the present time we don't have those numerical values

and I don't think, unless I have missed something in 10 CFR 20, that's being attempted here, and it probably is not appropriate for 10 CFR 20.

Turn the lights back on. That's my last slide.

I had hoped until I got here -- I'm sorry, Bob. I had hoped that not only this Committee, the NRC Staff, would really recognize that in practice any reference level becomes an action level; an action level becomes a working limit, and to the public that's the limit. Now, in the proposed regulations this situation is reinforced by the language of Section 20.301, which states that the basic annual limit to the public is 0.5 rem, and presumably that's the effective committed dose equivalent intended. This applies to some of all the sources of exposure, licensed and unlicensed, other than natural radioactivity and medical exposures.

Now in Section 20.303 it's quite rightly recognized that it's impractical, if not impossible, to determine an actual dose to individual members of the public precisely, and this is because of the presence of mixed sources from all of the sources. So now we will substitute the reference level as a means of demonstrating compliance with the NRC's intent.

I have to say, to me it's a questionable

practice to claim a limit for the licensee which is not really a limit you're asking them to live with, which in essence will be the 100 millirem.

Now in Section 20.401(c) I find that, "a licensee engaged in the uranium fuel cycle operations subject to the provisions of 40 CFR 190" shall comply with its requirements. In addition to the limits on releases of specific radionuclides -- and that particular section is referring to the subject of releases -- but in addition to that 40 CFR 190, it specifies annual dose equivalent limits for members of the public. Not only different numerical values, which I showed you on that last vugraph, but with a different basis, because that indeed is an annual dose and not an effective committed dose equivalent.

Fortunately, very few of the better than 10,000 licensees for the NRC and Agreement States are going to have to worry about that double bookkeeping because they are not going to have to face up to truly the effective committed dose equivalent or the 50-year dose equivalent, in fact.

Our studies by Battelle of the releases from the power reactors for example show that some 80 percent of the dose to the public appears to be from atmospheric releases, and nearly all radio-xenons and

radio-kryptons. So our annual dose is our annual dose equivalent.

There are other reference levels potentially available, but I won't bother you going into those. They've been previously addressed. But I do hope you will keep that point in mind, that the reference level is a limit.

On the basis for risk estimates, I can only shake my head. I don't claim any special expertise in this area of assessing public health risks from radiation exposures. All I know is what I read in the manuals. However, it does seem to me from what I've read that there is a valid question as to whether an assumed distribution of risk for a particular worker population should be used to determine some assumed level of risk for a mixed public with varying ages, habits, periods of exposure, and status of health and health care.

I mentioned several times before the need for a significantly expanded data base as a proposed system of dose regulation to achieve truly better estimates of population doses. I wish I could give you real data. I can't. We've asked for lots of money and lots of time to determine what that is, but we haven't gotten it yet. Unfortunately, I can -- not unfortunately; I beg

your pardon. I can foresee steady employment for a number of years for computer programmers for some time to come, adapting all our dose calculation models to the new models, and maybe that's inevitable.

I would like to pass on to you a quote from my co-worker Joe Soliat, who many of you know at least by reputation. Joe's reaction generally to the ICRP system now incorporated in 10 CFR 20 is: "My overall impression is that the elegance of the mathematics far exceeds the availability of the basic data needed to make it work."

Thank you.

MR. MOELLER: Thank you, John.

MR. CORLEY: You can call me "Jack," Dade.

(Laughter.)

MR. MOELLER: Herb, you had a comment?

MR. PARKER: Before I ask a question, Mr. Chairman, I would like to refer to the fact that at your table you have two Battelle-related people and presenting data you have three Battelle people. And while I applaud this high concentration of quality, I think it could raise questions of possible conflict of interest.

So for the record, I would like to stipulate that I for one have not consulted with any of these

gentlemen on the matters before your Committee, Mr. Chairman, and during the last year or so. I have worked with Ron Kathern on a book review which I think was clearly unrelated.

MR. MOELLER: Fine. Thank you for that.

MR. PARKER: I would like to ask a question after that.

MR. MOELLER: Sure.

MR. PARKER: May I address Ken Heid. Ken, this is not directly on the details that you gave us today, but you did say that you had been working with personnel records for something over 30 years and presumably know something about it.

Jack Selby gave us four cases where there was a very serious overlap between external dose and internal dose. It used to be in the old days that by and large you either got the one or the other, with a 10 or a 20 percent overlap. How does that separation stand in today's practice in the business?

Is it still largely true that you could take one and if you added 20 percent you would have a safe upper limit for what the man's risk was?

MR. HEID: I think the trend is still true. Of the 10,000 employees at Hanford, perhaps 5 percent are exposed to plutonium. Of this 5 percent, only a

small fraction are exposed to -- well, they are all exposed to the photons and neutrons that come from the plutonium. But only a very few, way less than one percent of these, are exposed to levels in excess of one rem.

So that the number that we have an overlap significantly different from the past trend you could almost count on your two hands. Other than that, the 20 percent overlap is still appropriate today.

MR. PARKER: Thank you.

MR. MOELLER: Thank you.

Ed, does that complete your formal presentation?

MR. VALLARIO: Yes. I would just like to make one final comment here. We are appreciative of this participation and we would like to make the recommendation that the ACRS continue to function as a forum in examining the considerations and the resolutions to these important issues during the tenure of the Part 20 development.

In this context, of course, we would be looking forward to perhaps some scheduled meetings such as this one in the near future.

Thank you.

MR. MOELLER: Thank you.

I think we will move ahead then now to hear from EPA. And I understand their presentation will be shortened. We will see then how that goes and make our decision about when to break for lunch.

The presentation will be by Glen Sjoblom.

For the record, and he will probably tell us, he is Director of the Office of Radiation Programs for the Environmental Protection Agency.

MR. SJOBLOM: In early June I became the Director of Office of Radiation Programs. When I became familiar with what the functions and ongoing tasks were shortly after coming, I realized that one of the very important ones was the resumption of the EPA's efforts towards updating the 1960 Federal radiation guidance.

As you know, in January or thereabouts in 1981, EPA published a proposed update of that guidance and held hearings a few months later. There were a lot of comments. I have with me Alan Richardson here today, who will give you a little bit more of detail on some of the issues that were raised during the public comment period.

We are now in the process of determining just where to go from here on this. Basically it is my intent that we reconvene the interagency process. There is something like 14 or 15 agencies in the government, not just DOE, not just NRC and not just EPA, that are interested in occupational radiation exposure.

So I believe that it is appropriate and essential that we derive what may be the Federal radiation guidance that lasts for the next 20 years

through the most open and discoursive measures that we can. I believe it is appropriate for the ACRS, of course, to be involved with any major update of a major NRC regulation.

As you know, the 10 CFR Part 20 derived from the original Federal radiation guidance. I have discussed with senior NRC people like Bob Minogue and have received assurance that NRC plans to function and participate fully in this interagency process that we anticipate resuming shortly. I plan to do this by sending a letter to each of the agencies, convening an initial meeting at the policy level, identifying in that meeting what the issues are that we believe need to be resolved, taking any recommended additional issues that the agencies feel need to be resolved, perhaps breaking up into smaller groups on individual issues and trying to resolve each of those, and then reconvening later the interagency group again to attempt to ratify or amend and subsequently ratify the recommendations which would subsequently go forward.

Our schedule, as I hope to do it, would end up about September, we hope, with a final package of recommendations.

I would like at this time to introduce Alan Richardson, who could perhaps give some more detail on

what we intend to do.

MR. RICHARDSON: I am pleased to be here. The last time I spoke to you was before we had proposed new guidance. I am glad this time to be able to report that it has been proposed. We have made some progress. I would like to review a little bit of the history first.

I would like to remind you that the Federal Radiation Council was created way back in 1959 and that the present guides that we now operate under were established in 1960, and in 1961 there were some additions. Those guides were derived, as you probably all well know, mainly from NRCP and ICRP recommendations that were in existence at that time.

Just to review what those guides were, the essence of them was that the whole body limit was 3 rems per quarter and 5N minus 18 rems to the average worker. The protection scheme was based on the critical organ approach. There were a variety of critical organ limits, 5, 15, 30, depending on the organ involved or the tissue.

There were two principles set forward in that guidance. One is that radiation exposure needed to be justified before it occurred at all and the second was that exposure should be as low as practicable, which is what we now call ALARA. Most of those things have stood

the test of time. Certainly the justification and the ALARA principles are still the principles that we are dealing with today.

The major change is in the expression of the actual dose limits themselves where there is now under ICRP 26 proposed a weighted dose scheme to replace the critical organ approach. Late in 1970 the functions of the Federal Radiation Council were transferred to the administrator of the EPA, as you all know, and the Council was abolished. About two years later, the first BEIR -- not the BEAR, the BEIR -- report was issued in 1972.

In 1974 we began to review occupational exposure guidance. We formed an interagency working group. It had a large membership back in 1974. The agencies represented were the Department of Energy -- well, then in those days the AEC, Department of Defense, the NRC, Department of Transportation. Bureau of Standards was involved, NASA was involved. HEW and DOL were not initially members, at their choice. They later joined the group as full members, and the Conference of Radiation Control Program Directors was also a member of the program.

Later in 1973 BIER-2 fwas issued, and then as Mr. Sjoblom just mentioned, in January of 1981 we

finally came to the end of this long process and proposed for public comment new guidance, which you have a copy of. The handouts that I gave you were, first, the now 22-year old Federal radiation guidance that we still operate under that was published in 1960 and 1961; the second handout was the Federal Register notice of these proposed revisions; and the third handout is the one that I will use in talking a little later about the changes that were proposed.

After publication in January of 1981, we held many days of public hearings in Washington, in Houston, in Chicago, because that is where a lot of the medical societies are centered, and on the west coast of San Francisco. We accumulated a very large record. And since people who don't like what you are doing are the people who come and talk to you at your hearings, most of that record was negative. There is about 4 feet of it.

Well, so much for history. I am going to try and be quick and just take about 10 or 15 minutes. I am going to summarize the proposals that we made briefly because you may not remember them a year and a half later, almost two years later. I will say a little bit about what kind of public comment we got, what we have been doing in the intervening years since public hearings, and then review once again what Glen outlined

in terms of what our future course would be.

First, to review what the proposals are.

(Slide)

This is a very poor Vu-graph, but you have a copy of it in front of you. My apologies to the back of the room.

There were nine major elements of the proposal. The first one was that exposure should be justified. It was required by 1960 guidance. There is no real change proposed in that except that alternatives to exposure were explicitly called out for consideration.

Let me just make some parenthetic remarks about ICRP 26 and 10 CFR 20 so you can get a picture of where there is a discrepancy and where these things are essentially the same. ICRP 26 is basically the same as what we are proposing here, and 10 CFR 20 I don't believe addresses the question of justification. Optimization of exposure was required under 1960 guides, was required under the proposed new guidance, and explicitly called out was the point that this means to minimize the collective dose because individual doses is dealt with separately under limitation of exposure.

That is identical to what ICRP 26 requires, and the translation in 10 CFR 20 proposed is kind of mixed. I guess I won't talk about it in much detail.

There is a requirement for ALARA. There are things like de minimis doses for collective exposures which are departures from ICRP 26.

Under limitation of exposure we distinguish whole body from partial body exposure. I mentioned earlier what the existing limits are under Federal guides. The new proposal was for 5 rems a year, which is identical to both ICRP 26 and the proposed 10 CFR 20.

For partial body the 1960 guides -- this is a fundamental difference -- involved individual critical organ limits. The proposed guidance was the limit on sum of organ risks, as is ICRP 26 and 10 CFR 20 proposed, but there is a fundamental difference. In the ICRP 26 system, somatic risk is lumped together with genetic risk, and in the EPA proposal the genetic limit of 5 rems which we have been operating under for 20 years is retained as an independent limit, and therefore it dropped out of the combined limit on sum of organ risk. There are also some other small numerical differences, but that is the essence of the differences.

On the question of combining internal and external exposure, under the existing 1960 guides the limits are applied independently of each other. In both the proposed new guides and ICRP 26 and, I believe, 10

CFR 20, they are combined, using the weighting factors for individual organs.

The proposal contained a new element, which is that there should be minimum radiation protection requirements. These dealt with matters such as monitoring, recordkeeping, supervision of workers and instruction of workers in very broad generalizations, and we propose in the new guidance three different levels, that this be divided into three different levels: highly exposed workers over several rems, a group of workers falling between the population limit of a half-rem, and then highly-exposed groups and then people exposed below the limits of the general population.

ICRP 26 has some of those elements but in two exposure ranges, and I can't speak for 10 CFR 20 in detail. In the 1960 guides this just was not specified at all. Regulatory limits lower than the RPGs for specific job categories was addressed by the proposed guidance. It was not addressed in the 1960 guides. The proposed guidance simply recommended that the regulatory agencies do this when it is appropriate.

ICRP 26 provides for just this sort of thing and leaves it to the regulatory bodies. 10 CFR 20, I believe, does not address that.

The next element was intake guides. I am not going to address the differences there. It is all coupled back to implementing the scheme, whichever one you have, on limiting internal exposure, and the recommendations were consistent with what had been recommended up here in the various cases.

Exposure of minors has been at one-tenth of the RPGs under all of these proposals. There are no changes. Exposure of the unborn was not addressed under the 1960 guides and is not addressed now in current Federal guidance.

We proposed four alternatives. Both the ICRP and the proposed 10 CFR 20 make specific recommendations which happen to be different from each other but not terribly different. The ICRP 26 and the 10 CFR 20 proposal are consistent with some of the proposals proposed for public comment in the proposed new guides.

Exceeding the radiation protection guides is, of course, permitted under the 1960 guides at the discretion of the agencies involved. There was proposed no change in that except there was added an explicit requirement for disclosing that it was taking place unless defense purposes precluded that. I don't remember what ICRP 26 and 10 CFR 20 say about that.

Well, so much for what was proposed in rough

general form and how that compares to ICRP 26 and 10 CFR 20 proposed. Let me go on now to the question of the reaction to our proposal.

Well, I think probably the most important thing to say about the reaction to our proposal was that our proposal was really the first time in this country, I think, that something like the ICRP system was actually proposed for public comment and we heard what people thought about it. There were other things in our proposal that weren't exactly ICRP 26, but we did get a strong response on the question of ICRP 26-type schemes, including these basic principles based on justification of exposure and optimization of exposure, which, if you will recall back in 1960, were developed privately by the ICRP and the NCRP, and the Federal Radiation Council made the recommendations to the President without public involvement.

This is the first time all of these principles have been put forward for public comment. One of the things that really surprised us was we get a lot of objection to the idea that radiation exposure should have to be justified and that there should be ALARA in the public comment. This proposal was set forth at a time when the country was reacting to regulatory requirements, was very conscious of paperwork burdens

imposed by government, and I think part of the reaction we got was coupled to that heightened awareness.

Nonetheless, what came through loud and clear is that you can't make motherhood statements like the 1960 guides did about justifying exposure and keeping exposures as low as reasonably achievable without people getting very worried about the paper requirements that would be put on them to do that. So one of the clear messages we got was we would have to find ways to express the guidance in ways that make it clear that the guidance itself is no an imposition of paperwork requirement, that that is a regulatory decision.

A second kind of major reaction disclosed had to do with the concentrations, minimum-maximum permissible concentrations, the changes in all the values that result from the adoption of ICRP 30 models and the new values for either the weights or the critical organs or whatever. What emerged from that is that there is very little understanding in the radiation protection community itself of the distinction between changes that are caused by new scientific information and changes in the models and changes that are due to the selection of the weighting factors or the limits themselves.

The fact of the matter is that most of the

changes that come about from the adoption of the ICRP 30 models plus new guides, most of the changes are due to the models, not to the choice of the numerical limits. There are order of magnitude changes in many of the values and there have not been proposed order of magnitude changes in the limits by any stretch of the imagination. Most of them stay about the same. Yet the changes were ascribed to the new guidance, the proposed new guidance; and that was simply not the case.

One of the remaining areas of controversy that is still not resolved, we still haven't resolved the basic controversy of whether this country should go forward with a weighted dose system or with critical organ limits. There was no clear answer coming out of the comment that we got. There are people on both sides of that issue, and that is going to be one of the major things that we will have to resolve in the interagency group as soon as we get it back together again.

Some commenters felt that health risk was a factor and we should wait for the results of the reevaluation of the Hiroshima-Nagasaki data. That, surprisingly, was not a very strong message in the public comment. I think there is a growing realization that the detailed health estimates are not all that important for choosing what the occupational limits

should be. I think there is a growing awareness that although these health risk factors bounce around a little bit, they don't bounce around by orders of magnitude, which is what would be required to really change the dose limits.

One area which is a real problem which emerged from the public comment was this question of committed dose for long-lived radionuclides and the need to look carefully at making distinctions between prospective application of dose limits, and in that case perhaps the committed dose and retrospective application possibly on an annual basis when you have major body burden and you are dealing with a specific worker. That is another thing we will be looking at in the interagency working group.

We have done a few things in the past year. As one of the speakers this morning mentioned, there was a comprehensive survey of occupational exposure in the United States published by the EPA a couple of years ago about the time this guidance was proposed. Its cut-off date was 1975 because it takes a long time to accumulate and evaluate comprehensive data for the whole country's radiation workforce.

We are in about six months, I think, going to complete an update of that for 1980. As an indication

of how difficult it is to do this, let me just point out that over half of all exposure is to medical employees, and the availability of records is much, much worse for medical employees than it is, for example, for nuclear power employees, which is something like 7 percent, and DOE employees, which is another small percentage.

We have done a detailed survey of the costs that would be associated with these proposed new guides here for implementation. That work is almost complete. As a sort of baseline for departures for the final guidance, we have been developing alternatives and reviewing the comments. I mentioned the size of the record.

Let me just finish by reiterating what it is we have ahead of us. We have essentially completed but we are not quite finished yet identifying and fleshing out a statement of the major issues that have to be resolved before this guidance can go final. We are in the process of reconvening the interagency working group, which, by the way, will also include in addition to those agencies the NCRP, a representative from the NCRP.

When that group reconvenes, we will be probably assigning individual issues to small groups of agencies so that we can work more quickly and

efficiently so that we can propose back to the main body resolutions which the main working group will then deal with. We expect to get that process completed in a matter of months, hopefully. Then will come a decision on whether we can move this forward as final recommendations or whether they will have to be reproposed. It will depend upon the magnitude and the character of the changes that develop out of this process, and then we will do that. We propose to go final.

MR. MOELLER: Thank you.

I have a couple of questions. I think now we should open it up to general discussion. One question. You mentioned that you are preparing cost estimates of the implementation of your proposed guides.

MR. RICHARDSON: Yes.

MR. MOELLER: Do you have any numbers?

MR. RICHARDSON: Not at hand, no. That contract report hasn't been delivered. We just have it in draft form. There are a couple of case histories -- we are doing it as case studies, and a couple of those aren't completed yet. But we should have them in a few months.

MR. MOELLER: Another question. You mentioned, of course, I guess it was the 1970 law that

transferred the functions of the Federal Radiation Council to the EPA. When President Carter was in office, he established the Federal Radiation Policy Council. How did that relate to the Federal Radiation Council?

MR. RICHARDSON: In many ways it was similar, and in other ways it was different. The purpose of that policy group was to deal with questions of policy involving radiation generally. What that group did not do, and I guess this is the key part of the answer to your question, it was not the Federal guidance function to make direct recommendations on radiation protection matters. It was not transferred to that group. It remained with the administrator.

MR. MOELLER: And then I guess when President Reagan abolished the Federal Radiation Policy Council, did everything transfer back to EPA? Is that the idea?

MR. RICHARDSON: I don't think anything was transferred away from EPA. That was a group which was created to deal with radiation policy issues in general between the agencies. The, if you will, statutory function that is in the Atomic Energy Act of making recommendations to the President was not affected by the creation of that group.

MR. MOELLER: I see.

Are there questions from our committee or consultants? Ron Kathern.

MR. KATHERN: I would just like to ask: when you went out for comment and received the objections about the protection schemes and adoption of the ICRP values, were these objections from a general cross-section of those who appeared or were they from one particular area?

MR. RICHARDSON: I would say they are pretty general. We got those kinds of objections from, for example, the medical community, who for the first time, perhaps, thought about Federal guidance and how it applied to them. We got it from the power industry. In 1960 when those things were originally set forth as Federal guides, we didn't have environmental impact statements. People have had a long painful history with what may be required as the result of a simple statement like that. Since 1960 I think we were hearing a lot of that.

MR. MOELLER: Jack Shapiro.

MR. SHAPIRO: I notice that you did make a statement in the Federal Register that you chose the limiting annual dose to most single organs to be 30 rem rather than the internationally adopted value of 50 rem "but we do not see a need for a value higher than any

now used in this country." Why did you use 30 rather than just retain the 15?

MR. RICHARDSON: There is also a value of 15 in the current -- there are two reasons for that, to be brutally frank about it. I don't have a copy of the guide, the 1960 guide that you have in front of you.

MR. SHAPIRO: This is your 1981 Federal Register notice.

MR. RICHARDSON: If you would look in the 1960 guides, you will find the value of 30 applies to some organs, and I've forgotten precisely which ones. So that is the highest value which was in current use. If you adopt a value as low as 15, then you might as well not bother weighting the organ doses.

What happens when you do that in the ICRP 30 models is that the 15 limit to the most exposed organs becomes controlling for almost every isotope, and there just didn't seem to be any point in doing that. The values that you get for the MPCs in air, for example, scatter fairly evenly on both sides of the old values for a choice of 30 or 50. As equal a number goes up as go down.

MR. MOELLER: Herb Parker, and then Ed.

MR. PARKER: I am confused about item seven. That is the exposure of minors that you have on the

chart, Mr. Richardson. Is this some occupational kinds of exposure of minors? What are we talking about?

MR. RICHARDSON: In the classroom only.

MR. PARKER: In the classroom only; that's not spelled out. Because in the 1960 guides, one of the purposes of the 5 into $N^{-18}$ accumulated dose formula was specifically to exclude employment of minors in radiation tasks.

MR. RICHARDSON: But the 1960 guidance also included that one-tenth.

MR. PARKER: As an exception to the 5 into $N^{-18}$.

MR. RICHARDSON: I guess as an additional requirement.

MR. PARKER: Otherwise there was an inadvertent contradiction in the rules. I am worried about this.

MR. RICHARDSON: I guess once you get to be 18, and no longer have the 1/10th rule applying to you, then the 5 into $N^{-18}$ then picks up.

MR. PARKER: It doesn't matter where they have the 1/10th rule applying. If 5 into $N^{-18}$ applies, it doesn't matter what you say about the other; it has to be zero. Isn't that correct?

MR. RICHARDSON: I see what you're saying. If

you apply it --

MR. PARKER: And that is why I am worried. I ask this question because I am worried about the new intention. We have eliminated the 5 into $N^{-18}$ for a reasonable cause because it was misused in the banking thing, which was never intended, but we have now opened that up wide to the employment of minors at some specified level. It is totally unnecessary to do that.

MR. RICHARDSON: I have not thought of the implications of allowing "N" to become less than 18. I guess you could interpret that as a requirement to save natural background dose.

MR. PARKER: I happen to be the originator of the 5 into $N^{-18}$. That is why it was 18, because the law at that time for employment of minors specified a lower age limit of 18. It was subsequently lowered to 16, I think.

MR. SJOBLOM: Do you think that should be explicitly stated in the new guidance?

MR. PARKER: I think it should be explicitly stated: Employment of minors should not be contemplated in the radiation industry.

MR. MOELLER: Ed Vallario.

MR. VALLARIO: Alan, two questions. One, will the interagency committee have the benefit of obtaining

a summary of all of the comments received as a consequence of the public hearings on the last EK draft, number one. Number two, in view of the rapid initiative on the part of the EPA to proceed in reconvening the interagency committee, do you view this in your discussions with the NRC as obviating the need for the NRC revision and proceeding and focusing on the EPA draft, or is this going to be a parallel development function?

MR. SJOBLOM: Let me take the latter one. I view the two as being a co-current process. I think we can and should be able to do the two together. Whether or not the specific details are exactly consistent with another will be part of the discussion. But as I mentioned, there are 14 agencies involved in one way or another with radiation protection in the country, and we feel the need to involve them all, and the NRC is certainly right up there as one of the more important ones, as is DOE.

I don't feel that the NRC should stop what they are doing, because I think many of the implementing decisions, the practicality of implementing certain parts of the guidance, we would be very much interested in. We want the guidance to be practically implementable, so I think it is essential that the

implementing agencies look at what it will mean to them and to their licensees, not only the NRC, but I would presume that the other agencies will want to do likewise, will want to consider from their constituent groups just what the results are in terms of implementation.

MR. VALLARIO: That question was raised reflecting on some comments that were made at the Richland Health Physics Contractor meeting. At that time this question was raised in the interest of concern over the possibility ultimately of having two separate standards in the country. This was the reason for the question.

MR. RICHARDSON: Ed, I think a corollary to what Mr. Sjoblom just said is we need to distinguish between "regulations" and "guidance." They are different things and they both need to go forward. That is the program that we are engaged in.

To answer the first part of your question, yes, there will be a summary of the comments that were made. And of course, anybody who wants to come and read that whole shelf of comments is also encouraged to do so. But there will be a summary of the major comments by commenter or commenter group.

MR. MOELLER: Other questions or comments on anything now that has been presented this morning?

MR. KATHERN: On anything that's been presented?

MR. MOELLER: We're now going to discuss the three presentations: DOE, NRC and EPA. Yes, Ron Kathern?

MR. KATHERN: I would like to ask a general question of the NRC presenters. The bottom line is simply, to me this system that is proposed in 10 CFR 20 revised, does this really provide any better protection for the worker than the existing 10 CFR 20? I listened to particularly the DOE arguments and I see what the EPA has proposed, and really I think this may be a rhetorical question, that you don't want to answer because it takes a long time.

But I really ask that question in a generic sense. There are some specific things that I think are not addressed where improvement really should be sought. One of these is related to the question of exposure from what I will call nontraditional occupational exposures. Perhaps the required medical X-ray as a condition of employment needs to be addressed a little more completely than you have done so, I think, in the introductory statement.

The travel -- people who travel as a condition or a requirement of employment may incur significant exposures, and perhaps this needs to be addressed, perhaps exempted or what have you as well. I would also ask about the transient worker problem. I am not really sure you have fully resolved that problem in my mind. Maybe you have and perhaps you would like to comment on

these items that I raised.

MR. MILLS: Bill Mills.

Let me take the last one first. As far as the transient worker is concerned, that has been a very important part of our discussion, for example, with the Atomic Industrial Forum. And in fact, what we've been encouraging them to do, somewhat at their own initiative, is in fact to consider the possibility of a centralized recordkeeping system whereby the transient workers would in fact use some of the current computer technology to transfer the records. This offers a benefit for the industry in that -- and it applies as well to temporary workers, such as some in the industry.

What the advantage to them of course is, is they don't have to -- with the centralized system they don't have to sit around waiting for a couple of days for the record to be transmitted. They think they can work it out so that in fact there will be some cost savings to them.

So we have sort of encouraged them to do so and have been working with them. So we think the transient worker problem and our requirement of a Form 4 will be in fact considered in that vein. So we have not pushed our own recordkeeping for that reason. We would

much prefer a voluntary system of keeping track of records, but still require them to report on an annual basis.

The inclusion of the exposures that arise from air transport, for example, or the requirement for medical X-rays pre-employment, we have not addressed either one of those problems. We think that it is something that perhaps we should consider, but it's also probably outside of what we can really regulate.

Now, that doesn't mean that we would be opposed to the licensees keeping a check of those exposures. However, we could not require such exposure to be recorded.

MR. KATHERN: Maybe it should be addressed from the standpoint of exclusion.

MR. MILLS: Basically, they are excluded, because we exclude exposures for medical reasons. We also exclude natural backgrounds. So I would think that both of those would be excluded already. But if you ask, should the licensee keep records of those exposures, I think that's something that we cannot regulate.

As to whether or not -- I'll not try to answer completely as to whether or not we are providing more protection to the worker. That question was referred to

earlier, I think, in my presentation. The point is, I think, that we can get better assurance of the protection by the separation of external and internal exposures and the recognition of such, for those few licensees who have a problem with both.

While I have the podium, let me make a point relative to the monitoring. Perhaps one of the areas of disagreement or misinterpretation of what we propose for monitoring requirements, it is in fact a requirement of ten percent of the external and ten percent of the internal in situations where you would expect the worker to be exposed above those limits. It does not say that you do not do any monitoring of the area or what have you.

The one example that was shown of the one worker who might be over the limit, if there is a potentiality, we say, for the licensee that individuals could be exposed above those limits, then we ask that the individual monitoring be applied. But it is not correct to assume that there is no monitoring at all of the situation. The licensee would have to do area monitoring, air sampling, and that sort of thing if he can expect that dose to be 30 percent.

MR. MOELLER: Are there other questions? Jack Selby?

MR. SELBY: Could I make an observation in connection with area monitoring? The data that you get from that, we have one situation -- I also was in the exposure evaluation program at Hanford for a number of years, and as a result I took all the telephone calls when we had suspected plutonium deposition cases. I can remember one vividly where the health physicist, who is probably the best informed person at the plant, called and asked for our help. He said, I don't have any real information to indicate that we've got a problem. All the air sampling data was negative, the surface contamination was negative, and there were several other aspects that he followed that were also negative.

And he would never ever explain to us why he felt that we should be investigating this, but we did respond to it. We sampled 19 people. 13 of them came up with minor depositions. As a result, the area monitoring gave absolutely no information. This was usually in the air sampling at a number of locations in the workplace, and using a high flow rate, not the very low flow rate.

I think the other example of this -- you're getting closer to personnel monitoring -- is the use of pocket dosimeters as a backup to a good dosimeter in cases where you have high exposure, not uniform, for

example during maintenance outages at reactors. Historically, the sum of those pocket dosimeter readings, which are reviewed daily, end up much higher than the actual recorded exposure with the dosimeter.

So area monitoring can only be one tool for a good health physicist and it cannot be the end-all for explaining what the individual is exposed to. I've heard the statement made that it can be the upper bound. I would submit that it's not even the upper bound in many instances, that what you have recorded based on your monitoring results may very well be less than what the individual was exposed to.

MR. RAY: Two questions. I learned this morning that your revision of 10 CFR 20 is based principally to a great degree on ICRP 26. It was indicated that the ICRP changes would be forthcoming within a two-year period.

What would be the impact on industry and any disadvantages they might incur if you deferred the 10 CFR 20 until that time?

MR. MILLS: Well, I won't attempt to speak to what the full impact is on the industry. This is something we would have to discuss with them. As I tried to point out this morning, as we go through the process, the public process, we would expect that after

we proposed it we would be in a process of two years of trying to address the public comments.

MR. RAY: From where you are today?

MR. MILLS: From where we are today, Mr. Ray, I suspect we are three years from any final -- it would be my guess we are three years from anything final.

MR. RAY: The implication here is that you would possibly have the NCRP input before you were ready to publish?

MR. MILLS: Yes, sir. If they came out within two years, we would have it. We are continuing, as I pointed out this morning, to continue the discussions with the NCRP.

MR. RAY: Would I be optimistic if I were to conclude that the NCRP releases would probably influence what you finally publish?

MR. MILLS: Certainly they would be a system that we would have to take under strong consideration and give reasons why not, I think. But as Mr. Parker pointed out, they have been working for some time on the NCRP approach. That too has to go through a vote within the NCRP, which I would imagine would be in itself a point of controversy.

So you've got all of these deliberations that will have to take place, I think, before. So while I do

not disagree that it would be possible that they would have a report in two years, I think we also have to recognize they may not have a report.

MR. RAY: Well, I would feel that it is highly desirable that the regulatory requirements on the American industry, to benefit the American public, would be well advised to consider the viewpoints of the national organization rather than the international organization, particularly since that's the latest view of the NCRP.

MR. MILLS: Well, as a member of the NCRP, I assure you we will do so.

MR. RAY: Another question. We've heard what I consider rather substantive comments from DOE and the DOE contracting organizations. I would like to know if the NRC Staff is considering these comments and will reflect on them and be objective about them as to how they might influence the final copy.

MR. MILLS: Yes, sir. We certainly -- as I mentioned earlier this morning, we are certainly willing to sit down with the DOE and go over their comments. Let me make a point, however, that some of the data you have seen today, this is the first time I've seen that data.

MR. RAY: That was the second part of my

question. So you really haven't assimilated in any degree these comments yet?

MR. MILLS: No, sir.

MR. RAY: Excuse me, Mr. Mills. You said, we would like to or we would be willing. Are you going to sit down with DOE?

MR. MILLS: We have made the offer to sit down with DOE the 22nd and 23rd of November. We think they have taken our offer up and we certainly intend to follow through.

MR. RAY: Good. Thank you.

MR. MILLS: There is one point that I would like to make. These are discussions which we hope will take several days, so that we fully understand where they are coming from, that they fully understand what our intent is, and that there is no misunderstanding of what the rule really says.

As I pointed out, I think there are areas of misunderstanding and misinterpretation of what we intended.

MR. RAY: Thank you.

MR. MOELLER: That's very helpful.

Herb, you have a question, I'm sure. May I ask you one, and if it is improper for you to answer just say so.

MR. PARKER: Try me.

MR. MOELLER: You are, of all of us probably in the room, you're more aware and more involved in terms of what the NCRP is proposing to do, and I'm not asking you to tell us what they propose because that's improper. But could you comment and tell us whether the exercise that the NRC is going through in revising 10 CFR 20, if it will be easy to blend in the newer recommendations of the NCRP, or is it so different that it would require going back to square one and starting over?

MR. PARKER: Well, it's very difficult to answer that question precisely. On the whole, it could be said to blend in, although there will be some amazing simplifications, such as throwing out the whole dose equivalent system, which is totally unnecessary and wrong. That's one of the reasons for the forthcoming changes, so there would be some radical changes that would be in the direction of simplification as far as I can foresee.

Is that responsive to your question?

MR. MOELLER: Yes. That's all we need.

MR. PARKER: Let me make two other comments. First let me support what Bill Mills said in this questioning on the NCRP. I in no way meant to imply

that he or his colleagues had been delinquent in the relationship for NCRP sources. They are indeed slow and cumbersome, and in my view the real progress was not made until the meeting about a month ago in Denver, which radically changed the current outlook and made me much more optimistic than I was before.

So I think we will just about beat that two years, Bill, although the review process is simply a mess.

If I could go to another subject --

MR. MOELLER: Yes, sir.

MR. PARKER: As a matter of clarification, when the NRC talked with us this morning they were really very brief and just explained their actions since the August draft. In the meantime, your consultants have been busily tearing that draft apart.

I am assuming that this is not the occasion where you want the benefits of all those comments.

MR. MOELLER: No, that's correct.

MR. PARKER: Yes, because there are some idiocies, if I can use that word, in the present draft.

MR. MOELLER: We may call upon you to either let us have the benefit or let the NRC Staff have the benefit of your notated copy or write them out separately. By all means we want that.

Ed Vallario and then Frank Arsenault next.

MR. VALLARIO: Two points apropos to Billy's comment regarding the interface with DOE -- I guess that is the 22nd and 23rd of this month -- to advise the Committee here that the 22nd and 23rd meeting we construe as a preliminary meeting. The last Friday meeting with the NRC, we made it clear that we needed some time to evolve an abundance of operational data. We will not have this completely by the 22nd.

So the scoping of the meeting, as I understand, Billy, the 22nd and 23rd is to address the periphery issues and perhaps touch on the main issues. But indeed, that is supposed to be one of several meetings as we understand it.

The second point I would like to make is that there are many things going on with respect to ICRP 26 because of the unsettling feeling regarding its application. In particular, you heard Ken Heid refer to Technical Committee 334 and the results of that Committee's deliberations and their unanimous decision that the 50-year dose commitment was inappropriate. I think that the IAEA Technical Committee's comments should be considered and the results should be considered by the NRC in their revision and their consideration regarding the 50-year dose commitment.

Further, to advise you that the NEA is quite steeped at this present time into the whole question of the implementation of ICRP 26, and it would seem appropriate to be plugged into these groups as well as the NCRP to gain the benefits.

Further, we were advised also today that the ICRP is structuring a group to come up with guidance on the retrospective application. So it would seem that to try to apply ICRP 26 at this time, with all these unsettling views, seems ill-timed, and perhaps what is needed is to follow the Committee very carefully in your deliberations.

Thank you.

MR. MOELLER: Thank you, Ed.

Frank Arsenault?

MR. ARSENAULT: Thank you, Mr. Chairman. I would just like to make a few general observations that may put together a few of the things we have heard previously this morning.

First of all, I would note that we gained a great deal from the EPA experience. It was the extent of the comments received by them that emphasized for us the need to solicit from a very broadly based source comments on the applicability of regulations and standards such as they had published and such as are the

basis for the revision of Part 20.

As a consequence, you heard the Staff describe the contacts they've made and the discussions they've had with a wide variety of sources. I think it is ample evidence that we are interested in receiving the benefit of comments and criticisms of that type. So I think there is evidence that we are receptive to the type of information that the DOE has provided us today and we look forward to analyzing the data they provided and discussing at some depth with them the points that they have made.

Now, I would expect fully in the discussions with them to have experiences similar to what we have had in industry, in which some of the comments go to parts of the revised Part 20 that are more or less immutable, inherently part of Part 20, and can't be changed in any major way without violating the very principles that underlay the draft. Other comments called our attention to places in the draft where our proposals could be significantly improved, simplified and clarified, and we will be delighted to make changes where those are possible.

Still a third category of comments made us realize that, however carefully we wrote the document, people would interpret it in light of their own

predilections and concerns. And for the record I would like to refer to at least two examples of that type of comment that were made this morning and to point out that Part 20 revision is getting a bad rap by being saddled with those criticisms.

I refer in the one case to comments made by, I think it was, Mr. Selby in that relieving the licensee of the requirement for individual monitoring below certain levels was contrary to the interests of the employer in that he would not have recorded data that he might need to protect himself in the event of charges. I don't think there's anything in revised Part 20 that could be read to preclude more accurate, more detailed, or more individual monitoring than is required by Part 20. So if the employer considers it to be in his best interest to implement personnel monitoring techniques that are more detailed than those we require, we certainly would not object.

I think generally in the revised Part 20 the best data available to reflect the exposure to workers is what we recorded. We simply have provided that in some areas more stringent requirements would not be necessary.

Another example where I think Part 20 was said to require something that indeed it does not require was

in the comment by, I think, Dr. Hall when he said that the application of the 50-year effective dose commitment might drive an employee over the limits in Part 20, where the current practice of DOE would not do so, and he would not be required to tell the employee he was overexposed and to remove him from his work and upset his family. That comes as close to a quote as I can come.

Part 20 doesn't require any of that. In fact, we would regard the calculated effective dose equivalent for that year as reading above the limits and would not represent necessarily an overexposure. We know the difference between a calculated and an actual dose.

Secondly, Part 20 does provide for the man being retained in radiation work with, however, some additional and more stringent limits applied to the incremental doses he would be permitted to get that year.

So neither of the two requirements that were inferred from Part 20 I think are valid. As far as upsetting the man's family, I would think that would in fact be an effect from the first two factors and not something that would be done as a matter of actual practice.

So I think a lot of clarification can be

offered to DOE regarding the intent and content of revised Part 20. And for our part, we expect to receive a great deal of additional information and data to allow us to understand more clearly the causes of some of the concerns that were expressed this morning.

MR. MOELLER: Thank you, Frank.

Rags Muller?

MR. MULLER: I just had one question maybe Frank can answer. If after all of these discussions are over it is apparent that DOE has requirements which extend beyond, because of some of the special work that some of those labs are doing, beyond what you normally would get in the electric power generation industry, is it possible there might be a bifurcation or two separate parts to cover the two separate areas?

I think you know what I mean.

MR. ARSENAULT: I think we are developing a revision of Part 20 based on the principles of the ICRP system of dose limitations. We intend however to accommodate wherever we can, without violating those principles, the practical difficulties of the implementation of the system within the industry. By that I mean to include all people who are required to exercise occupational radiation exposure.

If in the discussions with the DOE we find

difficulties that are real and substantive and suggest to us an additional modification of Part 20, we would of course introduce such modifications. If, however, we find the difficulties they feel are not real but are in fact, what should I say, unique and would not in our view justify a revision of the regulation which applies to licensees, it seems to me that it is within the power of DOE to develop an alternative approach and to justify it.

It is obviously to everyone's advantage if radiation protection systems and practices can be more uniform, but I think the question you ask is one that they will have to make a decision on.

MR. MOELLER: We have used up the morning and even used up a little bit of the afternoon, and we could go on for quite some time longer. But I think we have heard what we came here to hear, and we will have tomorrow for the Subcommittee to discuss this more in detail and decide what our possible role or contributions might be.

So let me wrap up this session with an expression of appreciation to the NRC group, Bill Mills and his group, for coming and talking to us, and to Ed Vallario and the DOE group for coming, particularly all their laboratory people who are here, and to Glen

Sjoblom and the EPA group for coming and sharing your thoughts with us.

With that, I will declare a recess and we will reassemble at five minutes after 2:00.

(Whereupon, at 1:05 p.m, the meeting was recessed, to reconvene at 2:05 p.m. the same day.)

AFTERNOON SESSION

MR. MOELLER: It is now 2:05, as I have been taught, and so we will resume our meeting.

The next topic on the agenda is a discussion of the draft federal policy statement on the distribution and use of potassium iodide for thyroid blocking in the event of an accident in a nuclear power plant.

Mr. R. Krimm, who was the scheduled representative from FEMA who was to discuss or simply place in the record the draft federal policy statement, was here at 1:00 o'clock, at the proper time, to offer his presentation, but then we were behind schedule and went to lunch, and he had to go to another meeting.

So, I would ask that we have placed in the record of the meeting a copy of the complete draft federal policy statement.

MR. MOELLER: I think, too, I would like to simply enter into the record the questions or comments that I would have offered him or would have asked of him had he been here to make his presentation.

This is not a criticism at all of FEMA, because this is a joint effort of federal agencies, but it was my conclusion after reading the draft federal policy statement, and particularly checking carefully the last paragraph, I found very little in the way of policy guidance in it.

In other words, it says, whether KI should be stockpiled and distributed depends on local conditions, and its use should be evaluated by each state or local jurisdiction based on the specific conditions and environment for each operating nuclear power plant, and that the local people will make the decision.

Well, that is non-policy guidance in my opinion, if you just simply -- maybe that is a decision, that we will leave it to the local people, but I personally, in looking through the policy and looking at the whole subject, have found that if I were a local authority and was faced with such a decision, that I don't have the guidance I need to know when and if I would require the distribution of KI and under what circumstances.

So, not knowing any more about it than I do, I would certainly recommend that some of the federal agencies consider offering more in the way of guidance to the state and local groups.

Do any of you have comments on the general policy statement?

MR. AXTMANN: Well, it seems to me that they decided that they didn't want -- for a while their neck was way out, saying, we are all ready to implement a KI distribution plan, and then found there was confusion in the ranks, and decided to bail out, and they did it that way. They might have also said, this is up to the utility to do it, or the NRC, or somebody else.

I don't see anything sinister.

MR. MOELLER: No, not at all. It was simply apparently a way that they handled the situation.

MR. MOELLER: I just had two comments on it. One, I think I want to call everybody's attention again to that German paper I ran across, which I think was distributed, wasn't it? Wasn't that German paper distributed to everybody?

MS. TANG: Last time.

MR. MOELLER: Since the last time, because I sent in something else.

MS. TANG: Since the last time you added some

tables to the last paper.

MR. MOELLER: Was that distributed?

MS. TANG: It is not in this current package. We can make some copies of it. The gist of it was, that was a discussion of some of the impact of plain iodine on the thyroid in the human system, and apparently it isn't at all clear that iodine isn't a problem, especially under certain conditions.

The other comment, I mean, last time we heard the American Thyroid Association indicate that there wasn't any known effect at any levels below 100 R to the thyroid, and it made me wonder why you would want to block it at any lower level, at one of the lower levels. Suggested, I think, was 25, and then there were some other papers last time that even suggested considerably lower than that.

MR. MOELLER: Okay. Why don't we move on, then, with the agenda, which calls for comments from the NRC staff on their views and positions on the draft federal policy statement?

For that presentation, I will call on Brian Grimes.

MR. GRIMES: Thank you.

As you pointed out, there has been an interagency working group which did work with FEMA to

develop a draft federal policy statement on the distribution of potassium iodide and in particular for the general public.

I would just note that the statement does set out the advantages and disadvantages of using potassium iodide, some of the logistical difficulties which might be encountered if one were to try to put that sort of thing in place.

As you correctly noted, the paper takes no federal position for or against the distribution of potassium iodide to the general public, and leaves the matter to the state or local groups to make a decision.

With respect to the NRC's status, the NRC staff sent this draft statement to the Commission for its review in SECY 82-396. After that statement was provided to the Commission, the NRC Office of Research indicated that they believed that the previous contractor cost benefit analysis done by Sandia could be refined at this point, and perhaps a firm position against the distribution of potassium iodide to the general public could be developed.

The paper sent by the staff to the Commission was therefore withdrawn by SECY 82-396A pending the promised research study which is due approximately January 1. We would anticipate after that study becomes

available deciding on a course of action at that point, and they are working with FEMA and other federal agencies after they digest the results of that study.

That's all the comments that I had to make.

MR. MOELLER: Yes, Jerry Ray?

MR. RAY: I have a question that is once again an elementary sort. Do we know, or has it been established whether there are any adverse radiological reactions on the part of some humans to the injection of KI?

MR. GRIMES: I believe we know that there are some adverse reactions in some segments of the population. There is a statement by the FDA which weighs those adverse effects and makes a conclusion that the drug -- that the benefits of taking the drug would outweigh the risks from taking the drug at an exposure, a projected exposure of about 25 rem to the thyroid.

MR. RAY: So even in the case of someone who was unresponsive to it, it would be an overriding consideration?

MR. GRIMES: No. I'm sorry. If an individual were known to have an adverse reaction, then that individual under the policy statement would be cautioned against taking it.

MR. RAY: Thank you.

MR. SHAPIRO: I might say we discussed that at our isotopes meeting at Massachusetts General, where we do have research workers, and the question was brought up as to whether they should be given potassium iodide, and our own thyroid specialist there recommended against it. He said you could have problems. So I think one has to determine at what level the benefit does outweigh the risk, because there is a risk.

MR. MOELLER: Thank you.

MR. PARKER: But that would be repeatedly different in your practice rather than the one-shot accident application.

MR. SHAPIRO: I don't know whether it would be considered one shot versus multiple use, but I think that is certainly a point.

MR. MOELLER: Do you hav that paper that was written by K-a-l-l-e-e? I think you don't Ms. Tang can provide you with a copy of i th the charts and everything. It is very interesting.

MR. RAY: Does that bear on this subject?

MR. MOELLER: Yes.

MS. TANG: I got you a copy, but I will try to get another one.

MR. AXTMANN: I have a question for Mr. Grimes. SECY 82-396A says, in the second paragraph of

the discussion, I am now informed by our Office of Research that in light of information available on the behavior of radio iodine during a reactor accident, a technical paper would show that the use of potassium iodide for the general public is significantly less cost beneficial than previously assumed.

What was the information, and where is it written down?

MR. GRIMES: I believe the office of research is now writing down the information which they have stated is available. I think they are referring to the general information that has been brought forward on source terms to date, and they believe that while they cannot come up at this point with a new general source term recommendation, that they do know enough to refine some of the assumptions that were made in the cost benefit study by Sandia which were done with respect to potassium iodides.

So they have in mind refining some of those things which were stated to be conservatisms, but not directly factored into the cost benefit calculations at that time.

MR. AXTMANN: I keep looking for written, not spoken, confirmation of what I have deduced from what you are saying, and you are saying that there is

significant new information on the degraded core reactor source term, and I have simply not seen any hint except SECY 82-396A and something I got in the mail one week ago NSAC 50, dated May, 1982, which says that EPRI studies concluded that the degraded core accident source term is lower than previously considered.

Now, we all realize that the TMI 2 source term was less, but there have been studies done that examine noit TMI 2 but the whole spectrum of conceivable degraded core accidents.

MR. GRIMES: It is my understanding that the Office of Research has such studies under way. I have not seen the material myself, and am awaiting myself to get the paper which the Office of Research has promised.

MR. AXTMANN: So there is no such paper. Is that what you're saying?

MR. GRIMES: I am saying I don't have it.

MR. MOELLER: I have the same problem that Dr. Axtmann does in that the implication in the SECY 82-396A is that there is new information and therefore we are going to ask them to recalculate it, and we know it is going to show that there is no need for KI pills to even be distributed, and I have read Mr. Minogue's paper he presented at the AIF meeting, October 3 to 6, 1982, in

New Orleans, Louisiana, and the paper covers three subjects.

The first one is the source term, and it says that -- it traces the history and then it says, "Our research program now is looking both experimentally and theoretically at the chemistry and physics involved in all phases of severe accidents, that is, accidents in which there is fuel damage such that fission products escape from the fuel."

Well, the Committee has been told, and we review it twice a year in terms of the reactor safety research program. We are thoroughly familiar -- I hope we are -- with all of this planned research, but I have yet to see the first numbers coming out of it.

How can you reach all of these decisions when the research has not been completed? Had SECY 82-396A said -- Had it been a recommendation to the Commissioners that you hold up on the policy statement on potassium iodide until such time as the results of this research are in, I would have understood that, but that wasn't what it said at all.

MR. GRIMES: Well, I will bring to the Office of Research's attention your concern and urge them in their January 1 paper to include the appropriate documentation. SECY 82-396A was rewritten based on

comments from the Office of Research on SECY 82-396, the submission of the reactor policy paper, and it was based on those initial offers that 396A was written.

MR. MOELLER: Are there any other comments on this subject?

Excuse me. Herb Parker?

MR. PARKER: I think one of the problems is, we have no concept of the shelf life of the potassium iodide. We have been told that the iodate is a catastrophe, and you give that up. Then the paper I've read so far simply says it is left to the manufacturers to determine the shelf life of their potassium iodide product, but surely someone knows whether this is on the order of one year or ten years, which might be the very factor that persuaded you whether the thing was feasible or a pain in the neck.

Is that number known?

MR. AXTMANN: I am told that the potassium iodide that showed up at TMI 2 came from a chemical manufacturing company whose name escapes me that is just outside of Princeton University -- pardon me, five miles outside of Princeton, New Jersey, and that they ginned up several tons of this in a few days because they had a process going, but they have no way of establishing a shelf life in the absence of orders, you see.

Up until that time, they had a few capsules, and I don't know what it takes to establish a shelf life of a chemical that apparently requires tonnage quantities and some kind of sponsorship which this rather small chemical company is not willing to undertake. So it's a Catch 22. The shelf life presumably is long, but there is so far no motivation or financing to establish what the FDA would accept as a shelf life.

MR. MOELLER: Dr. Bernard Schlein is here from the Food and Drug Administration Division of -- Is it Division or Office? -- Office of Devices and --

MR. SCHLEIN: National Center for Devices and Radiological Health.

MR. MOELLER: Why don't you take the floor, Bernie, and just solve our problems here? I would like for you to comment both on the shelf life of different forms of iodide as well as to repeat what you told us last time on the selection of 25 rem as the dose.

MR. SCHLEIN: Let me say something about the shelf life. I think it has been pointed out the FDA does not set shelf lives. The manufacturer has to submit samples that have been sitting on the shelf or having been tested under accelerated conditions and then an assay is done, and if the material is still up to

potency, the shelf life is that long.

The FDA does not go out and solicit a shelf life. The manufacturers thus far have submitted material that permits it to set a three-year shelf life on that particular drug. Until they care to submit material that is five years old, we can't do anything about it. It is just the matter of the law.

MR. AXTMANN: So that will be two years down the road?

MR. SCHLEIN: I am afraid so, yes.

MR. MOELLER: So you have no idea?

MR. SCHLEIN: We have no control over that, and neither do we have any data beyond what the manufacturers have submitted.

MR. MOELLER: Okay.

MR. SCHLEIN: I don't exactly know what you would like. I would prefer not to go back over my presentation from last year. Several questions have been raised, one concerning the German study, which I did take back and I did review.

MR. MOELLER: Would you comment?

MR. SCHLEIN: Germany is an area where there is an iodide deficiency. Consequently, one would expect a higher number of problems with the use of stable iodide that you would expect in the United States, which

is not an endemic goiter, not an endemic area where there is an iodide deficiency.

Also, I really do hesitate to go through my previous presentation or through the 20 or 30 pages in the FDA recommendations. Quite honestly, we weighed everything we knew about the carcinogenesis, and we weighed very heavily a paper which will appear in Aviation Research where we compared doses of radio iodine and external radiation to the thyroid, and found that the ratio of carcinogenic risk is one to one.

Therefore, we felt, given this particular factor which we feel is a new research factor, and given the fact of numerous external radiation studies that show increased induction of thyroid cancer down to nine rads, the Modan study, the 25 rem was a reasonable proving ground.

MR. AXTMANN: I have forgotten. How do the Germans make up their iodide deficiency? Do they do it through salt, like we do in the states? Or do they take pills? Do they take potassium iodide pills?

MR. SCHLEIN: Frankly, I have no idea. Some areas use -- for example, the diet in the United States has about 300 micrograms of iodide each day just from material that is used in bread baking, from vitamins. Some contain iodides.

MR. AXTMANN: Well, iodide salt.

MR. SCHLEIN: Well, then, of course, iodide salt. I don't know what the Germans do, frankly.

MR. AXTMANN: I thought maybe they might have a tablet that had been sitting around for 14 years perhaps.

MR. SCHLEIN: Interestingly enough, they did an independent study, and if I remember correctly, it was reported at the last meeting in Stockholm, the meeting that was held in Scotland last year, the Radiation Protection Society over there, and I believe they came up with, because they had this particular problem, that they came up with a number of around 100 rem where they would give potassium iodide.

As I say, given the difference in the risk factors, I don't think that's unappropriate.

MR. MOELLER: Thank you very much, Bernie. That is helpful.

Brian, I think about the only --

MR. SCHLEIN: Could I just make one other point?

MR. MOELLER: Certainly.

MR. SCHLEIN: In addition, they did not consider that particular animal study which I think very much influenced our deliberations.

MR. MOELLER: Thank you again.

Back to Brian. I think our only comment of significance is the one that Dr. Axtmann has made that I reinforce. That is, we would like to see the data that support the decision that was made.

All right, let's move on, it now being 2:30, and we will take up the proposed 10 CFR Part 140, the criteria for extraordinary nuclear occurrences, and Hal Peterson is going to be the NRC Staff spokesman on this.

MR. PETERSON: Now that I am wired up, thank you, Dr. Moeller.

The extraordinary nuclear occurrence definition is one that the Commission itself did not develop but was developed by Congress. Basically, as you can see, it has two substantial parts.

(Slide)

It requires a finding by the Commission that radioactivity has been released from its intended place of confinement in amounts offsite or levels offsite that the Commission finds to be substantial, and then it also requires that the Commission determine that those releases have caused damages which the Commission has determined are substantial.

I think it is very important here to recognize that what is substantial is a value judgment. It is not arrived at by any scientific analysis or so forth.

(Slide)

The reason we are revising the regulations, which I will come to, is that during the Three Mile Island accident, the Commission actually did go through

for the first time and ENO determination. It found that the Three Mile Island accident was not an ENO, primarily because of the fact that there were not substantial releases or doses, offsite doses. The damages were a difficulty in evaluating in terms of the magnitude. That was the primary purpose that we decided to redo the ENO definition, because the original phrasing included total damages, some of which the magnitudes could not be assessed without a court resolution, yet the Commission was required to make a prompt determination in order to provide a speedy processing of claims as a result of any reactor accident.

I might point out that the Commission's ENO determination, if positive, has three primary effects, all of which are legal. It removes the necessity of a claimant to prove negligence on the part of the reactor operator. That is implied. Once an ENO determination has been made, the claimant only has to prove damage.

Secondly, it consolidates all of the claims for a particular reactor accident within the nearest U.S. district Court without having multiple law suits wherever the claimant happened to be.

Thirdly, it extends any statute of limitations of the states out to 20 years, which would cover radiation-induced injuries.

Those are the three primary roles that an ENO determination has. They do not affect the availability of Price-Anderson liability funds, and they do not trigger the disbursement of the nuclear industry's own insurance payments. Those took place, at least the private funds, at Three Mile Island without any ENO decision.

MR. MOELLER: Has there every been an ENO?

MR. PETERSON: No. The current criteria for substantial releases are based in part on doses.

(Slide)

In fact, they use doses right here. As you can see, it is a 20 rem dose to the whole body, 30 rem to the thyroid, 60 rem to the skin. I took somewhat pleasure in reading the comment that came in this morning addressed to this issue simply because the suggestion was that we take into account the protective action guides in developing the ENO criteria. That, in fact, was the source of the 30 rem thyroid dose. This was the original protective action guide for an individual, not a suitable sample of the population that was specified by the Federal Radiation Council back in, I believe it was, 1965. That was the source of that number.

At that time there were no equivalent PAGs for

other organs except the bone. I should say that. The whole body did not have its own, nor did the skin, so they took a multiple of the occupational exposure. In the case of whole body it was four times the 5 rem per year limit.

The point is, I should point out, with regard to both the original selection and our modification it is the substantial release in the sense of being substantially above what we would expect from normal operation.

MR. RAY: Maybe I wasn't listening hard enough when you first addressed this slide. Are these either/or? Must they all be present in order to have a substantial release, or any one of them?

(Slide)

MR. PETERSON: Let me show you a logic table.

MR. RAY: I hope I can understand it.

MR. PETERSON: The event, this essentially always takes place. Any accident would be -- TMI, for example, did fit the event one, so that goes into this "and" box. The amount of radiation levels offsite, which is substantial, is an "or." It can be one or the other or both. So that finding must be made. That was one of the three.

Then with regard to the damages, the damages

to persons and damages to property, they either have resulted or will result and all of those are "or's." So any combination, anything that leads along one of these three paths will give an ENO. The first one almost always happens.

MR. RAY: Let's dwell on the second block. Commission determines that amounts offsite are substantial.

MR. PETERSON: That is correct.

MR. RAY: Now come back to this slide. Must I have each of one of these levels in that particular area of exposure or any one of them would determine substantial releases?

MR. PETERSON: Any one. You also don't even have to have a dose to anybody; you can just have substantial contamination. It refers here to amounts offsite.

MR. RAY: Are the levels quantitative levels to determine substantial contamination and you will come to that?

MR. PETERSON: Yes.

MR. MOELLER: And this is getting ahead, but will the proposed change in the definition of an ENO make TMI-2 an ENO?

MR. PETERSON: You are jumping ahead, but the

answer is no.

MR. MOELLER: It still won't do it?

MR. PETERSON: No.

MR. RAY: Do we have a copy of that slide?

MR. PETERSON: Sure.

MR. RAY: It wasn't in the handout.

MR. PETERSON: It was a backup slide.

[Slide.]

These are the contamination levels presently existing. You can see that they are fairly gross numbers. They concern alpha from transuranics, non-transuranics, beta or gamma emission of 4 MR per hour, 1 centimeter, .1 milligram per centimeter absorption. So they are really rather gross levels.

Now, we did look at -- I should point out there is another set that is ten times larger that applies to land which the licensee or the person indemnified owns. So I didn't clutter up the slide with that, but that is a minor point which we are dropping. We figure if the licensee's land is the only land contaminated, there is no reason for the ENO determination to be made.

MR. KATHERN: This is contamination outside of some boundary?

MR. PETERSON: The boundary is covered in the

indemnification agreement.

MR. MOELLER: I am pretty sure it is land beyond the border of the facility.

MR. KATHERN: Okay.

MR. PETERSON: These numbers are definitely -- the numbers I mentioned that were ten times higher would apply to land that was perhaps separate. One could see like a switching station that was separate from the site but was contaminated by the event.

MR. MOELLER: Hal Parker has a question on that same slide.

MR. PETERSON: Certainly.

MR. PARKER: I was trying to read what you said about beta or gamma. How are you going to measure the beta emission that way?

MR. PETERSON: With a very thin window.

MR. PARKER: You don't get roentgens out of it.

MR. PETERSON: The site is wrong, the rule is right. It is 4 MR.

MR. KATHERN: They read the scale.

MR. PARKER: That is one way of doing things.

MR. KATHERN: I hope not.

(Slide)

MR. PETERSON: What we are proposing is a 5 rem effective whole body dose, so that the effective

change is a 20 rem whole body dose and goes down to a 5 rem dose. This is still significant in terms of being far above normal release limits. Well, at the time the original limits were proposed, the operable number was the 500 millirem per year dose limit for the members of the public, so that the ratio was 40 between the 20 rem whole body dose and the normal release limit.

What we are proposing, you should bear in mind that the current release limit is based on EPA's 40 CFR 190 and is .025 rem. So that we actually are proposing a number where the difference between the normal operation and the ENO limit is a factor of 200, even though we are reducing that down.

I should also point out that at the current time we have a factor of 800 between the .025 and the current 20 rem ENO criterion, but essentially where we are coming down in terms of the total numerical value, we are still maintaining a substantial distance above what would be a normal operating level of a reactor for triggering this.

The basis we are using in part is the fact that both the FDA and the EPA have recommended proposed protective action guides that deal with whole body doses from either gaseous emissions or foods, and the FDA has proposed a two-level scheme using a preventive PAG of

half a rem and an emergency PAG of 5 rem, at which point you would start considering confiscation of foods. EPA has proposed a scale of 1 to 5 rem, the higher number being more mandatory.

We believe that the ENO concept is in fitting with the higher mandatory action level so that you would consider an ENO if you had to have taken protective action, and that is essentially what we are proposing as the equivalent of a substantial dose, is one that you would have had to take protective action to avoid.

I might add that the way the rule is worded on this, we are not requiring that protective action has been taken or what happens with regard to a particular actual event. Whether the authorities call for an evacuation or do not does not affect the ENO determination; it is whether they should have, because the ENO is going back. It is not a radiation protection limit per se; it is an internal number for the Commission's use in evaluating an accident that has already happened. I think that is an important viewpoint in viewing what the significance of this number is.

(Slide)

Now, the damages in the existing rule are five or more people killed with objective clinical evidence

of radiation injury, or $2.5 million of damage sustained by one individual, or $5 million of damage sustained in the total, or $5,000 sustained by 50 or more persons, and at least $1 million in total. I think you can see why the Staff has made recommendations to change some of those.

Actually, when you plot these you get an interesting effect that one person gets $2.5 million but the 50 people only need $1 million, and any number of people would take care of $5 million. So that there is no apparent proportionality between the total amount required to satisfy the physician and the people affected.

MR. MOELLER: Again, at TMI -- and I realize you have had these formulae where you allow, what, $100 a day while you are gone for loss of employment, and $25 a day for your expenses to shelter?

MR. PETERSON: That is the insurance industry's figures. Those are not the Commission's.

MR. MOELLER: Okay. You are saying to me there were not 50 people at TMI that incurred $5,000 or more loss in business or farming or anything?

MR. PETERSON: Well, loss of business is not covered. Maybe it would be --

MR. MOELLER: Loss of business is not covered?

MR. PETERSON: What was covered were evacuation costs.

MR. MOELLER: Why didn't we make it in ENO?

MR. PETERSON: Because of the first finding, the either/or. You have to have both substantial releases and substantial damages. If you have substantial damages without the releases, it is not an ENO.

MR. RAY: That did not come through in your first slide.

MR. PETERSON: I am glad Dr. Moeller raised the question, then, because now it is clarified. The damages that are covered in this part include the protective action, and this includes the evacuation costs. It also includes the cost necessary to put property back into use, or if it has lost its value, the cost of the loss of use. But it is hard to say that this arose from the toxic or explosive levels.

MR. MOELLER: Have you arrived at a value for psychological damage yet?

MR. PETERSON: You know that is a sore point. We did consider putting it in as a criteria to the revision. The big problem there is that our conclusion was that the damage, the magnitude of the damage was not necessarily proportional to the magnitude of the

accident, and without saying anything about certain agencies who perhaps added to that concern, that it is too hard to evaluate.

I think the psychologists could measure it. They could measure it at TMI, the anxiety, but is it related to the accident in terms of proportionality, or did some other incident that wasn't quite related to the accident, such as media coverage or something that got put out of proportion.

MR. KATHERN: I don't quite understand. Dr. Moeller asked a question about loss of business, and you said that wasn't a damage or injury. Did I hear you correctly?

MR. PETERSON: The loss of business per se was not. It says loss of use of affected property. In other words, if you had a business that got so contaminated that you had to close for a while.

MR. KATHERN: But if you evacuated the area so that people couldn't come to my place of business, that is the same thing, effectively, as contaminating it. In other words, the bottom line in either case is I lose my business.

MR. PETERSON: I think that is true, but there are certain expenses that were considered when the rule was initially formulated and some that weren't.

MR. MOELLER: Frank Arsenault is waving his hand.

MR. ARSENAULT: I think I am hearing something back here that may not be carrying up there. The distinction is between loss of use of property, including having to close down a business, either by reason of contamination or evacuation, as distinct from the loss of business occasioned by the nervousness of your customers, which is not loss of use, merely loss of business. I think that is the distinction he is trying to make here. The former, loss of use, either by evacuation or contamination, would be a loss, a damage. If people don't come to your front door, that is the criteria.

MR. KATHERN: That is the question I had, the actual physical prevention of people from coming to the front door.

MR. PETERSON: Thank you, Frank. I wish I had said that.

(Slide)

Finally, we are preparing to revise these two. We will call a substantial injury a 500 rem dose or greater to five people. This gets around the present restraint to identify clinical objective evidence of radiation injury, which we have --

MR. RAY: Excuse me. I didn't hear you read that the way it is printed. You said a 500 rem dose to five people.

MR. PETERSON: 100 rem. I'm sorry. It is printed right. The point that I am making here is that the previous criteria called us to find five people who were killed outright or who were hospitalized with objective clinical evidence of radiation injury. One of the psychological aspects of Three Mile Island, to me, was to point out a lot of the symptoms of stress are exactly the symptoms of the acute radiation syndrome: the nausea, the vomiting, the clammy hands. A lot of the symptoms are very much the same.

So I said now what do we use for clinical objective evidence of radiation injury? Chromosome aberrations could be used for small numbers of people, but there you don't have proof of injury. You have proof of maybe radiation exposure, but most physicians say it is not known how that relates to actual injury to the person.

So we decided that instead of trying to develop a better definition of objective clinical evidence of radiation injury with regard to that, in the old days I would have said just list the symptoms of acute radiation syndrome and we would have it, but it

looks like in fact that may just be a general stress on the body. The stress reactions have very similar symptoms and therefore would not be very useful in the kind of an accident where you would expect the population that was exposed to the radiation to be somewhat stressed.

So we are proposing a dose limit of substantial injury and then smaller doses to larger numbers of people in terms of the linear threshold approach, and then the definitions of damages would be only in three categories: contamination or loss of offsite property due to contamination, lost employment, and evacuation of at least 100,000 person days duration. These we figure we can get very good early readings on without waiting for court cases in order to decide what total damages would be. That is why we picked them. And yet they are representative of the types of things we would expect in the case of a very serious radiation accident.

MR. MOELLER: Excuse me. Before you take that down, I want to call to the attention of the Subcommittee that there are many ramifications in the first item. The 100 rem is 100 rem effective dose equivalent, and if you read the details, then, you are using ICRP 26's weighting factors. And in a sense, this

is then identical to our whole discussion this morning on the revision of 10 CFR 20. So we will have to keep that in mind.

MR. MULLER: So if that doesn't fly, then this doesn't fly.

MR. MOELLER: Correct. And this should not fly right if it doesn't, or else they could get around it by simply using a term something like whole body equivalent without giving the formula.

MR. PETERSON: Are there any other questions? If not, I am done.

[No response.]

MR. MOELLER: Okay. Any more questions? Let me just ask: how long is NUREG-0637, which gives the details of NRC's decision that TMI was not an ENO?

MR. PETERSON: I guess it is about an inch thick.

MR. MOELLER: I guess we have seen it. Has the Committee? If it went by, it went by real fast. Could you just -- or we can get someone here to get us a copy.

MR. PETERSON: I can probably send you a copy.

MR. MOELLER: But it simply took the criteria and laid them out, and it didn't work or it didn't fit.

MR. ARSENAULT: Mr. Chairman.

MR. MOELLER: Yes, Frank.

MR. ARSENAULT: A few additional observations of a more general character. First, I made the comment when we started on this paper that it would be hard for me to accept that an ENO could be caused by a reactor that had less substantive impact on people than I could create driving my Volkswagen bus home, and I suspect that if I tried real hard, that I could kill more than five people on the way home. So we really need to put the concept of an extraordinary nuclear occurrence in perspective.

The second observation is I think Congress did exactly that when it drafted the definition. It required that there be a substantial release or radiation or radioactive material and asked the Commission to define what that meant, and indicated that this release should result in substantial damage. I think the Congress conveyed in that definition what its intentions were with respect to the definition of the ENO.

So I have heard the question, well, why wouldn't TMI be an ENO? The fact is that there were damages or injuries, both psychological and practical, at the facility, but one must ask if they were in fact caused by the accident or the psychological environment

surrounding the accident and the way in which the accident was handled by different individuals. So these are additional perspectives I think the question has to keep in mind.

One final note. When we talked to the EDO's office on this point, one of the EDO staff raised the question, should the definition be changed? That is a question of legislative recommendations and was not one which the Staff addressed in attempting the revise the criteria so they would be more workable.

Obviously, if the Commission chooses to seek legislative adjustment or if the Congress itself chooses to modify its definition, then we would have to go back to square one. We have only addressed the question of a workable criteria under the current definition.

Thank you.

MR. MOELLER: Thank you.

I think for the Subcommittee the main point that I want to make is that this item and the previous item on the potassium iodide and thyroid blocking, those are two items in which the Committee has been specifically requested by the Commission to offer comment. So the previous one, I think I know what we will say, which I will repeat: that is, to request the data that support the decision that was made. On this

one I think we will have to discuss exactly what it is that we want to say.

Well, there being no other questions and that having completed that particular presentation, I will declare a 15-minute recess.

MR. MOELLER: The meeting will resume.

The next item on our agenda, and in fact for the remainder of the afternoon, is to discuss the de minimis concept. We are going to begin with a presentation by the NRC staff on the de minimis concept from a regulatory standpoint. That presentation will be made by Joanna Becker. Joanna?

MS. BECKER: Thank you.

I am subbing for Guy Cunningham, who had to go to another meeting, but I wrote the speech that he was going to give anyway, so I am quite familiar with the general subject.

MR. MOELLER: Maybe we had better harness you up with the microphone, because I want to be sure everyone can hear.

Excuse me. Before you begin, and this may be jumping the gun, but did you have then the major input into the section on de minimis that is in the draft 10 CFR 20? Or is this a separate thinking?

MS. BECKER: I had some input into the de minimis section in Part 20, but this really goes into the legal aspects.

MR. MOELLER: Good. Thank you. That will help me.

MS. BECKER: As I am sure you all know, or

maybe you don't, the so-called de minimis concept more properly referred to as de minimis non curat lex, means the law doesn't concern itself with trifles. I should point out that whether the term de minimis is used or not, the concept doesn't have the same legal connotations as a license exemption or a general license since those concepts are inherently recognize the existence of radioactive material and usually qualify the exempt or generally licensed activity to particular uses or characteristics.

Nor is the de minimis concept the same as the "as low as reasonably achievable," the ALARA concept. Persons interested in the NRC regulatory process have tended to equate the de minimis concept with the license exemption, general license or ALARA concept erroneously in the legal staff's opinion.

The NRC regulation of radioactive materials in the interest of protection of the general public may be characterized as a series of requirements in descending order relating to risk to the general population. At the top of the regulatory list, maximum permissible levels are presently set forth in Sections 2105 and 2106 of Part 20. Section 2105 provides that permissible levels of radiation in unrestricted areas shall be such that no individual is likely to receive a dose to the

whole body in a calendar year in excess of .5 rem.

Two, that radiation levels shall be such that no person continuously present in an area could receive a dose in excess of two millirems in any one hour or 100 millirems in any seven consecutive days.

And Three, licensees in uranium fuel cycle operations shall be in compliance with EPA's 40 CFR Part 190.

Section 2106 provides that licensees shall assure that radioactivity and effluence to unrestricted areas shall not exceed the concentrations in Appendix B, Table 2 of Part 20 except as specifically authorized or as authorized pursuant to Section 2302 relating to waste disposal, and that licensees engaged in uranium fuel cycle operations also comply with 40 CFR Part 190.

These permissible levels of radiation in unrestricted areas and discharge of effluents containing radioactive materials to unrestricted areas involve doses above which the Commission considers the risks unacceptable or at least unreasonable to expect under normal circumstances.

Below the levels established by license conditions imposed under Section 2105 and 2106 is the ALARA range of releases and or doses. Releases or doses permitted in the ALARA range are based upon

consideration of cost, benefits, and other considerations related to practicability. Paragraph 20.1(c) of Part 20 defines ALARA as follows:

The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology and the economics of improvements in relations to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.

Keeping doses ALARA is not presently stated as a general requirement in Part 20. However, the concept is frequently incorporated in materials license conditions by reference to commitments in license applications. Facility licenses contain technical specifications for keeping releases ALARA as provided in Sections 50.36a or Part 50.

ALARA quantities or concentrations in releases are not necessarily at or below a de minimis level. While licensees are not presently required to operate at lower than the ALARA level, the Commission does not by the very fact of consideration ignore the risk from ALARA releases.

The Commission has also established in its regulations exemptions from licensing requirements for

unspecified quantities or concentrations, forms or uses of radioactive material which may be below the ALARA range but which are not still necessarily de minimis.

The exemptions in Commission regulations usually permit use or disposal of exempted products or quantities without regard to their radioactivity. However, exemptions are issued by the Commission in rulemaking proceedings in which cost benefit considerations are the primary consideration.

A recent example of an exemption may be found in the recent amendments to Part 20 in 20.306, which permits disposal of liquid scintillation media and animal carcases containing tracer levels of tritium or carbon 14 without regard to their radioactivity, and raises the annual limits of those materials that can be disposed of by release to sanitary sewer systems by amendment of 23.303(d).

Section 20.306 specifically provides, however, that such disposal under the section does not relieve the licensee from maintaining records showing receipt, transfer, and disposal of such material as required by Part 30.

As the notice of rulemaking demonstrates, the Commission considered costs in terms of radiation hazard to sewage system workers and expected radiation doses to

the public as well as the savings in elimination of burial in radioactive materials in terms of cost to licensees, problems in transportation, and shortage of radioactive waste burial capacity.

By contrast, the de minimis concept, the lowest level in this hierarchy is not based on the ALARA concept or the cost-benefit considerations involved in the issuance of an exemption through rulemaking. Rather, the de minimis concept as used in the revision of Part 20 being drafted by the NRC staff is that any health risk to the members of the general public due to the presence of radioactive materials or radiation is so low that the radioactivity in such releases may be regarded as trifling.

The de minimis risk can be expressed in terms of dose rate as a surrogate for specification of quantities of radioactive material. As the ICRP said in Publication 22, "The use of the concept of population dose in the process of decision-making should ... be supplemented by consideration of the dose to individuals. At low levels of individual dose, e.g., those small by comparison with variations in local natural background, the risk to the individual is so small that his health and welfare will not be significantly changed by the presence or absence of the

radiation dose."

As an aside, it might be noted that the term "de minimis" which has been used in the notice of proposed rulemaking of the new Part 61 dealing with low level radioactive waste is somewhat misleading in that the term was used to refer to the possible development of an exemption for de minimis amounts of specific waste.

Thus, we have a regulatory scheme that has as an upper limit above which the calculated health risk is generally unacceptable and a lower bound value that implies a risk that, if it exists at all, we believe fully acceptable without further consideration.

In between these two values, regulatory requirements are based on the application of the ALARA concept, and any risk is judged acceptable on the basis of not only the magnitude of the health risk, but also social and economic factors that are involved. If the Commission adopts a de minimis concept in Part 20, NRC and its resources would be relieved of the burden of licensing activities relating to releases and disposal of de minimis quantities of radioactive materials, and also of enforcement activities relating to such quantities.

The Commission and its staff could thus avoid

the complex calculating of doses integrated over the entire population and over all time which would be inherent in the process of taking the "exemption from licensing" route rather than reflecting the de minimis concept in Part 20.

To express the concept in quantities, which is the usual form for an exemption, would involve the further calculational problem of considering the infinite number of pathways to man. Accordingly, the de minimis concept would be based upon risk and its surrogate dose, not quantities. The NRC staff, and I am sure that Dr. Mills will go into this further, is of the view that of necessity the de minimis quantity can only be applied to doses at very low levels. The concept would not likely be of help to the nuclear industry in easing the regulatory burden relating to waste streams.

Any relief in that area would have to be accomplished by the exemption route, as in the case of the exemption for carbon 14 and tritium wastes. A problem in NRC's incorporating the de minimis concept in Part 20 is the danger that doses above the de minimis level might be perceived by members of the public as unacceptable or even dangerous. This would result from the definition of "de minimis" which is that such matters, that is such doses, are a trifle.

Accordingly, higher doses might be perceived as more than trifling and perhaps even substantial. Such a perception could lead to unwarranted opposition to exemptions, general licenses, and operations under license conditions. From the standpoint of the licensee, adoption of the de minimis concept would relieve them of the burdens associated with licensing and regulation of releases or disposal of de minimis quantities which are de facto ALARA quantities.

Licensees would, of course, have the burden of establishing by calculation or otherwise that radioactive material released was in fact within the limits established by the Commission by regulation. The same result could be achieved if the Commission used its authority to exempt de minimis quantities from the licensing requirements of Sections 53, 62, and 81 of the Atomic Energy Act and 10 CFR Parts 30, 40, and 70. However, the difficulty of defining de minimis doses in terms of quantities or forms appears to preclude that regulatory approach as a practical matter.

The de minimis concept, in those words or equivalent, has formed the basis for some judicial and regulatory decisions in the United States. Cases in areas most analogous to the NRC statutory mission--protection of the public health and safety--are

those arising under sections of the Federal Food, Drug and Cosmetic Act, are not particularly relevant because of differences in interpretation of the statute. I will not go into those, although a discussion of them is included in the printed material.

A better analogy is found in the Food and Drug Rulemaking proceeding to implement an amendment to the so-called "Delaney Clause," which provides that "no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of the substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of exemption prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) of this section) in any edible portion of such animal after slaughter or in any food

yielded by or derived from the living animal, ..."

The notice of proposed rulemaking pertaining to the use of DES in cattle feed which followed the amendment which was published in the Federal Register March 20, 1979, discussed at length the linear theory of carcinogenesis, and adhered to the " no threshold" theory analogous to that used by the NRC. However, without using the term de minimis, the FDA concluded that a risk level of one DES-induced cancer in one million people was so low that the FDA could conclude that the risk level should not significantly increase the human cancer risk.

It should be noted, however, that the Delaney clause as amended speaks in terms of "no residue" being found, avoiding such words as "occur" or "remain." As pointed out by the FDA, the amendment emphasized detectability rather than non-existence. Thus the FDA has approved for use a carcinogenic compound if examination of edible tissues by an assay reveals no residue, and noted implicit approval of its interpretation in case law.

It should be noted, however, that the FDA regulations to which I referred were in proposed form. It was anticipated that substantial changes would be made in the effective rule on the basis of comments from

the meatpacking industry urging that a higher risk level be used. I am not aware that the FDA has taken any further action on the proposed rule. Although there are a number of judicial decisions in which the concept of de minimis is either determinative or discussed, most of those decisions are not particularly pertinent to the use of the concept by a regulatory agency, since most involve use of the concept in matters resulting in private litigation.

On individual occasions, and this is really ancient history, the old AEC permitted equipment contaminated with small traces of special nuclear material which could have been sold under Manual Chapters 5170 or 5182, if exempt contractors had been involved, to be transferred without a license required of the transferee. This determination was made because at that time there was no statutory authority for the Commission to exempt SNM from licensing requirements which was enacted in the omnibus bill of 1974.

In a memorandum prepared by the AEC's Office of the General Counsel, it was stated that on the basis of information that the traces of SNM on such contaminated equipment would not be economically recoverable, and would not subject personnel to radiation exposures as high as limits in Part 20 for

nonradiation workers, it could be concluded that the quantity of SNM involved was de minimis and without health or safety significance, that in these respects the contaminants would not be considered special nuclear material within the meaning of the Act, and that no licensing would be required.

The initial legal obstacle in the use of the de minimis concept in NRC regulations is the fact that the Atomic Energy Act does not provide for such a concept. However, the use of the concept in other agencies administering the laws mentioned above was also not specifically authorized by the governing statutes. The fact that the Act in Sections 57d, 62, and 81, on the other hand, provides for issuance of exemptions from licensing requirements suggests that the Congress intended that the AEC and its successor, the NRC, use the exemption mechanism to provide relief from the requirements for a license.

It might be argued that the line of NRC Licensing Board and Appeal Board decisions arising from the Perkins decision constitutes a recognition of the de minimis concept by the Commission and its application to licensing under the Atomic Energy Act. However, the issue in those cases was one arising under the National Environmental Policy Act considering the health effects

of a release of radon from uranium mill tailings piles, not one cognizable under the Atomic Energy Act.

As noted above, the NRC has authority to exempt from licensing requirements unimportant quantities of source material and quantities of special nuclear material and byproduct material that would not be inimical to the common defense and security and would not constitute an unreasonable risk to the public health and safety. Historically, neither the AEC nor the NRC has generally used its exemption authority to permit unrestricted releases or distribution of radioactive material.

Exemptions codified in NRC regulations ordinarily specify the form and/or use or user of the exempt materials, with the exception of the exemption in Section 40.13(a) for source material in chemical mixtures, components solutions or alloys in which the source material is less than .05 percent of the mixture. In view of the historical use of the exemption provisions in the Atomic Energy Act, it may be considered inappropriate to include the de minimis concept in the regulatory process through the exemption route.

On the other hand, because of the availability of statutory authority to exempt nuclear materials from licensing requirements, it might be argued that this authority indicates that the exemption route, rather

than the de minimis concept, should be used. To some, use of the de minimis concept may seem inconsistent with the "no threshold" or "no zero risk" concept applicable to carcinogenesis, which has always been the underlying premise of AEC and NRC regulation of radioactive materials.

However, it seems that as a practical matter the exemptions in Parts 30, 40 and 70 also run counter to that concept. Further, the so-called "consumer product criteria" published on March 16, 1965, indicate that in evaluating proposals for the use of radioactive material in consumer products, not only are potential doses to be considered, but also the potential benefit that will accrue or be denied the public because of the utility of the product by approval or disapproval of a specific product.

As I have noted above, the Food and Drug Administration in its rulemaking proceeding to implement amendments to the Delaney clause seems also to have reconciled the "no threshold" concept with unrestricted distribution of foods containing carcinogens.

The need for a de minimis feature in this Part 20 has long been recognized in order to avoid extending regulatory actions beyond what are needed to adequately protect the public health. Applied to radiological

protection, de minimis can be of a level of risk or a dose rate as a surrogate measure so low that it would be trivial in comparison to the risks which the individual is subjected to daily as a part of normal living habits and activities. It would constitute a level of risk so low that no resources could be justified to control it or to be further concerned with it.

There are a number of ways to establish a de minimis level where exposures to radiation are concerned. Suggestions have been made to select a value based on variations in the naturally occurring background radiation from cosmic and terrestrial sources.

Background levels are highly dependent on local geology and altitude. Background levels in the United States varying from less than 100 millirems to over 200 millirem per year can be found. Reference to natural background radiation levels provides a good perspective on radiation exposures, but it is not clear how this range could be used to select a de minimis level that has unique advantages over a judgment on risk in terms of serious health detriment.

Consistent with the Commission's proposed policy to use quantified risk as an important factor in decisionmaking, reflected in its Proposed Policy

Statement on Safety Goals for Nuclear Power Plants, in the current Staff draft of the revision of Part 20 the de minimis level would be based on considerations of an "acceptable" lifetime risk of one in one million of dying from radiation-induced cancer.

Since the total risk coefficient is about 1.65 x $10^{-4}$ per rem for whole body deep dose equivalents, a risk to one in one million persons in a lifetime, about 70 years, would be about 0.1 millirem per year. I will leave the justification of these figures in the draft of Part 20 to Dr. Mills.

A de minimis value of one millirem per year for an individual has tentatively been selected by the Staff in its draft revision as mentioned above. When radioactive materials are more widely dispersed, there is some possibility, but it is still not likely, of an individual receiving dose contributions from multiple sources, each at a de minimis level of 1 millirem per year. Consequently, a de minimis value of 0.1 millirem per year might be selected for consideration of collective doses to populations.

Some have correctly noted that the de minimis level in the August 1982 draft of Part 20 is too low to permit measurements with generally available survey instruments. Since the de minimis levels have been

selected on the basis that the risks are trifles, the associated dose values are indeed too low to be measured as a practical matter. The levels would therefore have to be derived from calculations.

Application of the de minimis level would, among other things, limit both the size of the population and the time over which collective dose would need to be considered in evaluating activities associated with release of radioactive materials to the environment. It appears that with the two de minimis values -- that is, one millirem per year for individuals and 0.1 millirem per year for determining collective doses -- no need is anticipated to constrain other parameters such as person-rem increments or quantities of radionuclides.

The de minimis level would be a lower limit which would be applicable to any licensed activity. The establishment of a de minimis dose level should not imply that at higher levels it is necessary to spend resources for radiation protection purposes. Indeed, when an ALARA level for a specific activity is determined, additional resources for radiation protection are not required beyond that level, but an ALARA level is not a de minimis level since such a level is not necessarily at or below the de minimis level.

Of course, should any licensee operate in a manner that the de minimis levels are satisfied, those operations are by definition ALARA, because to go lower would be unreasonable from a health protection standpoint.

I might mention in closing that by reason of Reorganization Plan No. 3 of 1970, EPA has the responsibility for setting generally applicable environmental standards for the protection of the general environment from radioactive material covered by the Atomic Energy Act, that is, limits on radiation exposure or levels, concentrations or quantities of radioactive material in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive materials.

The plan, as you know, also transferred to EPA all the functions of the FRC under Subsection 274h. of the Atomic Energy Act. Those functions include advising the President with respect to radiation matters directly or indirectly affecting health, including guidance for all federal agencies in the formulation of radiation standards.

These provisions of Reorganization Plan No. 3 of 1970 do not transfer responsibility for promulgation of Part 20, including de minimis provisions, to EPA.

However, the NRC's draft revision of Part 20, which includes the de minimis concept, is not in conflict with 40 CFR 190 and existing federal guidance. It can be expected that NRC will work with EPA in formulating the de minimis concept.

Are there any questions?

MR. MOELLER: Thank you.

Do we have questions for Ms. Becker? Yes, Ron Kathern?

MR. KATHERN: I just have one quick question. If you set a de minimis level for a whole series of operations, is each of these considered independently, as say in the case of drugs, where you have a de minimis level for aspirin and whatever, or do you somehow have to look at the collective aspects of all of these de minimis actions?

MS. BECKER: It's my understanding -- and Dr. Mills will correct me if I'm wrong -- that there would be one level. The de minimis level would not be selected selectively, is that right, Billy?

MR. MILLS: Right. To that point, Ron, one of the things we are engaged in right at the moment as the replacement for the Radiation Policy Council, the President has given to the Office of Science and Technology Policy the responsibility to establish -- I

don't know the name exactly, but it's the Committee for Radiation Policy Coordination, I think. Is that close?

One of the -- in accepting membership on that committee for Mr. Minogue, one of the things he specified was that all these agencies would consider as a priority item the de minimis concept. So I would imagine that even though we have attacked it only from the radiation standpoint, that any agency engaged in that activity would also reflect on it in terms of the other control that it has. For example, in the case of EPA I am sure it would apply to the control for air pollution as well.

MR. MOELLER: Thank you.

Other questions or comments?

(No response.)

MR. MOELLER: I think, Ms. Becker, you have started us off on a very good -- in a very good way. And now as we listen to the other people we can begin to put it together. Will you be with us for a while?

MS. BECKER: Oh, yes.

MR. MOELLER: That will be helpful, and then we can come back.

Why don't we move ahead, then, with our agenda. And the next presentation in this series will be the EPA program to develop standards for "below

regulatory concern" levels. Floyd Galpin is here to lead us in that discussion.

MR. GALPIN: One has to be careful when you interact with Dade. We had him over for a briefing on our activities in the waste area in general, and often one interaction with Dade leads to another and you don't know where you're going to be appearing. I believe what prompted his invitation to me to come here today was that I had mentioned to him in the course of that discussion that we were looking at setting a level below regulatory concern -- some people would call that de minimis -- for the radioactive waste area.

I further mentioned that it perhaps was not indeed a panacea and it perhaps raised more questions than it answered, and he replied later he was very curious as to how I came up with that and if I would follow up. So when I wrote this paper for an AIF presentation which I have had passed out, why, I sent a copy to Dade and got this invitation. I don't know whether he's laying for me or what the intention is.

MR. MOELLER: No, we simply want you to share your thoughts with us, and we appreciate your coming.

MR. GALPIN: Thank you.

I feel like there has been rather a series. Joyce Davis and I were both on the program at the AIF

meeting, and Billy Mills was there too. I think maybe we could put a dog and pony show on the road for different people's consideration of de minimis.

But let me just go into what EPA is doing. Its present activity regarding the de minimis or regulatory cutoff is restricted to the area of radioactive waste. Let me just go over a few things we are not doing.

We are trying to stay away from even using the term "de minimis." The reason that is so is it has come to mean different things to different people. There are those who are constituents of EPA who have gotten the idea that anybody that uses the term "de minimis" or "de minimis non curat lex," I believe is the Latin, is talking about legal care or we're not concerned, we don't give a damn. And they react to that.

So rather than confront people's already preconceived notions and therefore cause reactions, we are using terminology we hope is more descriptive of what we are actually trying to do. At the moment we are settled on something that we would call a level below regulatory concern. This is a level below which regulation is not warranted or may be minimal.

Now, we have tried to come up with different acronyms or different terminology to replace "de

minimis." I asked my staff to do this at one time, and I suspect highly that they first picked the acronym and then tried to fit words to it. The last one, they wanted to call it LAID waste. This was to be "levels allowed in dumps."

(Laughter.)

I think, however, we set that aside and charged them with working more along their bent.

Another thing we're not doing is, we are not attempting, as was discussed just a moment ago, to set an overall cutoff or even an overall truncation. We believe that those two levels, as NRC has pointed out, should appropriately be different levels, because one could calculate some level of population exposure that is beyond, let's say below or smaller than, the cutoff that one would make for an individual dose.

But this particular activity that we're involved in at the preset time does not attempt to do either one of those. We looked at that. I admire Billy and his people for taking that on. We could not see it as something we would tackle in the near future, nor did it seem to us like the sort of thing that was most significant, that being the case with the waste disposal.

You will hear an excellent paper or a

summarization of a paper when Mrs. Davis gets up next, and probably the most complete listing of different ways that one can consider setting an overall level, including the biological aspects and such things as background considerations. So I will leave that to Joyce and her excellent work.

Also, there has been some work done by Hoyt Whipple which would not only combine the background and its variability, but the variability of disease incidence, and Hoyt and I have exchanged some conversations over that. One of the things that bothered us in that area is that background's variability even is not constant over the eastern United States, nor is the disease incidence. If you will adopt one of those as a national basis for criteria, we can see certain problems there.

Although we are limiting this present activity to low level radioactive waste, we do see that it has some implications for some other things that EPA is involved in. Let me just mention those. One is, any consideration that we would make of setting standards for decontamination and decommissioning. Certainly the same kind of thinking that you get into when you talk about a regulatory cutoff for waste or exposure level below which there is no further concern has to become

involved when you look at what you are going to leave behind, what exposures that might entail when you get into decontaminating and decommissioning a facility.

Another activity that we are involved in that will be related is in setting protective action guides for the case of re-entry into any area that should be contaminated by an accident. Again, the same kinds of considerations arise there: What basis do you make for that cutoff?

One of the reasons that the numbers themselves might be different in all these cases, at least we feel, is that the cost-effective analysis which we would plan to use very well could show differences. We would suspect that to clean up an area, to take remedial action -- we certainly have found this in the case of mill tailings -- is going to be a much more expensive job than it is to take an action in a preventive mode. So it is making some type of cost-effective or cost versus risk balancing, and you might have so much more tremendous cost in the case where you're considering a remedial action versus something like low level waste, where you're trying to prevent something, that indeed you might allow different exposures as cutoffs in these two types of cases.

So we feel that we want to go through the

analysis, we want to look at the cost, we want to look at the effect, and hopefully come up with an evaluation of a level that just plumb doesn't warrant further expenditure or control.

Now, in the paper I passed out there is a section there on authorities that EPA has. I heard that just covered in the paper I was listening to when I came in. They are generally applicable radiation protection standards. Just to summarize that, such standards could establish numerical limits on the radiation exposure or levels or concentration or quantities of radioactive materials in the general environment outside the boundaries of locations licensed for low level waste disposal.

It's the same authority we used in setting 40 CFR 190. One perplexing part about the definition is, as it reads in the Reorganization Act, when you look at a low-level waste facility and you look at it after such time as institutional control is deemed to no longer be active, where is the boundary? That is one aspect that we are trying to fold into our consideration, that actually the bounidary considerations may change as time goes on and you may be looking at a different set of boundary conditions.-

The second authority we could use to set a de minimis is that of the Federal Radiation Council. At the present time we haven't locked in on using either one of those authorities. In fact, we might use possibly both. As we have gotten into this, we are certainly aware that the Radiation Policy Council made a statement on setting de minimis, or at least one of their committees made a statement on setting de minimis for waste disposal.

To quote them, they said, "An overall generic de minimis level is not a practical solution to a portion of the waste management problem because without knowing physical and chemical parameters of the waste involved, it is difficult to establish pathways to humans and resulting doses. Therefore, in order to establish a generic de minimis level, extremely conservative assumptions are dictated which are likely to lead to levels that are so small that they have little practical value in disposing of low activity waste. As an alternative, the task force endorses the approach of evaluating waste streams on a case-by-case basis. ..."

We believe that considerations of specific categories of waste streams and methods of disposal must be part of the analysis and we are proceeding in that

manner. We are pursuing those kinds of analyses as we go on with out effort. We are even quite clear that there probably will be part of that analysis that ought to be made in the licensing realm.

One of the things that is needed and we are going to do is carry out negotiations and discussions with the NRC as to where who does what ought to stop or that line ought to be. I have been talking with Ross Grunnel, who is the Low Level Waste Licensing Branch chief now, and we are both very interested in pursuing this and doing it jointly.

I think that my own consideration is that EPA can develop a context or an umbrella that will provide a lid for that source-by-source or case-by-case licensing evaluation to be done. As to how we may express our low level concern, there are several we have considered.

Probably a leading contender would be for an annual individual exposure rate, which a cost-benefit analysis has determined to not warrant further reduction. This could also be expressed as a collective population exposure. Any time you start doing that, I think you run into real implementation problems. We could express it in terms of concentrations or specific activities of radionuclides or define mixtures that could go into a disposal place. Again, I have a

question there as to whether that wouldn't be more appropriate for the NRC to do. This is certainly something we will be considering over the months ahead.

I have outlined in the paper some of the technical analysis that we are going to do, and I don't believe I will get into that. I know it is late in the day for all of you. Let me just briefly say we are going to do a cost-effectiveness analysis and a risk assessment for disposal of various low level waste waste streams, and we are going to do that for eight different methodologies of disposing of low level radioactive waste. This includes low level, shallow land burial, improved shallow land burial, sanitary landfills such as you have in the municipal sanitary landfill, and on down to such things as hydrofracturing, deep well injection, some type of engineered storage, eight different methods.

We plan to look at each of those in terms of examining what would happen if we took various streams that are presently identified by NRC, and there are 36 waste streams, and see what kind of risk, what kind of cost effects you would have if you took them stream by stream.

A more difficult problem and one we are really struggling with and hope to work with both DOE and NRC on is the matter of segregation of streams. I think in

that area, at least in the hard core nuclear industry, is where our hope might lie. In the institutional waste, why, we probably hope to be able to consider a whole stream. When you get into the nuclear power cycle, why, I think we are going to be in a mode where we want to look at the segregation of streams. There is really very little information on that. The only place I am aware of where it is documented as being successfully done has been with the Navy, and it took a lot of tooth pulling and head pounding to force some of their services into doing that.

So that is a real rough area that we are going to be spending a good deal of time on, and it is that area where we will need specific assistance as to where those volumes could be reduced, as to where measurements need to be made about those segregations, and I will raise some problems on that in just a minute.

In looking at the sanitary landfill case, where we are talking about either going to a sanitary landfill or being incinerated first and then the ash going to a sanitary landfill, we also look at the trade-offs on transportation. As you reduce volume, certainly you will be reducing transportation. On the other hand, you are going to -- that stuff evidently goes on to a low level waste site and you will be

increasing concentration of that because you are taking out the lower levels of that. Whether that is going to have any effect in terms of the NRC's Class A, B and C -- in other words, will we be enforcing more material into Class C by virtue of having taken out the diluting uncontaminated trash -- that is a question to be answered.

We have several uncertainties in terms of the waste volume. In that area the institutional and industrial waste probably are the greatest uncertainty as to what those volumes will constitute. There are several efforts going on that we are trying to get a handle on that. DOE has contracted with the Conference of Radiation State Program Control Directors to try on a state-by-state basis what comes out at the generator level, and that is going to be very useful but I am afraid it will be too late in terms of what we want to do in terms of a time schedule.

There are industrial date bases, one for the Hanford site in Washington, that unfortunately is only about seven or eight months old, that has a barrel-by-barrel inventory. That is where most of the institutional waste has been going over that six or seven-month period. We are working with DOE to capture that data base and put it into the DOE overall data

base, and we will have access to it.

The State of Massachusetts has made a survey of their generator level low level waste. That is another thing we can go to to try to get some better feel. However, how to extrapolate from Massachusetts to the United States of America is a problem that may be very perplexing.

Anyway, through this evaluation, this cost-effective analysis and these risk assessments, which will consider both the risks of the sanitary landfill and its associated incineration as well as the licensed and regulated options for disposing of waste, we hope to come up with some basis to make a judgment. Because we consider this activity to be very important and potentially a most meaningful thing in terms of solving the problem with regard to low level waste that EPA may be doing, we are looking at going at it in an accelerated mode and actually slowing down the rest of our development of the low level radioactive waste standard so that we can throw those resources into doing this activity and go ahead and get it out of the way and go on the street with it and then come back and develop the upper limit.

There are several considerations we must resolve before we decide to do that. One will be

whether we have an adequate analysis to describe the impact, both for the case of the population and individual risk before we complete the analysis for the overall standard. The other will be establishing the level below regulatory concern, whether it will rule out any viable options we should be considering for the standard itself. Will the additional administrative requirements in hearings and public interactions delay the actual upper limit standard so far that it is meaningless? We targetted May 1983 to make this decision as to whether to go with an early-on consideration of this level below regulatory concern.

The last area I wanted to get into and the one that I think prompted some of the concerns or questions that Dade raised in the first place is the reasons that we are continuing vigorously to get with some skepticism that a de minimis or regulatory cutoff as applied to level waste disposal may not be a panacea that some people consider it might be. You have got a very limited data bank or history basis to look at. But what we have seen gives us this skepticism.

One of the questions we raise is is there a willingness on the part of the institutions and the industry to do that segregation that would be necessary to utilize a regulatory cutoff? Now, our information

base on this is limited. Probably the best example we have to look at is when the NRC deregulated the carbon-14 and the tritium associated with animal carcasses and scintillation vials.

What we do know is that there are still people sending animal carcasses and scintillation viles to low level waste burial grounds rather than to sanitary landfills and to hazardous waste sites. Now, I know there are some reasons for that. There have been problems with incompatibility between DOT regulations and what they require to be labeling and what the NRC has done. I know that when a truck rolls up to a sanitary landfill with radioactive material on the side of it, they may not be too thrilled at the sanitary landfill to take it on or even at the hazardous waste site.

It also turns out relative to the hazardous waste site that even with all of the costs that you have in a low level radioactive waste site, some of the hazardous waste sites cost more. So for both of those reasons, I can see that this may not be a complete answering data base as to whether it will work or not, but it does allow us some skepticism.

Another question we had is the willingness of the operators, the institutions and the industry to take

the responsibility for possibly making an error. Not only have the regulators in the past been accused, and sometimes rightfully so, of being overly conservative, but the industry people themselves have been deathly scared of making an error and putting something out that they should not have.

Now, how willing are they going to be to take the chance to do that? Another one is how willing are they going to be to face the municipality and its operator of the landfill, its operator of a town incinerator and suggest to them what they are doing? Will those municipalities be willing to accept a national EPA-NRC agreed upon level of below regulatory concern?

We have in my own backyard or very close to my own backyard a sanitary landfill that is now being put in. From everything I can find out from our people who are in land disposal of garbage, why, it is an excellently designed facility removed from population centers, and you wouldn't believe, or maybe you would believe, being in the business you are in, the amount of public uproar that facility has received and the demands for liners to be put in the bottom and people laying themselves down across the roads so the trucks can't drive in, and nobody suggested putting any radioactive

or hazardous material there.

So, you know, what happens when you raise the spectre of having radioactive waste placed in such facilities. It might create an even greater issue, and as the generator, I don't want to face that. I don't know of any way to absolutely answer those questions.We are going to try to get some feel for what they are.

Dave Harwich is locked in the back of the room. It reminds me that Ross Garano and I were just talking today. We plan to go to AIF and see if we can't get some assistance from them in looking at the segregation of waste streams and its practicality. We are hoping that something can be worked out there.

MR. MOELLER: Very good, Floyd. We thank you.

Floyd has asked for specific comments from us on the question as to whether -- well, he would like general comments, but specifically he has asked that if a regulatory cutoff were established for the low level rad waste, should they express it in terms of a dose limit or should they express it in terms of waste concentration limits or quantities that can go in to the disposal area?

I guess I am a little bit in a quandary as to what to say. Do any of the members here have any idea? Herb.

MR. PARKER: First, I would like to applaud you not staying with the specific term "de minimis" for semantic reasons that I might talk about later. You are groping for an acceptable term all around, and I think you haven't found one, if I read you right, Floyd, your LAID proposal? We don't want rape waste in here yet, but we have been trying to do the same thing. The closest we came to it was a negligible dose level.

If someone could find a term like that that was acceptable, then you could play it either way in terms of what the Chairman asked for. You could say quantities of radioactive materials reflecting negligible dose levels under such and such conditions.

So I think the prime need is to find some reasonably agreeable term, on the order of "indifference level," "negligible dose level," put the best one on the market and go with that, I would suggest.

MR. GALPIN: IAEA in the ocean waste disposal area has gone so far as to set individual dose exposure several years ago, which they called de mimimis. They have been struggling for the last three or four years with how do you implement that. I feel that it is certainly something both agencies need to work on, and together, on where the line gets drawn. I'm not sure.

MR. MOELLER: Jack Shapiro.

MR. SHAPIRO: The best way to see what to do is to do it and see what happens. I think the Massachusetts example so far is an excellent one to look at. From our own experience, the minute you deregulate it as the NRC deregulated scintillation vials, we sent them out through our chemical waste disposal contractor, who burns them locally, and everything has been completely uneventful, which means that you are not dealing with the technical problem at all. If there is someone here who finds you can get mileage out of a waste disposal problem, however de minimis you get, you may be in trouble. If no one is concerned, then the problem never appears. But the experience at Massachusetts has been very, very good so far.

MR. GALPIN: Take a look at New York City.

MR. SHAPIRO: New York is different. Maybe the air is so dirty in New York that you feel guilty trying to put anything else into it. I think that is a problem. I would be very, very careful about burning anything in the middle of Boston. I think we might have problems if we tried that. And yet if you go up to some town that had an industrial area outside of Boston -- Wait, erase that from the record.

[Laughter.]

I don't know just what the term is.

You just have to jump and hope things work out.

MR. GALPIN: We argue upon the head of an analysis. One thing I didn't mention. We have TRW on the Board as a contractor working with this -- it is the first time we have been able to buy a body of that magnitude or any proportion of such a body -- which is working with us on the low level radioactive waste area. We are trying to get them a little bit in bed, you know, with the big boys like EG&G and others that are dealing in this area.

MR. SHAPIRO: I think the most important task is to try to get some perspective and equate radioactive hazards with the other hazards. The economy does accept waste disposal. It accepts burning of certain materials. It accepts burning just in connection with industrial operations. I think you have to realize that if you are going to have an economy, you are going to have to have waste, and if it is accepted in other areas, it will be accepted perhaps with radioactive materials if you can get the hazard impaired without having an absolute risk. Maybe a relative risk would be accepted.

MR. MOELLER: Ron Kathern.

MR. KATHERN: I think of your question on how do you evaluate this on the basis of concentration or dose or whatever, and I am struck with the Oregon example, which I think we should all learn from. You are laughing, so you are familiar with it. The state of Oregon, in what had to be a fit of legislative wisdom or passion or whatever, defined radioactive waste as anything that contained radioactivity, and these could not be disposed of in the state of Oregon.

Of course, that was a little difficult on the undertakers, because human bodies, of course, contain radioactive waste.

There appears to be -- I think Herb made the point very well, perhaps inadvertently, Herb. There appears to be a psychology associated with the term "waste" and "radioactive," and put together. I would like to suggest that perhaps the best approach might be on the basis of concentration rather than dose or dose equivalent if you want to go that route, because I think that concentration is very much simpler to measure, very much simpler to define, and it could eliminate if set appropriately, could eliminate natural, I won't say normal natural levels of radioactivity as opposed to technologically enhanced things or perhaps radioactive oars, so that's my oars, o-a-r-s.

MR. GALPIN: Somebody is going to have to set concentration levels just as an implementing procedure. Even if we, EPA, doesn't, NRC or somebody is going to have to do it to make the thing work.

MR. KATHERN: When we start playing around with doses, it seems we go through a big mathematical exercise that ends up in the implication that we can actually calculate these to insignificant figures, and I doubt seriously that we can do it to even one significant feature.

MR. SHAPIRO: I think again you go back to the concentrations in the areas.

MR. KATHERN: If you set them appropriately, you would have categories like alpha emitting and beta emitting, so it would be independent of whatever nuclides were in there. You might exclude tritium, because obviously tritium is a different state of affairs, but you could have, say, one concentration value for alpha emitters and one for beta emitters.

MR. GALPIN: That's very difficult. You would almost have to go isotope by isotope, like Part 20 tables do.

MR. AXTMANN: Which is what a lot --

MR. KATHERN: You could probably categorize them into a half a dozen or so categories.

MR. GALPIN: That could be.

MR. SHAPIRO: I think the liquid scintillation is a real triumph for the regulatory process. There, you went with concentrations, and it has worked very well.

MR. KATHERN: I might point out that the liquid scintillation things are actually a category in and of themselves. What are you dealing with mostly? Carbon 14 and tritium. So they are both low energy beta emitters, and there is perhaps a precedent in that is the first cut.

MR. GALPIN: I commend NRC for taking that step.

MR. AXTMANN: That would work for general waste.

MR. MOELLER: Frank Arsenault has a comment.

MR. ARSENAULT: On the question -- I don't have the answer, but I would like to make a few observations about it. When you ask which way to frame the level, the standard, that is the solution, but I am not sure we have yet formulated the problem correctly. If we use the term, and I want to come back to something you said and ask a question about this, but if we use the term below the level of regulatory concern, the first question is, what is the nature of the regulatory

concern.

If it is public risk or individual risk or whatever it is, you can find within that some level at which you say, below that I am not concerned. Now, having established that, and if it is risk, you express it, you then translate that into whatever surrogate you will find practical, but to lead right to a determination of whether you use concentration or dose or what level without asking in what way they are related to the nature of the concern that we are below is in my view a mistake we have been making for many, many years, and the type of intuitive jump that has caused us a great deal of difficulty in dealing with the public.

The question I wanted to ask was, earlier you indicated the trouble you have with the phrase de minimis. You said you are terming what you are going for is a level below regulatory concern. Well, below concern is not clear no matter what you are talking about. But then you talk about the possibility of deriving the benefits by doing a cost benefit analysis.

That, it seems to me, comes very close to make your level below level of regulatory concern an ALARA response.

Joanna mentioned that if you are working at a

de minimis level or ALARA level, you are at a de minimis level, but the opposite is not true. I can see where a cost benefit analysis can be used to derive ALARA, but not how it could be applied to establish de minimis. I will use my term.

MR. GALPIN: It would be a reverse cost benefit if you would, or the inverse. You would be looking at an evaluation of levels where it clearly didn't even warrant the cost that might be called for within an ALARA band to be considered or applied. There would be an evaluation that absolutely not one nickel would be warranted below that level, as in contrast to, say, when we set up something like 40 CFR 190, where you were looking at a broad span of overall what it would take in terms of engineering controls to bring something down to a level.

One concern I have with the term de minimis for another reason other than what I mentioned before is, I'm afraid if you tag that number on or that value issue onto something, people will begin to think that anything above that is of concern. That could also now happen with the value we're talking about, the level below regulatory concern, except that you have that advantage that saying something is below regulatory concern, it's all right to say that things above that

are to the extent that ALARA ought to be applied.

I certainly don't claim to have the magic answers or vernacular at this stage.

MR. MOELLER: Floyd, you mentioned comparing, you know, rad waste to other types of waste, meaning toxic chemicals and so forth. Within EPA, are you working with your toxic chemical people? Are they looking at these same types of questions?

MR. GALPIN: We are probably closer to the thinking processes and rationale of the NRC low level people as we are our own toxic people. They are putting things like putting liners in hazardous waste trenches and trench drains and calling for continuous pumping, and I asked the question of them, how long do you plan to continue pumping, and how do you know when you are done, and I don't get good answers to that kind of question, and I don't think we can afford that kind of obligation to potential perpetual care in the nuclear area, and I don't think that they know that they are doing that.

MR. MOELLER: I agree. Well, thank you for a very interesting presentation. We will move on, then, to the next item, where Dr. Joyce Davis will talk to us about the feasibility and methodology for establishing de minimis levels, and Joyce is with General Physics

Corporation.

MS. DAVIS: Good afternoon, ladies and gentlemen. I am very happy to be here.

I guess I am here because of a project I am connected with at the Edison Electric Institute. As Mr. Galpin said, we have been giving talks around. The last one was at the AIF meeting in New Orleans, where this topic of de minimis had a half-day on the program.

I am using the word de minimis in its very broad sense, and I will try not to use it, but I am afraid I will from now on.

What I am really talking about is the concept of a regulatory cutoff. The concept I am talking about is a little broader, for example, broader than the concept that Ms. Becker talked about, the legal de minimis. It is broader even than radiation regulation. It is really as broad as the whole field of regulation, but I will concentrate on how it applies to the radiation area.

This started about a year ago. Sol Harris was then at the Edison Electric Institute, and for several years had been collecting information on the concept of de minimis. He talked to people about it in the radiation protection community. The idea of a dose of no concern has been floating around for quite a few

years.

He suggested that a short study be done by EEI to see what the feasibility of the concept was and where it stood. So, I was the consultant who prepared the report. It was just a short two-month review of the literature. Because I also have a background in law, I looked at some of the legal aspects as well as the technical part.

As a result, we came up with a feasibility study that I believe has been distributed to everybody. It's a General Physics report that is feasibility of -- Today I am really talking about some of the ideas in that report, some of the things that have happened since then in the EEI program. I prepared a little outline which I also guess was also distributed just describing some of the things I will try to get to talking about today. I may not get to all of them, but most of the things are discussed in the feasibility report.

First, I wanted to start out talking about the full de minimis concept. First of all, as Ms. Becker has very ably presented earlier, there is a legal concept of de minimis, something that is negligible. I found that in talking about this idea and applying it to radiation or anything, lawyers really understand it better than the technical people because they have

worked with it. The courts are very familiar with the concept, and she mentioned some of the cases. There is a Supreme Court case, benzine case, which I have in my paper, where in a concurrence Justice Burger cited an appeals court case that talked about de minimis. He even gave some limits on where the area of regulatory concern should cut off as far as risk is concerned.

This was in the benzine and OSHA case, but he said somewhere between a risk of one in 1,000 and one in a billion an agency should be able to do a cutoff. That is a very broad range, of course. He used something like the regular correlation, the linear correlation, something between ten rem and less than 100th of a millirem. So, somewhere in there someone could draw a line, and actually anywhere in there it's possible.

So, that brings us to the regulatory concept of below regulatory concern. The courts recognize de minimis, and they recognize that regulatory agencies can cut off their regulation, that the purpose of regulation is to achieve some end, and it is necessary in the practical world to cut off where you regulate at some point when you are not having much of an effect, even though theoretically there may be an effect out there.

That brings us to another concept that gets involved in the negligible risk. Again in the nuclear

area, this has been floating around for many years. People have compared risks to many things, acceptable risks, negligible risk, and done it on a comparative basis, so that works its way into this de minimis idea.

Finally, there is this concept of radiation doses of no concern which the radiation people have been talking about for a while. Putting this together in my report, I sort of divided it into the scientific and legal approaches. The de minimis program of the Edison Electric Institute, after we did the initial feasibility study, the next thing, early last year I prepared a few documents to illustrate what a radiation cutoff policy statement would look like, for example, if the President would want to give one, and also an implementing statement by an agency, what that would look like, and perhaps some possible criteria.

Now, I think the idea is that first you have a policy, then you have guidelines for how you want to implement that policy, and based on that you develop criteria and methodologies, and as a result of using those criteria and methodologies, you would be able to derive their regulatory cutoff level each of the different places where you want the regulatory cutoff level.

Then the next thing we did, we sent out a

questionnaire to all of the nuclear utilities, the utilities that have nuclear plants, asking for their opinion on whether this was a concept that they felt would be useful, feasible, and try to get from them some indication of how it would be useful and what benefits they see. Also, whether they had any what we called horror stories of cases where things either went right because somebody came up with a cutoff or they went wrong because there was no cutoff limit set. And we got some of those back. In fact, I am giving a paper next week at ANS at one of their reactor sessions on the results of that survey.

It turned out that most people think it's a good idea, but a lot of people think it will never get through. But we did get some good information on it and a few horror stories.

Currently, we are talking about the concept. I commented personally on the de minimis aspects of the Part 20 regulations, and I have given out a copy of that. We have been talking to people in the regulatory agencies and the industry trying to develop a feeling for where the concept is going and really what is needed to support it. It was decided, for example, that it might come up in the Part 20 rulemaking, and we intend to do that in the future. EEI is still supporting this

project, and is using my services to continue working on this subject.

All right. The nature of a regulatory cutoff policy for low level radiation doses. I said that the first thing is, you have a policy statement. We originally thought it would be wonderful to get a policy statement from the President, go right to the top and have a statement, that actually the most general statement would be something that says, all regulations should have a low cutoff. All regulations for everything ought to have a lower cutoff. That really makes sense, and I think it would be nice if that happened.

But we are not putting all our eggs in one basket. We are also working with the agencies that are developing regulations to try to develop it on a local level, for example in Part 20. So, if you were doing it from the policy level down, you would have a policy statement. Based on that, you develop guidance for implementation. For example, that is where you decide what it is that is negligible when it is of no regulatory concern. And you decide what you are going to use as the basis.

For example, are you going to use the concept of risk and say it's a negligible risk to an

individual? Are you going to use the concept of comparison to something else like background? That really has to be developed before you work out the individual levels. Then you can develop criteria based on that for setting the de minimis levels.

For example, if you decide that it's comparison to background that you want to use as your basis, then you would in your criteria set up what measure of background you are going to use. For example, if you are going to use a standard deviation of the background averaged over a population, or something like that. And then you would have to develop methodologies for setting particular cutoff levels.

Now, that is working down from the top. It may be that the best way rather than trying to work from the top is to come in from an intermediate level where there is a chance to do something, for example, as the Part 20 rulemaking, to come in sort of on the guidance and criteria level and develop some good guidance and criteria for that particular rulemaking which then could be carried over to other places.

In this report that I have done, I describe some of the ways people have suggested to set cutoff levels. The first part I call scientific approaches. In the report, for the scientific thing I used de

minimis. I said, setting up a hypothetical case, a de minimis dose is one that a reasonable expert in radiological health would not consider of concern for his own or his family's health and day to day life.

Other people have postulated, for example, the dose that a person wouldn't worry about, a person would find of no concern. The trouble is that people aren't really aware. The ordinary person isn't aware of background or its variability or anything like that. So I think that the scientific level, what I call de minimis or negligible dose really has to be set in relation to experts.

In the report I list some of the things the experts have suggested. Dr. Eisenbud gave a paper several years ago at the NRCP conference where he discussed some of these possibilities. He talked about, for example, the practical threshold of latency based on the work of Dr. Evans with the radium dial painters where it appeared that eventually the latent period got so long at the lowest doses that the cancer wouldn't occur during the person's lifetime, so therefore you had a practical threshold.

He said it would be nice if we could get enough radiobiological information on that to actually use that kind of threshold, and that is the nearest

thing we have to a biological threshold, something that would be scientific. For most things, we really don't have that much information yet. Dr. Eisenbud among other things recommended a lot of effort be put into that area of research.

Other effects -- there is another way to get a practical threshold which I don't know if anybody recommended, but just logically I came up with it. If you're thinking about dose to a large number of people, you can get a practical threshold by saying there shall be less than one health effect in this population, and that is sort of a cutoff thing. Once you get to below one, zero. That is also not too useful unless for a specific case where you are talking about a specific population.

So, if you can't derive a threshold, you are sort of stuck with comparative approaches. The kind of comparative approaches I included were things like non-detectability of the radiation level, or non-detectability of health effects. In other words, if it doesn't turn up in the epidemiological study, or one which also relates to non-detectability of the background risk.

Now, Dr. Whipple, for example, proposed that kind of criteria. He said he plotted the effect against

-- compared to the background risk of cancer in the United States with its standard deviation, which is quite wide, and said, if you are within that plus or minus standard deviation, then that would be a radiation level that should be of no concern.

One problem with that is, he came out with quite large levels. He came out with 500 millirem per year for beta gamma radiation, which is in effect saying if you look at it that way the upper limit is de minimis, and I don't know if people are ready to go that far, but using the numbers he used, that's where he gets.

Another approach is to look at background radiation. I have some slides but I don't know whether it's worthwhile showing them. I gave out the list.

MR. MOELLER: These are in your paper?

MS. DAVIS: Yes, most of them are from the paper. I guess I ought to backtrack to catch up with the slides. This one I just put together. This is something like what Ms. Becker was talking about, the hierarchy of levels that we're talking about, to put this thing in perspective. I have on the left side the characterization of the risk, and on the right side the characterization of the dose rate.

It is not meant to be to scale. It is just meant to try to put things in an order. There are no

numbers connected with it. It is decreasing risk and decreasing regulatory concern as you go down the chart, and down here, here is zero, theoretical absence of radiation, since in this world we don't get the absence of radiation. Zero dose. I put zero question mark risk, because we really don't know what the risk at zero is. There are people that say that you're better off with some radiation than with none. So some identified value of risk, probably close to zero down at zero dose. If you are down at the background level, you have zero incremental risk over background zero incremental dose.

Up here is some level that is hazardous, and naturally this is all in the area of regulatory concern. Here is the ordinary limit. That is permissible dose and under the Atomic Energy Act, the inference is that that is no undue risk. In exceptional cases, the Commission can grant exceptions from the regulations, and then there are emergency things. Where you might be up to a somewhat higher level that's an allowable risk and a permissible dose in an exceptional case. Somewhat below that we might have an administrative limit or action level. Part 20 added that action level dose the new Part 20 proposed.

Then, down here in this region between the

limit and down here (indicating) is the ALARA region, and that is the ALARA level for a specific case. That can be anywhere between here and down to this exemption level, and that is the risk that is as low as reasonably achievable. The exemption level which Ms. Becker mentioned are these levels that NRC sets on a cost benefit basis, which can be looked on as sort of a generic ALARA.

I would call that a minimum practical dose and a minimum practical risk. So your ALARA can be anywhere in this level.

Now, there haven't been exemption levels set for everything, so in some cases these levels exist for some particular type of limit; for some they don't. Anyway, below that somewhere is our friend the de minimis level: negligible dose, negligible risk. If there is no exemption level, it acts as a floor for ALARA. Otherwise, the exemption limit is the floor of ALARA. This ALARA, depending on specific circumstances, could be anywhere around here, but it never goes below the de minimis level. That is because, by definition, there is no more benefit in going below de minimis.

(Slide.)

Ms. Becker said all that. I am just showing the picture. I have listed some of the people who have

made suggestions about de minimis levels or doses, the scientific type doses of no concern. Dr. Eisenbud gave a level below which exposures are ignored, and he -- in his paper he didn't recommend any particular level, but in the discussions he made it looked as if it would be something whole body external between 20 and 100 millirems per year would be a level that he thought was of no concern.

Dr. Rossi had a letter in the Health Physics Journal a few years ago saying that there should be a cutoff for ALARA because he can keep putting wet sheets in front of his source forever, and someone can tell him to stop and he can decide that it should have been just one more. So he suggested something like 30 percent of background would be an appropriate number for that.

Dr. Whipple, who I mentioned, his criterion was no observable effects on health, and he got, using the cancer statistics, got 500 millirem per year for low level radiation.

Drs. Webb and McLean in England looked at this problem, and they got -- they determined the level that an individual does not consider in decision-making. They really based it on risk levels in correlating the dose, and they came up with ten millirem per year to an organ and to the whole body. Then they went beyond

which was their scientific value negigible dose, and then they said, we want to apply this to a regulation, make it a regulatory cutoff for ALARA, where under the ICRP and so forth for each practice you want to maximize it to ALARA.

This came down. They said, well, let's take 100th of that, assuming somebody could do 100 practices in a year and make it a tenth of a millirem per year for a cutoff like that. Dr. Weinberg and Adler had a chart that was presented in the health physics data on variation of background, and they calculated the standard deviation of state by state background, weighted average background, state by state weighted with background. They came up with a standard deviation of 20 millirems a year. They have proposed that as a low dose radiation standard for individuals in the population. They didn't really talk about de minimis or negligible dose, but the way they derived it, and other people have used it in that sense, is that would be an approach to getting a de minimis or negligible dose level.

NCRP, and I talked to Dr. Kasserett last year when I was writing the report. At that time his Committee 1 was debating the possibility of establishing a de minimis dose. It has been reporte in the NCRP.

The year before they were talking about ten millirem a year. I don't know whether that stands today. Some of you probabaly know more than I do.

ICRP doesn't, at least in the publications I reviewed, didn't express the concept of de minimis negligible dose per se, but they do have the statement that says, we are doing a dose effect calculation impact assessment. You can stop when -- to go any further would not change your results by more than a factor of two or three, so that's a way to cut things off. It's a different kind of cutoff, but it's the same idea that you can cut things off that way.

MR. MOELLER: Do you have any rough idea as to what dose would be associated with that for the ICRP?

MS. DAVIS: It really depends on the distribution of what you are looking at. It depends on -- I think that's a purely relative one.

MR. MOELLER: Ron Kathern?

MR. KATHERN: Kathern. I just wanted to ask if you looked at the DOE ALARA guide which suggests that one millirem is an ALARA dose, the ALARA threshold, if you will.

MS. DAVIS: I haven't seen that specifically.

MR. KATHERN: Based on the work of Roger largely 1 percent of the background level in the United

States and also the fact that that gives a somewhere around $10^{-6}$ probability of a health effect, that's a little lower than these other scientifically based studies.

MS. DAVIS: Well, yes, that's what I wanted to get to, the next thing. These are the kind of numbers that the scientific community sort of throws around. When you get to the regulatory, when you get to applying it in the regulatory context, you probably don't want to use -- you may not want to use exactly the same number. You want to take into account what the scientific community thinks, but they are really talking about an actual exposure to an actual person, whereas in the regulatory concept you are talking about predictions, evaluations, and safety factors, you are talking about things where you have to -- you don't know what the uncertainties are, so in the regulatory context you may have to step back from, say, as far as I'm concerned, I would think something like 50 millirem is of no concern to me.

But I might not necessarily say that I think therefore that the ALARA cutoff for everybody should be 50 millirem. The regulatory people have to apply additional criteria to derive their particular regulatory level based on the particular case in

question. Some things, for example, some things that will only happen once in a lifetime will be evaluated differently than if you get the dose year after year.

That's why I say this regulatory concept should really be a set of criteria and methodologies and not just a level, such and such is the de minimis dose. I don't think it should be approached that way. Among the ways you can derive it from a regulatory approach, derive it from current standards, in the report I have a whole list of what some of the standards are that could be used as a basis. For example, do you want to use something like the Appendix I levels, or the levels, the EPA environmental levels, and some of these other levels.

Just take somebody's current number. For example, you could define radioactivity. Maybe you should start off adopting the Department of Transportation definition of radioactivity if you wanted to get a quick level. You can derive it from current standards. You can derive it from the safety goal, a safety goal or some quantitative risk guidance value.

One thing the President could do or the Department of Health or the NRC or somebody could set a number saying a risk of such and such is negligible for all uses. Then you could derive your de minimis dose level from that kind of number. The NRC is proposing a

safety goal. In my comments on the safety goal separately, I pointed out I think that what they proposed is really a de minimis level, because in effect they said, for accidents, this is a negligible risk.

So, that same kind of level then, maybe that should be the same level for a negligible risk from radiation in general, or maybe it should be some fraction of that, or bear some other relation to it, but maybe there should be a relationship, and it should be a reasonable relationship.

MR. MOELLER: Excuse me. I thought on that though that the Commissioners in their footnotes were quite clear in stating that the death of even one person is unacceptable, and so forth, and that these goals were simply the degree of safety that they would require, not saying additional safety is not necessary, but it is simply what would be required by regulatory requirements.

MS. DAVIS: Well, depending on whatever form the thing takes from it, you should be able to get some indication of what risk is acceptable for this kind of thing, whether it's this number or some other related number.

MR. MOELLER: I agree.

MS. DAVIS: I am just giving you the kind of

guidance you might be able to use. You might be able to derive something from the expert opinions that we're talking about from the experts getting together and helping out. You may be able to derive it from other indications of acceptable risk through the studies that have been done on what people deem acceptable, and so forth.

You could also limit it to less than one projected effect, have some level that, for example, the whole population of the United States, there would be less than one death if the whole population of the United States were affected, and then you could also do it by -- for something like what Ms. Becker called exemption levels. You do a cost benefit balancing and set levels for regulatory cutoff that might be somewhat above an absolute de minimis level, but nevertheless would give you a regulatory cutoff.

I list here, and we go through with the things that are currently going on, Part 20, Part 61, where de minimis may or may not be involved in the safety goal, the EPA entry criteria, and also state regulation.

I want to mention that we spoke to the state radiation program people. The states really need guidance in this area. There is no guidance for them, and they are faced with these kinds of decisions, just

like the NRC people in the regions are faced with having to make these kinds of decisions in the absence of guidance.

I spoke with someone who was involved in the decommissioning of cyclatron. That is something the state was responsible for. It was very difficult for them to come up with criteria. The problem was, there was a lot of copper that was very valuable, and mostly not radioactive, but parts of it had been exposed enough so parts of it were very hot. Most of it was not. And, of course, there was an intermediate level, and they wanted to be able to sell the copper as scrap, the part that was acceptable as scrap, and there was no guidance on that.

The health physicist and the state finally got together and set up a county system, and agreed that if the piece of copper showed twice as less background than background in that particular arrangement, that could be released, but that was developed totally ad hoc. There is no guidance for that kind of thing.

So, something developed on the federal level I am sure would be immediately adopted by the states, because they need something like that.

Other areas where this is useful is setting regulatory priorities. Even if this comes out and hits

the licensees, if things like that are used by the regulators themselves, it may prove very useful. The decommissioning area was mentioned. Other areas that it may be used in can serve as a cutoff for determining how wide an area you have to consider in deciding whose interests might be affected as to whether they can be let into the licensing cases. They might be put into the compensation cases, both the ones against the government and for any private case.

It may not be totally dispositive, but if there were a level that was recognized as de minimis, the courts would look very carefully at that in deciding whether or not to accept that, and say, these levels are de minimis, and clearly someone can't be liable for exposure at that level.

I list some of the problems and I discuss them in the report. The first I call opposition of anti-radiation programs. There are people who are for one reason or another afraid of radiation and opposed to any kind of change in the regulations that would appear to be a weakening of the regulation. I think that when this de minimis idea gets into the rulemaking and the regulatory arena, that certainly there will have to be very good backup by the people who are proposing it, and they will have to have a good case and a good, clear

explanation to try to have people understand that it is a reasonable approach and that it really is protecting them because it's putting the resources of the agencies on the things that they really -- paying attention to the things they really should pay attention to.

Regulatory racheting, that is my shorthand. I have talked to people who now believe that the linear non-threshold theory was handed down by God and cannot be violated in any way, and that this would, by drawing any line, you are being arbitrary. It is true you are being arbitrary. I think that in the world, in the real world, particularly in the legal world, one has to draw lines at some point, and in the sense that on the one side it's yes and the other side it's no is arbitrary, but they can still have a rational basis, but that is something that proponents of a cutoff policy are going to have to counter.

Then there is the problem, once a policy is in effect, there is a problem of what I call regulatory racheting. This goes two ways. One is the agency tending to accept the idea that, well, since this level is certainly okay, the de minimis level, why don't you go down to that level, and in effect lowering the limit so that the limit and the de minimis level come together.

The other problem is, as Ms. Becker mentioned, the effect of interest groups trying to ratchet the agency to do the same thing, and I think those are just things that have to be guarded against, and both the agency and the people involved have to very carefully spell out what this cutoff level means, and that is not necessarily a limit. Then, the problem, I think, the logical and technical problem involved in this, which I don't think -- in most cases doesn't turn out to be a real problem, but it is very difficult to counter theoretically, I guess it is impossible to counter, and that is the idea that you can accumulate -- if you accumulate enough de minimis doses or concentrations or quantities, eventually you are going to reach some significant level.

Part of this, the cure for that, I think, is this hierarchy of levels where the agency, when they set a regulatory cutoff, look to how it's going to be used to make sure that it is not going to be -- there is not going to be a high probability of accumulation to significant levels.

The other thing is that because these proposed levels are generally relatively small, this is not the kind of thing where overnight the background is going to double. The thing is, I think the answer to that is

vigilence. The EPA and the NRC have to monitor backgrounds. We have to monitor what people are doing, and certainly if the background in the United States all of a sudden started increasing so that you saw a 10 or a 20 percent increase, you go back and re-examine your policy and make sure that the de minimis is not getting out of control.

But that is a very hard thing. Logically, you cannot refute that. If you keep adding little things, eventually you will have a lot, but if you look at it in the real world context where one licensee can affect everybody in the country, and the background is varying, so a person can't really control what he's getting, these numbers should be such that they are less than background.

The benefits, I listed public assurance. That's a question mark. If it's done the right way, I think it is helpful for the public to know that there are levels that the regulatory agency considers of no regulatory concern, and there are levels that radiological scientists consider of no threat to their health and their family's health.

If this could be presented in the right way, I think it could be beneficial to people and would increase understanding. If it is based on background, I

think it is particularly helpful because people are not aware of background, and it would be nice to show them a way that it does exist and explain the relationship of those levels to this natural stuff.

Economic savings. Some of the horror stories have had to do with the shipment of practically non-radioactive materials to radioactive waste sites because they couldn't be -- they were licensed material and they weren't able to -- they weren't able to get them out from under, so $100,000 was spent shipping the stuff to waste sites, and they were utilizing some of the scarce space at the waste sites with various lowly contaminated stuff.

There was also savings in regulators' time and energy. That is optimum use of resources. The time that is spent on reviewing things that are not of importance to health could be spent and the effort could be spent on things that are. If you look at -- I want to go back and look at some of the past calculations. If you look at calculations, for example, of the total dose from Three Mile Island or a lot of these probabilistic risk assessments that are now being done, an awful lot of those gigantic numbers of cancers coming out are coming from the tail of the distribution. People are getting 100th of a millirem, but there are

millions of them, or they are getting $10^{-9}$, but it is integrated over 250 million years, and you start getting a body count.

And a cutoff on that would save a lot of effort, and it would also save a lot of misleading of people who don't understand that. I think it would also make the people who are doing it feel better, because people who do things like this know, the technical people know that it is not a real -- they are not really solving the real problem when they are doing these kinds of calculations.

Another benefit I just put in, the idea of deregulation, you know, nowadays we are supposed to be the right guys to have less government regulation and free people from the yoke of government constraints. This is one area. Certainly we are not going to deregulate nuclear energy. The fission process and so forth are inherently dangerous. But it is certainly reasonable to deregulate the parts that are not hazardous, and that is the approach that we think, at least I am speaking for EEI at the moment -- EEI has decided to go ahead and continue to support this kind of approach.

As I said, I gave out the copies of that report, and I would appreciate if anybody has any

comments. I would love to get them, particularly if you know of any horror stories or any references where these kind of levels have been talked about, and we could sort of update that report and maybe have it as backup when the de minimis comes up in rulemaking.

MR. MOELLER: Thank you.

MR. PARKER: Dr. Davis, let me compliment you on an excellent paper. I think it is by far the best I have heard. At the same time, let me bring you up to date on the NCRP position to the extent I can without violating committee confidences.

I think it is sure that the NCRP will not use the term de minimis. That is a semantic issue that was presented at the Denver meeting, and they wisely listened. They will be seeking some substitute for the same concept, negligible dose level, negligible risk, not yet determined. The level, I think you will accidently find in part of your elegant conversation on Page 3 of your document, and I do hope if you have not already done so you will send a copy of both of these to Dr. Kasserett.

MS. DAVIS: I actually have already done that. I spoke to him.

MR. MOELLER: A question I have, and this again, I'm sure, reveals my ignorance, but I don't know

how to grasp or to handle this particular problem that I have with the concept. That is, for radiation there is a natural background, so you have that situation. Well, for food and carcinogens in food, I realize obviously there are naturally occurring carcinogenic agents in food, but I don't know or I am fairly certain with no facts that the natural background level of carcinogens in food is not as high relative to the de minimis level for carcinogens in school.

How do you handle that?

MS. DAVIS: I think radiation in a way is, if I want to use a little Latin, sui generis. It is sort of one of a kind among these things, that it has this relatively large natural background. I think for other things, some things have no natural background at all. They are totally manmade. I think you have to use another approach if you are going to have an overall policy that includes other things as well as irradiation.

You may have to use some kind of a comparative risk approach estimation or detectability. I didn't talk much about detectability. That could be somewhat used in irradiation. It can also be used in some of these other things.

Also, these things aren't really mutually exclusive. Actually, with radiation, whether you use

comparison to background or risk, the kind of numbers people are talking about, you always come out in the region, say, between one and 100.

MR. MOELLER: Yes.

MS. DAVIS: So it may give you a good idea that it is coming there regardless of what approach you take, so you really can use a combination of approaches.

MR. MOELLER: Yes. Jack Shapiro.

MR. SHAPIRO: Somehow or other, we have missed the point here which hit me just as you were talking again. That is that in this whole de minimis concept, you haven't said a word about the fact that we are getting benefit out of the radiation, and just because you are killing just one in a million doesn't give somebody the license to go around and kill 200 people just because it is only about one out of a million in the population. Even though we know it is a benefit. We keep talking about de minimis without talking about the benefit. All people end up thinking about is that these people are going around just killing one in a million, and that came across in Massachusetts when I found that I got the most results in talking to our Boston city council when we were talking about our radioactive wastes.

I said, look, we are not in the business of making radioactive waste. We are in the business of doing research. Massachusetts is the world center for research. It is the world center for medical therapy, and therefore it generates the stuff because it is doing this, and suddenly the light dawns on these people too and they realize that this was the concept, that there was a benefit, and you have to talk about the benefit versus what is being done here.

We have come to the conclusion as far as low level waste siting is concerned in Massachusetts that the only way we will get it is to get a town that will get enough economic benefit and enough sweeteners so they will accept going down to a millirem or a half a millirem or a 100th of a millirem is not going to convince anybody if they are not going to get anything out of it.

So, I think we have to keep pushing the benefits that come along and weigh it against whatever we are doing.

MS. DAVIS: I think that's right, and I think that's why all the levels above the de minimis level are really set on the basis that there is a benfit associated with the irradiation. In a way, you can say the de minimis level, that very small risk is balanced

against the benefit of sort of regulatory convenience, even just the benefit of not having to -- freeing the regulators to work on these more important things is enough benefit to outweigh this extremely small risk.

I think it is that kind of outlook you have to take on that, and that must certainly be the emphasis when you are dealing with people.

MR. AXTMANN: I have a thought on the early part of your talk in which you dealt with the question of how you set the de minimis level. You had two suggestions I wrote down. One was something a real expert wouldn't worry about, and two, something within the standard deviation of the risk from cancer from all causes.

In the first case -- and you would publicize the de minimis concept this way. Something that an expert wouldn't worry about, I think experts are increasingly distrusted in this society, particularly nuclear experts, and I don't think that would be a particularly convincing argument to the more vocal part of the population that worries about such things. And something within the standard deviation makes people go numb. Standard deviation? What's a standard deviation?

I think you have to --

MS. DAVIS: You are right, and the way you present it to people can't be -- I was giving sort of a scientific background. I think you're right. That's why I say, when you are setting the regulatory level, you really have a somewhat different approach than just strictly the scientific approach, and you really have to look at those kinds of things. On the other hand, personally, I don't think that it is necessarily a total given to the current feeling that only if it's done by amateurs is it any good.

MR. AXTMANN: Oh, no, no, no. I am saying you can't always explain to amateurs that their instincts are wrong. The final thing is whether I should worry about the whole thing at all. If something is de minimis, then I flush it down the toilet, right? But I keep creating de minimis quantities of material and I keep flushing it down the toilet. Pretty soon it all winds up in this one cesspool two miles from my house. Then I begin to worry about the whole idea of de minimis, if you follow me.

MS. DAVIS: Yes, that's what I said. The concept of the accumulation of de minimis levels.

MR. KATHERN: What about concentration, though? Do you base it on concentration unless it is somehow concentrated later on? You don't have the

problem?

MR. AXTMANN: No, but then you are worrying about it, and you are worrying about it in a regulatory sense. If there are natural, as you put it, natural concentration --

MR. KATHERN: There is.

MR. AXTMANN: Natural concentrations, perhaps the concept is flawed, at least in some cases.

MS. DAVIS: Well, also, if somebody was watching the background in general, you would pick up that there was a major --

MR. AXTMANN: Oh, sure.

MS. DAVIS: You would get to a major increase, but you certainly can't postulate that you are going to get up to levels that are clearly above the de minimis level.

MR. AXTMANN: I guess what I am worrying about is you are putting something out of the regulatory framework and therefore out of the observatory, if that is the word, framework.

MR. MOELLER: Well, thank you, Dr. Davis. It was good of you to come and to share your thoughts with us, and certainly you show that you have given it a lot of thought.

The last person to appear on our schedule for today is John Auxier from the Oak Ridge National Laboratory. Dr. Auxier is going to summarize all about de minimis for us and just wrap it all up in a nice, neat bundle.

MR. AUXIER: Dave, if you were as optimistic about everything I was going to say, we could have solved the de minimis problem a long time ago. Actually, it is not too bad to be the last person on the program because it means at least I am talking to a bunch of real survivors today.

First of all, I would say that my definition of de minimis is precisely that the NRC and everybody else is using, the legalistic one, and I am not today interested in what you call it later. I am talking about the principle, and therefore to me de minimis is the same as every other term I am talking to now.

Up until about two weeks ago, I would have come in here with a stack of Vu-graphs about equivalent to this to show you the facts and figures and graphs to show you how to arrive at a de minimis. I will take about three minutes to tell you what I would have told you in a half-hour, and then I will spend the rest of the time on something that may not be as productive but what I find interesting and bears on some of the observations we have had in the last few minutes.

First, there are a lot of problems with the de minimis approach. I think almost all of them have been mentioned this afternoon and some in the last few minutes. There is a need for it, especially when you consider the cost-benefit think that Jack Shapiro was talking about.

We can't forget that there are advantages to the use of radiation. That is what we are in the business for, and therefore we can't lose that particular thing. And the need for de minimis is enormous when you do that equation, the cost-benefit analysis, the risk-benefit analysis.

There is a big disadvantage, however, there is a disadvantage not to have one, but there is a bigger disadvantage in having one that is obscenely low. In other words, if it gets down to where -- you can get

involved with the problems here this afternoon, the perceptions of the public. If you set a tenth of a microroentgen per year, anything above that will tend to look worse to the public and therefore it would be better to leave the issue alone.

But using three approaches over the year, I started this business when Appendix I was first drafted. Some of you remember those days back in about 1971. In those days the first thing that occurred to me was a number that was well below the natural background, and then we played on it and the number that Weinberg quoted was something I calculated for him in those days based on EPA distribution of dose by states. We just did a root mean square deviation and we came out with 17 or 18 millirem, which we rounded to 20, which is in my opinion a reasonable number and one approach. It is not all together defensible with everybody, but nevertheless, it has some logic to it.

Secondly I would talk about the risk. I would start with a risk and compare them to the risks of everyday living that people accept willingly and then divide them by some number, and all of us love to play with factors of 10's and 2's and 100's. So I divide those risks by 100, by 10, and you come out with numbers like for a given individual I chose to limit the risk to

$10^{-4}$ for a representative group of the population, the old NCRP 170 millirem thing. I would for de minimis talk about a risk of $10^{-5}$, and then for a large, large population, maybe one in a million.

On the other hand, I would resist strongly the tendency to take 200 million people, $2 \times 10^{8}$, and multiply it by anything and come out with anything useful. In other words, measuring $2 \times 10^{-8} \times 10^{-6}$ is not a meaningful number because the uncertainties in what you are multiplying are enormous, as you know.

Now, also everybody here is aware of the fact that how we reach numbers by consensus is in groups such as this and that is why we get together, but we also know that there are real problems. For instance, NCRP is made up of a bunch of committees of which several of us here have been involved in for many years, and so was ICRP and so is the BEIR committee and the INSCR committees.

When they sit around tables, it is not always science that ends up, it is consensus. And experts, as has been noted, have a wide range of opinions. So we take the best data we can and then we compromise. BEIR III gave us the numbers that are being used. They are the same as BEIR II, about, but you are familiar with the contortions they went through to get a number based

on the difference between a linear extrapolation which some of them figured they had agreed on in advance, quadratic for low LET radiations, and finally a linear quadratic. And the pure scientific data, most everybody, you get them aside and you talk to them and they will say that for low level radiation, the quadratic form is best. We have lots of models that substantiate that. On the other hand, if you take high LET radiations and you use the quality factor based on the LET, it comes out and moves the curve over until it is always on the conservative side too.

So I use numbers like $10^{-6}$ per rad instead of $10^{-4}$, and I think I can defend those better than you can $10^{-4}$ if you want to be scientific about it. So I used those numbers. If you do that and go through one or two other series of caveats, series of parameters that are in the form of caveats, first of all, when we did the analysis for Appendix I, it turns out that no matter how you situate your power plants, and let's talk for a moment about nuclear power stations, whether they are single reactor units or multiple reactor units, the way you are formulating a power station is that you are not going to ever have them bundled up together. If you do, you have a power park and then it is looked at as a unit, or would be.

As a consequence, this business of saying, okay, if we put in magic fencepost number of five, then the whole world average of that is just nonsense. We have tried every kind of mathematical manipulation and if you take a number of -- well, Sternglass Goff talk about the 170 millirem per year killing everybody.

Well, even if you take radiation and explode it in nuclear weapons and spread it around the world the best you can, you cannot get a uniform distribution such that if you take 170 millirem as the highest, that the average dose to the population will be more than a small fraction of that. If you take a power plant and do the same thing, it turns out that if you limit it to, say, 170 millirem to a representative part of the population, or if you limit it to 20 millirem at the boundary, the average dose to the population is a very small fraction of that.

It depends on several things, but typically it is from 100 to 1000th of that. So we are not talking about giving everybody the number we list as de minimis. Also in the de minimis concept when you are talking about a de minimis dose, or a regulatory dose, for that matter, you are talking about a dose that takes into account the accumulation in the environment in the biosystems.

We can release stuff in generally two ways: through the air and through the water, if you take the accumulation into account, so let's don't reiterate it again to go the next step. Okay. That is one way to take the risk. If you do that, I come out with a number that varies between 10 and 20, and it is close enough to the other one not to worry.

Finally, the easiest and the quickest to explain, and I expect that a lot of people would use, we take the ICRP, NCRP, 170 millirem to the representative part of the population, divide it by 10, another safety factor, and say 17 millirem, and they could round it either way, it would be a reasonable number. You could take three approaches, where you base two of them on the prestigious committees of the past, or you could take one and look at the natural background; but you always come out with numbers of 10 to 20 millirem per year.

But when I was asked to do this and was preparing these charts, someone mentioned to me that they thought maybe I was a spokesman for the Health Physics Society or for the health physics profession. Well, I am not. I have no cloak for that at all. As a matter of fact, in disclaiming it, I recognized then that somebody might still perceive it that didn't hear me say that, so just in case, I would see how far off I

was from the rest of the health physics community.

For the next few minutes, then, I will show you the results of something I did. You have got copies of all these, so I will only go through part of it. But I decided in a very short scale, and this is not very scientific -- those of you who have done polls know it is extremely difficult to do it and do it right -- but about 10 or 12 days ago I made up a little form, making it as simple as possible recognizing there was a need for several caveats, and then I transmitted this by telephone to about 20-some peers around the country who I thought might be willing to collaborate and help me get data in a hurry.

(Slide)

I gave them this form, gave them the caveats and some explanations and said I will call you back in two days, give me a time; and in the meantime, transmit this to some of the staff around you, and then when I call you back, you can just read off, yes, no, two, four, whatever to the questions and I can get data.

Now very crudely, but I got about 80 responses to this poll. Now, this is the health physics community, and for obvious reasons I left off regulatory groups. Now, I wanted to know if education and training sorts of things had any bearing on what people would

perceive of as a de minimis value -- and these are health physicists. So I looked at highest academic degree, years of experience in health physics, whether or not they are certified with the American Board of Health Physics, yes or no, the type of facility from which they work -- university, DOE labs, plants, utilities, other industry and so forth.

Then I said, okay, within the NRC definition of de minimis, give me numbers for these three questions as if you were playing God and could set these numbers for individuals where the first one would be a single individual, the old Appendix I magic fencepost sort of individual, for B for the 170 millirem equivalent in the ICRP, NCRP for the representative population but limit it to five miles, and then see what you could do if you could control the people out to 50 miles, a region that shows up in all the NRC regulations, as you are aware.

Finally, I asked the question, this is what takes caveats: Should person-rems be the governing factor, yes or no? And, I said, give me your comments there because that will probably be the most useful thing, and surely enough, they were.

(Slide)

So with that in mind, I then got all these data from 79 or 80 people. Actually I think I had 80

and then threw mine out so I wouldn't bias the data. But I got this kind of a distribution of responses in terms of degrees. So you can see that there are a few health physicists, long-term trainees that have only a high school education or so, but BS's, MS's and Ph.D's. There is a pretty good represenatation. Most senior health physicists in the country I thought were at the MS level, but I got a distribution that was not as far different as I had expected. But at least there are some people with various degrees.

(Slide)

Then I looked at years of experience. The percentage is still on the ordinate, abscissa, years of experience. As you see, there are a few people with two, three, four years, all the way out to a few with 33, 35 years of experience, and sort of a peak in the middle around 15 to 17 years. But I had no pre-expectation, or no expectation at all about how that would be.

(Slide)

Then I had certified health physicists. As you see, it is not a 50-50 match but surprisingly a good representation from the CHPs.

(Slide)

By facilities: There are universities, DOE

labs, other, industry, and utilities. These two in the middle are low because I didn't know many people, actually in industry that worked with enough health physics to give an opinion. I got a few. "Other" included two people that accidentally got in from the NRC because they were asked by utility guys, and it turns out their numbers are not among the lowest by any means.

Universities. We had quite a few, but obviously a high bias from the DOE labs because I asked three labs and all of them gave me lots of numbers and I took them. But I was going to show you where they came from so you could take into account your own idea of biasing.

(Slide)

Then that first question, maximum exposed individual, this is the raw data responses. Again, the percentage of the responses, and you see there are some down here at one, and some up here at 1000. As a matter of fact, there was just one at 1000, I believe, one at 650, which I had no idea how the person got it.

MR. MOELLER: Excuse me. This is millirem per year?

MR. AUXIER: Millirem per year, yes. Excuse me. And that is the distribution (indicating). So you

can see it covers a wide spectrum. We mentioned big numbers, a variation of numbers today. You can see, of course, there are little spikes representing people's tendency to round off, 5 and 10 and 25 and 100, and you would expect there might have been a 500 and at 170, that there might have been more, but I was surprised. A lot of things about this surprised me. One was that very few people picked the 170 or one-tenth of that.

(Slide)

Now you see a similar thing for within 5 miles, more of a bias toward the low end of the dose curve, as you would expect. But again, it is a completely wide spectrum with some people going up to 250 millirem, a few, one.

(Slide)

Out to 50 miles, more to the left, except not remarkably so, with 5 being a little more of a choice than usual, and 7 and 8, after all, and 2 are not round numbers in the normal thinking. So, anyway, you see a bias a little more toward the low end as you would hope for and expect.

Now the final question, and this one I got surprised on, too. I figured some people thought person-rems were more important, but overwhelmingly the people thought that person-rems shouldn't be a

consideration in setting de minimis levels in the environment. But, as I say, the discussions, the comments were extraordinarily enlightening, and they did cover a lot of things we have mentioned today.

One is that for ALARA concepts then person-rems can be quite important. And in doing emergency planning, person-rems should be paramount. But for setting de minimis levels in the environment, the person-rems people said it shouldn't be. After all, some plants like Indian Point may be close to large population centers and the risk per person is what counts; and some may be way out where person-rems would be zero even with significant levels to a few individuals. So that one they were quite clear on.

I won't show you these because you have got them, but I have got two of these that list every single case, the data that gives the degree, the whole thing.

MR. MOELLER: Excuse me. Hal Peterson has a question.

MR. PETERSON: Yes, if I may. You made an implication, I think, about the man-rem being useful or not useful when in fact the questionnaire says: Should man-rem be the governing factor?

MR. AUXIER: That's right.

MR. PETERSON: Okay. Just for the sake of the

record, I wanted to straighten out the difference between implications and governing factor.

MR. AUXIER: You've got it precisely correct. As I say, we asked them the question: Should it be the governing factor? And they said overwhelmingly "no, but." And that is where the clarification was revealing. It actually told me more maybe than if we had asked the question and had time to ask several questions. Namely, the comment says, for the risk to individuals, whether there is a few or a lot out there, it shouldn't be important; but when you start planning for accidents or when you worry about ALARA, actually in this area the people, these HPs out there seem to have done a lot more in-depth thinking than they did about the other. I think that may be reflected more as they go along. But you are correct.

MR. MOELLER: Rags Muller, did you have a question?

MR. MULLER: I just had one question, John. What significance do you attach to the fact that perhaps a lot of the degrees that you checked are not in health physics but in some other discipline?

MR. AUXIER: I put no significance in it because my Ph.D. is in nuclear engineering, but there was until recently no place you could get a Ph.D in

health physics, so we are all radiobiologists, physicists, mathematicians. Walter Snyder was a mathematician, K. Z. was a physicist. That is their academic degree, but they call themeselves health physicists on the basis of training and experience. But if I put importance on what their degree is in, I would just have to throw them out. Now the master's degrees, a lot of those are in health physics in the old AEC fellowship program and in the Public Health Service program. A lot of the BS's, Most of those, up until the very recent ones of course, were in one of the disciplines such as physics, chemistry, math or biology.

Okay, I will just go through a few of these. You have already gotten them but I left off all the statistical parameters at the bottom to keep from cluttering it any more, but to show you how to use this in case you decide you want to play with it.

(Slide.)

Question 1 was degree. Question Q4A is the maximum exposed individual. This, then, is the degree versus their chosen numbers, and this in there is the percentages of people responding, and under that, right in there is the number of actual respondents, the lower number being percentage. As you can see, 79 responses is the 100 percent, 2 is 2.53 responses, and so forth.

If you look at this, and of course I had the computer playing with it, there is no correlation. There is nothing statistically significant about anything about the distribution that we can see here. Now, we can go through one or two more, but if you look at that Question 1 by Question Q4C, that is Q4C was the 50 miles. Again the same thing.

But if you go through them all by degree, by -- well, I thought for certain that there would be a difference between the people in the nuclear power industry as opposed to those maybe in the national labs or other places, and I thought maybe the difference between certified HPs might be correlated to their numbers. No correlation. No significant correlation.

[Slide.]

Anyway, if you look back, I thought the university folks would be the lowest and the utility would probably be the highest. As you can see, there is no statistical difference between them. Now, where am I leading with all this stuff? Simply -- that will be all the slides.

Namely, I had over a period of years in talking with other people arrived at numbers that I had a feeling were sort of representative of the science and that could be defended, at least qualitatively, on a

scientific basis. And I felt then that the HPs out there using the same sort of approach with some science would come out with numbers that wouldn't be too much different. And lo and behold, as you see clearly, there is no correlation between the most experienced and the best trained HPs and the neophytes.

So I conclude, and I told Bill Mills, and unfortunately Bill had to leave, but I wanted to tell him that in this case I sort of have to change sides on him and say that after all, it is the HP out there that is as emotional about these issues as everybody else. The only explanation is that people are reaching for numbers intuitively, and any time you are talking about intution, you are talking about some impact on the emotions or reflecting emotional status, and therefore we are all in the same boat.

The HP is not going to be able, if you involved the HPs in helping you arrive at numbers, they are really not going to be much help to you, and that includes me.

Thank you.

Are there any questions?

MR. MOELLER: Questions. Frank Arsenault.

MR. ARSENAULT: Yes. I am not sure whether this is a question or an observation. I guess the

question I would like you to react to is this. There was, in fact, a correlation I notice, though, of the results you presented in that most of the people you consulted did not see person-rem as a basis for the de minimis level. I wonder if that is because they are health physicists and not regulatory personnel. You would think a regulatory body might have a societal risk basis for its perspective as distinct from the practicing health physicist who tends to think in terms of the individual he deals with.

MR. AUXIER: That is a good observation. I have no data from the other side, but it certainly sounds reasonable.

MR. ARSENAULT: The other part of my observation is closely associated. That is that if you had asked the individuals responding what the objective was for the regulation of dose, you probably would have found as wide a scatter in the answer to that question as you did in the levels of the proposed for de minimis.

MR. AUXIER: I think you are exactly right. As a matter of fact, in a session like this I learn a lot more than I feel like I could contribute, but on the other hand, in a poll of this type where you are forced to ask a few simple questions, you learn immediately that you either asked the wrong questions or certainly

didn't ask the right questions. But it would be fun to follow up. I may, if time permits, use the Health Physics Society Newsletter with Jack Colen's cooperation, I might with the help of a lot of people design a simple form and do a better poll. I am not sure at the moment, though, it would be useful. I need the right input first. It wouldn't pay to go to a lot of work and come out with the same thing unless we thought that, gee, it is important to know just that.

MR. MOELLER: Well, I guess I had a question in looking at this. You said you did it by telephone, but did they really, like in Question 4A, the maximum exposed individual at the fencepost, did they really give you a number for de minimis dose or did they give you an Appendix I type of ALARA answer?

MR. AUXIER: I will give you an example of how I did it. Jim Watson of the University of North Carolina. I called him, I explained this to him. I said, now, to be clear -- everybody, by the way, was 100 percent agreeable. Nobody said, gee, they didn't have time. Everybody helped. Some of them worked quite a bit, including Jim. But I said, now, when you talk to other people, make sure that everybody is as far as possible talking about the same thing. He played back to me the definition, NRC's definition of de minimis,

and I said, now -- as a matter of fact, it was after the first call or two that I said light the magic fencepost, because I wanted to make sure they knew the maximum exposed individual. And I usually used 170 millirem NCRP to indicate we are talking about men, women and children and a representative population.

Everybody played it back to me quite well. Now, I don't know how they played it to the other people or how those people perceived it. From some of the numbers, I think, from the same place, there was quite a different perception, but I can only use what data I have.

MR. MOELLER: Well, again following up on what Frank said, and I realize this is simplistic and I'm not saying it correctly, but you told us that by a high percentage they said, no, that person-rem should not be a governing factor, and yet the de minimis dose level went down from the fencepost from 5 miles to 50 miles. That means they are thinking collective dose.

MR. AUXIER: For certain they are saying that if you --

MR. MOELLER: If you expose more people, you have to have less dose, because we are looking solely at individual risk.

MR. AUXIER: If you look at the raw data you

will find there are a few people who had the same number all the way across but not many. I had expected that there would be more. A lot of things about this surprised me. That was one of them, that the same person who would say no would also have a number that would vary by an order of magnitude. But it is a complex issue. But when an individual looks at it, their own perceptions may get complex in a way different from how you or I would look at it.

MR. KATHERN: John, you left us hanging with some of the important comments that might have been made free-handed. Is there anything that came out of those that you would like to comment on?

MR. AUXIER: I am sorry, I did mean to put those in. Number one -- I mentioned two of them. The other is that even though the numbers didn't always agree, people said there should be some de minimis value, and nobody complained about the term "de minimis" in this, but then they didn't have much room to, anyway. But two or people, at least, several people said it would be better not to have one than to have one too low. Most people are convinced that we will have lower standards, guidelines for population than NCRP by far, independent de minimis. They are concerned about how low they will go.

Those are the chief ones. I did have a list of them but I didn't bring it up here with me.

MR. MOELLER: Well, I think that is a very interesting way to end the day, with a poll such as that.

MR. MULLER: It would be interesting to get medical radiologists to respond to a similar poll.

MR. SHAPIRO: Are you kidding? 1000 R.

MR. AUXIER: That is not a bad guess, because I did talk to a number of them.

MR. MOELLER: Well, it has been a long day, not only for us but for our reporter. We will resume tomorrow morning at 8:30, so I will declare a recess.

[Whereupon, at 5:50 p.m. the meeting was recessed, to reconvene at 8:30 a.m. the following day, Saturday, November 13, 1982.]

NUCLEAR REGULATORY COMMISSION

This is to certify that the attached proceedings before the

in the matter of: ACRS/Subcommittees on Reactor Radiological Effects and Site Evaluation

Date of Proceeding: November 12, 1982

Docket Number:

Place of Proceeding: Washington, D. C.

were held as herein appears, and that this is the original transcript thereof for the file of the Commission.

Patricia A. Minson

Official Reporter (Typed)

Patricia A. Minson

Official Reporter (Signature)

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Jane N. Beach

Official Reporter (Typed)

Jane N. Beach

Official Reporter (Signature)

Tel. (216) 352-1680

advance copy

RUSSELL M. BIMBER
10471 Prouty Road
PAINESVILLE, OHIO 44077



Nov. 4, 1982

Ms. R. C. Tang
Advisory Committee on Reactor Safeguards
NRC
Washington, D. C. 20555

The Combined Subcommittees on Reactor Radiological Effects and Site Evaluation will meet Nov. 12, per 47 FR 47343. I wish to comment on the agenda items Nos. 1, 3, and 7.

I'm a chemist with more than thirty years of industrial experience, including some work with radioactive materials. In addition to my regular job, I'm helping Lake County draft its Radiation Emergency Plan, related to the Perry Nuclear Power Plant.

1. I haven't seen FEMA's draft policy on potassium iodide as a thyroid blocker. But the FDA advice, that KI be used when the projected dose exceeds 25 rem, (47 FR 28158-9; 6/29/82) sounds reasonable; I urge that it be adopted as Federal Policy.

3. Please do not increase the permissible levels of radiation, especially for unrestricted areas (10 CFR 20.105). Although the higher Protective Action Guides of EPA 520/1-75-001, cited in NUREG 0654 FEMA-REP-1, Rev.1 may be acceptable for incidents occurring no more than once a decade, their justification has not been properly documented. See the enclosed three pages of my communications with EPA on this subject.

7. I haven't seen NRC's proposed 10 CFR 140, but urge that the requirements for declaring an Extraordinary Nuclear Occurrence be reduced. For example, an ENO might be declared whenever radiation from a nuclear power plant exceeds 10 CFR 20.105 levels offsite, or whenever EPA's PAGs lead to recommendations for offsite protective action. I understand the courts have declared that state and local government can't get reimbursement for their part in the TMI incident. I believe non-governmental agencies, such as the Red Cross, who are expected to participate in radiation emergency response, should be assured of reimbursement, preferably from the nuclear plant responsible. Making it easier to declare an ENO may make such agencies more cooperative.

Thank you for this opportunity to comment on these vital topics; I hope this helps.

Sincerely,

Russell M. Bimber

encl: 3 pp

(216) 352-1680

RUSSELL M. BIMBER
10471 Prouty Road
PAINESVILLE, OHIO 44077

July 30, 1982

To: A. Stewart, Lake DSA
W. Kulash, PRC Voorhees

EPA Response on Protective Action Guides

Harry Calley (spelling?) of the EPA phoned today in response to my letter to David Rosenbaum, 7/15/82, wuich I copied you on.

He said 10 CFR 20.105 applies only to routine operation of nuclear power plants, not to accidents.

10 CFR 20 does not explicitly exempt accidents, but 20.501 does allow the NRC to grant exemptions. But the Draft Environmental Statement on PNPP, NUREG 0884 (March, 1982) implies that its accidents are not exempt; page 5-16 says,"even under unusual operating conditions which may temporarily result in releases higher than (normal) but still well within the limits specified in 10 CFR 20.....". It goes on to state additional requirements of 10 CFR 51 and 40 CFR 190. (But again and again, the NRC can make exceptions, which are not mentioned in the DES.)

Appendix C of EPA 520/1-75-001, which was to summarize the technical bases for PAGs of 1-5 rem, still has not been developed. Mr. Calley agrees that Appendix C is the most important part of the entire Document, and personally would place a high priority on getting it done. But EPA has received few questions about it and does not even have a target date for getting it done. In 1975, EPA used three rationales for the PAGs:

1. PAGs should not allow anyone to get a dose large enough to produce an acute effect, manifested within 30 days, or perhaps even out to one year.
2. PAGs should limit long term injuries to an acceptable range. EPA still has no exact definition of what an acceptable range is.
3. EPA would not make recommendations that could not be implemented. EPA was asked by many people to consider lower PAGs, and did consider 0.1 rem. This would lead to recommendations to evacuate unmanageably large areas.

I cited CEI's adoption of a 5 rem PAG without saying why they didn't adopt the 1 rem favored by EPA 520/1-75-001. Mr. Calley said this conflicts with EPA's intent, and that we should challenge CEI's interpretation of PAGs and make them change to 1 rem, unless they provide convincing arguments.

I mentioned densely populated North Madison, only four miles downwind, and generally with low radiation protection factor housing. He said a lower PAG may be appropriate for special situations like this; the risks of evacuation are low relative to certain radiation injuries in part of the exposed population.

Mr. Calley welcomes phone calls (703-557-7390) in preference to letters, but will follow up this call with a letter, and I'll copy you when I get it. This should contain the same information, probably in more detail than this letter.

Sincerely,

Russ

(encl as pt 2 of 3 with 11/4/82 letter)

(216) 352-1681 (or M-F, 9-5) 357-3137

RUSSELL M. BIMBER
10471 Preuty Road
PAINESVILLE, OHIO 44077

July 15, 1982

David Rosenbaum, Dep. Asst. Admin. for Radiation Programs
EPA
401 M St., SW
Washington, D. C. 20460

I'm a scientist-volunteer helping Lake County, Ohio draft its Radiation Emergency Plan for the Perry Nuclear Power Plant. The Cleveland Electric Illuminating Company, which is to operate the Plant, says it must comply with 10 CFR 20.105 which sets a limit of 0.1 rem/week for whole body radiation exposure in unrestricted areas. This appears to conflict with CEI's proposed adoption of Protective Action Guides of 1-5rem/incident W.B., based ultimately on EPA 520/1-75-001, Sept. 1975.

The EPA sent me a copy of that document in October, 1979, including Chapter 5, revised 6/79, and Appendix D (Jan. 1979), yet Chapters 6,7,& 8, and Appendices A, B, and C were still "to be developed". I think Appendix C is the most important part of the entire document because it was to summarize the technical bases for the numerical values of the PAGs.

If Appendix C has been developed, I would like to have a copy, along with any other help you may be able to provide, or direct me to, for understanding why a PAG in excess of 0.1 rem may be acceptable.*

Sincerely,

Russell M. Bimber

Russell M. Bimber (MS, chemistry)

* P. S. I have NUREG -0396, EPA 520/1-78-016 (Dec. 1978) and NUREG -0610 (Sept. 1979) which both cite the earlier EPA 520 Document as the authority for the numerical values of the PAGs.

(encl as #1 of 3 with 11/4/82 letter)

# ACRS BRIEFING
# U.S. DEPARTMENT OF ENERGY POSITION
# 10 CFR PART 20 REVISION

PRESENTED BY
E. J. VALLARIO, GROUP LEADER, HEALTH PHYSICS
OFFICE OF NUCLEAR SAFETY

NOVEMBER 12, 1982

DOE POSITION

# PROPOSED REVISION 10 CFR PART 20

- RETROSPECTIVE vs PROSPECTIVE
- 50 YEAR EFFECTIVE DOSE EQUIVALENT
- RADIATION DOSE MANAGEMENT
- GESTATION DOSE
- INDIVIDUAL MONITORING REQUIREMENTS
- IMPLEMENTATION COSTS
- OTHER

# PROSPECTIVE vs RETROSPECTIVE

10 CFR 20 APPLICATION OF ICRP-26

- PROSPECTIVE ADVANTAGE
  - OCCUPATIONAL RISK
- RETROSPECTIVE PROBLEMS
  - STANDARD REFERENCE MAN
  - LONG LIVED NUCLIDES
    - TIME REQUIRED FOR INDIVIDUAL ASSESSMENT
    - DOSE ASSESSMENT BASED ON AIR SAMPLING
    - INCREASED MEASUREMENT SENSITIVITY REQUIRED BY 50-YEAR DOSE COMMITTMENT
  - ACCIDENTAL EXPOSURE DATA

PARAGRAPH 176 - ICRP 26

"Only in a few circumstances can the results of programs of monitoring of the workplace be used to estimate the dose equivalents or intakes of individual workers. The use of derived or authorized limits is essential in the interpretation of environmental monitoring programs."

# 50 YEAR COMMITTED EFFECTIVE DOSE EQUIVALENT

RE: §20.201

ISSUES:

- EXTRAPOLATION OF 50 YEAR DOSE TO 1ST YEAR — AFFORDS NO GREATER PROTECTION
- MEASUREMENT SYSTEMS ARE INADEQUATE
  - ENVIRONMENTAL AIR MONITORING
  - IN VIVO ASSESSMENT
  - BIOASSAY
- LOW EXPOSURES BECOME TECHNICAL OVER EXPOSURES
- MANAGEMENT OF SUBSEQUENT YEARS EXPOSURE DATA — A PROBLEM

EFFECTED HEALTH PHYSICS PRACTICES:

- EFFECTIVE UTILIZATION OF WORKFORCE BASED ON TRUE EXPOSURE
- CREDIBILITY OF PROTECTION CONTROL
- MAINTAINING REASONABLE OPERATIONS COST BASED ON OPTIMUM SAFETY PERFORMANCE

# AIR SAMPLING INSTRUMENTATION PROBLEM

CONTINUOUS AIR MONITORS ARE LIMITED IN SENSITIVITY BY:

- INABILITY TO ADAPT TO VARIABLE BACKGROUNDS
  - $^{242}Cm$ AND $^{244}Cm$ ARE SPECIAL PROBLEMS
- POOR SAMPLING EFFICIENCY FOR LARGER PARTICLE SIZES

CAM ANALYSIS - MPC - HOURS

| | PARTICLE SIZE | | |
|---|---|---|---|
| INTEGRATION TIME | 0.6 μM | 1.5 μM | 2.4 μM |
| 1.0 MIN | 17.3 MPC-HR | 24.8 MPC-HR | 225 MPC-HR |
| 5.0 MIN | 7.3 MPC-HR | 10.5 MPC-HR | 95 MPC-HR |
| 10.0 MIN | 5.1 MPC-HR | 7.3 MPC-HR | 66 MPC-HR |

# INDIVIDUAL MONITORING REQUIREMENTS

RE: §20.502, WITH REFERENCE TO §20.201, APPENDIX B

ISSUE: INDIVIDUAL MONITORING OF WORKERS WITH A POTENTIAL FOR A DEMONSTRABLE, POSITIVE INTAKE WOULD NOT BE REQUIRED IN MANY CASES UNDER THE "30%" MONITORING CRITERION. CURRENT DOE PRACTICE REQUIRES THAT EACH INDIVIDUAL BE MONITORED AND RESULTS RECORDED OF ALL POSITIVE INTERNAL DEPOSITIONS.

EFFECTED HEALTH PHYSICS PRACTICES:

- AVAILABILITY OF EXPOSURE TREND DATA
- POSITIVE WORK PLACE CONTROL
- ALARA

PROPOSED NRC MONITORING-RECORDING REQUIREMENTS

1. Limits (20.201)
   a. Effective Dose Equivalent = Deep Dose Equivalent + Committed Effective Dose Equivalent = 5 rem

Or b. Dose Equivalent = Deep Dose Equivalent + Committed Dose Equivalent = 50 rem

2. Summation (20.203)
   10% of the Deep Dose Equivalent (0.5 rem) and 30% of the Annual Limit of Intake (1.5 rem)

3. Individual Monitoring (20.502)
   a. External: 0.5 rem Deep Dose Equivalent or 30% of the limit for eye (15 rem), skin (50 rem), or extremity (50 rem)

   b. Internal: 30% of the Annual Limit of Intake

4. Recording of Individual Monitoring Results (20.1103) /
   a. Required to record <u>if</u> required to maintain records (internal or external)
   b. Not required to record individaul intakes less than ALI/1000 (2-DAC-hours) in a day, or ALI/200 (10 DAC-hours) in a week, provided that for any assessment in excess of these amounts the entire amount is included (equates to 1.25 rem per year or 25% of the ALI)

5. Occupational Exposure History (NRC Form 4) -- Where monitoring is not required--assume 1.5 rem per year

6. Current Occupational Exposure Record (NRC Form 5) -- Lifetime Effective Dose Equivalent (including assumed exposure-see NRC Form 4) shall be add4d to the current year Effective Dose Equivalent to obtain new lifetime exposure

# RADIATION DOSE MANAGEMENT

RE: §20.207, §20.502, §20.1103, 20.102

ISSUES:

- INFERRED HANDLING OF NON ROUTINE EXPOSURE DATA WILL A BE PROBLEM
- ASSURED COMPLIANCE WITH EFFECTIVE DOSE EQUIVALENT TO THE FETUS IMPOSSIBLE UNDER PROPOSED SYSTEM
  - LACK OF INDIVIDUAL MONITORING REQUIREMENTS (1.5 REM RULE)
  - EMBRYO AGE SPECIFIC PARAMETER IS IMPORTANT IN CONTROLLING FETUS DOSE BUT APPLICATION IS NOT POSSIBLE IN ABSENCE OF INDIVIDUAL MONITORING REQUIREMENTS
- RECORDS WILL REFLECT ANOMOLIES IN DATA (1½ REM MONITORING RULE)
- EPIDEMIOLOGY STUDIES WILL LACK LOW DOSE DATA BASE
- ALARA APPLICATION EFFORT TO LOWER INDIVIDUAL EXPOSURES WILL BE HAMPERED

EMBRYO/FETUS - PART 20 APPLICATION

POTENTIAL UNMONITORED EXPOSURES

| | DEEP DOSE EQUIVALENT | COMMITTED EFFECTIVE DOSE EQUIVALENT | CALCULATED EFFECTIVE DOSE EQUIVALENT |
|---|---|---|---|
| AGE-SPECIFIC PARAMETERS KNOWN | 0.49 REM | 1.00 REM | 1.49 |
| AGE-SPECIFIC PARAMETERS UNKNOWN | 0.49 | 2.00 | 2.49 |

# BOTTOM LINE
# (IMPLEMENTATION COSTS)

- PROGRAM
  - FACILITIES, WORKER, EQUIPMENT
  - TRANSITION PERIOD
- FACILITIES
  - FACILITY MODIFICATION
  - PLANT RETROFIT (REMOTE OPERATIONS)
- LITIGATIONS
  - NO INDIVIDUAL RECORDS BELOW 1½ REM (EFFECTIVE DOSE EQUIVALENT)
  - "TECHNICAL" OVEREXPOSURE WILL BE COMMON

federal register

Friday
January 23, 1981

Part XV

# Environmental Protection Agency

## Federal Radiation Protection Guidance for Occupational Exposures

[RH-FRL 1722-5]

## Federal Radiation Protection Guidance for Occupational Exposures; Proposed Recommendations, Request for Written Comments, and Public Hearings

**AGENCY:** U.S. Environmental Protection Agency.

**ACTION:** Proposed recommendations for radiation protection of workers.

**SUMMARY:** We are proposing to make recommendations to the President for new guidance to Federal agencies for the protection of workers exposed to ionizing radiation. These proposals are based on a review of existing guidance in the light of scientific knowledge of radiation risks and of experience in the control of occupational exposure. The proposed recommendations include both qualitative guidance on radiation protection and numerical guides for maximum allowed dose equivalents (RPG's[1]). The most significant changes proposed are (a) that a graded set of minimum radiation protection requirements be introduced in three levels; (b) that the RPG for maximum whole-body dose equivalent be reduced from three rem [2] per quarter to five rem per year, and that regulatory agencies establish lower limits for specific types of work situations; (c) that limitation of internal doses [3] take into account the sum of the risks to all organs, rather than continue to be based only on the most significantly exposed organ; (d) that the RPGs for the whole body apply to the appropriately weighted sum of the doses from both internal and external exposures; and (e) that the dose to the embryo and the fetus be limited through one of several alternative recommendations.

We welcome written comments on these proposals and will hold public hearings as discussed below. We will carefully consider all oral and written comments in preparing our final recommendations to the President.

**DATES:** 1. All written comments in response to this notice must be received by us by April 24, 1981, in order to be used.

2. Public hearings will be held at the following locations, beginning no earlier than 60 days following publication of this notice: Washington, D.C., Chicago, Illinois, San Francisco, California, Houston, Texas. We will publish the times and addresses for these hearings shortly.

3. Instructions of interest to those who wish to appear at the public hearings are given below under the heading "Public Hearings."

**ADDITIONAL INFORMATION:** We will be happy to send a copy of a background report which provides additional information on these proposed recommendations to anyone requesting it. Please send requests to Mr. Luis F. Garcia at the address below. This report is also available for inspection and copying at EPA's Central Docket Section and ten Regional Offices (addresses below).

**ADDRESSES:** Written comments should be addressed to the Director, Criteria and Standards Division (ANR-460), U.S. Environmental Protection Agency, Washington, D.C. 20460, Attention: Docket No. A-79-46. These comments and the public hearing record will be filed under the above docket number and will be available for inspection and copying at the U.S. Environmental Protection Agency's Central Docket Section, Room 2903B, Mall 401 M Street, S.W., Washington, D.C. 20460, and at the Agency's library in each of its ten regional offices: *Region I:* JFK Building, Room 2100-B; Boston, Massachusetts 02203 (Tel. 617-223-5791); *Region II:* 26 Federal Plaza, Room 1002, New York, New York 10278 (Tel. 212-264-2881); *Region III:* Curtis Building, 6th & Walnut Streets, Philadelphia, Pennsylvania 19106 (Tel. 215-597-0580); *Region IV:* 345 Courtland Street, N.E., Atlanta, Georgia 30365 (Tel. 404-881-4216); *Region V:* 230 South Dearborn Street, Room 1417, Chicago, Illinois 60604 (Tel. 312-353-2022); *Region VI:* First International Building, 1201 Elm Street, 28th Floor, Dallas, Texas 75270 (Tel. 214-767-7341); *Region VII:* 324 East 11th Street, Kansas City, Missouri 64106 (Tel. 816-374-3497); *Region VIII:* Radiation Program Office (in lieu of library), 1860 Lincoln Street, Second Floor, Denver, Colorado 80203 (Tel. 303-837-2221); *Region IX:* 215 Fremont Street, 6th Floor, San Francisco, California 94105 (Tel. 415-556-1841: *Region X:* 1200 Sixth Avenue, 12th Floor, Seattle, Washington 98101 (Tel. 206-442-1289).

**FOR FURTHER INFORMATION CONTACT:** Contact Mr. Luis F. Garcia, U.S. Environmental Protection Agency (ANR-460), Washington, D.C. 20460 (Telephone 703-557-8224), about these proposed recommendations or the public hearings.

**SUPPLEMENTARY INFORMATION:**

### Statutory Authority

The Administrator of the Environmental Protection Agency (EPA) is charged under Executive Order 10831, Reorganization Plan No. 3 of 1970, and Public Law 86-373 to "* * * advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." This guidance has historically taken the form of qualitative and quantitative "Radiation Protection Guidance." The recommendations we propose here would replace those portions of existing Federal guidance that apply to radiation protection of workers, which were adopted in 1960 (25 FR 4402).

### Previous Actions by EPA

We began this review of the 1960 radiation protection guidance for workers in 1974. The most recent notice of this activity listed the principal issues being addressed and announced our intent to hold public hearings on proposed recommendations (44 FR 53785, Sept. 17, 1979).

We have sponsored two major studies in support of this program. First, the Committee on the Biological Effects of Ionizing Radiations, National Academy of Sciences—National Research Council, has reviewed the scientific data on the health risks of low level ionizing radiation developed since its 1972 report. Second, we have carried out a study of occupational radiation exposures and published our findings in a report entitled: "Occupational Exposure to Ionizing Radiation in the United States: A Comprehensive Summary for the Year 1975." We have also considered recent recommendations of the National Council on Radiation Proctection and Measurements.

In developing these proposals, we have also consulted with the technical staffs of the Federal agencies that regulate or influence the regulation of occupational exposure, and will continue this consultation in developing final recommendations. These agencies are the Occupational Safety and Health Administration, the Nuclear Regulatory Commission, the Mine Safety and Health Administration, the Department of Defense, the Department of Energy, the Department of Transportation, the Food and Drug Administration, the National Aeronautics and Space Administration, the National Institute for Occupational Safety and Health, and

[1] Radiation Protection Guides.

[2] A *rad* is a unit of measure for dose, i.e., the amount of ionizing radiation energy absorbed per unit weight of tissue. Thus, the same energy absorbed by twice as much tissue gives only one-half the number of rads. The *rem*, a unit for dose equivalent, is a rad multiplied by factors which describe how damaging the type of radiation is.

[3] In this notice we henceforth use "dose" to mean "dose equivalent."

the National Bureau of Standards. These agencies, which have not formally endorsed these recommendations, will formally review final proposals when they are developed following public review.

### Issues Addressed

The principal issues we addressed in formulating these recommendations were identified in the advance notice cited above. They were:

1. Are the doses currently received by workers and the maximum doses permitted under existing guidance adequately low? In this regard, a) how adequate is the basis used for estimating risks to health from radiation exposure, and b) what are the appropriate bases for judging maximum individual and collective radiation doses in the work force and the tradeoffs between these two indices of the health impact of occupational exposure?

2. Should the same guides apply to all categories of workers (e.g., dental workers, nuclear medicine technicians, nuclear maintenance personnel, industrial radiographers)? Should specific guides be developed for pregnant women, female workers who could bear children, and/or men?

3. On what time basis should the guides be expressed? Quarterly? Annual? Should the lifetime occupational dose be limited? Should the age of the worker be a factor?

4. Should the guidance reflect or cover medical, accidental, and/or emergency exposures?

5. Is existing guidance for situations that involve exposure of less than the whole body adequate? In this respect, a) what organs and parts of the body should have designated limits, and b) on what basis should guidance be expressed for exposure of more than one organ or portion of the body?

6. How should the radiation protection principles requiring a) justification of any exposure, and b) reduction of the dose from justified exposures to the lowest practicable or as low as is reasonably achievable level be applied to exposure of workers? Should the concept of lowest feasible level be applied to exposure of workers?

7. What, if any, relationship should be maintained between permissible levels of risk to health from radiation exposure and other regulated hazards of disease or accidents?

Additional issues suggested since publication of the advance notice include:

8. Should the guidance include numerical values for the factors (called "quality" and "modifying" factors) used to convert dose (measured in rads) to dose equivalent (measured in rem)? If so, should this be developed now or issued later as supplementary guidance?

9. What guidance should apply to workers who do not use radiation sources, but who are exposed to radiation due to the activities of workers under the control of other employers?

10. Are there situations that may require doses higher than normally permitted? Should we provide special guidance for them?

Many of these issues are addressed below. However, for a more complete and extensive discussion please refer to the background report cited above under the heading "Additional Information."

### Risks From Occupational Exposure

There are three kinds of risks from the low levels of ionizing radiation characteristic of occupational exposures. The most important of these is cancer, which is fatal at least half the time. Another risk is the induction of hereditary effects in descendants of exposed persons. The severity of these effects ranges from fatal to inconsequential. We assume that at low levels of exposure the risk of cancer and hereditary effects is in proportion to the dose received, and that the severity of any induced effect is independent of the dose level. That is, while the probability of a given type of cancer occurring increases with dose, such a cancer induced at one dose is equally as debilitating as that same type of cancer induced at another dose. Thus, for these effects we assume that there is no completely risk-free level of radiation exposure.

The third type of risk includes a variety of other effects on workers and on the children of women exposed during pregnancy. These effects range from serious effects on children, such as mental retardation, to less serious effects on workers, such as opacification of the lens of the eye and temporary impairment of fertility. For these effects we believe the degree of damage (i.e., the severity) depends to some extent on the dose level. At the dose levels allowed by current radiation protection guides, we believe that none of the effects on workers themselves occurs to a degree sufficient to be clinically detectable. At these levels, however, effects on children exposed in utero may be serious.

The risks of effects on health from low level ionizing radiation were reviewed for EPA by the National Academy of Sciences (NAS) in reports published in 1972 and in 1980. We have used these studies and others to estimate the risks associated with the current and proposed Federal guides for limiting radiation dose. Details of these and other risk estimates we use are provided in the accompanying background report.[4]

A worker who received the largest lifetime dose allowed under present guides (5 rem per year from age 18 to assumed retirement at age 65, or 235 rem) would have a lifetime risk of about 3 to 6 in 100 of dying from radiation-induced cancer, and numerically comparable chances both of nonfatal cancer and, for male workers, of mutational effects in his descendants.[5] Risks of mutational effects from exposure of female workers are assumed to be three to four times smaller. However, in our recent national survey of exposures for the year 1975, 99% of all workers received less than half of, and only 0.15% exceeded, an annual dose of 5 rem. Based on these and other data, we believe that only a few workers involved in accidents have received close to the current maximum allowed lifetime dose.

The average worker exposed to radiation sustains only a small risk of death from radiation. The estimated average risk of death due to radiation-induced cancer is smaller, for example, than the risk of job-related accidental death in the safest of all major occupational categories, retail trades, for which the annual death rate was 60 per million workers in 1975. We estimate that the collective dose to the more than one million workers potentially exposed to radiation in their workplace for that same year will not lead to more than 15–36 premature cancer deaths. Other ways of expressing this risk are that the exposure of an average worker to radiation in 1975 represented an average lifeshortening of about two to three and a half hours, or an average increase in his chance of cancer death of about one to three in 100,000. In 1975 about one sixth of United States deaths were from cancer.

The comparative time-loss associated with nonfatal cancer is also estimated to be very small. The average time lost by

[4] Our estimated ranges of risk for cancer death are based on absolute and relative linear risk models used by the 1972 BEIR Committee and the assumption that the risk of incurring most radiogenic cancers continues throughout the lifetime of exposed persons. The 1980 BEIR report, which was just published, gives estimates based on a variety of risk models, some of which yield lower and some higher values. Based on our preliminary review, we do not believe that the differences between these values and those we have adopted here would lead to any changes in these proposals.

[5] Mutational effects here mean those hereditary effects included by the BEIR Committee in their 1972 report as serious disabilities. Examples are congenital malformations leading to premature death, hemophilia, sickle cell anemia, cystic fibrosis, diabetes, schizophrenia, and epilepsy.

U.S. workers due to all occupationally-related injuries and illnesses over a working lifetime is one month. For radiation-induced nonfatal cancers it is estimated to be about four days for a hypothetical individual receiving the largest lifetime dose allowed (235 rem), and for the average worker it is about two hours.

**Limitation of Whole Body (External) Exposure**

Based on these observations, risks due to occupational exposure to radiation do not appear to be unreasonably high for the average worker. They are comparable to risks of accidental death in the least hazardous occupations. However, a worker exposed to the current maximum allowed dose year after year would sustain substantial risks. The proposed radiation protection guidance contains provisions to avoid the accumulation of large lifetime doses through reduction of the maximum allowed annual dose and through specific minimum radiation protection requirements for workers in high-dose work situations. These include on-the-job radiation protection supervision for high-dose jobs, maintenance of lifetime dose records, and an admonition that exposure of workers should be managed so that their lifetime doses do not exceed 100 rem.

Existing Federal guidance permits doses up to 3 rem per quarter (or 12 rem per year), within an overall cumulative limit of 5(N–18) rem, where N is the age of the worker. This flexibility, which allows annual doses greater than 5 rem, does not permit specific tasks that require doses to individuals of more than 5 rem (since the 3 rem per quarter limit prohibits this), but it does permit the same worker to accomplish several tasks requiring doses at or near this quarterly limit in a given year. In view of the risks, it is our judgement that repeated exposures in a year at such levels should not occur, and these recommendations would eliminate this flexibility. One appropriate solution in cases where workers with specific skills are in short supply is to train additional workers, rather than to impose higher risks on a few individuals.

Because we assume that any exposure carries some risk, we believe that it is important to avoid unnecessary exposures at any exposure level. Although more than 97% of all workers in our survey received annual doses less than one rem, these same workers accumulated about half of the collective dose received by the entire work force. Many of these workers, because their doses are low compared to the limits, may receive only minimal training, supervision, and monitoring for radiation protection. Many also work in situations where there is no need for exposures to ever approach the existing or the proposed new RPGs. On the other hand, some exposures at higher doses are justified. The proposed recommendations, therefore, provide a graded system of radiation protection which would establish minimum radiation protection requirements for each of three different ranges of exposure within the basic guides for maximum allowed dose to all workers. We anticipate that maximum exposure of the vast majority of workers would be effectively limited to the lowest of these ranges (less than approximately 0.5 rem to the whole body per year) through the deterrent of requirements for increased justification, on-the-job radiation protection supervision, and monitoring in the two higher ranges. In addition, the recommendations encourage regulatory agencies to establish more restrictive regulatory limits for work situations not requiring the maximum doses allowed under the basic guides.

The proposed guidance leaves agencies considerable discretion in implementing the minimum radiation protection requirements for justification of exposure of workers in each of the various ranges. We are considering additional guidance which would recommend the establishment of more explicit requirements for the highest range (Range C). These requirements could include establishment of criteria for use of Range C, or prior application to and approval by the regulatory agency of Range C exposure (either for specific or more general job situations). We request specific comments on these and similar approaches to further restrictions on the exposure of workers at these higher levels.

We have considered both higher and lower alternatives to the proposed 5 rem/year RPG for whole-body exposure. This value is proposed because (a) it is the current internationally-accepted value, (b) there appear to be essential jobs requiring near 5 rem per year, and (c) the risks to the few workers in these jobs are not high compared to other industrial hazards. In addition, the costs for levels significantly lower (one rem/year or less) appear to be unwarranted, both in terms of increased collective dose to the entire workforce (in return for a few lower individual doses), and in terms of increased economic costs.

In 1975 the National Council on Radiation Protection and Measurements took the position that no change was required in the recommendation given by it in 1971. That recommendation is that "The maximum permissible prospective dose equivalent for whole body irradiation from all occupational sources shall be 5 rems in any one year" (NCRP Report No. 39, Jan. 15, 1971). Likewise the International Commission on Radiological Protection in 1977 recommended a basic dose-equivalent annual limit of 5 rem for whole body exposures to ionizing radiation (ICRP Publication 26, Jan. 17, 1977). In support of its recommendation the ICRP states that "The Commission believes that for the foreseeable future a valid method for judging the acceptability of the level of risk in radiation work is by comparing this risk with that for other occupations recognized as having high standards of safety, * * *." The radiation risk factors given in ICRP Publication 26 in arriving at its recommendation were reviewed by ICRP in May 1978 and no changes were made (ICRP Publication 28, 1978).

Nevertheless, these recommendations are all value judgments; there is not now compelling evidence for any particular value and it is hard to get such evidence. In judging the acceptability of the risks involved, it is necessary to identify (a) activities that cannot be performed at particular maximum dose levels, (b) skilled professionals and workers in limited supply whose numbers would be difficult to quickly increase in order to reduce average annual doses, and (c) the costs for additional workers and equipment that would be needed to meet different limits. For example, we are aware of a small number of maintenance tasks at nuclear power stations that could not be done under some limits less than 5 rem/year. There may be many more examples of professions, principally in medical areas, with limited labor pools. These include cardiologists performing catheterizations using fluoroscopy; and radiologists, neuro-radiologists, and nuclear medicine technologists with large patient loads for special procedures. Finally, studies by the Department of Energy and the nuclear power industry report that large costs and many more workers would be needed to greatly reduce the dose limits for many operations. Their projections of costs and personnel requirements increase expotentially with decreasing limits. We therefore request, in addition to comment on reduction of the current RPG of 3 rem/quarter to our proposed recommendation of 5 rem/year, comment on the above factors for reduction of the current RPG to 0.5 rem/year, 1 rem/year, and 3 rem/year.

**Limitation of Partial Body Exposures**

Exposure of portions of the body can occur through localized irradiation of

extremities (such as hands in glove boxes), or by breathing or swallowing radioactive materials, which then migrate to different organs of the body.

Current guidance limits such exposures through separate numerical guides for organs and for individual parts of the body that are easily exposed, such as hands and feet or lens of the eye. Some organs recognized as easily subjected to high doses or as particularly sensitive to radiation have specific guides.

These current guides are applied separately. For example, even though a worker has received the maximum allowed dose to his thyroid, he may also receive doses to his lungs, skin, or any other organ, as long as no single organ receives more than the dose specified by its guide. We assume that the risks associated with such multiple doses are additive.

An alternative approach is to limit the total risk of fatal cancer in all exposed organs. This method has been adopted by the International Commission on Radiological Protection (ICRP). It is also adopted in these recommendations, but only when it leads to a greater degree of protection than limiting the dose to critical organs. Specifically, the recommended guidance provides that (a) either the combined risk of fatal cancer from all doses to individual organs not exceed the risk permitted under the whole body guide or (b) the dose to the most significantly exposed organ not exceed its guide, whichever is more restrictive. The recommendations also provide, when workers receive both external doses from whole-body exposure and internal doses from radionuclides, that the sum of the risks of fatal cancer from external whole-body doses and those due to breathing or swallowing radioactive materials not exceed the risk of fatal cancer allowed by the whole-body guide.

The numerical weighting factors chosen to relate risks to individual organs to whole-body risk are discussed in the background report cited above. In general, they are consistent with recent determinations of risk of fatal cancer by national and international scientific bodies, such as the NAS and the ICRP.

We have chosen the limiting annual dose to most single organs to be 30 rem, rather than the internationally-adopted value of 50 rem, because we do not see a need for a value higher than any now used in this country. The risk associated with 30 rem to any of these organs is equal to or less than that of 5 rem to the whole body. Additional differences from internationally-used values for gonads, lens of eye, and hands are discussed below.

It is usually impractical to directly monitor the dose received by a worker who breathes or swallows radioactive materials, but it is useful to be able to predict doses that may be received from breathing contaminated atmospheres or swallowing contaminated materials. To make decisions about radiation protection of such workers possible, it is necessary to calculate the amounts of different kinds of radioactive materials which, when breathed in or swallowed, give the maximum dose allowed by the RPGs. Those calculations require complex models of metabolism and dosimetry. We propose that these limiting amounts of radioactivity be designated the "Radioactivity Intake Factors" (RIFs), and that they replace the currently used "Radioactivity Concentration Guides."

Recent advances in modeling metabolism and dosimetry have produced significant changes in the doses calculated for radioactive materials in the body. For many radioactive materials the changes in the RIFs due to changes in the models are considerably larger than the changes due to the proposed new RPGs. These new models more often reduce allowable intakes than raise them. However, for those cases where the RIF for any specific radionuclide would be increased, the question arises whether regulations adopted by implementing agencies should retain existing values, in accordance with proposed Recommendations 2 and 6. We believe that, for existing applications, experience gained over the past two decades shows that current values can be reasonably achieved. Accordingly, in cases where the RIF for any specific radionuclide would be increased under the proposed guidance, we recommend that the value adopted in regulations governing existing applications be no higher than that now in use. A summary of the changes due to the new models and to the proposed new guides is provided for the more significant radionuclides in the background report.

**Limitation of Risk From Mutations**

The current guides for limiting dose to the gonads are identical to those for the whole body. For a given annual dose, the risk of mutational effects in all of a male worker's descendants combined is believed to be numerically comparable to his lifetime risk of fatal cancer. The risk to a female worker's descendants is smaller. The medical severity of these hereditary effects is usually less than, and, at worst, comparable to, death from cancer. For these reasons we do not believe that a more restrictive guide is required for the gonads than for the whole body. The proposed new guide for gonadal dose is therefore identical to that proposed for the whole body. This guide is specified separately and not included in the scheme proposed above for weighting partial-body doses because the risks involved are of a fundamentally different nature: the affected individual is not the one exposed to radiation and the effects include different types of harm.

**Limitation of Risk to the Unborn (Fertilized Oocyte, Embryo, and Fetus**

Protection of the unborn from radiation is an already well-established principle; the purpose of the guide for gonadal exposure is to limit mutational effects in children conceived after the exposure. However, those conceived but not yet born, the "unborn," are also at risk. Their risks are greater, for a given dose, than the risks to those not yet conceived. Current guidance does not contain a dose limitation to protect the unborn from these risks.

The risk of serious harm following in utero exposure requires careful attention because of the magnitude and diversity of the effects, because they occur so early in life, and because those who suffer the harm are involuntarily exposed. These risks are not as well quantified as those to adults. Nevertheless, available evidence indicates that at critical periods in the development of the unborn, for the same dose, risks may be many times greater than those to adults.

There are several factors which mitigate this situation. First, the exposure of most workers under annual limits is relatively evenly distributed over the year, so that only a quarter of a worker's annual dose is delivered to the unborn during any trimester. Second, the mother's body provides considerable shielding of the unborn for most types of exposure. Finally, the total period of potential exposure is small for the unborn compared to that for a worker—a period of months compared to a working lifetime.

It is difficult to provide for protection of the unborn without affecting the rights of women to equal job opportunities. This difficulty is compounded because the critical period for most harm to the unborn occurs soon after conception—during the second and third month after conception, when a woman may not know that she is pregnant. Based on our assessments of the risks and the other factors noted above, we believe that the maximum dose to the unborn should be a factor of ten below the maximum permitted adult workers in any year. This is also the current recommendation of the National

Council on Radiation Protection and Measurements. In Recommendation 8 we propose four alternatives which would, with varying degrees of certainty, achieve this objective.

The first two alternatives rely upon voluntary compliance and, therefore, should have less impact on equal job opportunities for women. The first assumes a woman knows she is pregnant within six weeks of conception, and will then, along with her employer, take appropriate protective action. It therefore does not guarantee that doses to the unborn during the critical early stages of pregnancy will be less than 0.5 rem.

The second alternative adds a voluntary limit on dose rate to women who can bear children in order to protect the unborn whose existence is not yet known. It permits women to hold any job, but encourages women able to bear children not to take those few jobs which potentially involve high dose rates.

The third alternative insures protection of all unborn throughout gestation by making the voluntary requirements of the second mandatory. It would bar women of child-bearing capacity from those few jobs which involve high dose rates.

The final alternative would restrict the exposure of all workers, male and female, to a level which would protect the unborn at the level of the first alternative. This alternative preserves equal job opportuntity for women at the cost of causing more total harm. Studies of several high exposure activities show that decreasing the dose limits to this extent would significantly increase the collective dose to workers, and that some current activities would not be possible.

None of these alternatives is completely satisfactory; they each involve either varying degrees of adequacy of protection of the unborn, some sacrifice of equal job opportunity for women, or causing more total harm, or foregoing some of the benefits to society from activities using radiation. We invite public comment on the relative importance to be attached to each of these factors in formulating guidance, and on whether or not the guidance should address this matter now. We would also be happy to receive suggestions for other alternatives.

**Limitation of Other Risks**

The risk of nonfatal cancer is not only intrinsically less important than that of fatal cancer, but is very much smaller than other nonfatal occupational risks. Thus, we believe the protection provided against fatal cancers includes adequate protection against nonfatal cancers.

While adequate protection against cataracts of the lens of the eye might be provided by a higher maximum average annual dose than the 5 rem now allowed, no operational difficulty is reported with use of 5 rem as an annual limit. That value is therefore retained in these proposals.

The maximum annual dose for skin of the whole body is maintained at 30 rem, since a need for allowing higher doses has not been demonstrated. However, the current guide permits 75 rem to hands and forearms, or feet and ankles, because of the assumed lower risk when only these portions of the skin and underlying tissue of these extremities are involved. We agree that at low dose rates the risk depends in some degree on the amount of skin and tissue exposed, and that exposure of the extremities is therefore less dangerous than of the whole body. However, for forearms, feet, and ankles such a high value is not needed and we propose that the guides for skin and the whole body apply to these extremites. For the hands a higher value appears to be justified for work in glove boxes. It is proposed to be 50 rem, the limit recommended by the ICRP.

**Other Considerations**

These recommendations apply to workers exposed to other than normal background radiation on the job. It is sometimes hard to identify such workers, because everyone is exposed to natural sources of radiation and many occupational exposures are small. Regulatory agencies will have to use care in selecting classes of workers whose exposure does not need to be regulated. In selecting such classes we recommend that the agency consider both the collective dose which is likely to be avoided through regulation and the maximum individual doses possible.

The question often arises whether or not exposure for medical purposes and other nonoccupational exposures should be considered in calculating the doses that workers receive within the guides. If there were a threshold for risk of health effects from radiation, this could be an important consideration. However, since we assume that the risk at low doses is proportional to the dose, each exposure must be justified on its individual merits. For this reason, in Note 1 to the recommendations we exclude medical and other nonoccupational exposure from the total calculated occupational radiation exposure of workers.

In many jobs diagnostic x-ray examinations are a routine part of periodic or pre-employment physical examinations. Some of these examinations are a condition of employment and some are not. Federal radiation protection guidance on use of diagnostic x-rays was issued by the President on February 1, 1978 (43 FR 4377). These recommendations provide that, in general, use of such x-ray examinations should be avoided unless a medical benefit will result to a worker, considering the importance of the x-ray examination in preventing and diagnosing diseases, the risk from radiation, and the cost. Although all of the recommendations in that guidance may be usefully applied to x-ray examinations of workers, Recommendations 1 through 4 are particularly pertinent. Because this matter has been addressed by separate Federal guidance, exposure from such diagnostic x-ray examinations is not included in this guidance for occupational exposure.

Current Federal guidance provides that occupational doses to minors (those below the age of eighteen) be limited to one tenth the RPGs for older workers. We propose no change.

No other general types of exposed workers are singled out for special protection by these recommendations. However, one special class of workers—underground uranium miners—is already subject to a separate Federal guide (36 FR 12921). That guide limits exposure of their lungs to radioactive decay products of radon gas. The Mine Safety and Health Administration regulates exposure of all underground miners in accordance with this guide. We expect to review the guide on the exposure of miners to decay products of radon in the future. Exposure of miners to other radiation is governed by the Federal radiation protection guidance in these proposed recommendations.

We have not addressed the issues of emergency exposures or of whether overdoses in one year should lead to additional restrictions on doses in future years. Such situations must be dealt with on the merits in each case and under the regulatory mandate of the controlling Federal agency. We do not consider it either practical or reasonable to prejudge or prescribe general conditions for such situations beyond the general principles which apply to all radiation exposure that are set forth below in Recommendations 1 and 2.

We recognize, in addition, that some situations may exist which justify planned exposures exceeding the guides. Recommendation 9 provides for this. It requires that the controlling Federal agency fully consider and disclose the reasons for any such exposures.

**Estimated Impact of These Proposals**

We estimated above that the exposure of 1.1 million workers in 1975 (the latest year for which we have complete statistics) will lead to 15–36 additional premature cancer deaths and comparable numbers of serious mutational effects and nonlethal cancers. If this new guidance is adopted, workers should be harmed less in the future. We are not able to quantify the improvement because we cannot predict how efficiently the guidance will be implemented and we do not know how much of existing exposure is unjustified. However, the proposed recommendations provide a framework of graded minimum requirements to cut down the amount of unjustified exposure, and a recommendation that implementing agencies establish lower regulatory limits for workers who can operate significantly below the new maximum limits. We believe that most workers can. The proposals also reduce the maximum annual and lifetime dose that any workers can get by about 60%.

We have made only a limited assessment of the costs of implementing this proposed guidance. We do not believe it would be prudent to attempt a detailed analysis, because agencies developing regulations to carry out this guidance may use different means, and their specific proposals will be subjected to public review and economic analysis when they are developed.

The principal cost will be that associated with reduced RPGs. in order to comply with a reduced RPG an enterprise can hire more workers, reassign (and, if necessary, retrain) present employees, improve its procedures or technology, or curtail the activity. In general, a mix of these will be used, depending on the value of the reduced RPG, on the cost of each alternative, and on other factors. Since we do not know what mix will be used, for the purpose of developing rough numberical estimates of the upper bounds of costs we have used a simple model based on the costs for hiring new workers only.

From the distribution of doses found in our national survey of exposures for the year 1975, we computed the total excess collective dose between the old RPG of 3 rem per quarter and the proposed RPG of 5 rem per year. Dividing this excess by the value of the proposed new RPG gives the minimum number of workers that must be hired to absorb this dose. The average labor cost, including overhead, for each additional worker was assumed to be $40,000 per year. This method yields a cost of about $35 million per year. We believe the actual cost of meeting the new RPG will be much less.

We have also attempted to evaluate costs if existing workers now receiving lower doses are retrained to do high-dose jobs instead of hiring new workers. Some workers are very difficult to replace (e.g., medical professionals, such as cardiologists and radiologists; and workers in small enterprises with very limited labor pools). However, we believe that most workers can be relatively easily retrained (e.g., medical technicians and skilled laborers, such as welders and pipe fitters) to handle tasks which cause higher exposures. We estimate that workers that can be reassigned to these jobs would require training varying from a few days to a few months. For these workers, the costs are expected to range from a few percent to a few tens of percent of the annual cost of new hires. In addition, these costs are incurred only once instead of annually, as in the case of new hires. We therefore estimate that the costs based on the above new hires model may be as much as ten times too high, for the first year, and an even greater over-estimate in succeeding years. We welcome comments on the costs of implementing these proposals, on whether or not the costs are reasonable, and why.

**Proposed Recommendations**

We propose nine recommendations as guidance to Federal agencies in the formulation of Federal radiation protection standards for workers, and in their establishment of programs of cooperation with States. In all cases but one we have made single recommendations for public comment. The exception, Recommendation 8, addresses protection of the unborn during gestation. Because this recommendation involves issues that go beyond simple radiation protection of workers, including equality of employment rights and the rights of the unborn, we have proposed four alternatives for public consideration. The recommendations follow:

1. All occupational exposure should be justified by the net benefit of the activity causing the exposure. The justification should include comparable consideration of alternatives not requiring radiation exposure.

2. For any justified activity a sustained effort should be made to assure that the collective dose is as low as is reasonably achievable.

3. The radiation dose to individuals should conform to the numerical Radiation Protection Guides (RPGs) specified below. Individual doses should be maintained as far below these RPGs as is reasonably achievable and consistent with Recommendation 2.

*Radiation Protection Guides*

a. The sum of the annual dose equivalent [6] from external exposure and the annual committed dose equivalent [7] from internal exposure should not exceed the following values:

Whole body—5 rem
Gonads—5 rem
Lens of eye—5 rem
Hands—50 rem
Any other organ—30 rem

b. Non-uniform exposure of the body should also satisfy the condition on the weighted sum of annual dose equivalents and committed dose equivalents, $H_w$, that

$$H_w = \Sigma_i w_i H_i < 5\text{rm},$$

where $w_i$ is a weighting factor, $H_i$ is the annual dose equivalent and committed dose equivalent to organ $i$, and the sum excludes the gonads, lens of eye, and hands. Recommended values of $w_i$ are:

Breast—0.20
Lung—0.16
Red bone marrow—0.16
Thyroid—0.04
Bone surfaces—0.03
Skin—0.01
Other organs [8]—0.06

c. When both uniform whole-body exposure and nonuniform exposure of the body occur, in addition to the requirements of 3a, the annual uniform whole-body dose equivalent added to the sum of weighted annual dose equivalents from additional nonuniform exposure, $H_w$, should not exceed 5 rem.

4. The following Minimum Radiation Protection Requirements should be established by appropriate authorities and carried out in the workplace, on the basis of the range of doses anticipated in individual work situations. The numerical values specifying the dose ranges may be adjusted to fit the needs of specific situations by implementing agencies.[9]

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[6] "Dose equivalent" means the quantity expressed by the unit "rem," as defined by the International Commission on Radiation Units (IU73).

[7] "Annual committed dose equivalent" applies only to dose equivalents from radionuclides inside the body. It means the sum of all dose equivalents that may accumulate over an individual's remaining lifetime (usually taken as 50 years) from radioactivity that is taken into the body in a given year.

[8] Applies only to each of the five other organs with highest doses.

[9] Suggested numerical ranges are: Range A, less than 0.1 RPG; Range B, 0.1–0.3 RPG; Range C, 0.3–1.0 RPG.

*Minimum Radiation Protection Requirements*

*Range A*

a. Determine that exposures result only from justified activities and are as low as is reasonably achievable. These determinations may often be made on a generic basis, that is, by considering groups of similar work situations and protective measures.

b. Monitor or otherwise determine individual or area exposure rates to the extent necessary to give reasonable assurance that doses are within the range and are as low as is reasonably achievable.

c. Instruct workers on basic hazards of radiation and radiation protection principles, and on the levels of risk from radiation and appropriate radiation protection practices for their specific work situations. The degree of instruction appropriate will depend on the potential exposure involved.

*Range B*

The above requirements, plus:

d. Provide professional radiation protection supervision in the work place sufficient to assure that both individual and collective exposures are justified and are as low as is reasonably achievable.

e. Provide individual monitoring and recordkeeping.

*Range C*

The above requirements, plus:

f. Justify the need for work situations which are expected to make a significant contribution to exposure in Range C and provide professional radiation protection supervision before and while such jobs are undertaken to assure that collective and individual exposures are as low as is reasonably achievable.

g. Carry out sufficient additional monitoring of workers to achieve Recommendation 4f.

h. Once a worker has been exposed in Range C, maintain a lifetime dose record, including at least all subsequent annual doses (as specified in Recommendation 3c) in Ranges B and C.

i. Maintain lifetime doses as low as is reasonably achievable. The accumulation of doses (as recorded under Recommendation 4h) by individual workers should be managed so that their lifetime accumulated dose is less than 100 rem.

5. a. "Radioactivity Intake Factors" (RIFs) should be used to regulate occupational radiation hazards from breathing, swallowing, or immersion in media containing radionuclides. The RIF for a radionuclide is defined as the maximum annual intake (in curies) for which the committed dose equivalent to a reference person satisfies the Radiation Protection Guides in Recommendation 3. RIFs may be derived for different chemical or physical forms, and for intake by breathing, swallowing, or for external exposure from air containing a radioactive gas. Exposure regulated through use of the RIFs should meet the same Minimum Radiation Protection Requirements as equivalent exposure under the Radiation Protection Guides.

b. When a RIF for a specific radionuclide in a specific chemical or physical form determined on the basis of part (a) is larger than that currently in use, a value no greater than that in current use should be adopted in regulations governing work situations identical or similar to those currently in existence.

6. Federal agencies should establish limits and administrative levels that are below the RPGs and the RIFs, when this is appropriate. Such limits or levels may apply to specific categories of workers or work situations.

7. In addition to any other Federal restrictions, the occupational exposure of individuals younger than eighteen should be limited to one tenth of the Radiation Protection Guides for adult workers.

8. Exposure of the unborn [10] should be restricted more than that of workers. This should include special consideration of ALARA practices for women. Women able to bear children should be fully informed of current knowledge of risks to the unborn from radiation. In addition, employers should assure that protection of the unborn is achieved without loss of job security or economic penalty to women workers. Due to the complexity of the issues involved, we propose four alternative recommendations on numerical limitation of dose to the unborn for public comment. We would be glad to receive other recommendations for dealing with exposure of the unborn.

a. Women are encouraged to voluntarily keep total dose to any unborn less than 0.5 rem during any known or suspected pregnancy; or

b. Women able to bear children are encouraged to voluntarily avoid job situations involving whole-body dose rates greater than 0.2 rem per month, and to keep total dose to the unborn less than 0.5 rem during any known pregnancy; or

c. Women able to bear children should be limited to job situations involving whole-body dose rates less than 0.2 rem per month. Total dose to the unborn during any known period of pregnancy should be limited to 0.5 rem; or

d. The whole-body dose to both male and female workers should not exceed 0.5 rem during any six month period.

9. In exceptional circumstances the RPGs may be exceeded, for cause, but only if the Federal agency having jurisdiction carefully considers the specific reasons for doing so, and publicly discloses them unless this would compromise national security.

The following notes clarify application of the above recommendations:

1. Occupational exposure of workers does not include that due to (a) normal background radiation and (b) exposure as a patient of practitioners of the healing arts.

2. When the uniform external whole-body exposure occurs in addition to exposure from radioactive materials taken into the body, the requirement of Recommendation 3c may be satisfied by the condition that

$$\frac{H_{ext}}{RPG_{wb}} + \sum_j \frac{I_j}{RIF_j} \leq 1,$$

where $H_{ext}$ is the annual external whole-body dose equivalent, $RPG_{wb}$ is 5 rem, $I_j$ is the intake of radionuclide j, and $RIF_j$ is defined as in Recommendation 5.

3. The values currently specified by the ICRP for quality factors and dosimetric conventions for measurement of the various types of radiation may be used for determining conformance with the RPGs. The model for a reference person and the metabolic models currently specified by the ICRP may be used to calculate the RIFs. We will recommend other factors, conventions, and models when and if they are more appropriate.

4. Numerical guides for emergency exposures are not provided by this guidance. Agencies should follow the general principles established by Recommendations 1, 2, 7, 8, and 9 in dealing with such situations.

5. Procedures for handling overexposures are not addressed by this guidance. The equitable handling of such cases is the responsibility of the employer and the Federal agency having regulatory jurisdiction.

6. Limits for periods other than one year may be derived by Federal agencies from the annual RPGs and RIFs when necessary for administrative

[10] "Unborn" here means the fertilized oocyte, the embryo, and the fetus.

they wish. Questions should be designed to elicit relevant information and should not be repetitious of questions asked by others. The views of questioners should be expressed in their statements and not as prefaces to questions. Such informal questioning will be at the discretion and under the control of the presiding officer.

d. Members of the public who are not able to attend the hearings or prefer not to ask questions themselves may suggest questions to the hearing panel to ask of speakers. These must be submitted no later than 14 days before any hearing to the Director (see "Addresses" above). The panel will decide whether or not to ask these questions.

e. Members of the public may also submit comments during the post-hearing comment period set by the presiding officer. These post-hearing comments should be confined to responses to data and opinions submitted at the hearings or to written comments received by the Agency.

f. In addition to these public hearings, we would appreciate any written comments on these proposals. These will be given equal consideration in formulating final recommendations. The procedure for submitting such written comment is given above under the headings "Dates" and "Addresses." Participants in the hearings may refer to and comment on such written comments, which will be available for public inspection and copying as specified below under "The Public Hearing Record."

*5. Opening Statement*

At the opening of each hearing, EPA will provide a summary statement of the proposed recommendations and of the major issues involved. At that time speakers and other members of the public can ask questions of the EPA representatives in order to clarify the proposed recommendations and the reasons why EPA is proposing them.

*6. The Public Hearing Record*

The procedures for filing documents in these hearings will be specified by the presiding officer, except as already provided herein.

The hearing record will include the transcript of oral statements by speakers, the questions and answers, and all written materials filed in connection with these hearings. Items in the public hearing record will be filed under EPA Docket No. A–79–46 and will be available for public inspection and copying as soon as possible following their receipt, at the U.S. Environmental Protection Agency's Central Docket Section, Room 2903B, Mail, 401 M Street, S.W., Washington, D.C. 20460, and at each of the Agency's ten regional offices (see "Addresses" above).

Dated: January 16, 1981.

**Douglas M. Costle,**

*Administrator.*

[FR Doc. 81-2385 Filed 1-22-81; 8:45 am]

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purposes. Such limits should be consistent with Recommendation 2 and the three ranges in Recommendation 4.

7. The existing guide for limiting exposure of underground uranium miners to radon decay products is not changed by these recommendations.

These proposed recommendations would provide general guidance for the radiation protection of workers. They would replace that part of existing guidance (see 25 FR 4402 of May 18, 1960) which applies to workers. Individual Federal agencies, with their knowledge of specific worker exposure situations, would use this guidance as the basis upon which to develop detailed standards and regulations to meet their particular statutory obligations. We propose to follow the activities of the Federal agencies as they implement the final Guidance, to issue any necessary clarifications and interpretations, and to promote the coordination necessary for an effective Federal program of worker protection.

**Public Hearings**

Public hearings on these proposed recommendations will be held as indicated above under the heading "Dates." Because of their major responsibilities to regulate radiation exposures in work places, the Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA) will participate in sponsoring these hearings. The following conditions and procedures will govern the conduct of the hearings:

*1. Purpose, Type, and Scope*

These hearings are to provide additional opportunity for people to express opinions and provide factual information to aid EPA, OSHA, and NRC in carrying out their respective responsibilities for guidance on and regulation of occupational exposure to ionizing radiation. The hearings will be informal and legislative in nature rather than adjudicatory or formal rulemaking hearings. Technical rules of evidence, discovery, subpoena powers, testimony under oath, and similar formalities will not apply.

The issues to be covered by these hearings are those listed above under the heading "*Issues Addressed.*" They include those listed in our advance notice of September 17, 1979 (44 FR 53785) and additional issues suggested since then. As indicated in that notice, both EPA and NRC have been petitioned by the Natural Resources Defense Council, Inc., to revise occupational guidance and standards. The subject matter of these hearings encompasses the issues raised in those petitions (See 40 FR 50327 of October 29, 1975).

*2. Presiding Officer and Panel*

The hearings will be conducted by a presiding officer. A six member panel consisting of representatives of EPA, OSHA, and NRC will assist the presiding officer. A principal responsibility of the panel will be to clarify the testimony by eliciting views, comments, and factual information from participants. Members of the panel will not present views or respond to questions on behalf of their agencies. The membership of the panel may vary from time to time.

The presiding officer and panel shall have the joint responsibility to assure a fair and impartial hearing and to encourage the development of testimony that will contribute to informed decision-making. It will not be the function of the presiding officer or the panel to issue an opinion or to make decisions at the conclusion of the hearings. The presiding officer shall conduct the hearings in an orderly, fair, and expeditious manner and make procedural decisions. His functions shall include, but not be limited to, the following:

a. Regulating the course of the hearings and the conduct of participants, including establishing reasonable time limits for the hearings, establishing the sequence and length of presentations and questioning, and opening and closing each hearing session;

b. Making determinations concerning procedure and similar matters;

c. Assuring that questioning of speakers by panel members and others is consistent with the nature and purpose of these hearings;

d. Making determinations on the relevance of oral testimony and questions to the issues identified as within the scope of the hearings, or, in consulation with the panel, to additional issues pertinent to the proceedings; and, as necessary, terminating irrelevant presentations;

e. Ruling on late requests to participate;

f. Deciding how long the hearing record will remain open for written comments and additional data after the end of the oral proceedings.

*3. Participation in the Hearings*

Persons or organizations who wish to give presentations longer than ten minutes or present extensive data and evidence must give written notice to the Director, Criteria and Standards Division (ANR–460), U.S. Environmental Protection Agency, Washington, D.C. 20460, no later than 28 days prior to the scheduled date of a hearing. The notice should include: (1) the name, address, and telephone number of the participant; (2) the hearing at which they wish to testify; (3) the organization (if any) that they will represent; (4) the amount of time requested; and (5) which of the issues they want to address. Oral presentations will generally be restricted to 30 minutes. Detailed or lengthy material should be summarized orally and presented in full in written submissions. Requests for longer times for oral presentations will be condsidered only on the basis of a detailed summary of the material to be presented. The Agency will notify participants in advance if their allocated time is less than that requested.

An opportunity will be provided each day of the hearings for persons who have not submitted a notice as specified above to make brief oral statements. A register will be provided at the beginning of each hearing for this purpose. A minimum period will be set aside for such statements in the agenda for each hearing, and the presiding officer may allocate additional time, as necessary. The maximum time allowed for such statements will depend on the number of registrants and the availability of time, but will generally be limited to periods of no more than 5 to 10 minutes each. In order to assist the management of the hearings, persons wishing to make such statements are encouraged to register promptly at the beginning of the hearing.

Attendance at the hearings will be open to all members of the public, and seating will be made available on a first-come first-served basis.

*4. Testimony and Written Submission*

a. The oral proceedings will be recorded verbatim and a transcript made availabe promply for inspection and copying, as specified below under the heading "The Public Hearing Record." It will help the panel if speakers supply copies of their oral testimony before they give it. However, this in not required.

b. Fourteen copies of any written statements and documents on which speakers intend to base their oral statements must be submitted to the Director (see "Addresses" above) no later than 14 days before the beginning of the hearing in which they will testify. We would appreciate if speakers would also provide eight additional copies for the use of the panel.

c. Questions may be directed to speakers by the hearing panel, by other speakers, and by other members of the public. Speakers may respond or not, as

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# FEDERAL RADIATION COUNCIL

## RADIATION PROTECTION GUIDANCE FOR FEDERAL AGENCIES

### Memorandum for the President

Pursuant to Executive Order 10831 and Public Law 86-373, the Federal Radiation Council has made a study of the hazards and use of radiation. We herewith transmit our first report to you concerning our findings and our recommendations for the guidance of Federal agencies in the conduct of their radiation protection activities.

It is the statutory responsibility of the Council to "* * * advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States * * *"

Fundamentally, setting basic radiation protection standards involves passing judgment on the extent of the possible health hazard society is willing to accept in order to realize the known benefits of radiation. It involves inevitably a balancing between total health protection, which might require foregoing any activities increasing exposure to radiation, and the vigorous promotion of the use of radiation and atomic energy in order to achieve optimum benefits.

The Federal Radiation Council has reviewed available knowledge on radiation effects and consulted with scientists within and outside the Government. Each member has also examined the guidance recommended in this memorandum in light of his statutory responsibilities. Although the guidance does not cover all phases of radiation protection, such as internal emitters, we find that the guidance which we recommend that you provide for the use of Federal agencies gives appropriate consideration to the requirements of health protection and the beneficial uses of radiation and atomic energy. Our further findings and recommendations follow.

*Discussion.* The fundamental problem in establishing radiation protection guides is to allow as much of the beneficial uses of ionizing radiation as possible while assuring that man is not exposed to undue hazard. To get a true insight into the scope of the problem and the impact of the decisions involved, a review of the benefits and the hazards is necessary.

It is important in considering both the benefits and hazards of radiation to appreciate that man has existed throughout his history in a bath of natural radiation. This background radiation, which varies over the earth, provides a partial basis for understanding the effects of radiation on man and serves as an indicator of the ranges of radiation exposures within which the human population has developed and increased.

*The benefits of ionizing radiation.* Radiation properly controlled is a boon to mankind. It has been of inestimable value in the diagnosis and treatment of diseases. It can provide sources of energy greater than any the world has yet had available. In industry, it is used as a tool to measure thickness, quantity or quality, to discover hidden flaws, to trace liquid flow, and for other purposes. So many research uses for ionizing radiation have been found that scientists in many diverse fields now rank radiation with the microscope in value as a working tool.

*The hazards of ionizing radiation.* Ionizing radiation involves health hazards just as do many other useful tools. Scientific findings concerning the biological effects of radiation of most immediate interest to the establishment of radiation protection standards are the following:

1. Acute doses of radiation may produce immediate or delayed effects, or both.

2. As acute whole body doses increase above approximately 25 rems (units of radiation dose), immediately observable effects increase in severity with dose, beginning from barely detectable changes, to biological signs clearly indicating damage, to death at levels of a few hundred rems.

3. Delayed effects produced either by acute irradiation or by chronic irradiation are similar in kind, but the ability of the body to repair radiation damage is usually more effective in the case of chronic than acute irradiation.

4. The delayed effects from radiation are in general indistinguishable from familiar pathological conditions usually present in the population.

5. Delayed effects include genetic effects (effects transmitted to succeeding generations), increased incidence of tumors, lifespan shortening, and growth and development changes.

6. The child, the infant, and the unborn infant appear to be more sensitive to radiation than the adult.

7. The various organs of the body differ in their sensitivity to radiation.

8. Although ionizing radiation can induce genetic and somatic effects (effects on the individual during his lifetime other than genetic effects), the evidence at the present time is insufficient to justify precise conclusions on the nature of the dose-effect relationship at low doses and dose rates. Moreover, the evidence is insufficient to prove either the hypothesis of a "damage threshold" (a point below which no damage occurs) or the hypothesis of "no threshold" in man at low doses.

9. If one assumes a direct linear relation between biological effect and the amount of dose, it then becomes possible to relate very low dose to an assumed biological effect even though it is not detectable. It is generally agreed that the effect that may actually occur will not exceed the amount predicted by this assumption.

*Basic biological assumptions.* There are insufficient data to provide a firm basis for evaluating radiation effects for all types and levels of irradiation. There is particular uncertainty with respect to the biological effects at very low doses and low-dose rates. It is not prudent therefore to assume that there is a level of radiation exposure below which there is absolute certainty that no effect may occur. This consideration, in addition to the adoption of the conservative hypothesis of a linear relation between biological effect and the amount of dose, determines our basic approach to the formulation of radiation protection guides.

The lack of adequate scientific information makes it urgent that additional research be undertaken and new data developed to provide a firmer basis for evaluating biological risk. Appropriate member agencies of the Federal Radiation Council are sponsoring and encouraging research in these areas.

*Recommendations.* In view of the findings summarized above the following recommendations are made:

It is recommended that:

1. There should not be any man-made radiation exposure without the expectation of benefit resulting from such exposure. Activities resulting in man-made radiation exposure should be authorized for useful applications provided in recommendations set forth herein are followed.

It is recommended that:

2. The term "Radiation Protection Guide" be adopted for Federal use. This term is defined as the radiation dose which should not be exceeded without careful consideration of the reasons for doing so; every effort should be made to encourage the maintenance of radiation doses as far below this guide as practicable.

It is recommended that:

3. The following Radiation Protection Guides be adopted for normal peacetime operations:

| Type of exposure | Condition | Dose (rem) |
|---|---|---|
| Radiation worker: | | |
| (a) Whole body, head and trunk, active blood forming organs, gonads, or lens of eye. | Accumulated dose | 5 times the number of years beyond age 18. |
| | 13 weeks | 3. |
| (b) Skin of whole body and thyroid | Year | 30. |
| | 13 weeks | 10. |
| (c) Hands and forearms, feet and ankles | Year | 75. |
| | 13 weeks | 25. |
| (d) Bone | Body burden | 0.1 microgram of radium-226 or its biological equivalent. |
| (e) Other organs | Year | 15. |
| | 13 weeks | 5. |
| Population: | | |
| (a) Individual | Year | 0.5 (whole body). |
| (b) Average | 30 year | 5 (gonads). |

The following points are made in relation to the Radiation Protection Guides herein provided:

(1) For the individual in the population, the basic Guide for annual whole body dose is 0.5 rem. This Guide ap-

plies when the individual whole body doses are known. As an operational technique, where the individual whole body doses are not known, a suitable sample of the exposed population should be developed whose protection guide for annual whole body dose will be 0.17 rem per capita per year. It is emphasized that this is an operational technique which should be modified to meet special situations.

(2) Considerations of population genetics impose a per capita dose limitation for the gonads of 5 rems in 30 years. The operational mechanism described above for the annual individual whole body dose of 0.5 rem is likely in the immediate future to assure that the gonadal exposure Guide (5 rem in 30 years) is not exceeded.

(3) These Guides do not differ substantially from certain other recommendations such as those made by the National Committee on Radiation Protection and Measurements, the National Academy of Sciences, and the International Commission on Radiological Protection.

(4) The term "maximum permissible dose" is used by the National Committee on Radiation Protection (NCRP) and the International Commission on Radiological Protection (ICRP). However, this term is often misunderstood. The words "maximum" and "permissible" both have unfortunate connotations not intended by either the NCRP or the ICRP.

(5) There can be no single permissible or acceptable level of exposure without regard to the reason for permitting the exposure. It should be general practice to reduce exposure to radiation, and positive effort should be carried out to fulfill the sense of these recommendations. It is basic that exposure to radiation should result from a real determination of its necessity.

(6) There can be different Radiation Protection Guides with different numerical values, depending upon the circumstances. The Guides herein recommended are appropriate for normal peacetime operations.

(7) These Guides are not intended to apply to radiation exposure resulting from natural background or the purposeful exposure of patients by practitioners of the healing arts.

(8) It is recognized that our present scientific knowledge does not provide a firm foundation within a factor of two or three for selection of any particular numerical value in preference to another value. It should be recognized that the Radiation Protection Guides recommended in this paper are well below the level where biological damage has been observed in humans.

It is recommended that:

4. Current protection guides used by the agencies be continued on an interim basis for organ doses to the population.

Recommendations are not made concerning the Radiation Protection Guides for individual organ doses to the population, other than the gonads. Unfortunately, the complexities of establishing guides applicable to radiation exposure of all body organs preclude the Council from making recommendations concerning them at this time. However, current protection guides used by the agencies appear appropriate on an interim basis.

It is recommended that:

5. The term "Radioactivity Concentration Guide" be adopted for Federal use. This term is defined as the concentration of radioactivity in the environment which is determined to result in whole body or organ doses equal to the Radiation Protection Guide.

Within this definition, Radioactivity Concentration Guides can be determined after the Radiation Protection Guides are decided upon. Any given Radioactivity Concentration Guide is applicable only for the circumstances under which the use of its corresponding Radiation Protection Guide is appropriate.

It is recommended that:

6. The Federal agencies, as an interim measure, use radioactivity concentration guides which are consistent with the recommended Radiation Protection Guides. Where no Radiation Protection Guides are provided, Federal agencies continue present practices.

No specific numerical recommendations for Radioactivity Concentration Guides are provided at this time. However, concentration guides now used by the agencies appear appropriate on an interim basis. Where appropriate radioactivity concentration guides are not available, and where Radiation Protection Guides for specific organs are provided herein, the latter Guides can be used by the Federal agencies as a starting point for the derivation of radioactivity concentration guides applicable to their particular problems. The Federal Radiation Council has also initiated action directed towards the development of additional Guides for radiation protection.

It is recommended that:

7. The Federal agencies apply these Radiation Protection Guides with judgment and discretion, to assure that reasonable probability is achieved in the attainment of the desired goal of protecting man from the undesirable effects of radiation. The Guides may be exceeded only after the Federal agency having jurisdiction over the matter has carefully considered the reason for doing so in light of the recommendations in this paper.

The Radiation Protection Guides provide a general framework for the radiation protection requirements. It is expected that each Federal agency, by virtue of its immediate knowledge of its operating problems, will use these Guides as a basis upon which to develop detailed standards tailored to meet its particular requirements. The Council will follow the activities of the Federal agencies in this area and will promote the necessary coordination to achieve an effective Federal program.

If the foregoing recommendations are approved by you for the guidance of Federal agencies in the conduct of their radiation protection activities, it is further recommended that this memorandum be published in the FEDERAL REGISTER.

ARTHUR S. FLEMMING,
*Chairman,*
*Federal Radiation Council.*

The recommendations numbered "1" through "7" contained in the above memorandum are approved for the guidance of Federal agencies, and the memorandum shall be published in the FEDERAL REGISTER.

DWIGHT D. EISENHOWER

MAY 13, 1960.

[F.R. Doc. 60-4539; Filed, May 17, 1960; 8:51 a.m.]

25 FR 4402 Vol. 25

[Reprinted from the Federal Register of September 26, 1961, as corrected]

# FEDERAL RADIATION COUNCIL

## RADIATION PROTECTION GUIDANCE FOR FEDERAL AGENCIES

### Memorandum for the President

SEPTEMBER 13, 1961.

Pursuant to Executive Order 10831 and Public Law 86-373, the Federal Radiation Council herewith transmits its second report to you concerning findings and recommendations for guidance for Federal agencies in the conduct of their radiation protection activities.

*Background.* On May 13, 1960, the first recommendations of the Council were approved by the President and the memorandum containing these recommendations was published in the FEDERAL REGISTER on May 18, 1960. There was also released at the same time, Staff Report No. 1 of the Federal Radiation Council, entitled, "Background Material for the Development of Radiation Protection Standards," dated May 13, 1960.

The first report of the Council provided a general philosophy of radiation protection to be used by Federal agencies in the conduct of their specific programs and responsibilities. It introduced and defined the term "Radiation Protection Guide" (RPG). It provided numerical values for Radiation Protection Guides for the whole body and certain organs of radiation workers and for the whole body of individuals in the general population, as well as an average population gonadal dose. It introduced as an operational technique, where individual whole body doses are not known, the use of a "suitable sample" of the exposed population in which the guide for the average exposure of the sample should be one-third the RPG for the individual members of the group. It emphasized that this operational technique should be modified to meet special situations. In selecting a suitable sample particular care should be taken to assure that a disproportionate fraction of the average dose is not received by the most sensitive population elements. The observations, assumptions, and comments set out in the memorandum published in the FEDERAL REGISTER, May 18, 1960, are equally applicable to this memorandum.

This memorandum contains recommendations for the guidance of Federal agencies in activities designed to limit exposure of members of population groups to radiation from radioactive materials deposited in the body as a result of their occurrence in the environment. These recommendations include: (1) Radiation Protection Guides for certain organs of individuals in the general population, as well as averages over suitable samples of exposed groups; (2) guidance on general principles of control applicable to all radionuclides occurring in the environment; and (3) specific guidance in connection with exposure of population groups to radium-226, iodine-131, strontium-90, and strontium-89. It is the intention of the Council to release the background material leading to these recommendations as Staff Report No. 2 when the recommendations contained herein are approved.

Specific attention was directed to problems associated with radium-226, iodine-131, strontium-90, and strontium-89. Radium-226 is an important naturally occurring radioactive material. The other three were present in fallout from nuclear weapons testing. They could, under certain circumstances, also be major constituents of radioactive materials released to the environment from large scale atomic energy installations used for peaceful purposes. Available data suggest that effective control of these nuclides, in cases of mixed fission product contamination of the environment, would provide reasonable assurance of at least comparable limitation of hazard from other fission products in the body.

Establishment of the Federal Radiation Council followed a period of public concern incident to discussions of fallout. While strontium-90 received the greatest popular attention, exposures to cesium-137, iodine-131, strontium-89 and, in still lesser degrees to other radionuclides, are involved in the evaluation of over-all effects. The characteristics of cesium-137 lead to direct comparison with whole body exposures for which recommendations by the Council have already been made.

Studies by the staff of the Council indicate that observed concentrations of radioactive strontium in food and water do not result in concentrations in the skeleton (and consequently in radiation doses) as large as have been assumed in the past. However, concentrations of iodine-131 in the diets of small children, particularly in milk, equal to those permitted under current standards would lead to radiation doses to the child's thyroid which, in comparison with the general structure of current radiation protection standards, would be too high. This is because current concentration guides for exposure of population groups to radioactive materials in air, food, and water have been derived by application of a single fraction to corresponding occupational guides. In the case of iodine-131 in milk, consumption of milk and retention of iodine by the child may be at least as great as by the adult, while the relatively small size of the thyroid makes the radiation dose to the thyroid much larger than in the case of the adult. In addition, there is evidence that irradiation of the thyroid involves greater risk to children than to adults.

*Recommendations as to Radiation Protection Guides.* The Federal Radiation Council has previously emphasized that establishment of radiation protection standards involves a balancing of the benefits to be derived from the controlled use of radiation and atomic energy against the risk of radiation exposure. In the development of the Radiation Protection Guides contained herein, the Council has considered both sides of this balance. The Council has reviewed available knowledge, consulted with scientists within and outside the Government, and solicited views of interested individuals and groups from the general public. In particular, the Council has not only drawn heavily upon reports published by the International Commission on Radiological Protection (ICRP), the National Committee on Radiation Protection and Measurements (NCRP), and the National Academy of Sciences (NAS), but has had during the development of the report the benefit of consultation with, and comments and suggestions by, individuals from NCRP and NAS and of their subcommittees. The Radiation Protection Guides recommended below are considered by the Council to represent an appropriate balance between the requirements of health protection and of the beneficial uses of radiation and atomic energy.

It is recommended that:

1. The following Radiation Protection Guides be adopted for normal peacetime operations.

TABLE I—RADIATION PROTECTION GUIDES FOR CERTAIN BODY ORGANS IN RELATION TO EXPOSURE OF POPULATION GROUPS

| Organ | RPG for individuals | RPG for average of suitable sample of exposed population group |
|---|---|---|
| Thyroid | 1.5 rem per year | 0.5 rem per year. |
| Bone marrow | 0.5 rem per year | 0.17 rem per year. |
| Bone | 1.5 rem per year | 0.5 rem per year. |
| Bone (alternate guide). | 0.003 micrograms of Ra-226 in the adult skeleton or the biological equivalent of this amount of Ra-226. | 0.001 micrograms of Ra-226 in the adult skeleton or the biological equivalent of this amount of Ra-226. |

It will be noted that the preceding table provides Radiation Protection Guides to be applied to the average of a suitable sample of an exposed population group which are one-third of those applying to individuals. This is in accordance with the recommendations in the first report of the Council concerning operational techniques for controlling population exposure. Since in the case of exposure of a population group to radionuclides the radiation doses to individuals are not usually known, the organ dose to be used as a guide for the average of suitable samples of an exposed population group is also given as an RPG.

*Recommendations as to general principles.* Control of population exposure from radionuclides occurring in the environment is accomplished in general either by restriction on the entry of such materials into the environment or through measures designed to limit the intake by members of the population of radionuclides already in the environment. Both approaches involve the consideration of actual or potential concentrations of radioactive material in air, water, or food. Controls should be based upon an evaluation of population

exposure with respect to the RPG. For this purpose, the total daily intake of such materials, averaged over periods of the order of a year, constitutes an appropriate criterion.

The control of the intake by members of the general population of radioactive materials from the environment can appropriately involve many different kinds of actions. The character and import of these actions may vary widely, from those which entail little interference with usual activities, such as monitoring and surveillance, to those which involve a major disruption, such as condemnation of food supplies. Some control actions may require prolonged lead times before becoming effective, e.g., major changes in processing facilities or water supplies. The magnitude of control measures should be related to the degree of likelihood that the RPG may be exceeded. The use of a single numerical intake value, which in part has been the practice until now, does not in many instances provide adequate guidance for taking actions appropriate to the risk involved. For planning purposes, it is desirable that insofar as possible control actions to meet contingencies be known in advance.

It is recommended that:

2. The radiological health activities of Federal agencies in connection with environmental contamination with radioactive materials be based, within the limits of the agency's statutory responsibilities, on a graded series of appropriate actions related to ranges of intake of radioactive materials by exposed population groups.

In order to provide guidance to the agencies in adapting the graded approach to their own programs, the recommendations pertaining to the specific radionuclides in this memorandum consider three transient daily rates of intake by suitable samples of exposed population groups. For the other radionuclides, the agencies can use the same general approach, the details of which are considered in Staff Report No. 2. The general types of action appropriate when these transient rates of intake fall into the different ranges are also discussed in Staff Report No. 2. The purpose of these actions is to provide reasonable assurance that average rates of intake by a suitable sample of an exposed population group, averaged over the sample and averaged over periods of time of the order of one year, do not exceed the upper value of Range II. The general character of these actions is suggested in the following table.

TABLE II—GRADED SCALES OF ACTION

| Ranges of transient rates of daily intake | Graded scale of action |
|---|---|
| Range I | Periodic confirmatory surveillance as necessary. |
| Range II | Quantitative surveillance and routine control. |
| Range III | Evaluation and application of additional control measures as necessary. |

*Recommendations on Ra-226, I-131, Sr-90, and Sr-89.* The Council has given specific consideration to the effects on man of rates of intake of radium-226, iodine-131, strontium-90 and strontium-89 resulting in radiation doses equal to those specified in the appropriate RPG's. The Council has also reviewed past and current activities resulting in the release of these radionuclides to the environment and has given consideration to future developments. For each of the nuclides three ranges of transient daily intake are given which correspond to the guidance contained in Recommendation 2, above. Routine control of useful applications of radiation and atomic energy should be such that expected average exposures of suitable samples of an exposed population group will not exceed the upper value of Range II. For iodine-131 and radium-226, this value corresponds to the RPG for the average of a suitable sample of an exposed population group. In the cases of strontium-90 and strontium-89, the Council's study indicated that there is currently no known operational requirement for an intake value as high as the one corresponding the RPG. Hence, a value estimated to correspond to doses to the critical organ not greater than one-third of the RPG has been used.

The guidance recommended below is given in terms of transient rates of (radioactivity) intake in micromicrocuries per day. The upper limit of Range II is based on an annual RPG (or lower, in case of radioactive strontium) considered as an acceptable risk for a lifetime. However, it is necessary to use averages over periods much shorter than a lifetime for both radiation dose rates and rates of intake for administrative and regulatory purposes. It is recommended that such periods should be of the order of one year. It is to be noted that values listed in the tables are much smaller than any single intake from which an individual might be expected to sustain injury.

It is recommended that:

3. (a) The following guidance on daily intake be adopted for normal peacetime operations to be applied to the average of suitable samples of an exposed population group:

TABLE III—RANGES OF TRANSIENT RATES OF INTAKE (MICROMICROCURIES PER DAY) FOR USE IN GRADED SCALE OF ACTIONS SUMMARIZED IN TABLE II.

| Radionuclides | Range I | Range II | Range III |
|---|---|---|---|
| Radium-226 | 0-2 | 2-20 | 20-200 |
| Iodine-131 [1] | 0-10 | 10-100 | 100-1,000 |
| Strontium-90 | 0-20 | 20-200 | 200-2,000 |
| Strontium-89 | 0-200 | 200-2,000 | 2,000-20,000 |

[1] In the case of iodine-131, the suitable sample would include only small children. For adults, the RPG for the thyroid would not be exceeded by rates of intake higher by a factor of 10 than those applicable to small children.

(b) Federal agencies determine concentrations of these radionuclides in air, water, or items of food applicable to their particular programs which are consistent with the guidance contained herein on average daily intake for the radionuclides radium-226, iodine-131, strontium-90, and strontium-89. Some of the general considerations involved in the derivation of concentration values from intake values are given in Staff Report No. 2.

It is recommended that:

4. For radionuclides not considered in this report, agencies use concentration values in air, water, or items of food which are consistent with recommended Radiation Protection Guides and the general guidance on intake.

In the future, the Council will direct attention to the development of appropriate radiation protection guidance for those radionuclides for which such consideration appears appropriate or necessary. In particular, the Council will study any radionuclides for which useful applications of radiation or atomic energy require release to the environment of significant amounts of these nuclides. Federal agencies are urged to inform the Council of such situations.

ABRAHAM RIBICOFF,
*Chairman,*
*Federal Radiation Council.*

The recommendations numbered "1" through "4" contained in the above memorandum are approved for the guidance of Federal agencies, and the memorandum shall be published in the FEDERAL REGISTER.

JOHN F. KENNEDY.

SEPTEMBER 20, 1961.

## SUMMARY OF PROPOSED CHANGES

## IN OCCUPATIONAL RADIATION PROTECTON GUIDANCE

| | Requirement | 1960 Guides | Proposed New Guides |
|---|---|---|---|
| 1. | Justification of exposure | required | required (also consider alternatives to exposure) |
| 2. | Optimization of exposure | required | required (include collective dose) |
| 3. | Limitation of exposure | | |
| | a) Whole body | 3 rems/quarter; 5(N-18) cumulative rems, (N = age) | 5 rems/year |
| | b) Partial body | individual critical organ limits* | limit on sum of organ risks* |
| | c) Combined internal and external exposure | independent limits | combined limit |
| 4. | Radiation Protection Requirements | not specified | in three ranges for instruction, supervision, monitoring, and recordkeeping (including lifetime dose) |
| 5. | Regulatory limits lower than the RPGs for specific job categories | not addressed | recommended |
| 6. | Intake guides | Radioactivity Concentration Guides (RCGs) | Radioactivity Intake Factors (RIFs) |
| 7. | Exposure of minors | 1/10 RPGs | 1/10 RPGs |
| 8. | Exposure of the unborn | not addressed | four alternative recommendations |
| 9. | Exceeding the RPGs | permitted | permitted (disclosure now required) |

*Some limits are raised and some lowered; some organs are deleted and some added. See the specific guides for numerical values.

# IMPACT OF DRAFT 10 CFR PART 20 ON THE SAVANNAH RIVER PLANT

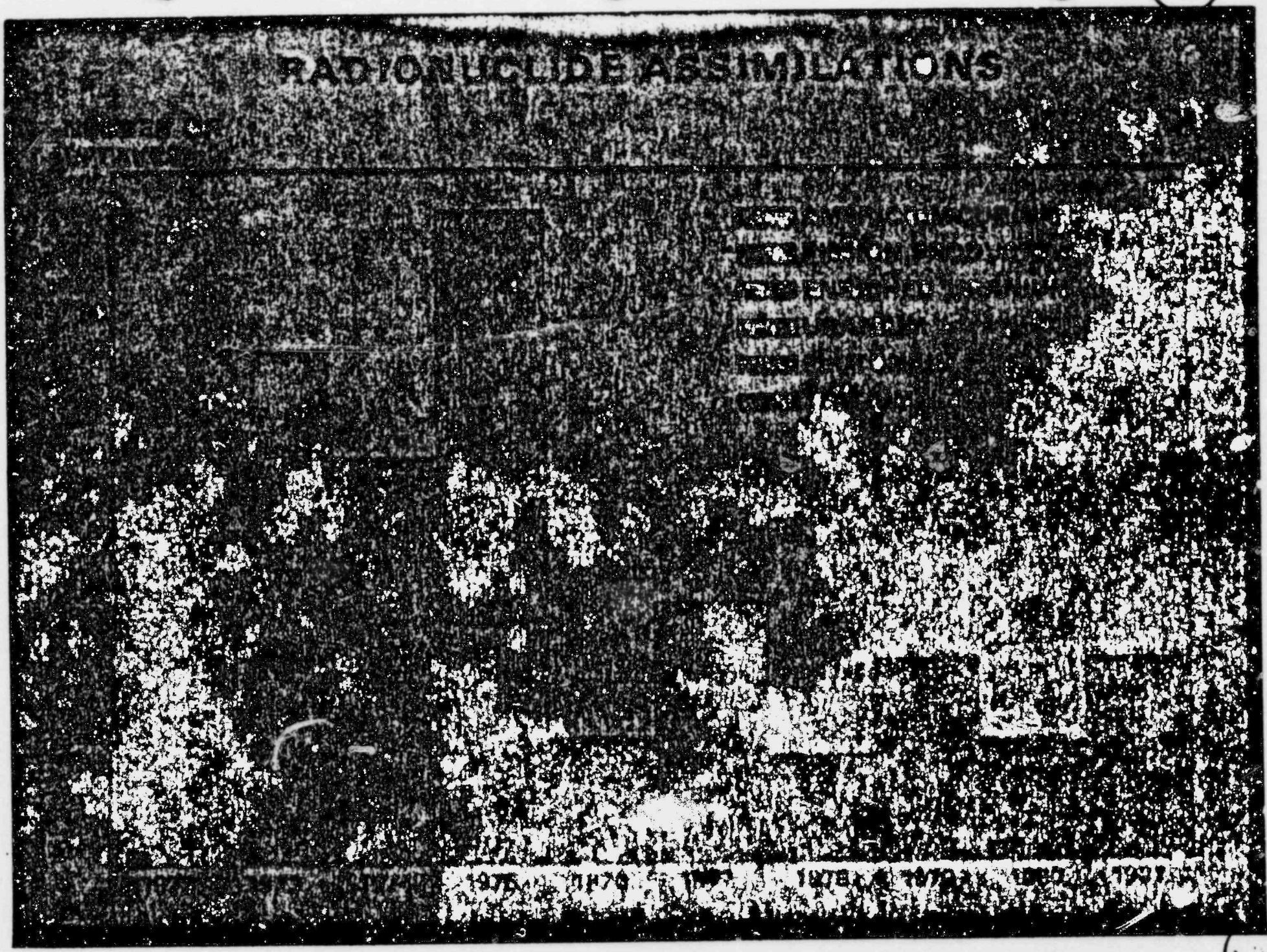
# OPERATIONAL PROBLEMS

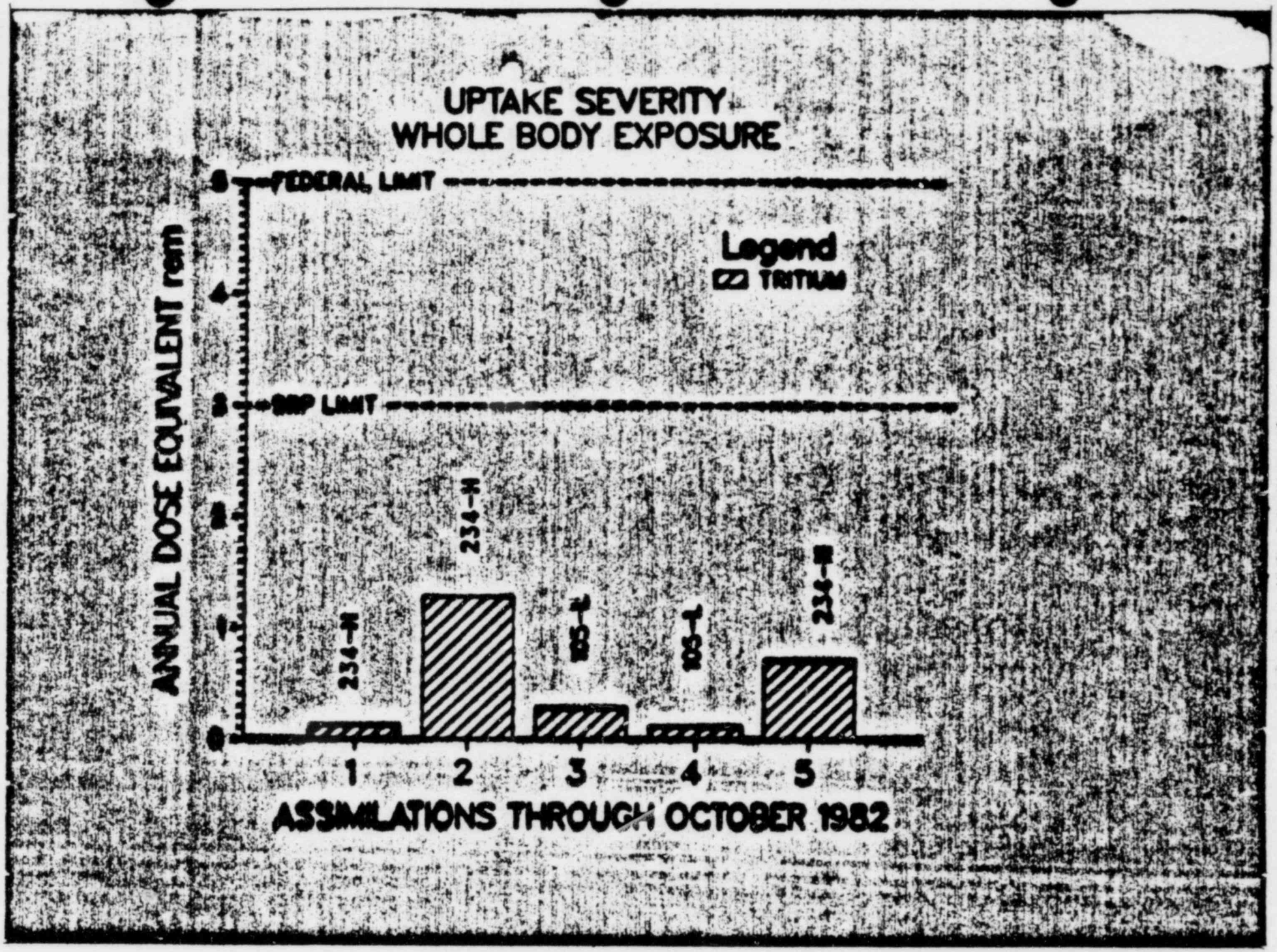
## ASSIMILATION OF RADIONUCLIDES IN BODY

- PLUTONIUM - ISOTOPIC ABUNDANCE
- AIR SAMPLING
- BIOASSAY - IN VIVO LUNG COUNT
- 50-YEAR DOSE COMMITMENT

## INHALATION OF AIRBORNE CONTAMINATION

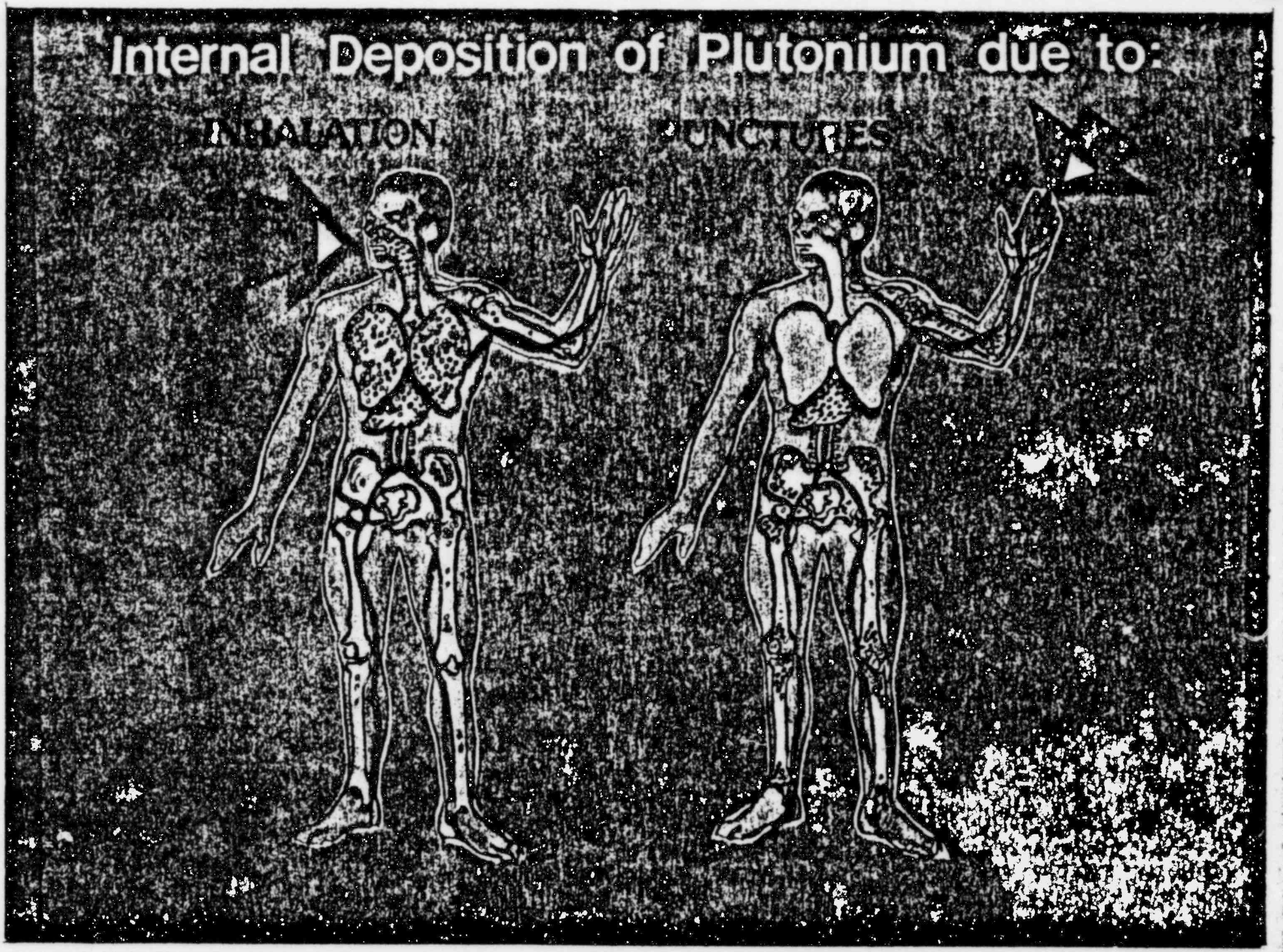
- PROTECTIVE EQUIPMENT FAILURE
- LOSS OF CONTAINMENT
- PROCEDURE VIOLATION
- FACILITY EVACUATION


RADIONUCLIDE ASSIMILATIONS


UPTAKE SEVERITY
WHOLE BODY EXPOSURE
FEDERAL LIMIT
DOE LIMIT
Legend
TRITIUM
ANNUAL DOSE EQUIVALENT rem
234-M
234-M
234-M
234-M
1
2
3
4
5
ASSIMILATIONS THROUGH OCTOBER 1982

Plutonium Intake Inhalation

(5)



## OPERATIONAL PROBLEMS

ASSIMILATION OF RADIONUCLIDES IN BODY

- PLUTONIUM - ISOTOPIC ABUNDANCE
- AIR SAMPLING
- BIOASSAY - IN VIVO LUNG COUNT
- 50-YEAR DOSE COMMITMENT

INHALATION OF AIRBORNE CONTAMINATION

- PROTECTIVE EQUIPMENT FAILURE
- LOSS OF CONTAINMENT
- PROCEDURE VIOLATION
- FACILITY EVACUATION

## ASSIMILATION INVESTIGATION TECHNIQUES

- DETERMINE MODE OF ASSIMILATION, INHALATION
- PROBABLE RADIONUCLIDES
- AIRBORNE CONTAMINATION CONCENTRATION
- DURATION OF EXPOSURE
- CLOTHING, SKIN, OR NASAL CONTAMINATION
- WHOLE BODY COUNT
- URINALYSIS - FECAL ANALYSIS
- METABOLIC MODELS - DOSE ASSESSMENT

(8)

## AIR SAMPLING

### PERSONNEL AIR SAMPLERS

- 2 LITERS/MINUTE FOR 8 HOURS
- MINIMUM DETECTABLE - $1 \times 10^{-11}$ μCi | $^{238}Pu$/cc
- ANNUAL MDA - 25 nCi

### ROOM AIR SAMPLERS

- 150 LITERS/MINUTE FOR 8 HOURS
- MINIMUM DETECTABLE - $2 \times 10^{-13}$ μCi | $^{238}Pu$/cc
- ANNUAL MDA - 0.5 nCi

### 10 CFR PART 20 APPENDIX B

| RADIONUCLIDE | DAC | ALI |
|---|---|---|
| $^{239}Pu$ | $2 \times 10^{-12}$ μCi/cc | 5 nCi |
| $^{241}Pu$ | $1 \times 10^{-10}$ μCi/cc | 300 nCi |
| PLUTONIUM (MIXTURE) | $3 \times 10^{-13}$ μCi/cc | 0.7 nCi |

# PLUTONIUM

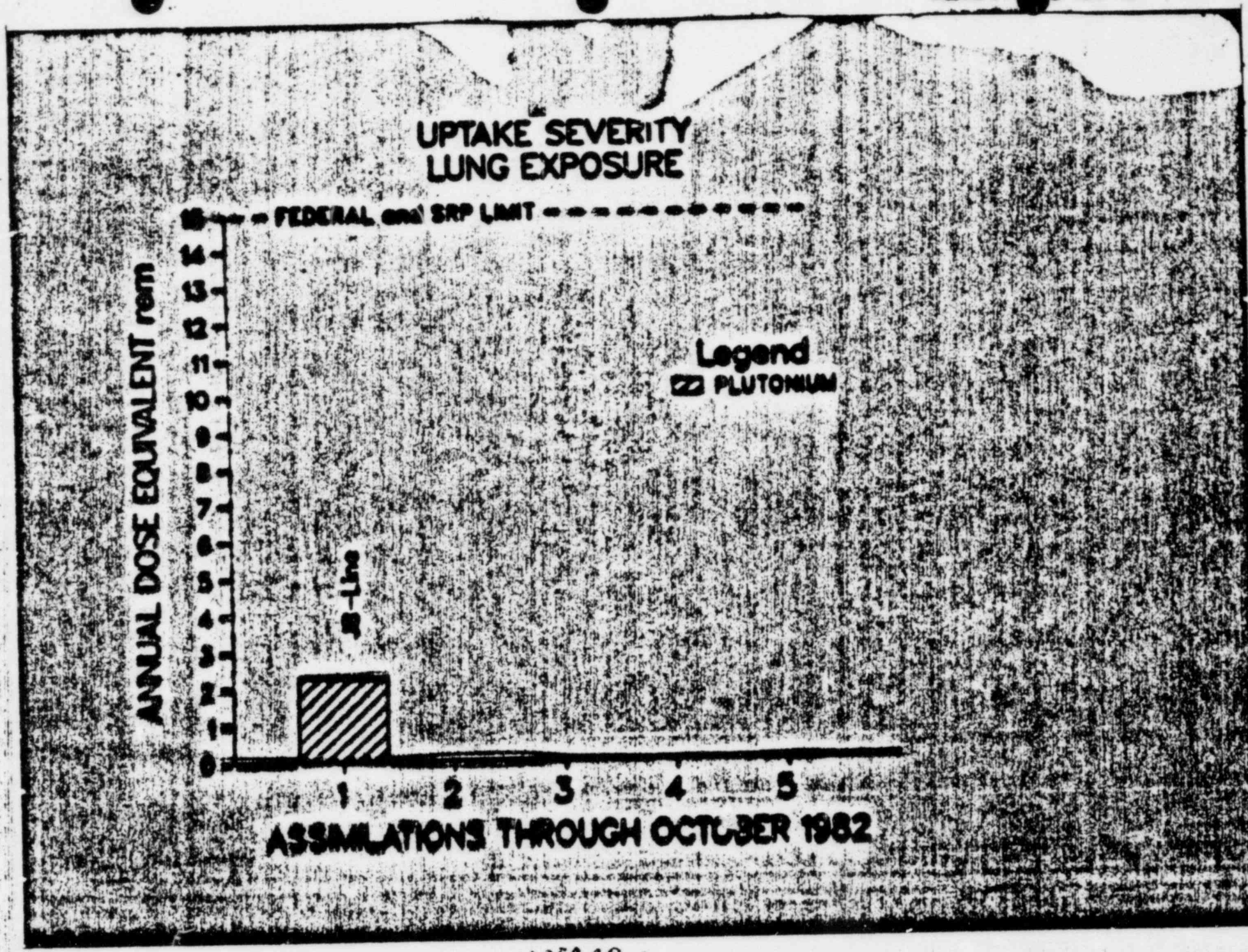
## TYPICAL ISOTOPIC ABUNDANCE

| ISOTOPE | ABUNDANCE BY WEIGHT | SPECIFIC ACTIVITY ALPHA | SPECIFIC ACTIVITY BETA |
|---|---|---|---|
| $^{238}Pu$ | .0001A | 0.0024 Ci/g | — |
| $^{239}Pu$ | .9358 | 0.0582 Ci/g | — |
| $^{240}Pu$ | .0575 | 0.0131 Ci/g | — |
| $^{241}Pu$ | .0062 | — | 0.6360 Ci/g |
| $^{242}Pu$ | .0004 | <0.0001 Ci/g | — |
| TOTAL | 1.000 | 0.0737 Ci/g | 0.6360 Ci/g |

3%
78%
19%

8/

∴ the identity of each radionuclide is known; ... 1 ... 0.1


UPTAKE SEVERITY
LUNG EXPOSURE
FEDERAL and SRP LIMIT
ANNUAL DOSE EQUIVALENT rem
Legend
PLUTONIUM
1
2
3
4
5
ASSIMILATIONS THROUGH OCTOBER 1982

# RECORDS

- CONTAIN ALL PARAMETERS USED TO CALCULATE DOSE EQUIVALENT

- DOE UPGRADE PROGRAM

# AREAS OF AGREEMENT

## OCCUPATIONAL EXPOSURE LIMITS

- 5 REM ANNUAL LIMIT SHOULD NOT BE LOWERED
- LIFETIME LIMITS NOT APPROPRIATE
- "TWO-TIER" LIMIT NOT APPROPRIATE

# ALARA - DOE

- ALARA PROGRAM
- EQUAL PRIORITY TO INDIVIDUAL AND COLLECTIVE DOE EQUIVALENT
- AUDIT PROGRAM

# ALARA

## PROPOSED 10 CFR 20 REVISION

- ALARA PROGRAM
- PRIORITY TO INDIVIDUAL RATHER THAN COLLECTIVE DOSE EQUIVALENT
- AUDIT PROGRAM

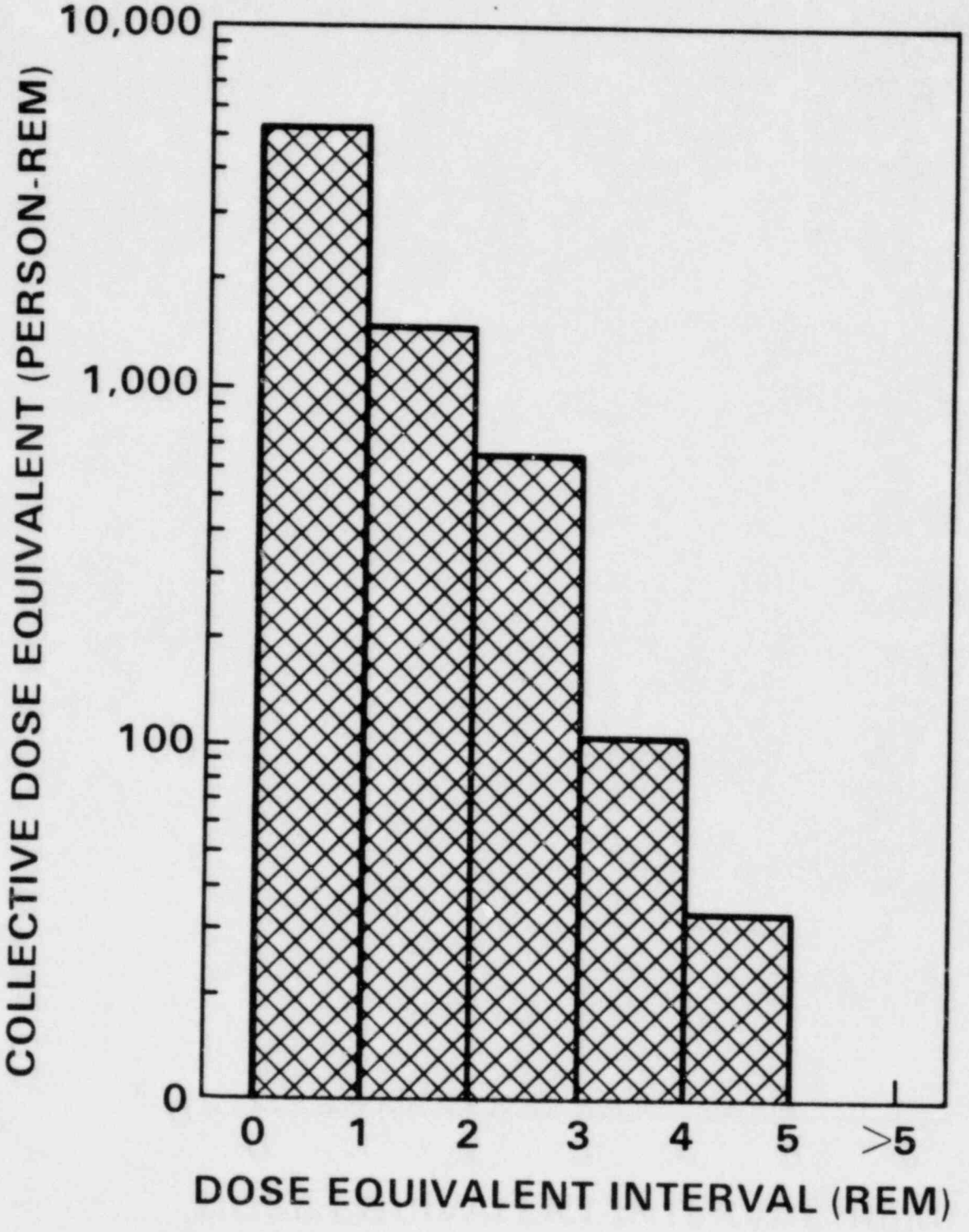
# TOTAL OCCUPATIONAL EXPOSURE (EXTERNAL + INTERNAL)

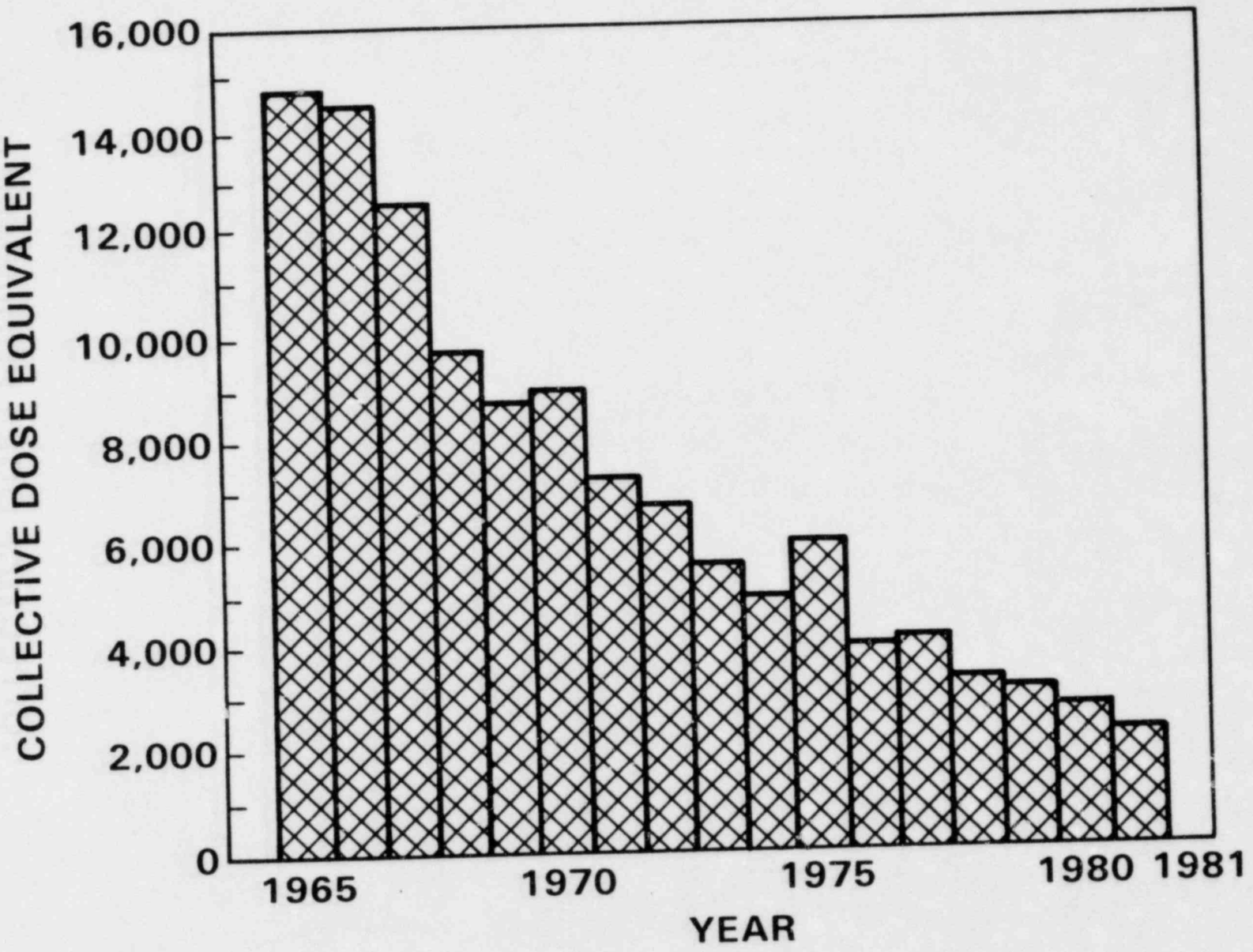
| WORKER | ACCUMULATED DOSE (REM) | INTERNAL DOSE COMMITMENT STOCHASTIC (REM) | TOTAL WHOLE BODY DOSE (REM) |
|---|---|---|---|
| A | 68.5 | 180 | 248.5 |
| B | 65.1 | 14 | 79.1 |
| C | 61.1 | 20 | 81.1 |
| C | 60.4 | 25 | 85.4 |

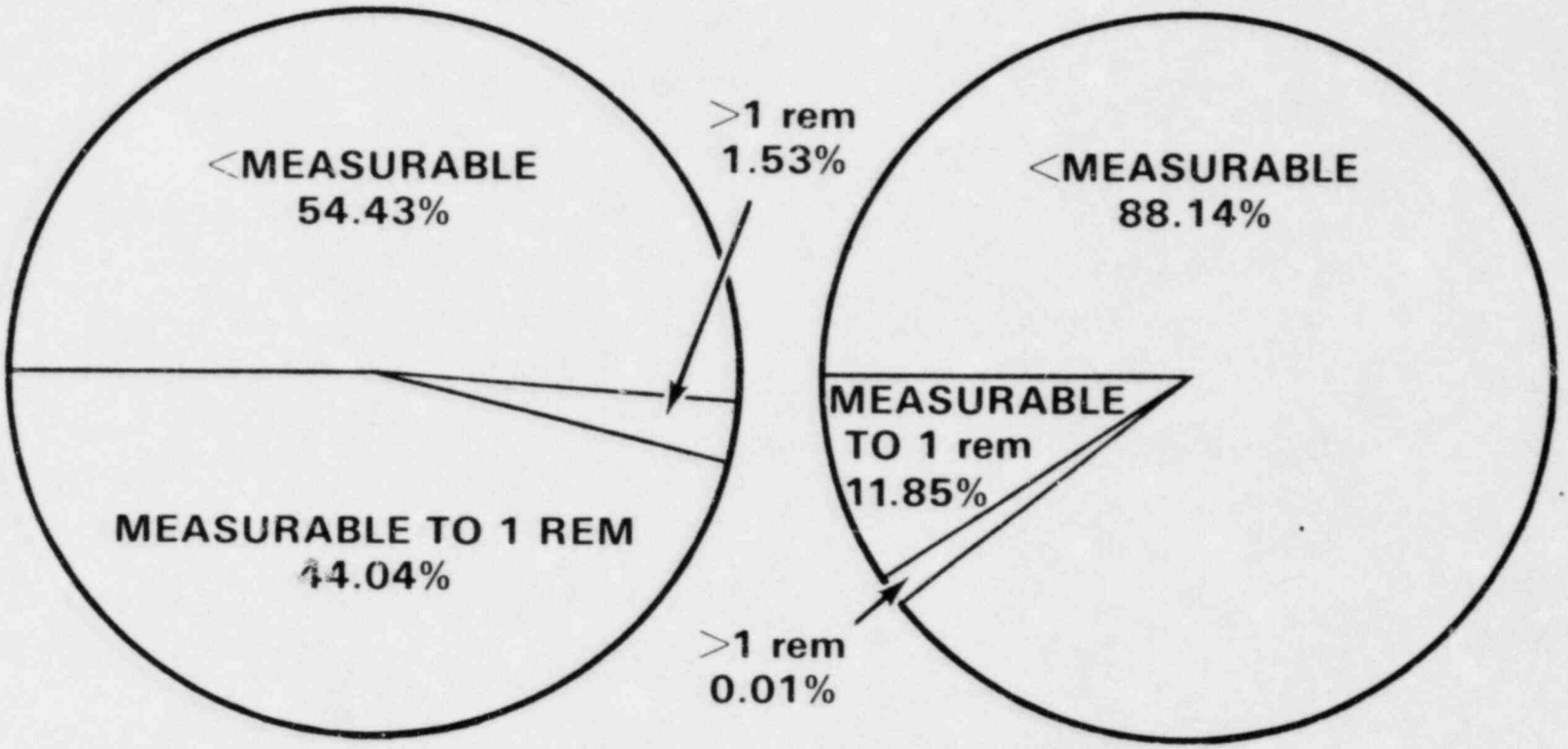
# UNITS AND DEFINITIONS

- CONSISTENT WITH ICRU AND ICRP

- CONVERSION FACTORS IN REGULATORY GUIDES


10,000
1,000
100
0
COLLECTIVE DOSE EQUIVALENT (PERSON-REM)
0
1
2
3
4
5
>5
DOSE EQUIVALENT INTERVAL (REM)


16,000
14,000
12,000
10,000
8,000
6,000
4,000
2,000
0
COLLECTIVE DOSE EQUIVALENT
1965
1970
1975
1980
1981
YEAR




DOE AND
DOE CONTRACTOR EMPLOYEES
(82,873 MONITORED)

VISITORS
(84,343 MONITORED)

| WORKER | CLASSIFICATION | ACCUMULATED DOSE (REM) | SERVICE | AVERAGE ANNUAL EXPOSURE |
|---|---|---|---|---|
| A | SEP. OPERATOR | 68.5 | 31 | 2.2 |
| B | SEP. OPERATOR | 65.1 | 30 | 2.2 |
| C | SEP. OPERATOR | 61.1 | 29 | 2.1 |
| D | REACTOR OPERATOR | 60.4 | 36 | 1.7 |

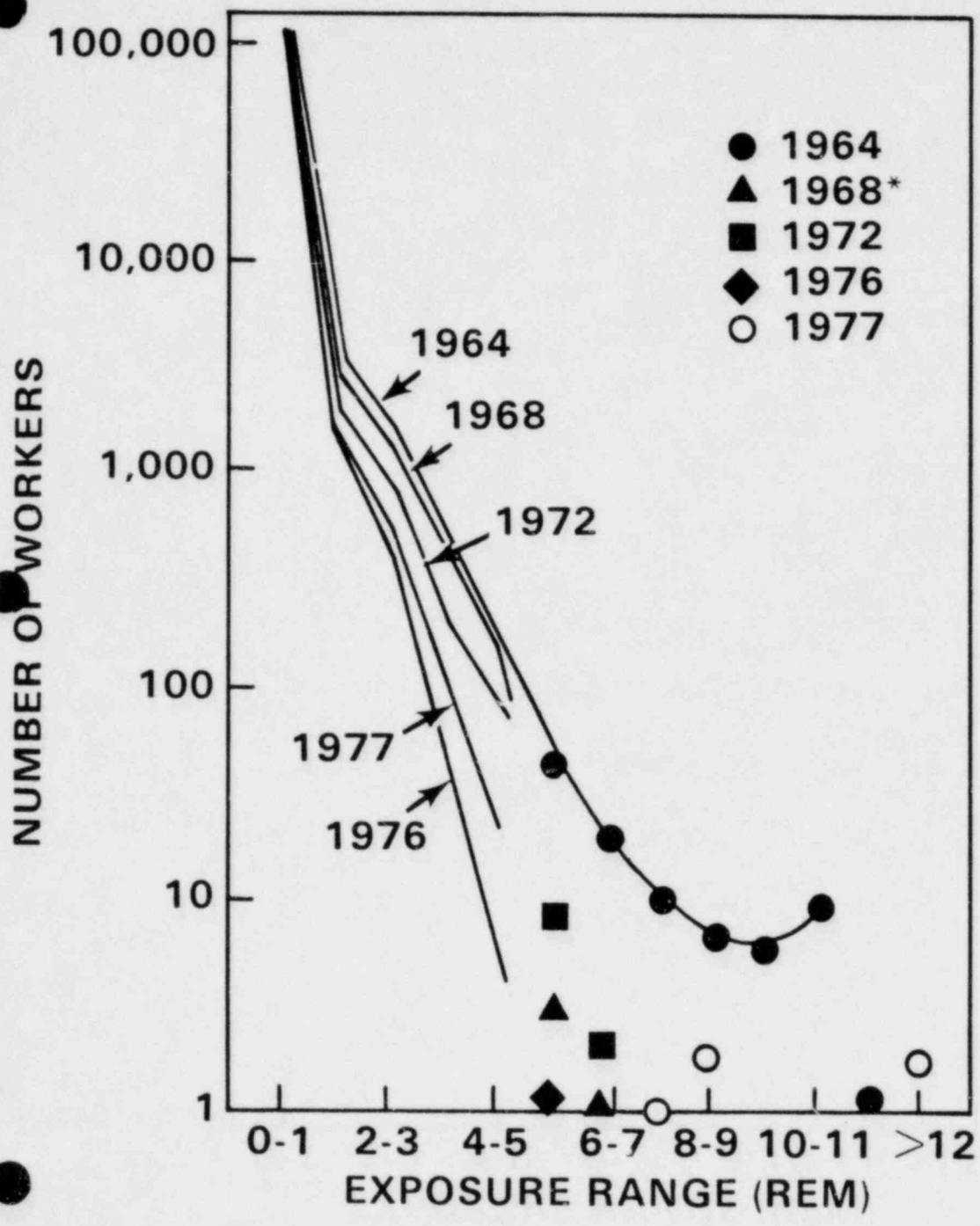
# WHOLE BODY EXPOSURE EXPERIENCE* WORKERS GREATER THAN 60 REM ALL TIME

| WORKER CLASSIFICATION | ACCUMULATED DOSE | SERVICE | AVERAGE ANNUAL EXPOSURE |
|---|---|---|---|
| SEP. OPERATOR | 144** | 25 | 5.8 |
| REACTOR INSTR. SP. | 76 | 29 | 2.6 |
| REACTOR MONITOR | 74 | 26 | 2.9 |
| SEP. OPERATOR | 68.5 | 31 | 2.2 |
| REACTOR MONITOR | 68.5 | 27 | 2.5 |
| REACTOR MONITOR | 67.4 | 30 | 2.2 |
| REACTOR MONITOR | 66.9 | 25 | 2.7 |
| REACTOR MONITOR | 65.8 | 26 | 2.5 |
| SEP. OPERATOR | 65.1 | 30 | 2.2 |
| REACTOR MONITOR | 63.9 | 35 | 1.8 |
| REACTOR OPERATOR | 61.6 | 29 | 2.1 |
| REACTOR OPERATOR | 61.2 | 29 | 2.1 |
| SEP. OPERATOR | 61.1 | 29 | 2.1 |
| REACTOR TECH. | 60.8 | 26 | 2.3 |
| RADIATION CONTROL TECH. | 60.6 | 27 | 2.2 |
| REACTOR OPERATOR | 60.5 | 33 | 1.8 |
| REACTOR OPERATOR | 60.4 | 36 | 1.7 |
| REACTOR MONITOR | 60.3 | 31 | 2.0 |
| REACTOR MONITOR | 60.1 | 33 | 1.8 |

*DATA OBTAINED FROM RL PROGRAMS

**KNOWN ACCIDENT WHERE INDIVIDUAL RECEIVED ABOUT 110 REM

# TRENDS IN WHOLE BODY EXPOSURES




*FOR YEARS BEYOND 1968 THE POINTS ABOVE 5 REM REPRESENT ACCIDENTAL EXPOSURES

# RADIATION PROTECTION PROGRAM

- DOE EXPERIENCE
- IMPACT ON WORKER PROTECTION
- APPARENT LEGAL IMPLICATIONS

# IMPACT ON WORKER PROTECTION

- OCCUPATIONAL EXPOSURE HISTORY
- INCOMPLETE DATA BASE
- CALCULATION OF ASSUMED EXPOSURE
- ALARA

# APPARENT LEGAL IMPLICATIONS

- 50-YEAR COMMITTED DOSE
- TECHNICAL OVEREXPOSURE
- INCOMPLETE DATA BASE

# HANFORD WORKERS WITH MEASURED PLUTONIUM DEPOSITIONS

| INTERNAL DEPOSITION % OF $^{239}Pu$ MPBB | NUMBER OF WORKERS | CALCULATED 50-YEAR DOSE EQUIVALENT COMMITMENT (REM) STOCHASTIC |
|---|---|---|
| < 5 | 114 | <20 |
| 5–10 | 25 | 20–40 |
| 10–15 | 7 | 40–60 |
| 15–20 | 11 | 60–80 |
| 20–30 | 4 | 80–120 |
| 30–40 | 3 | 120–160 |
| 40–50 | - | 160–200 |
| > 50 | 4 | 260–3100 |

| | |
|---|---|
| TOTAL CURRENT HANFORD WORKERS WITH PLUTONIUM DEPOSITIONS | 168 |
| TOTAL CURRENT HANFORD RADIATION WORKERS | 8164 |

STATEMENT
PREPARED FOR DOE OFFICE OF NUCLEAR SAFETY
FOR ACRS SUBCOMMITTEE MEETING, NOVEMBER 12, 1982

J. P. CORLEY
STAFF ENGINEER
BATTELLE, PACIFIC NORTHWEST LABORATORY

I am John Corley, a Staff Engineer with the Radiological Sciences Department of Battelle ~~Memorial Institute~~'s Pacific Northwest Laboratory. ~~I~~ have been a health physicist for 35 years, for eight of which I was in charge of the environmental surveillance program for the AEC's Hanford Site. For the past ~~eight~~ years I have been responsible for a technical assistance project in the area of radiological environmental protection to first the AEC and now the Department of Energy. As such I have had primary responsibility for the preparation of guides of good practice for radiological environmental surveillance and effluent monitoring.

It should be understood that ~~my statement~~ presents my own views ~~and does~~ and not DOE or Battelle positions.

~~these moves, especially if a significant additional commitment of resources is required.~~

~~Protection of the public from ionizing radiation involves a parallel set of concerns to those~~ for occupational exposures. ~~As recognized by the NRC, however,~~ practical applications of ICRP recommendations to population groups introduces different problems and constraints. In large part, this is due to the lack of specific identification of maximally-exposed individuals (or individuals constituting a "critical group"), ~~the~~ a mixed and continually-changing population, and the inability to control directly future exposures to the same groups as individuals ~~except~~ by remedial actions at the source or intervention in the exposure pathways is of course possible.

~~I have listed here (Figure 1)~~ several aspects of the proposed 10CFR20 regulations, ~~both those which~~ generate similar concerns for environmental surveillance as for occupational protection responsibilities, ~~and those which~~ others engender different responses. It ~~may be~~ is noted that several of these concerns are inherent in the adoption of ICRP Publication No. 26 recommendations, e.g., the assignment of a 50-year dose commitment to the year of intake and the use of weighting factors to calculate an effective whole body dose equivalent. Others have been introduced in the NRC drafting process, e.g., the use of factored ALIs for population dose estimates and the directed ALARA emphasis,

## USE OF 50-YEAR COMMITTED DOSE EQUIVALENT

In principle, The use of 50-year committed dose equivalents from radionuclides with long biological half-lives seems ~~much~~ more appropriate for ~~control~~ assessment of population exposures than for occupational ~~control~~ doses. For the latter some capability will exist to substantiate a priori estimates through external and internal monitoring procedures. For members of the public, ~~generally lacking specific identification, continually changing, and with future individual exposures largely uncontrolled except by remedial actions at the source or by intervention in the exposure pathways,~~ use of committed dose equivalents may be necessary to demonstrate compliance as well as for prediction. As noted earlier ~~this~~ acceptance of this principle does not extend to use of ~~the~~ effective committed dose equivalents and requires ~~some~~ additional caveats.

## USE OF WEIGHTING FACTORS - THE "EFFECTIVE COMMITTED DOSE EQUIVALENT"

~~In principle~~, the conversion of risks of health effects to individual body organs to an equivalent whole body risk for ~~summation~~ and control purposes is as valid for uncontrolled area populations as for occupational exposures. The practice may indeed be useful for comparison of collective health risk impact ~~as an aid to~~ to provide design analysis, or ~~as~~ a trend indicator for a given facility or group of similar facilities with mixed effluents. However, loss of pertinent epidemiological information will inevitably occur if no other record is maintained of predominant organ dose calculations, especially where the nuclides and pathways of population exposure are limited. Such masking of probable risk of health effects to specific body organs (as well as genetic risk) is especially questionable where specific nuclides are highly concentrated in one body organ. Ready examples would be thyroid doses from radioiodines and bone doses from plutonium. One would find it difficult to ~~explain away an apparent~~ evaluate excess ~~of thyroid~~ cancers incidence solely on the basis of effective dose equivalents well within limits ~~where no record exists of predominant dose within existing~~ organ dose data.

~~With the recognition that~~ the weighting factors recommended involve many assumptions as to physiological parameters, and relative risk, which for diverse population groups would be expected to show large deviations from standard values and for which adequate data is frequently lacking. Perhaps no ready alternative is ~~available~~ apparent if a single coefficient of risk must be derived for assessment of total public health risk ~~for calculational purposes~~, however, ~~it must be recognized that~~ determination calculation of an effective committed whole body dose equivalent may well involve ~~significant~~ increases in effluent and environmental monitoring programs. The potential need for and cost of extending specific radionuclide measurements from sources with complex mixtures of nuclides in their effluents facilities ~~to include all those nuclides which might contribute significantly to~~ ~~be~~ derived to ~~find~~ a total risk coefficient, has not really been evaluated. I would also be concerned about the potentially misplaced emphasis in effluent reduction

~~commitments, and warrants some additional caveats.~~

USE OF FRACTIONAL ALI/DAC VALUES

Of greatest concern to those concerned with evaluating population doses is the proposed use of the ICRP's ALI and DAC tables with constant factors to adjust for lower limits, different exposure periods, and an assumed age distribution. Aside from the fact that the ICRP has specifically stated in No. 26 and 30 that these tables should not be used for this purpose, application of standard factors ~~to~~ for all nuclides and for all the diverse "critical groups" to be found at various licensee facilities will largely negate any claim to more precise control of population exposures. If all such calculated annual intakes were equivalent to less than de minimis levels, one could probably ignore the weakness of the assumptions used. I am not ~~that~~ confident that such is the case.

Figure 1 is taken from a paper by Roy Thompson given at the Vth IRPA meeting,(a) and shows some order of magnitude differences in several factors that must be taken into account to adjust a population ALI for just one age group, nuclide, and exposure mode. I suggest that the ability to adjust ALIs for all nuclides and all such factors is some years away. I understand in fact that Commmittee 2 of the ICRP has been struggling with this problem for some time. ~~In the Battelle evaluations of LWR power reactor dose impacts, previously referred to, four age groups are used~~.

In the interim I suggest that the ICRP in its more recent publications has provided internal dosimetric models which can be ~~applied~~ used, without recourse to the ALI and especially the DAC tables. To ~~the~~ some extent these models can be realistically adapted to different age groups and effective years of exposure to each age group. ~~they should~~ be. ~~Even so I~~ unnecessarily. This committee is probably aware that considerable uncertainty exists as to the adequacy of the data base for doing so for many radionuclides, at least to the extent that any better precision of dose and risk calculation can be claimed.

(a) Thompson, R.C. 1980. "An Approach to the Derivation of Radionuclide Intake Limits for Members of the Public", in Radiation Protection-A Systematic Approach to Safety, Proceedings of the Vth International Congress of the IRPA. Pergamon Press, New York.

RADIONUCLIDE-SPECIFIC EXPOSURE ADJUSTMENT
FACTORS FOR $^{239}Pu$ INHALATION BY THE PUBLIC

| PARAMETER | FACTOR FOR: INFANCY | LIFESPAN |
|---|---|---|
| ORGAN SIZE | 0.1 | 1 |
| VOLUME INHALED | 10. | 1 |
| FRACTION DEPOSITED AND/OR RETAINED | 2. | 1 |
| ENHANCED GASTROINTESTINAL AND/OR POLMONARY ABSORPTION | 0.2 | 1 |
| DISTRIBUTION AND RETENTION IN: | | |
| BONE (2X FOR INFANT) | 0.6 | 1 |
| LIVER (0.5X FOR INFANT) | | |
| G.I. TRACT (100X FOR INFANT) | | |
| FRACTION OF COMMITTED DOSE RECEIVED | 40. (W) | 1 |
| | 4. (Y) | |
| OVERALL VALUE OF $F_J$ | 10. (W) | 1 |
| | 1. (Y) | |

FIGURE 1.

## ALARA PRIORITIZATION

Section 20.102 of the proposed regulations addresses the prioritization of ALARA efforts. With due respect to my colleagues primarily concerned with occupational protection, I submit that the general public in no way would accept in an either-or situation the principle of minimizing occupational doses, at the expense of somewhat larger doses (and risks) to members of the public. I also submit that the referenced section ignores the members of the public most apt to be affected and to which the population dose limits are addressed, the maximally-exposed individual (or "critical group" as defined by the ICRP). Proper implementation of the ALARA principle requires consideration of all categories of exposure, and indeed involves socio - political judgments which presumably the NRC must and should make, with full consideration of collective and individual doses, to the worker and to the public.

either individual or collective,

## PROLIFERATION OF LIMITS (or action levels)

The use of reference levels for special reporting or for initiating investigative action is basically sound and generally accepted as good radiation protection practice. However, those responsible for reporting to the public must be concerned with the continuing proliferation of such levels, which in some instances seem unrelated to previous regulatory efforts and which undoubtedly contribute to public confusion and misunderstanding of the differences between reference levels, ALARA values, and limits. A reference level of 100 mrem has been proposed for members of the public in a recent draft (8/82) of 10CFR20. The proposed reference level of 100 mrem is without antecedent in U.S. practice, and is in addition to other limits applicable to individual members of the public. (Figure 2). These limits include the basic effective dose equivalent limit of 0.5 rem per year, design objectives for light water reactors contained in 10CFR50, Appendix I of 3 to 15 mrem per year depending on pathway, the drinking water limit in 40CFR141 of 4 mrem/yr, and a total dose limit for the bulk of the uranium light water fuel cycle of 25 mrem/yr. Note that I have not even attempted to indicate other specific organ dose limits. I question the need for still another number other than to conform to ICRP recommendations.

(DRAFT)

# DOSE CRITERIA
# MAXIMUM EXPOSED INDIVIDUAL

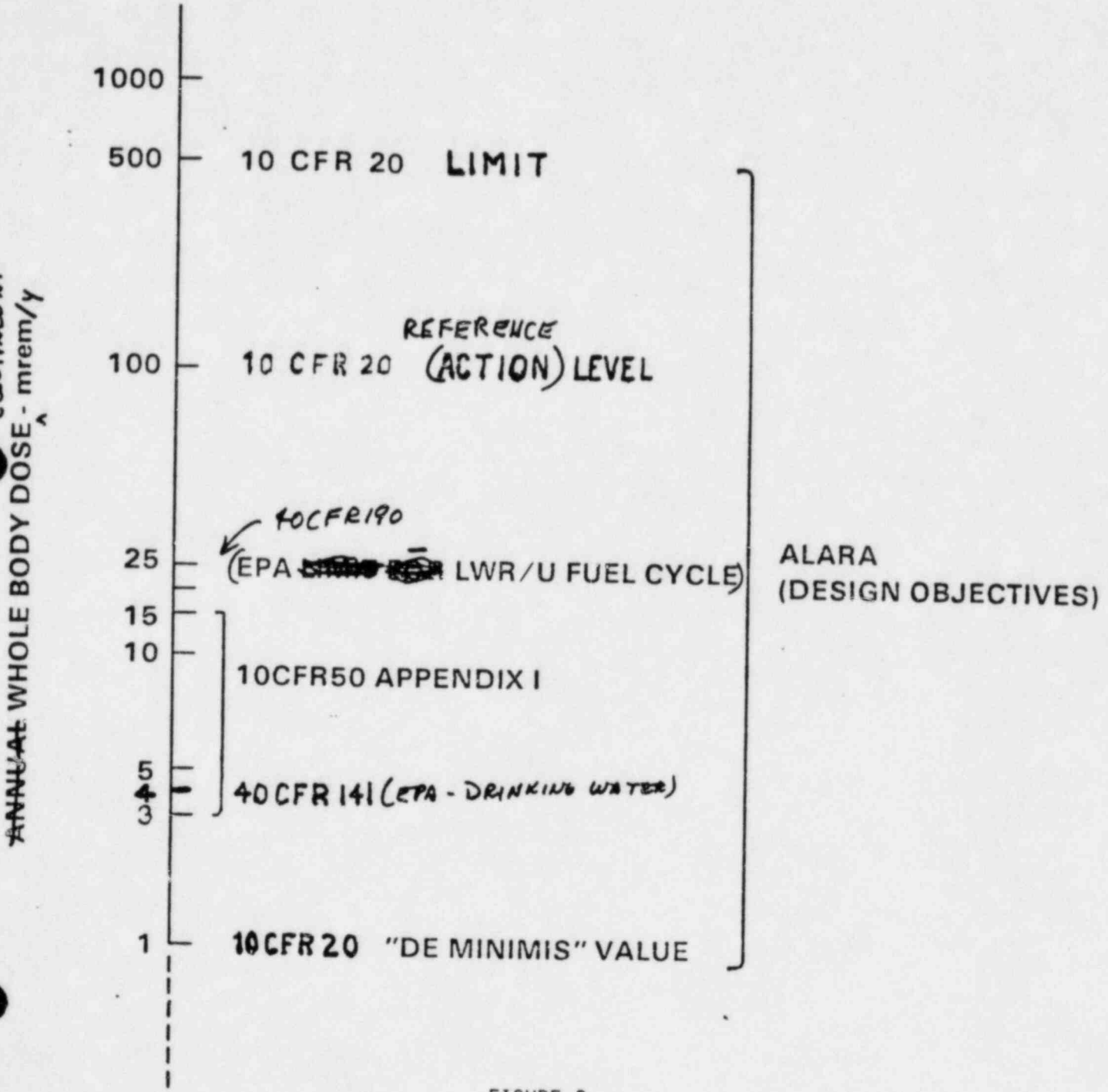



FIGURE 2.

I had hoped that the NRC staff and this Subcommittee will recognize that, in practice, any Reference Level is an Action Level, which thereby becomes a Working Limit, which to the public is the Limit. In the proposed regulations, this situation is reinforced by the language of Section 20.301, which states that the basic annual limit for members of the public is 0.5 rem (presumably the effective dose equivalent commitment is intended) and applies to the sum of all sources of exposure, licensed and unlicensed, other than natural radioactivity and medical exposures. In Section 20.303, it is quite rightly recognized that "It is impractical, if not impossible, to determine an actual dose (to individual members of the public) precisely", in part because of multiple sources. As a substitute, the Reference Level is offered as a means of demonstrating compliance with the NRC's intent. It seems to me a questionable practice to propose a limit for the licensee which is not really the limit he must live with.

Then in Section 20.401(c), I find that "a licensee engaged in uranium fuel cycle operations subject to the provisions of 40CFR190" shall comply with its requirements. In addition to limits on releases of specific radionuclides, 40CFR190 specifies annual dose equivalent limits for members of the public, with not only different numerical values (shown in Figure 2), but on what would now be a different basis (annual dose equivalent vs. effective dose equivalent commitment). Fortunately very few of the more than 10000 existing NRC and agreement state licensees would find necessary the double-entry dose bookkeeping. According to Battelle-Northwest studies of population doses from nuclear power reactors done for the NRC, some 80% of the dose to the public is from atmospheric releases, nearly all due to radioxenons and radiokryptons.

Several alternative Reference Levels are available. An annual dose-equivalent of 25 mrem to an individual member of the public would be in keeping with the 40CFR190 fuel cycle limit and apply adequately to the large majority of licensees. Another alternative would be to put the Reference Level at 170 mrem per year effective dose equivalent commitment. There is at least some antecedence for this value in earlier assumptions by the ICRP and the Federal Radiation Council. Although the intent was different, the reasoning was much the same.

(a) Peloquin, R.A., J.D. Schwab, and D.A. Baker. June 1982. Population Dose Commitments Due to Radioactive Releases from Nuclear Power Plant Sites in 1978. NUREG/CR-2201 (PNL-4039). Battelle, Pacific Northwest Laboratory. Richland, WA.

## BASIS FOR RISK ESTIMATES

I cannot claim any special expertise in the assessment of public health risk from radiation exposures. However it seems to me that a valid question exists as to whether an assumed distribution of risk for a worker population should be used for a mixed public of varying ages , habits, periods of exposure, and states of health and health care.

## EXPANSION OF THE DATA BASE FOR POPULATION DOSE ESTIMATES

I have mentioned ~~several times~~ in the foregoing ~~need a potential~~ need for a significantly expanded data base if the proposed system of dose regulation is to achieve better estimates of population doses. Unfortunately I cannot at this time give you any real data. I can foresee steady employment for a number of computer programmers for some time to come to adapt our existing computerized dose calculations to ICRP models.

## SUMMARY

To sum up, I believe that certain provisions of the proposed regulations would permit more consistent and logical assessment and control of population exposures, notably the fixing of de minimis values and the assessment of 50-year committed dose equivalents for the year of intake. ~~whether the latter~~ whether the necessary database epidemiological can be justified without ~~would justify~~ different systems of record-keeping is open to question. I have major concerns for the proposed conversion system of ALI/DAC tables for dose calculation for members of the public, for the potential loss of epidemiological data and ~~potentially~~ misplaced emphasis through reliance on an effective committed dose equivalent, and for inappropriate balancing of ALARA considerations.

~~Thank you~~

May I pass on a quote from my co-worker, Joe Soldat, known at least by reputation to most of you, referring to the ICRP system adopted for 10CFR20:

"My overall impression is that the elegance of the mathematics far exceeds the ~~capability~~ availability of the basic data needed to perform [with confidence] the calculations demanded by the system."

## RADIONUCLIDE-SPECIFIC EXPOSURE ADJUSTMENT FACTORS FOR $^{239}Pu$ INHALATION BY THE PUBLIC

| PARAMETER | FACTOR FOR: INFANCY | LIFESPAN |
|---|---|---|
| ORGAN SIZE | 0.1 | 1 |
| VOLUME INHALED | 10. | 1 |
| FRACTION DEPOSITED AND/OR RETAINED | 2. | 1 |
| ENHANCED GASTROINTESTINAL AND/OR POLMONARY ABSORPTION | 0.2 | 1 |
| DISTRIBUTION AND RETENTION IN: | | |
| BONE (2X FOR INFANT) | 0.6 | 1 |
| LIVER (0.5X FOR INFANT) | | |
| G.I. TRACT (100X FOR INFANT) | | |
| FRACTION OF COMMITTED DOSE RECEIVED | 40. (W) | 1 |
| | 4. (Y) | |
| OVERALL VALUE OF $F_J$ | 10. (W) | 1 |
| | 1. (Y) | |

FIGURE 3.

# SELECTED DOSE CRITERIA
# MAXIMALLY EXPOSED INDIVIDUAL

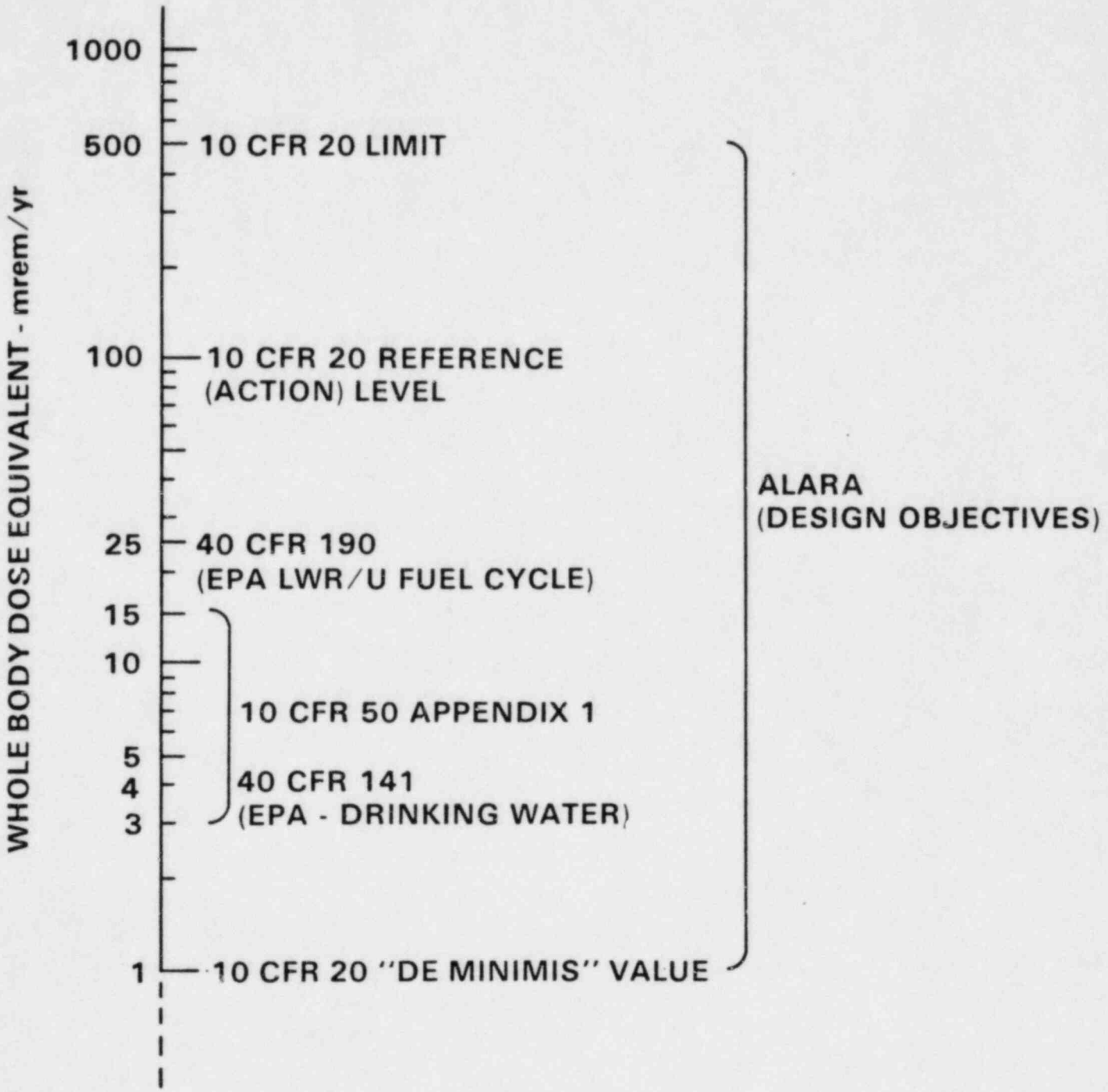



FIGURE 2.

Peterson
78

# ENO DEFINITION

(SEC 11J OF AEA)

AN EXTRAORDINARY NUCLEAR OCCURRENCE IS ANY EVENT WHICH:

CAUSES A DISCHARGE OR DISPERSAL OF SOURCE, SPECIAL NUCLEAR OR BYPRODUCT MATERIAL FROM ITS INTENDED PLACE OF CONFINEMENT

IN AMOUNTS OFFSITE, OR CAUSING RADIATION LEVELS OFFSITE, WHICH THE COMMISSION DETERMINES TO BE SUBSTANTIAL

AND WHICH THE COMMISSION DETERMINES HAS RESULTED OR WILL PROBABLY RESULT IN SUBSTANTIAL DAMAGES TO PERSONS OFFSITE OR PROPERTY OFFSITE

# REVISED CRITERION FOR "SUBSTANTIAL RELEASES"

- INDIVIDUAL OFFSITE RECEIVES EFFECTIVE WHOLE BODY DOSE OF 5 REM OR MORE

OR

- OFFSITE CONTAMINATION LEVELS EXCEED LIMITS (IN CURRENT PART 140 - NOT CHANGED)

REDUCES 20 REM WHOLE BODY DOSE AND ASSOCIATED ORGAN DOSES TO 5 REM EFFECTIVE DOSE

IF AN ACCIDENT HAD "SUBSTANTIAL RELEASES" THEN IT WOULD HAVE REQUIRED PROTECTIVE ACTIONS

## REVISED CRITERION FOR "SUBSTANTIAL DAMAGES"

- "SUBSTANTIAL INJURY" 100 REM TO 5 PEOPLE
  SMALLER DOSES TO LARGE POPULATIONS LIMITED BY 1 REM (10,000 PEOPLE OR MORE)

OR

- DECONTAMINATION REQUIRED OF OFFSITE PROPERTY WORTH $2,500,000

OR

- LOST EMPLOYMENT OF AT LEAST 25,000 PERSON-DAYS

OR

- EVACUATION OF AT LEAST 100,000 PERSON-DAYS DURATION

## PROBLEMS FOUND IN TMI ENO DETERMINATION

1. EVALUATION OF MAGNITUDE OF DAMAGES DIFFICULT

2. INTERPRETATION OF "COULD BE" AND "MIGHT BE"

3. ADEQUACY OF ENO CRITERIA

4. ENO NOT CONSIDERED DURING OR IMMEDIATELY AFTER ACCIDENT

BACK UP

## EXISTING CRITERION I FOR "SUBSTANTIAL RELEASES"

PROJECTED DOSE TO INDIVIDUAL OF

30 REM TO THYROID

20 REM TO WHOLE BODY

20 REM TO BONE MARROW

60 REM TO SKIN

30 REM TO OTHER TISSUES

## EXISTING CRITERION I FOR "SUBSTANTIAL RELEASES"

SURFACE CONTAMINATION OF 100$M^2$ OR MORE IN EXCESS OF:

| | $\mu Ci/M^2$ |
|---|---|
| ALPHA FROM TRANSURANIC ELEMENTS | 0.35 |
| ALPHA NON-TRANSURANICS | 3.5 |
| BETA OR GAMMA EMISSION | 4 MR/HR @ 1 CM AND 7 MG $1CM^2$ ABSORPTION |

BACKUP

EXISTING CRITERION II FOR "SUBSTANTIAL INJURY OR DAMAGE"

1. 5 OR MORE PEOPLE KILLED OR HOSPITALIZED WITH "OBJECTIVE CLINICAL EVIDENCE OF RADIATION INJURY"

OR

2. $2.5M OF DAMAGE SUSTAINED BY 1 INDIVIDUAL OR $5M OF DAMAGE SUSTAINED IN TOTAL

OR

3. $5K OR MORE OF DAMAGE SUSTAINED BY 50 OR MORE PERSONS WITH AT LEAST $1M SUSTAINED IN TOTAL

BACKUP

Box 13 Thetford
Vermont 05074
July 16, 1982

Ms. Rung C. Tang, Staff Engineer
Advisory Committee on Reactor Safeguards (H1016)
U.S. Nuclear Regulatory Commission
Washington D. C. 20555

JUL 27 1982

PM

Dear Ms. Tang,

As indicated in my letter of July 7, I am forwarding herewith translations of the table and figures from the Kallee paper on KI which I had forwarded to you prior to the June 23 subcommittee meeting.

I have not previously included Kallee's bibliography but I am enclosing a copy of the paper in the original German and the references, which are for the most part obvious, are listed on the final page of the paper.

If the above items are appended to the earlier translation, a complete version of Kallee's paper will be available for the meeting minutes.

Sincerely,

Ragnwald Muller
Consultant

cc: Dr. Dade W. Moeller

Table and Figures Accompanying Paper by E. Kallee, Medical University Clinic, Tuebingen. Internist (May 1981) Vol. 22, No.5, pp 304-307 (Translated by Ragnwald Muller, ACRS Consultant)

Table 1. Possible Side Effects of a 3-Day Prophylaxis with 300 mg KI. The multiplicity of the listed side effects is rare. (See text)

THYROID

(A) Euthyroids:

Dominant decrease of $TT_4$ and $TT_3$ with a rise in TSH or fleeting rise of $TT_4$ and $TT_3$. Iodine goiter and iodine myxodema in adults only after long-term therapy.

(B) Hyperthyroids:

1. Obvious, treated Hyperthyroids: Under Thionamid - Thyreostatika no damaging effect from iodine to worry about. Perchlorate suppressed by iodide.

2. Latent Untreated Hyperthyroids: Here KI could result in up to a thyroid-toxic crisis in severe hyperthyroids. Endangered are principally persons with multiple adenomas (nodular tumors) and diffuse micro adenomas, but also singular adenomas such as goiter patients.

3. Colloid-poor follicles can resume absorption of colloids because of KI which can result in acute colloidal tumors.

(C) Hypothyroids:

1. Obvious Hypothyroids: No specific thyroid side effects expected.

2. Latent primary Hypothyroids: So-called "Iodine deficiency" can, as a result of iodine saturation be converted to hyperthyroids.

(D) Large Tumors of Unknown Etiology:

Acute volume increase with blockage of the trachea possible.

(E) Pregnancy:

Endangered is solely the fetus, due to tumors or hypothyroidism.

ALLERGIC REACTIONS

(A) Non-specific drug rash, principally in sensitized patients (genuine iodine allergy is rare), facial edema, glottic edema (toxic ?)

(B) Iodine idiosyncrasy with dermatitis herpetiformis Duhring.

(C) Nodous periarteritis with eosinophil

TOXIC EFFECTS

(A) Iodine skin blisters: poxxform hemorhaging necrotic, can end lethally. Only observed with long-term therapy.

Table 1 (Continued)

(B) Iodine tuberous skin and iodine-stimulated skin growth equally only observed with long-time therapy or locally as a result of pigmentation treatment with 40% KI vaseline.

(C) "Iodine Sniffles" and side-effect sinusitis caused by increased secretion; itching and burning of the eyes; headaches.

(D) Swelling of the salivary glands (Iodine mumps); on awakening - a salty-bitter aftertaste.

(E) Stomach complaints assumed caused by build-up of $I_2$ from ICl of the stomach juices.

Preventative: Vitamin C, protein-containing nourishment.

(F) Iodide Fever: only at higher doses

PSYCHOLOGICAL EFFECTS

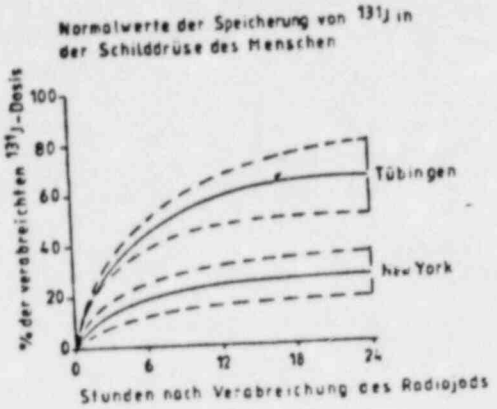
(A) Fear caused by threatening catastrophes can lead to consumption of tranquilizers, sleep inducers, and analgesics, as well as to excessive alcohol or nicotine use. The direct results thereof, or the later effects up to deformities, could be attributed possibly not only to the radioiodine release but also to the iodine prophylaxis.

(B) Stress: Gastritis, stress ulcers, incontinence, leucocytosis reactive psychoses.

(C) Not taking iodine pills or, conversely, harmful overdosing of iodide.

Figure 1

Normalized values of Absorption of $^{131}I$ in the Human Thyroid




% of the applied dose

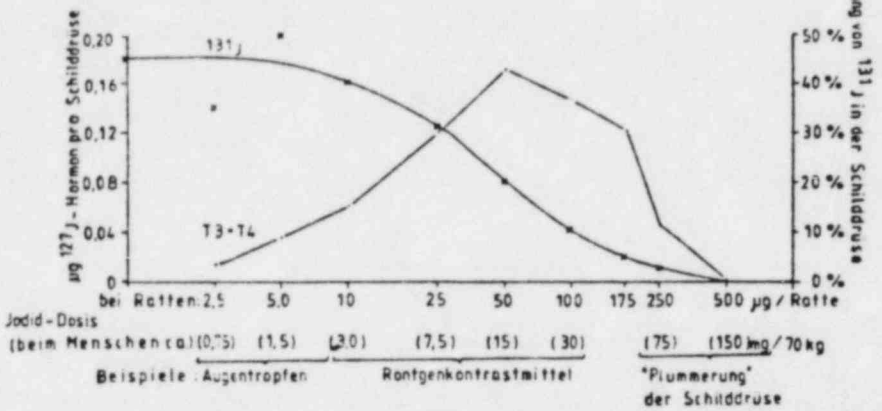
Hours post-application of the radioiodine

The radioiodine absorption in New York was measured in 62 patients with a whole-body counter mainly 24 hours after application of 1.5 nCi $^{131}INa$. (From data of Blum and Eisenbud 1968 (12). The Tuebingen values were obtained from 70 experimentees 6 and 24 hours after 30 pCi $^{131}INa$.

Figure 2

Wolff-Chaikoff Effect: Rise and blockage of new synthesis of Thyroxin ($T_4$) and Triiodinethyronin ($T_3$) of the thyroid of rats 4 hours after injection of $^{127}I$ (Method of Nagataki and Ingbar (16)). In the lower abcissa the iodine quantities converted to 70 kg man from 200-250 g rat data are given in parenthesis. The region indicated for xray contrast media is estimated assuming that of a 10 gram given dose of a 60% iodine-content contrast medium, about 0.05-0.5 % will be split off in the form of iodide during the first day.. (The upper abcissa gives the iodine dose for rats in µg. The lower abcissa gives the iodine dose for 70 kg man in mg)

µg $^{127}I$ hormone per thyroid

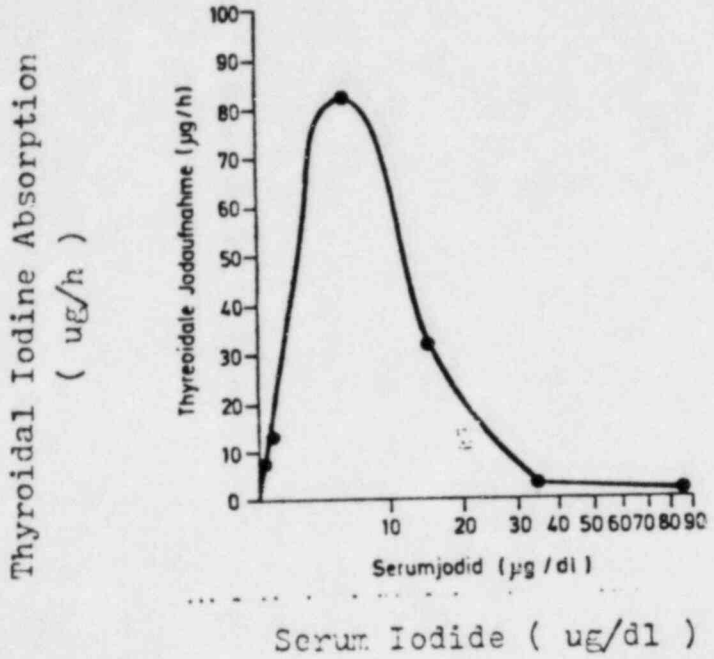



Absorption of $^{131}I$ in the Thyroid

Examples: Eyedrops X-ray contrast media "loading" of thyroid

Figure 3

Absolute iodide absorption by the human thyroid in relation to the serum iodide level (17). (From Oberdisse et al. (1967) Diseases of the Thyroid; 1st ed. Thieme, Stuttgart, p60).



Internist (1981) 22: 304–307

**Der Internist**




*Kurze Informationen*

# Nutzen und Risiko der Jodprophylaxe bei Kernreaktorunfällen*

E. Kallee
Medizinische Universitätsklinik Tübingen

Jod ist als Schlüsselelement der Schilddrüse zugleich ein lebenswichtiges Spurenelement [1]. Der Mensch sollte davon täglich etwa 100 bis 200 µg zu sich nehmen [2, 3]. In den USA und in anderen Jodüberflußgebieten mit hohen Zusätzen von Kaliumjodid (KJ = Kalium jodatum DAB VII; Kalii iodidum Eur.AB I) zum Speisesalz – oder Kaliumjodat ($KJO_3$) als Backzusatz zum Brot – beträgt die tägliche Jodzufuhr etwa 400 bis 1200 µg. Jodat vernetzt die SH-Gruppen des Klebers oxydativ zu S-S-Brücken und wird während des Backvorgangs zu Jodid reduziert. Gargebackenes Brot enthält also in den USA kein Jodat mehr, sondern nur noch Jodid. In der Bundesrepublik Deutschland ist über die alimentäre Jodaufnahme nur wenig bekannt, aber die Ausscheidung von Jod im Urin liegt mancherorts wahrscheinlich unter 50 µg pro Tag [4, 5].

Der sog. Jodmangelkropf beruht sicher nicht immer auf alimentärem Jodmangel [2, 6–8], unter Jodmangel treten aber stets Strumen auf. Die Schilddrüse enthält hierzulande normalerweise etwa 5–15 mg Jod [3, 9, 10]. Strumen enthalten durchschnittlich etwa die Hälfte, können aber auch viel weniger Jod enthalten. Besonders jodarm sind Schilddrüsen bei latenten und floriden Hyperthyreosen, extrem wenig Jod enthalten toxische Adenome [10, 11]. Die freie Speicherkapazität der Schilddrüse für Jod ist in unserer Gegend auf mindestens 5–10 mg einzuschätzen, bei jodarmen Drüsen entsprechend höher. Einen Parameter hierfür stellt der Radiojodtest dar.

Bei klinisch euthyreoten Probanden speichert die Schilddrüse binnen 24 h hierzulande 60–70% des verabreichten Radiojods. Bei Jodmangelzuständen können die Speicherwerte annähernd 100% erreichen, wobei das Radiojod nachhaltig, oft tagelang, gespeichert bleiben kann.

In Jodüberflußgebieten, beispielsweise in den nordamerikanischen Staaten New York und Massachusetts, ist die freie Jodidbindungskapazität der Schilddrüse auf die Hälfte bis ein Viertel unserer Werte reduziert [3, 12, 13]. Daher lassen sich US-amerikanische Untersuchungen und Überlegungen zur Jodprophylaxe nur mit erheblichen Korrekturen auf unsere gegenwärtigen Verhältnisse übertragen.

Von entscheidender Bedeutung für das Verständnis des Nutzens und der Gefahren einer Jodprophylaxe ist der Wolff-Chaikoff-Effekt: Bei der Inkubation von Gewebsschnitten von Schafsschilddrüsen in vitro bauen die Zellen zunächst um so mehr Jod in organische Jodverbindungen ein, je höher die Jodidkonzentration im Nährmedium ist [14]. Wird eine bestimmte kritische Jodidkonzentration überschritten, so nimmt die Bildung organischen Jods wieder ab und kehrt zum Ausgangsniveau zurück. Jodid stimuliert also bei niedrigen bis mittleren Konzentrationen die Hormonsynthese, wogegen hohe Jodidkonzentrationen das Gegenteil bewirken.

Ein ähnlicher Vorgang spielt sich auch in vivo ab [15]. Erhalten Ratten konstante Tracerdosen Radiojod zusammen mit steigenden Mengen Jodid intraperitoneal injiziert, so nimmt die Bildung von Jodhormonen in der Schilddrüse ebenfalls zunächst zu, obwohl die Radiojodspeicherung gleichzeitig zurückgeht (Abb. 2). Das Maximum der Hormonsynthese wird

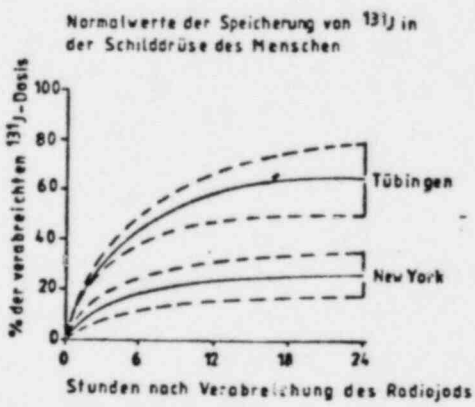



**Abb. 1.** Die Radiojodspeicherung in New York wurde bei 62 Patienten mit einem Ganzkörperzähler hauptsächlich 24 h nach Verabreichung von 1,5 nCi $^{131}JNa$ gemessen (umgezeichnet nach Blum u. Eisenbud 1968 [12]). Die Tübinger Werte wurden an 70 Probanden 6 und 24 h nach 30 µCi $^{131}JNa$ ermittelt [3]

* Gekürzte Fassung eines Vortrags, gehalten auf der Tagung der Vereinigung Deutscher Strahlenschutzärzte in München am 29. November 1980. Alle Vorträge dieser Tagung erscheinen in einem Sammelband beim Georg-Thieme-Verlag, Stuttgart

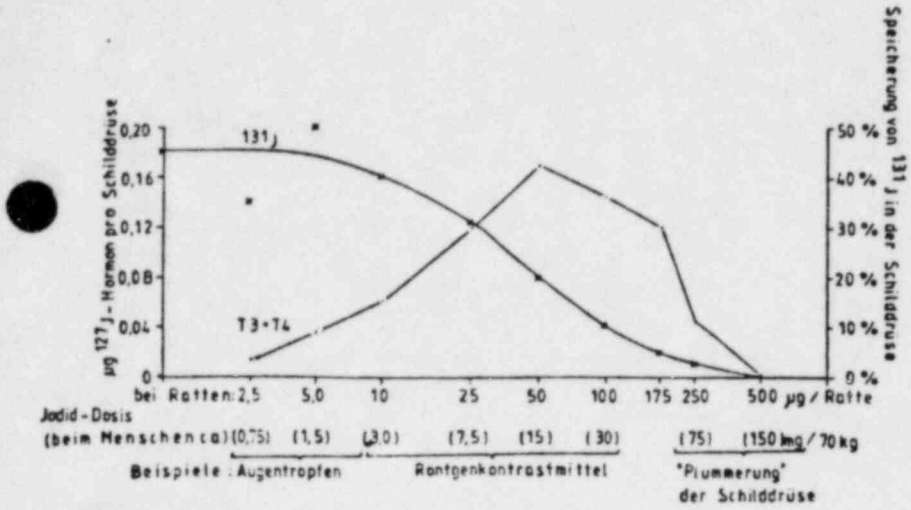



Abb. 2. Wolff-Chaikoff-Effekt. Steigerung und Blockade der Neusynthese von Thyroxin ($T_4$) und Trijodthyronin ($T_3$) der Schilddrüse von Ratten 4 h nach Injektion von $^{127}J^-$ (modif. nach Nagataki und Ingbar [16]). In der zusätzlichen Abszisse sind die Jodidmengen, die von 200–250 g Ratte auf 70 kg Mensch umgerechnet wurden, in Klammern angegeben. Der für Röntgenkontrastmittel angegebene Bereich ist geschätzt unter der Annahme, daß nach Gabe von 10 Gramm eines 60% Jod enthaltenden Kontrastmittels am ersten Tag etwa 0,05–0,5% in Form von Jodid abgespalten werden

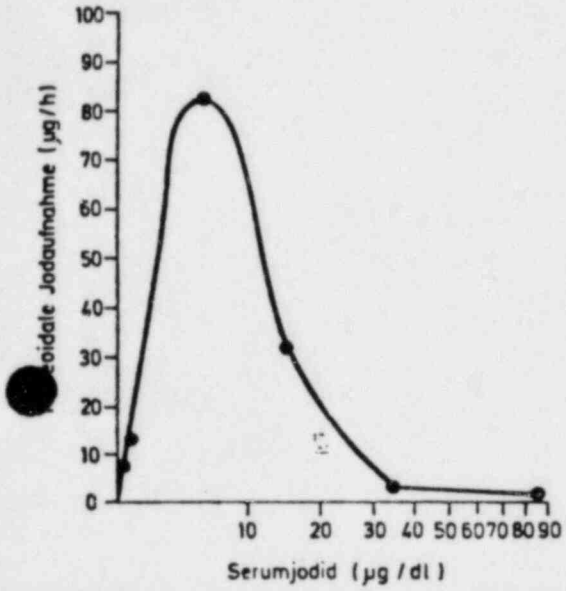



Abb. 3. Absolute Jodidaufnahme der menschlichen Schilddrüse in Abhängigkeit vom Serumjodidspiegel [17]. (Nach Oberdisse et al. (1967). Die Krankheiten der Schilddrüse; 1. Aufl. Thieme, Stuttgart, S 60)

bei einer mittelhohen Jodid-Dosis von 50 µg pro 200–250 g Ratte erreicht. Nach Überschreiten dieser kritischen Dosis kehrt sich der Vorgang analog dem Verhalten in vitro allmählich um, und ab 500 µg sistiert die Hormonsynthese [16]. Bei einer Jodid-Dosis, die ausreicht, die Radiojodspeicherung auf 5% zu supprimieren, findet aber immer noch eine submaximale Hormonsynthese statt, und selbst bei 2% Radiojodspeicherung ist die Hormonbildung noch deutlich erhöht.

Beim Menschen erfolgt der Einbau von Radiojod in die Schilddrüse ähnlich wie bei der Ratte. Im Rattenversuch wird das Maximum der Neubildung von organischem Jod bei einer Serumjodidkonzentration von etwa 15 µg/dl erreicht [15]. Da die Jodidkonzentrationen der Dosis-Wirkungskurven von Mensch und Ratte in der Größenordnung gut übereinstimmen, erscheint der Analogieschluß vom Rattenversuch auf den Menschen gerechtfertigt (Abb. 3) [17].

Der Wolff-Chaikoff-Effekt bietet eine naturwissenschaftliche Erklärung für eine schon lange zuvor bekannte klinische Tatsache: Im physiologischen Bereich von 100 bis 1000 µg täglich ist Jod zur Erhaltung der Gesundheit erforderlich. In Dosen zwischen 1 mg und 50 oder 100 mg täglich kann Jod bei prädisponierten Personen Hyperthyreosen bis hin zum thyreotoxischen Koma auslösen [18, 19]. Diese Reizdosen sind die verhältnismäßig kleinen Jodidmengen, beispielsweise in Augentropfen, oder die mittleren Jodidmengen, welche aus Kontrastmitteln und anderen jodhaltigen Medikamenten wie Clioquinol gewöhnlich frei werden. Im Bereich oberhalb 200–300 mg täglich wird die stimulierende Wirkung mittlerer Joddosen wieder aufgehoben. Eine Überfunktion der Schilddrüse, die durch gefährliche mittlere Jodmengen ausgelöst wurde [20], läßt sich also durch sehr hohe Dosen rückgängig machen [18]. Bei mehr als zweimonatiger Behandlung mit täglichen Dosen von 500–1000 mg KJ und mehr können sogar Jodkröpfe mit primärem Myxödem entstehen. Diese verschwinden aber nach Absetzen des KJ spontan [21].

Bei der Wahl der optimalen Joddosis zur Prophylaxe eines Strahlenschädigung der Schilddrüse kommt es darauf an, die Drüse so stark mit Jodid zu sättigen, daß mit einiger Sicherheit weniger als 1% radioaktives Jod in die Drüse gelangt. Zugleich muß sichergestellt sein, daß die gewählte Dosis oberhalb der gefährlich stimulierenden Dosis liegt. Andererseits sollte die Sättigungsdosis unterhalb der lästigen Expektorationsdosis oder gar der direkt toxischen Dosis liegen.

Theoretisch genügen für eine wirksame Blockade der Radiojodspeicherung durch Jodid in den USA 30–100 mg KJ [12, 13], in Griechenland etwa 40 mg [22], und auch in Deutschland wird eine solche Dosis vermutlich in vielen Fällen ausreichen. Da aber die Schilddrüse in Deutschland infolge eines relativen Jodmangels eine etwa zwei- bis vierfach höhere Speicherkapazität besitzt als in den USA, muß die KJ-Dosis entsprechend höher angesetzt werden. Für unsere Verhältnisse erscheint eine Dosis von 300 mg KJ pro Tag – 229 mg Jodid entsprechend – sicher ausreichend, die Radiojodspeicherung in allen Fällen wirksam zu unterdrücken. Zugleich sind bei dieser hohen

Tabelle 1. Mögliche Nebenwirkungen einer dreitägigen Prophylaxe mit 300 mg Kaliumjodid pro Tag. Die Mehrzahl der aufgeführte Nebenwirkungen ist selten (vgl. Text)

*Schilddrüse*

(A) Euthyreosen:
Vorübergehender Abfall von $TT_4$ und $TT_3$ mit TSH-Anstieg oder flüchtiger Anstieg von $TT_4$ und $TT_3$. Jodkropf und Jodmyxödem bei Erwachsenen nur durch Langzeittherapie

(B) Hyperthyreosen:
(1) Manifeste, behandelte Hyperthyreosen: Unter Thionamid-Thyreostatika keine schädlichen Wirkungen von Jodid zu befürchten. Perchlorat wird durch Jodid verdrängt
(2) Latente, unbehandelte Hyperthyreosen: KJ kann hier floride Hyperthyreosen bis hin zur thyreotoxischen Krise auslösen. Gefährdet sind hauptsächlich Träger von multiplen Adenomen („Knotenstruma") und diffusen Mikroadenomen, aber auch Solitäradenomen sowie Basedow-Patienten
(3) Kolloidarme Follikel können durch KJ wieder Kolloid einlagern, wodurch eine akute Kolloidstruma entstehen kann

(C) Hypothyreosen:
(1) Manifeste Hypothyreosen: keine schilddrüsenspezifischen Nebenwirkungen zu erwarten
(2) Latente primäre Hypothyreosen: sog. „Jodmangel" kann durch Jodsättigung in Hyperthyreose umschlagen

(D) Große Strumen unbekannter Ätiologie:
Akute Volumenzunahme mit Einengung der Trachea möglich

(E) Gravidität:
Gefährdet ist ausschließlich der Fetus durch Struma und Hypothyreose

*Allergische Reaktionen*

(A) Unspezifische Arzneimittelexantheme, vor allem bei sensibilisierten Patienten (echte Jodallergie ist selten), Gesichtsödeme, Glottisödem (toxisch?)
(B) Jod-Idiosynkrasie bei Dermatitis herpetiformis Duhring
(C) Periarteriitis nodosa mit Eosinophilie

*Toxische Wirkungen*

(A) Jododerma bullosum: varicelliform, hämorrhagisch-nekrotisierend, kann letal enden. Bisher nur bei Langzeittherapie beobachtet
(B) Jododerma tuberosum und Jododerma vegetans ebenfalls nur bei Langzeittherapie oder lokal infolge Leukotaxis durch 40%-KJ-Vaseline
(C) „Jodschnupfen" und Begleitsinusitis durch vermehrte Sekretionsleistung; Jucken und Brennen in den Augen; Kopfschmerzen
(D) Schwellung der Speicheldrüsen (Jod-Mumps); beim Aufwachen salzig-bitterer Mundgeschmack
(E) Magenbeschwerden vermutlich durch Bildung von $J_2$ aus JCl des Magensafts
Vorbeugung: Vitamin C, proteinhaltige Nahrung
(F) Jodidfieber: nur nach höheren Dosen

*Psyche*

(A) Angstzustände wegen drohender Katastrophe können zur Einnahme von Beruhigungs- oder Schlafmitteln und Analgetika sowie zu exzessivem Alkoholgenuß und Nikotinabusus etc. verleiten. Deren unmittelbare Folgen oder Spätschäden bis hin zu Mißbildungen werden dann möglicherweise nicht nur der Radiojodexposition, sondern auch der Jodprophylaxe zugeschrieben
(B) Streß: Gastritis, Streßulzera, Inkontinenz, Leukozytose, reaktive Psychosen
(C) Nichteinnahme der Jodidtabletten oder umgekehrt panische Überdosierung von Jodid

Dosis weniger jodinduzierte Hyperthyreosen als bei der scheinbar vorsichtigeren mittleren Dosierung zwischen 30 und 100 mg KJ zu erwarten. Denn unter der hohen Dosierung werden in der Schilddrüse wegen des Wolff-Chaikoff-Effekts keine größeren Hormonvorräte gebildet. Daher ist auch kaum mit einer Ausschüttung von Schilddrüsenhormonen im Sinne eines „escape"-Phänomens oder einer Hormon-„Leckage" zu rechnen. Die Dosis von 300 mg liegt überdies weit unterhalb der toxischen Grenze und verursacht bei der vorgesehenen kurzfristigen Anwendung keine manifesten Hypothyreosen.

Eine Dosis von 100 mg NaJ reicht selbst in den USA nicht immer zu einer wirksamen Blockade voll aus. Außerdem verfliegt die sättigende Wirkung ziemlich rasch, und 100 mg bewirken bei einer nachträglichen Einnahme nicht viel [23]. Das bedeutet für den Ernstfall, mit der Jodprophylaxe nicht früher als 1–2 h vor und möglichst nicht später als 1–3 h nach einer Radiojodexposition zu beginnen und eine möglichst hohe Initialdosis zu wählen [24].

Unerwünschte Nebenwirkungen einer dreitägigen Behandlung mit jeweils $3 \times 100$ mg KJ ($= 229$ mg $J^-$) werden voraussichtlich nur selten auftreten, und die meisten Nebenwirkungen verschwinden von selbst nach Absetzen der Prophylaxe. In Tabelle 1 sind alle bisher bekannten möglichen Nebenwirkungen von Jodid in hohen – vorwiegend toxischen – Dosen aufgeführt.

In erster Linie gefährdet sind Menschen mit latenter Hyperthyreose. Auch hinter scheinbar harmlosen „Jodmangelstrumen" kann sich eine symptomlose Hyperthyreose verbergen. Daher empfiehlt sich hierzulande eine Kontrolle des Thyroxinspiegels und eines Parameters für das $FT_4$ ab der dritten Woche nach Beendigung der Jodprophylaxe bei allen Personen, die Jodidtabletten eingenommen haben. Solche Kontrollen lassen sich mit modernen Methoden ohne weiteres durchführen, auch wenn tausende oder zehntausende von Proben pro Woche anfallen sollten.

Schwangere sollten möglichst nicht an der Jodprophylaxe teilnehmen, sondern das gefährliche Gebiet

rechtzeitig verlassen. Jedoch müssen notfalls auch Schwangere das Kaliumjodid einnehmen, denn ein fetaler Jodkropf ist im allgemeinen post partum therapeutisch reversibel, ein fetaler Strahlenschaden an der Schilddrüse dagegen wahrscheinlich irreversibel.

Patienten mit Dermatitis herpetiformis Duhring sind von der Prophylaxe wegen der notorischen Jod-Idiosynkrasie auszuschließen [27, 28].

Magenbeschwerden können auch bei Gesunden auftreten, vor allem wenn der Magen leer ist. Durch Salzsäure entsteht aus HJ das Chlorjod (JCl), aus dem teilweise elementares $J_2$ frei wird. Durch reaktionsfreudige anorganische Jodverbindungen kann die Schleimhaut des Magens gebeizt und damit gereizt werden. Die Reizerscheinungen lassen sich aber durch Vitamin C (etwa 500 mg pro die) oder durch proteinhaltige Lebensmittel leicht verhüten und beheben. Dagegen müssen erhebliche Magensymtome immer an eine Krankheit denken lassen, die nicht primär mit der Einnahme von Kaliumjodid zusammenhängt.

Aufmerksamkeit verdienen bei Reaktorstörfällen auch psychische Alterationen wegen ihrer somatischen Auswirkungen und versicherungsrechtlichen Folgen. Vor allem bedürfen Streßulzera – im Gegensatz zu jodbedingten Magenbeschwerden – einer intensiven Therapie.

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# EPA APPROACH TO DE MINIMIS
## For Radioactive Waste

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For Presentation at the October 1982 Atomic Industrial Forum Conference
on Radiation Issues for the Nuclear Industry

T11

EPA APPROACH TO De Minimis
For Radioactive Waste

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## PROJECT SCOPE

EPA's present activity, within the context of this Conference session on Exploring the Use of a De Minimis Concept in Radiation Protection, is specifically intended to determine if there are radioactive wastes that are of sufficiently low activity they do not need to be regulated as to their radiation hazard. A potential alternative would be that the wastes could be handled and disposed with only minimal radiation protection controls. We are pursuing this as a part of a broader project to prepare standards and possibly guidance for the disposal of low-level radioactive waste.

In carrying out this activity we are presently avoiding the use of the term "de minimis." This term from the legal profession originates from the Latin quotation "De minimus non curat" meaning, the law is not concerned with trivialities. We have found that some have come to interpret this to mean that "you don't care" or that the risks people face are to be considered as trivialities. Rather than confront people's established misconceptions, we have chosen to use language more directly descriptive of our intentions. We prefer that people have a clear understanding that we have done the analysis and determined a level below which regulation is not warranted or may be minimal.

In describing the scope of the effort I shall point out a couple of aspects that we are not presently pursuing so that there will be no misunderstanding.

We are not developing an across the board regulatory cutoff for all radiation control activities. However, we are following the activities of others pursuing this, which has provided some useful insights for our effort. The most complete listing I have seen of the possible approaches to developing such general criteria are given in the paper "The Feasibility of Establishing a 'De Minimis' Level of Radiation Dose and a Regulatory Cut-off Policy for Nuclear Regulation"(1) prepared by Joyce Davis of the General Physics Corporation for the Edison Electric Institute. Two general bases are suggested for a generic "de minimis." First, one based on biological effects data and the second based on a comparison with background. Neither of these have been found to be directly adaptable to our current effort. As pointed out in the Davis paper itself there is not sufficient data to substantiate any of the biological approaches.

Furthermore, definition of a threshold or similar biological finding is not likely in the near future. The use of background and or its variability provides a useful perspective but is not directly applicable to our problem. A similar approach, which also incorporates the use of cancer incidence and its variability, has been proposed by G. Hoyt Whipple[2] which also provides a useful perspective to our considerations. One problem in using background or cancer incidence variability is that they both change with geography and are therefore difficult to apply on a national basis. Another problem is that these approaches do not take into consideration any evaluation of a collective exposure to the population.

Another aspect that is not covered by our current effort is the defining of a truncation value on individual doses for use in calculating a collective population dose. This is quite different than defining a level below which regulation is not warranted. It would be expected that a collective dose truncation on individual doses would be more restrictive than a regulatory cut-off. That is to say, it is appropriate to estimate the population exposure that results from a regulatory cutoff on individual exposures.

Although the present effort to determine a regulatory cut off is restricted to low-level waste disposal, it will probably have implications for some other efforts we are involved in. It is not expected that the level determined would be the same in all cases, but some carry over in approach is probable. Other standards and guidance areas that may be influenced include decommissioning and decontamination standards and Protective Action Guides for recovery and re-entry.

One of the basic reasons that the criteria may not all be the same, in these cases, is that the cost-effective analyses, which determines how much it would cost to control various levels of exposure, may show quite different results. It is conceivable, for instance that remedial costs after a contaminating event, where Protective Action Guides are to be applied, will be much more expensive for a given level of exposure than the costs of planned activities to prevent exposure at the same level from disposal of low-level radioactive wastes. Other practical considerations, such as the measurements to be used in implementation and the determination of critical pathways, may also be very different in each case.

## PROJECT AUTHORITIES & APPROACH

The EPA project to set standards for low-level radioactive waste disposal, including the determination of a level below regulatory concern, is being carried out under authorities transferred to EPA by Reorganization Plan No. 3 of 1970.

The first authority, which came from the Atomic Energy Act of 1954, as amended, is for "generally applicable environmental radiation protection standards." Such standards could establish numerical limits on radiation exposure or levels, or concentrations or quantities of radioactive materials, in the general environment outside the boundaries of locations licensed for low-level radioactive waste disposal. This authority was used to set EPA standards for uranium fuel cycle facilities (40 CFR 190). Its use is restricted to Atomic Energy Act materials.

The second authority, which came from the former Federal Radiation Council (42 U.S.C. 2021(h)), is for the EPA Administrator to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards." This authority is the same one that the Federal Radiation Council used to issue reports, numbers one and two, which established the basic limits on exposures used by the Federal agencies today.

Both authorities could be used for setting a level below regulatory concern. We have not decided to use either one of these authorities to the exclusion of the other. We plan to keep our options open as we continue our analysis. It may be that we would want to use both authorities for different aspects.

In carrying out this activity, we are aware of the conclusions of the Task Force on Low-Level Radioactive Waste of the U.S. Radiation Policy Council[3] which stated: "that an overall generic 'de minimus' level is not a practical solution to a portion of the waste management problem because, without knowing physical and chemical parameters of the waste involved, it is difficult to establish pathways to humans and resulting doses. Therefore, in order to establish a generic 'de minimus' level, extremely conservative assumptions are dictated which are likely to lead to levels that are so small that they have little practical value in disposing of low activity waste. As an alternative the Task Force endorses the approach of evaluating waste streams on a case-by-case basis...." We agree that considerations of specific categories of waste streams and methodologies of disposal must be a part of the analysis and we are proceeding in that manner. There may even be aspects which will need to be left to a specific licensing consideration. However, we also believe we can at least develop a context within which this can be fostered.

There are several possibilities for the form of expression for a level below regulatory concern. One leading contender for EPA is in terms of an annual individual exposure rate which a cost-benefit analysis has determined to not warrant further reduction. Such criteria could conceptually also be expressed as a collective population exposure, but this would create implementation difficulties.

A regulatory cutoff could be expressed in terms of concentrations or specific activities of radionuclides or defined mixtures of radionuclides which could be disposed of without concern for their radiation hazard. Whether this level of detail is best done by EPA or should be determined by the NRC through regulation and specific licensing requirements is a matter we will discuss in planned interagency meetings. We would also appreciate your comments on this aspect.

Another possible way of accomplishing the purpose, technically, would be to limit the total quantity of radionuclides that might go into some municipal facility, such as a sanitary land fill. This would be difficult to administer however, and it is not clear who would have the authority to enforce this.

## PROJECT TECHNICAL ANALYSIS

There are additional reasons why a technical analysis is required, let me just mention a couple. First, a regulatory cutoff must be realistic and accomplish something in terms of reducing the amount of actual radioactive waste that must be handled with full regulatory controls. Unless the potentially excluded waste streams and their disposal options are evaluated, one cannot be sure of accomplishing this.

Secondly, any regulatory cut-off must be shown to be practicable using available management systems and radiation measurement instruments. The necessary measurements for waste segregation must be ones that can be made within the regulatory framework.

The analysis framework we are using follows fairly closely to that described in the IAEA report "Definition of De Minimis Quantities for Release of Low-Level Solid Radioactive Waste Into the Terrestrial Environment From Incineration Plant and Landfill Facilities."(4) Although we had not read this report when we initiated our technical analysis it was reassuring to see we were so closely in line.

Using the basic waste stream categories established by the NRC we have identified some low activity streams as possible candidates for being "below regulatory concern". We will determine estimates for the cost of disposal of these waste streams with and without their being included below a regulatory cutoff. This must include the differences in transportation costs and the increased cost of segregating the wastes in the case of "below regulatory concern". We also will evaluate the cases of with, and without, special treatment and packaging. Straight sanitary landfill and incineration followed by landfill of the ash will be considered.

For each of the alternatives for which we will make a cost estimate, we will also make a risk estimate, determining maximum individual and population doses. This will also have to consider the exposure for workers at an incinerator or a sanitary landfill who cannot be considered radiation workers.

Most of the information needed for this analysis is available at some level of certainty. Those that are particularly uncertain are the volumes of industrial and institutional wastes that might be effected, the potential cost savings, and the costs of the potential additional waste segregation. Any information you might develop through case studies for specific types of facilities would contribute to this analysis, and would be greatly appreciated.

The analysis described will give us a basis to make some initial judgments on the appropriate level of a regulatory cut-off. At the same time we must evaluate the program implications of the judgments we make. This will include considerations of compatibility and consistency with other present and anticipated radiation standards and regulations. The AIF report "de minimus Concentrations of Radionuclides in Solid Wastes"(5) should be particularly helpful in this respect. We must also evaluate, through our intra-agency working group, whether our aproach has any implications for other EPA standard setting programs. The process has already begun and at this time we see no problems with the general approach.

Because we think that establishing a level "below regulatory concern" for low-level radioactive waste disposal is potentially very important to assisting the nations disposal problems, we are considering proposing it ahead of the complete low-level waste disposal standard. Several considerations must be resolved in making this decision:

- Will we have an adequate analysis to describe the impact, both in population risks and economics, before we complete the analysis for the whole standard?
- Will the early establishment of a "level below regulatory concern" or "level requiring minimal control" rule out any viable options for a final standard?
- Will the additional administrative requirements and hearings delay the final standard issuance beyond an acceptable time?

We have targeted May 1983 to make this decision.

## NONTECHNICAL ISSUES

There are several issues that do not lend themselves to technical analysis. We would particularly appreciate discussions with you on these.

We have seen some indication that there may not always be a willingness to take on the administrative difficulties of doing a waste segregation as would be necessary to utilize a regulatory cut-off. Our information base on this is limited, and primarily reflects recent experience with carbon-14 and tritium wastes in scintillation vials and animal carcasses that NRC has deregulated. We understand some facilities still send these to low-level radioactive waste disposal facilities. We realize there have been other difficulties in implementing this regulation such as incompatible DOT labeling requirements and the high cost of disposing of these wastes as hazardous wastes, therefore, it may be too early to make a true evalution.

There is some question as to whether there is a willingness to take the responsibility for waste segregation where there is the possibility of making an error. We know that even today there are materials placed in low-level radioactive waste containers, not because they really fit that definition, but because they are merely suspect and the disposer did not want to take the chance of being wrong.

One of the most difficult circumstances to evaluate is the potential interactions that may occur with the municipalities and their waste disposal authorities. Will they be willing to accept the definitions established at the Federal level? Similarly, will the waste generator be willing to undergo the difficulties that may result from dealings with such authorities? We have seen instances in recent times when even the best designed sanitary landfills become entangled public issues. Will the specter of having "radioactive waste" placed in such facilities create an even greater issue that the waste generator may not want any part of?

I believe that these questions, and others that have come to your own minds, provide an excellent basis for dialogue. I invite you to let us hear your points of view and questions.

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DRAFT

Aug 26, 1982

Enclosure 7

# FEDERAL POLICY ON DISTRIBUTION OF POTASSIUM IODIDE TO THE GENERAL PUBLIC AROUND NUCLEAR POWER PLANT SITES FOR USE AS A THYROIDAL BLOCKING AGENT

Lay in T7

The use of potassium iodide (KI) is effective as a thyroidal blocking agent in preventing the accumulation by the thyroid gland of radioiodine which has entered the body through inhalation or ingestion. The radioiodine accumulation in the thyroidal can be reduced to less than 10% of what it would be without a blocking agent by a daily oral intake of 130 milligrams of KI providing administration is started before or simultaneous with the exposure to the radioiodine and treatment continues for at least 48 hours beyond the time of the last exposure. This effectiveness decreases to less than 50% blocking of the radioiodine uptake if the administration of the KI is delayed until 4 hours after the ingestion or inhalation.

It has been proposed that KI be distributed to the population surrounding all commercial nuclear power plant sites so that it could be administered in the event of an accident which results in a large airborne release of radioactivity which includes large quantities of radioiodine. The Food and Drug Administration has evaluated the medical and radiological risks of administering KI for thyroidal blocking under these emergency conditions and has concluded that it is safe and effective and has approved over the counter sale of the drug for this purpose. Recent FDA guidance states that risks from the short term use of relatively low doses of KI for thyroidal blocking in a radiation emergency are outweighted by the risks of radioiodine induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 REM.

The U.S. Nuclear Regulatory Commission (NRC) and the Federal Emergency Management Agency have already issued guidance to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG-0654/FEMA-REP-1, Rev. 1 recommending the stockpiling and distribution during emergencies of KI for thyroidal blocking to emergency workers and to institutionalized individuals who might be difficult to evacuate.

This recommendation was made because: (1) the number of individuals for any site is small and requires a limited supply of KI that can be readily distributed; (2) these individuals would be more likely to be exposed to a radioactive plume in the event of an accident; (3) the medical histories of the limited number of such individuals can be reviewed and the distribution and administration of KI readily controlled; and (4) these individuals can be readily monitored for adverse side effects by medical personnel. This guidance on the distribution and use of KI for all commercial nuclear power plant sites is hereby Federally endorsed as a viable protective action for this limited number of individuals in the event of a catastrophic nuclear power plant accident.

It is recognized that the decision to use KI for thyroidal blocking to protect the public health and safety resides with the State and local health authorities. Therefore, with the exception of the NRC licensee's personnel located onsite during the accident, the decision for use of KI during an actual emergency by all other individuals for whom the use of KI is recommended are the responsibility of these authorities. In addition, because the factors bearing on the desirability of stockpiling and distributing KI for thyroidal blocking of the general population within Emergency Planning Zone for the Plume Exposure Pathway (a radius of approximately 10 miles around the plant) depend heavily on local conditions, this matter is a decision for State and local authorities to make. In deciding whether to distribute and use KI for the general population, these authorities should carefully evaluate advantages and possible problems in implementing this program for the specific nuclear power plant(s) within their jurisdiction.

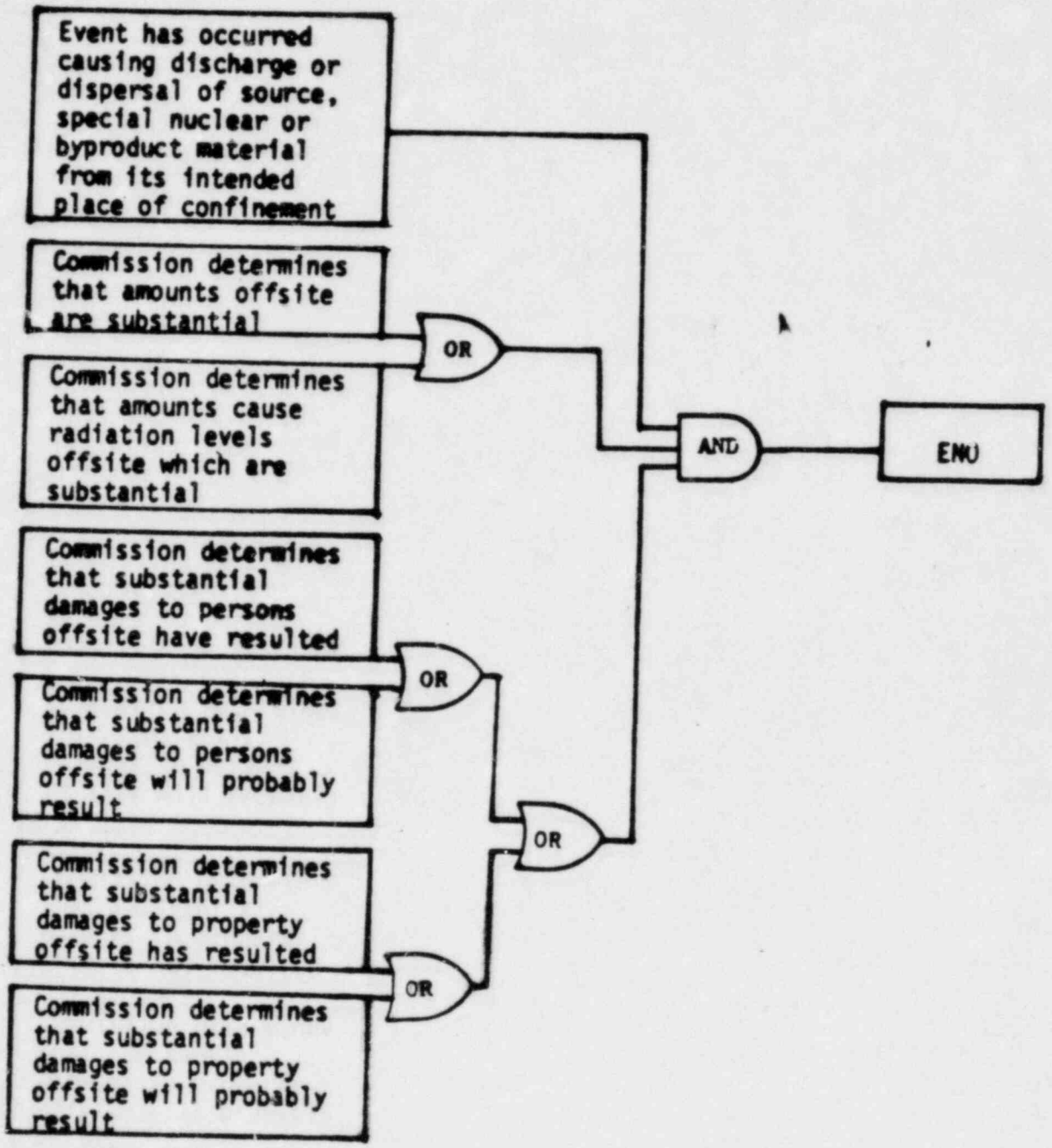
One of the considerations in deciding whether to implement the use and distribution of KI for the general population is that KI blocking only effectively reduces the radiation exposure of the thyroid gland. While this is an important contribution to the health and safety of the individual, it is not nearly as effective as measures which protect the total body of the individual from radioactivity. Both in-place sheltering and precautionary evacuations can reduce the exposure to the total body. As an example, if a precautionary evacuation of the population can be instituted with little or no radiation exposure, this may be the most effective protective action. However, there are instances where evacuation may not be preferred. Evacuation may be unnecessary because the amount of protection afforded by in-place sheltering is adequate to reduce exposures to values below protective action guideline levels. There are also possible situations when evacuation cannot be accomplished in time to prevent exposing large numbers of individuals to a significant amount of radiation during the evacuation. In those instances where shelter is used because the evacuation cannot be completed in time to avoid a substantial radiation insult, the administration of KI could be a useful ancillary protective action which could provide some additional exposure reduction to the thyroids of the exposed individuals. The use of KI for thyroidal blocking is not an effective means by itself for protecting individuals from an airborne release of radioactivity from a nuclear power plant accident and therefore should be used in conjunction with sheltering, evacuation or other protective methods.

Other considerations and problems to be evaluated by the State and local authorities in deciding whether to institute this program include: (1) whether the KI should

be distributed to the population before the accident occurs or be distributed as soon as possible after the accident occurs; (2) whether evacuation can be completed more quickly than distribution of KI for the particular nuclear power plant site in question; (3) how the KI will be distributed during the emergency; (4) what medical assistance will be available to assist the individuals who may have some adverse reaction to KI; (5) how medical authorities will advise the population to take KI and under what circumstances this advice will be given; (6) if KI is predistributed, what assumptions should be made about its availability; (7) how the authorities will provide KI to transient populations; and (8) whether use of other respiratory devices (e.g., dust masks) may be equally cost-effective.

In summary, the use of KI to prevent radioiodine from accumulating in the thyroid gland can be an effective ancillary protective action during a nuclear power plant accident. Whether KI should be stockpiled and distributed for the general public around a particular site depends on local conditions and a decision on its use during an emergency depends on accident and environmental conditions that may prevail at the time. Its use should be evaluated by each State or local jurisdiction based on the specific conditions and site environment for each operating commercial nuclear power plant. If the decision is made to use KI to protect the general population, specific plans for the distribution, administration and medical assistance should be developed to assure its effectiveness.

DEFINITION OF PROCESS FOR DETERMINING WHETHER
"AN EXTRAORDINARY NUCLEAR OCCURRENCE" HAS OCCURRED
AS GIVEN BY SECTION 11j. OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED



## SUMMARY OF EEI "DE MINIMIS" PROJECT

### Introduction

For several years, the radiation scientific community has been discussing the question as to whether there was a level of radiation exposure (or quantity or concentration of radioactive material) that is so trivial that it would represent a cut-off point below which scientists and regulators can ignore the exposure. The possible value of such a regulatory cut-off, a regulatory threshold, continues to be discussed and debated by several radiation standards-setting organizations, by the radiation scientific (medical, biologic, health physics, etc.) community, by regulated users of radiation sources, and by the various state and Federal regulators.

The law has long recognized that there are trivial matters that need not concern it. The maxim, "de minimis non curat lex" (the law does not concern itself with trifles) expresses that principle, and has generally been used in the shorter phrase: de minimis.

Currently, scientists debate the hazards of very low exposures to radiation, arguing whether the effects on people are represented by a biological threshold and whether there is some effect even at very low exposures. Currently, regulatory policy is based on the prudent assumption that effects are possible even from very low exposures and that the effects on populations of people are the same whether the exposures are high for one person but low for the rest or generally even among the population.

However, even current regulatory policy (and generally the statutes under which the regulations have been derived) provide for specific exemptions from regulation of certain categories of radiation exposure, or quantities or concentrations of radioactive material. Maximum exposure standards establish the high level for a range of permitted exposures, with the lower level either set by exemptions or, theoretically, down to zero.

These exemptions are set forth in NRC and EPA regulations, but have been derived without the existence of consistent and uniform criteria. In most instances, it is difficult to identify the bases on which many exemptions were calculated and included in regulations. Compliance inspectors tend to use such arbitrary numbers in regulations as firm and binding on radiation users and issue orders to comply without consideration of alternatives or possible exposure to people and issue citations and fines for failure to comply. A

scientifically derived de minimis level, or set of criteria, would be an essential element in the development of rational, objective, consistent and uniform regulatory cut-off levels.

As a further practical reality, radiation exposures can never reach zero, well below a natural background radiation level. This level varies from place to place and from individual to individual and will exist relentlessly regardless of any additional radiation exposures, no matter how large or small, arising from the activities of man. The variation will depend on many factors, including diet and smoking habits, and results in a potentially wide range of biological effects.

EEI Objectives

EEI funded a study of the feasibility of establishing a de minimis level of radiation dose and a regulatory cut-off policy for nuclear regulation. The report, prepared for EEI in December 1981 by General Physics Corporation, concluded that such a program was feasible using the variation in natural background as one approach. The report further recommended industry initiative in encouraging the radiation regulatory agencies to establish and adopt such a policy.

EEI's objective is to seek mechanisms through which a national regulatory cut-off policy for radiation can be proposed and set in place to assure a consistent and uniform approach to dealing with low level radiation situations, to cease regulating trivial exposures. An Executive Order from the President, with a reasonable time, is desirable to implement such a policy. This Order could be a product of the Presidential Task Force on Regulatory Reform, of an interagency task force established by EPA under its radiation guidance authority, or of other regulatory review authority. A target date of early 1983 would seem appropriate.

Alternatively, or initially, EEI would seek such a regulatory policy within NRC for all licensees including nuclear utilities. A directive from the NRC Commissioners to the NRC staff would be necessary to define the internal NRC generic criteria and then to implement the criteria for all current and pending NRC rulemaking.

A similar regulatory cut-off policy implemented by state radiation control agencies will also be encouraged. The states' radiation control directors have urged such a policy for low-level radioactive wastes.

Development of Criteria

The EEI effort is directed toward the development of consistent and uniform criteria for use by radiation regulatory agencies, whether Federal, state or local. EEI will not propose dose, quantity, concentration, or effluent levels for radiation or radioactivity. The criteria will recognize that below derived de minimis levels there may be some risk but that the risk, when compared to the variation in risks of natural background or to general societal risks, need not be regulated.

EEI will urge the responsible Federal agencies, with input from states, to work together in a timely manner to develop such criteria. In addition, a coordinated industry effort by EEI and AIF should be started to draft and propose such criteria, with input from INPO and EPRI, for consideration by the agencies, or by NRC.

A petition for rulemaking by industry may be in order which could propose that all current and pending NRC regulations that, for example, provide for exemptions be amended simultaneously to require the use of the criteria as the common basis for any decisions on generic or specific exemptions. Other aspects of NRC's rules may require modification as well.

Current and Future Efforts

EEI has provided copies of the December 31, 1981 feasibility study report to many Federal and state regulatory agency contacts and to staff of other interested organizations of radiation users. Very close and cordial cooperation with AIF staff has developed and continues. EEI committees have been provided copies and have been requested to provide comments. Affected AIF committees are being encouraged to review the report and be prepared to reference it in future comments to NRC on a variety of topics.

An effort is underway to identify radiation problems which are currently being over-regulated, in the absence of a national regulatory cut-off policy. Nuclear utility "horror" stories have been solicited from several sources. Estimates of current costs imposed on nuclear utilities and ratepayers because of the absence of this policy, either by NRC or among other Federal or state radiation control agencies, indicate that millions of dollars are being required to satisfy arbitrary regulations.

An initial draft of proposed criteria has been completed and discussed with nuclear utilities' health physicists and others. As one possible action, a draft of a Presidential memorandum to Federal agencies encouraging an interagency task force on de minimis has been prepared along with a draft of a possible Presidential Executive Order implementing the anticipated report of the task force in a timely manner.

To date, contacts have been made with staff members of the Nuclear Regulatory Commission and the Environmental Protection Agency. In addition, EEI staff will discuss the de minimis effort with participants in the 14th Annual Conference of (state) Radiation Control Program Directors (CRCPD) on May 26, 1982.

Other interested groups have also been contacted, including the Atomic Industrial Forum (AIF) and the National Council on Radiation Protection and Measurements (NCRP). A de minimis project has been organized by the Health Physics Society's Committee on State and Federal Legislation.

EEI Consultant Services

EEI continues to contract with General Physics Corporation, Columbia, Maryland, for the services of Joyce P. Davis. Ms. Davis is the author of the feasibility study and combines the technical expertise of a Certified Health Physicist, Professional Engineer and attorney. This unique combination provides EEI with a balanced approach to the scientific and legal arguments and precedents relating to this program.

May, 1982

Comments on the "De Minimis" Concept Presented in
Proposed Revised 10CFR Part 20
(August 1982 Rough Draft)
by Joyce P. Davis, General Physics Corporation

NRC staff is to be congratulated for taking a giant step toward the rationalization of radiation control regulation by its explicit adoption of the concept of de minimis radiation exposures, and its program of lower "cut-off" levels for most regulations. This approach serves to focus the resources of both the regulator and regulatee on those radiation exposures that could have potentially serious consequences, and stop the waste of resources on trivial matters.

We strongly support the de minimis concept and its use by the NRC. We believe, however, that NRC could apply the regulatory cut-off concept even more widely in the proposed part 20. We also believe that the basis for the levels specified in the proposed regulations needs further discussion. Our specific comments follow:

The De Minimis Concept - Regulatory Cut-Off

The idea of a trivial (or de minimis) dose level is part of a larger concept of cut-off levels for all regulations, expressing the lower limits of regulatory concern. In addition to the doses specified as de minimis in this draft, which apply to ALARA and collective doses to the public, NRC has proposed cut-offs for monitoring, reporting, etc., applicable to specific aspects of the regulations. We support such an approach and encourage NRC to develop a de minimis policy and internally consistent cut-off levels for all its regulations.

Acceptable Risk

The NRC's approach to setting de minimis levels for the general population purports to rely on a quantitative risk assessment. The "acceptable" risk used as guidance is a level advanced by the Food and Drug



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Administration in a proposed rulemaking to establish an acceptable risk level for the presence of a carcinogen in food - a value of one DES-induced cancer death in a million per lifetime. This is a value proposed by one agency and is not a government-wide guideline. Others, in and outside of the government, have looked at values of risks that could be considered "acceptable," "trivial," or "negligible," based on the apparent unconcern with which they are viewed by the public, and have generally come up with numbers on the order of $10^{-5}$ to $10^{-6}$ per year.

Furthermore, most carcinogens, or suspected carcinogens, are substances that are not present in the natural environment in substantial quantity. Radiation, on the other hand, is not only one of the best understood and most detectable of environmental agents, but one that has been naturally present in man's environment since the dawn of human existence.

We do not take issue with the interim use by NRC staff of the FDA value, as quantification of a risk level that is certainly "trivial," in the context of proposing, for comment, levels of de minimis exposure of the general public, recognizing that it is a very conservative value. However we urge NRC to develop its own criteria for the determination of risk or dose levels that can be considered negligible in various regulatory contexts.

The Commission itself has proposed some guidance on quantified risk levels such that "individuals living or working near nuclear power plants should be able to go about their daily lives without special concern by virtue of their proximity to such plants" (emphasis added) (NUREG-0880). This is clearly a definition of a de minimis level. The proposed quantitative guidance for the risk of fatal cancers from accidents at nuclear power plants is an increment of no more than about 2 in a million per year (0.1% of the sum of cancer fatality risks arising from all other causes).

One might argue that the guidance level for the acceptable risk of a facility like a nuclear power plant that has substantial benefits associated with it should be higher than a de minimis level. However, the NRC proposed guidance in question was not based on risk-cost-benefit analysis but on the smallness of the risk relative to the normal incidence of fatal cancers.

Therefore, that proposed guidance level seems of direct applicability to setting de minimis levels for radiation-induced cancers from whatever cause.

A de minimis risk of 2 in a million per year, using the risk coefficient of Table I (which is probably a gross overestimate - see discussion below) would imply a de minimis dose of more than 15 mrem/yr, rather than the 0.1 mrem/yr used in proposed Paragraph 20.303(b)(ii).

Basis for "De Minimis" Level - Application to Calculations Relating to Public Dose

The NRC staff states that it is using a "quantified risk" approach to setting the de minimis level. The acceptable risk level is equated to a dose level by means of the "total risk coefficient" of Table I. There is no discussion of the applicability of that risk coefficient to extremely low doses in the range of 0.1 to 1.0 mrem/yr. Earlier in the discussion, however, at pg. 9, it is stated that "the risk coefficients, which were derived for exposure conditions with doses higher than are expected to occur in the application of this revision, are more likely than not to overestimate the true risk." The context in which these risk coefficients of Table I are introduced, and first used, is the setting of occupational dose limits. These limits are 5,000 to 50,000 times those that are deemed de minimis on page 39. Most radiological health experts would agree, we believe, that the assumption of linearity of risk over the range from high to these extremely low levels is, at best, only an approximate one. In this regard, the use of even two significant figures in the risk coefficient at dose rates in this very low range is unwarranted and misleading. As stated on page 17, "there is substantial reason to believe that for some radiation (x-rays, gamma-rays, electrons) the actual relationship between dose and effects is non-linear, such that the risk for low levels of exposure is actually lower than predicted by the linear assumption." In the subject draft, NRC staff acts on that belief in admonishing licensees to choose lower individual doses, generally, in preference to lower collective doses.

If NRC chooses to use risk coefficients to estimate dose, as shown on page 39, it should make it clear that this is not a true mathematical equation. It is more in the nature of an inequality: A dose of 0.1 mrem per year corresponds to a risk of less than (probably much less than) $10^{-6}$ cancer deaths per lifetime. The last full sentence on page 39 should therefore state: "Thus, if an individual were to receive an incremental 0.1 mrem per year every year for a lifetime, the estimated incremental risk of cancer death induced by that lifetime increment of radiation would be less than one in one million." (Text changes underlined.)

As an alternative to the use of extrapolated risk coefficients, the de minimis level for the general population could be set by reference to average background radiation dose levels or the variability of background. Whatever the risk associated with background radiation, it is not large enough to be detected, even in sophisticated epidemiological studies. It is generally treated as a negligible risk. A de minimis level of the order of the average annual natural background dose (about 100 mrem) to an individual in the U.S., or a substantial fraction of that dose, would not seem unreasonable. A de minimis level could also be set in relation to one or more measures of the average variability of background radiation in the U.S. over time or space. Such statistical measures could be derived from data already in existence.

An additional advantage of using background levels rather than extrapolated risk coefficients as the basis for a de minimis level lies in the fact that background levels (and their variability) are measured and known to a fair degree of certainty. Their order of magnitude is well documented. Risk coefficients, on the other hand, are "known" only by extrapolation over five or more orders of magnitude.

Other Applications of the "De Minimis" Approach

a. Occupational Levels

The concept of a level of "no regulatory concern" is a broad one and can apply to all regulations. Every time an upper limit is set, there should be a lower cut-off set as well. In particular, as applied to 10CFR20, we believe

that, in addition to cut-off limits for personal monitoring, there should be a de minimis level for occupational exposure that would serve as a floor for occupational ALARA calculations and for truncation of collective occupational dose estimates. Based on the internal logic of the proposed regulations, using the staff assumptions and the proposed de minimis value for dose to the public, it appears that an analogous de minimis level for occupational dose would be about 50 mrem/yr. Because plant populations are small and comprise only adults, a different level for collective doses does not seem appropriate. If these additional de minimis levels were adopted, occupational ALARA calculations would never have to include doses below a level of about 50 mrem/yr (1% of the occupational dose limit) and collective dose calculations could be truncated at about the same level.

This suggestion is consistent with NRC's allowances of a 1% additional dose to overexposed workers. It is, in effect, saying that 1% of the occupational limit is negligible for workers. It would also serve to foster the reduction of relatively larger doses in preference to collective doses, since the contribution of very small doses (below .05 rem) to collective dose calculations would be eliminated.

Suggested Addition to Regulations, Para. 20.21(d)

> A de minimis dose level of 50 mrem (.5 mSv) per year may be applied to any individual occupational dose estimate and may be used to truncate collective occupational dose estimates.

b. Waste Disposal

NRC should consider establishing de minimis quantities and concentrations of radioactive materials, in addition to the quantities derived from ALI and DAC tables, for application to radioactive effluents, wastes and scrap. NRC should also consider setting a lower limit on "radioactivity" (e.g., 10CFR Section 71.7 sets 0.002 uCi/gm for shipping) and "contamination." Quantities and concentrations paralleling those in other parts of the regulations (e.g., "exempt" and "unimportant" quantities or fractions thereof) could be set as de minimis. The setting of de minimis levels does not imply that those levels must be met before particular waste materials can be disposed of. For wastes

for which there might be regulatory concern (i.e., those not meeting de minimis criteria), approval would still be required pursuant to 20.1002, and a particular or generic ALARA level, above the de minimis level and consistent with the requirements of part 20, would be involved.

The de minimis guidance for concentrations in air and water (derived from ALI and DAC tables) are useful for airborne and aqueous effluents and wastes. The availability of similar guidance for solutions and dispersions in oil, soil, sludge, resin, concrete, etc., and for contamination levels for protective clothing and similar materials would permit the saving of regulatory and administrative effort and the optimum use of disposal site space. It would also reduce unwarranted shipping and burial costs for wastes that are only nominally radioactive and not at all hazardous.

The concentration of natural radioactivity in rock and other materials might provide a basis for setting de minimis levels for such solid materials.

Comments on Text of the Regulations

Paragraph 20.2 Definitions (Individual definitions should be numbered)

On page 6, item (d):

Alphabetically "de minimis exposure" should be (c) not (d). We suggest, in the second line, "a calculated" be replaced by "an estimated." First of all, "calculated risk" has a special idiomatic meaning not intended here. Secondly, the "calculations," as described above, are very inexact. To avoid misleading implications of accuracy, "estimated" is better.

(page 11)

"Radiation" (a)

"Radioactive material" - we suggest adding a lower limit, i.e., "means material which emits radiation spontaneously, having a specific activity in excess of 0.002 microCurie per gram."

(page 32)

Paragraph 20.303(b) (Suggest re-numbering as 20.304)

The introductory material in section (1) should be deleted. It is ambiguous, since it can be read as permitting the use of the de minimis level in a particular case only if one first determines that there would otherwise be an unwarranted commitment of resources. A de minimis level is one that is so trivial that once it has been set, no such prior determination need be made. If this language is intended to be merely introductory descriptive material, it should not be part of the regulation, but should be put into the statement of considerations. If NRC believes it must appear in the regulation, as a statement of the basis for the regulation, it should be included only as a footnote.

Section (2) should be deleted in its entirety. There is no need for a separate accounting procedure for sub-de minimis doses. If a licensee must prove compliance with this section, he must keep records and do calculations below the de minimis levels and NRC will have to inspect and review them. That is exactly what setting these de minimis levels is meant to prevent. The licensee is responsible for keeping all doses, to everyone, below the applicable limit, ALARA, and generally below the reference level. That is all that is necessary. The de minimis level should be treated, not as a limit, but as an administrative convenience. Any gross misapplication of the de minimis regulations is likely to be readily detected. The cumulation of de minimis levels would be subject to detection long before the reference action levels were reached.

Thus, the section (b) should contain only the items now numbered (i) and (ii).

We believe the values of de minimis dose, used in the August 1982 draft revision, are quite conservative and could be increased by a factor of 10 or more without compromising the triviality of the risks involved.

Nomenclature

Because the term "de minimis" has been used by different people in somewhat different contexts, and because the use of Latin might appear obfuscatory to the public, we believe NRC should denominate the levels it now calls "de minimis" in some other way. They might be called "cut-off" levels, "levels of no regulatory concern," etc. Alternatively they could be called "reference levels" generically, and then specifically denominated by their function, i.e., "minimum termination level for public ALARA calculations," "collective public dose truncation level," "minimum termination level for occupational ALARA calculations," etc.

October 25, 1982

For Presentation at ACRS the Joint Meeting of the ACRS Subcommittee Reactor Radiological Effects and Site Evaluation, November 12, 1982.

Feasibility and Methodology for Establishing Regulatory Cut-Off Levels

- Joyce P. Davis, General Physics Corporation, Columbia, MD

I. The "De Minimis" Concept

A. The Legal Concept of "De Minimis"

B. The Regulatory Concept of "below regulatory concern"

C. The concept of negligible risk

D. The concept of radiation doses of no concern

II. The "De Minimis" Program of the Edison Electric Institute

A. Initial Feasibility Study

B. Document Preparation

C. Industry Benefits Questionnaire

D. Current Status

E. Future Efforts

III. The Nature of a Regulatory Cut-Off Policy for Low-Level Radiation Doses

A. Policy Statement

B. Guidance for Implementation

C. Criteria for "De Minimis" Levels

D. Methodologies for Setting Particular Cut-Off Levels

IV. Approaches to Setting Cut-Off Levels for Radiation Doses

A. Scientific Approaches

1. Practical Thresholds

a. Latency

b. Integer Effects

2. Comparative Approaches

a. Non-Detectability

(1) Radiation

(2) Health Effects

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(3) Risks

b. Relation to Background

(1) Background Radiation Doses

(2) Background Health Effects

(3) Background Risks

c. Relative Contrubution to Regulated Dose

B. Regulatory Approaches

1. Derivation from Current Standards

2. Derivation for "Safety Goal" guantitative risk guidance value

3. Derivation from expert opinion

4. Derivation from dose, effect, or risk levels deemed "acceptable" to the public

5. Limitation to less than one projected effect

6. Risk-Cost-Benefit Balancing

V. Current Applications

A. 10CFR Part 20

1. "De Minimis" Public Dose - included in August draft

- ALARA Cut-Off

- Impacts Truncation

2. "De Minimis" Occupational Doses - not addressed

3. "De Minimis" Effluents and Wastes - included in August draft by implication for water and airborne radionuclides; other media not addressed

4. Definition of "Radioactive" and "Contaminated" - not addressed in August draft.

B. 10 CFR Part 61

1. Category of wastes "Below Class A" not defined

C. NRC Safety Goal

1. "Negligible" risk criterion for accidental deaths.

D. EPA Re-Entry Criteria

E. State Regulation

VI. Other Areas of Application

A. Setting Regulatory Priorities

B. Guidance for Enforcement

C. De-Commissioning

D. Legal Implications

1. Cut-Off for Interests Affected

2. Cut-Off for Compensation

3. Guidance for Reviewing Courts

E. Public Understanding

VII. Problems

A. Opposition of Anti-radiation Persons

B. Scientific "Purism"

C. Regulatory "Ratcheting"

D. Accumulation to Significant Levels

VIII. Benefits

A. Public Assurance

B. Economic Savings

C. More Optimum Use of Resources

D. De-Regulation

References:

"The Feasibility of Establishing a "De Minimis" Level of Radiation Dose and a Regulatory Cut-Off Policy for Nuclear Regulation" by J. P. Davis General Physics Corporation Report GP-R-33040 (December 31, 1981).

Summary of EEI "De Minimis" Project (May, 1982).

ELEMENTS OF A DE MINIMIS POLICY

- IDEA OF CUT-OFF LEVELS
- BASES FOR DETERMINING CUT-OFF LEVELS
- GUIDANCE FOR REGULATORY IMPLEMENTATION

## INCREMENTAL DOSE AND RISK - REGULATORY LEVELS

Schematic Diagram - Not to Scale

Decreasing Risk

Decreasing Regulatory Concern

| Lifetime or Annual Risk | | Dose or Dose Rate |
|---|---|---|
| Substantial Risk of (non-stochastic) Injury | Hazardous Level | Hazardous Dose |
| Allowable Risk | Exceptional Limit | Permissible Dose in Exceptional Case |
| No Undue Risk | Limit | Permissible Dose |
| | Action Level (Administrative Limit) | Action Level Dose |
| ALARA Risk | ALARA Level for specific case (can be anywhere between limit and exemption level) | ALARA Dose |
| Minimum Practicable Risk | Exemption Level (Generic ALARA) | Minimum Practicable Dose |
| Negligible Risk | "De Minimis" Level | Negligible Dose |
| Zero Incremental Risk | Background Level | Zero Incremental Dose |
| Zero? Risk | (Theoretical) Absence of Radiation | Zero Dose |

J. P. Davis 10/82

Summary of Previously Proposed De Minimis Levels

| Name | Definition and Application | Suggested Quantitative Value |
|---|---|---|
| Eisenbud (1980)<br>Ref 1 | Level below which exposures are ignored. | Whole body external - 20 - 100 mrems/yr. |
| Rossi (1981,82)<br>Refs 24, 25 | Level of "no concern" Cut-off for ALARA. | 30% of natural background. |
| Wilson (1981)<br>Ref 2 | No observable effects on health. | 500 mrems/yr for low-LET radiation, as low as 100 mrems/yr. |
| Webb & Watson (1977)<br>Ref 26 | Level that individual does not consider in decision making. Proposed cut-off level for ALARA and optimization. | 10 mrems/yr to organ or to whole body. Cut-off for a single "practice" at .1 mrems/yr. |

| Name | Definition and Application | Suggested Quantitative Value |
|---|---|---|
| Weinberg & Miller<br>Refs 27, 28 | Low dose radiation standard for individual in population. | 2 mrems/yr. |
| NCRP (1979)<br>Ref 29 | "de minimis" dose. (Draft) | 10 mrems/yr. |
| ICRP<br>Refs 30, 31 | Calculation of collective doses. | Stop calculations when further summations change results by less than a factor of 3. |
| | | |

## POSSIBLE BASES FOR DE MINIMIS LEVELS

RISK COMPARISON

- "ACCEPTABLE" RISK
- "NEGLIGIBLE" RISK

BACKGROUND DOSE COMPARISON

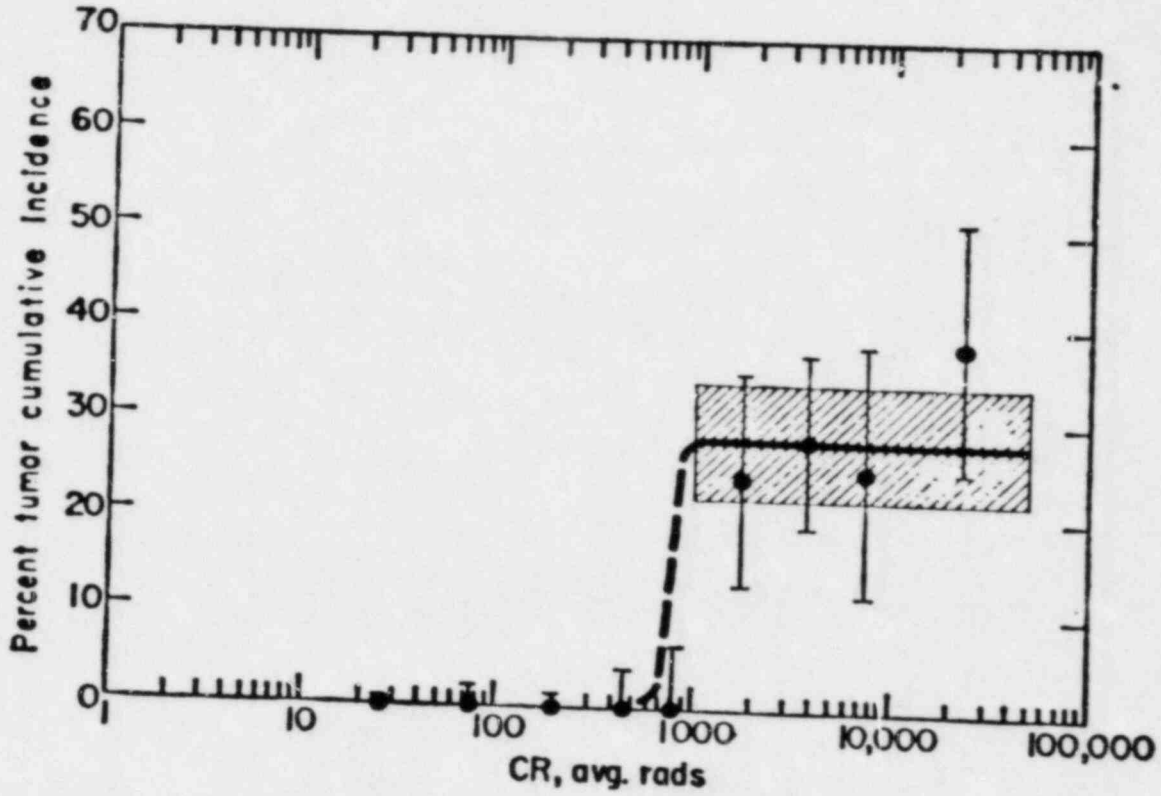
- FRACTION OF BACKGROUND
- RELATED TO VARIABILITY OF BACKGROUND

GENERIC BENEFIT/RISK EVALUATION

RELATIVE LEVEL COMPARISON

- FRACTION OF LIMIT
- INCREMENTAL EFFECT ON TOTAL

ADOPTION OF A CURRENT GUIDANCE VALUE




Practical Threshold of Latency

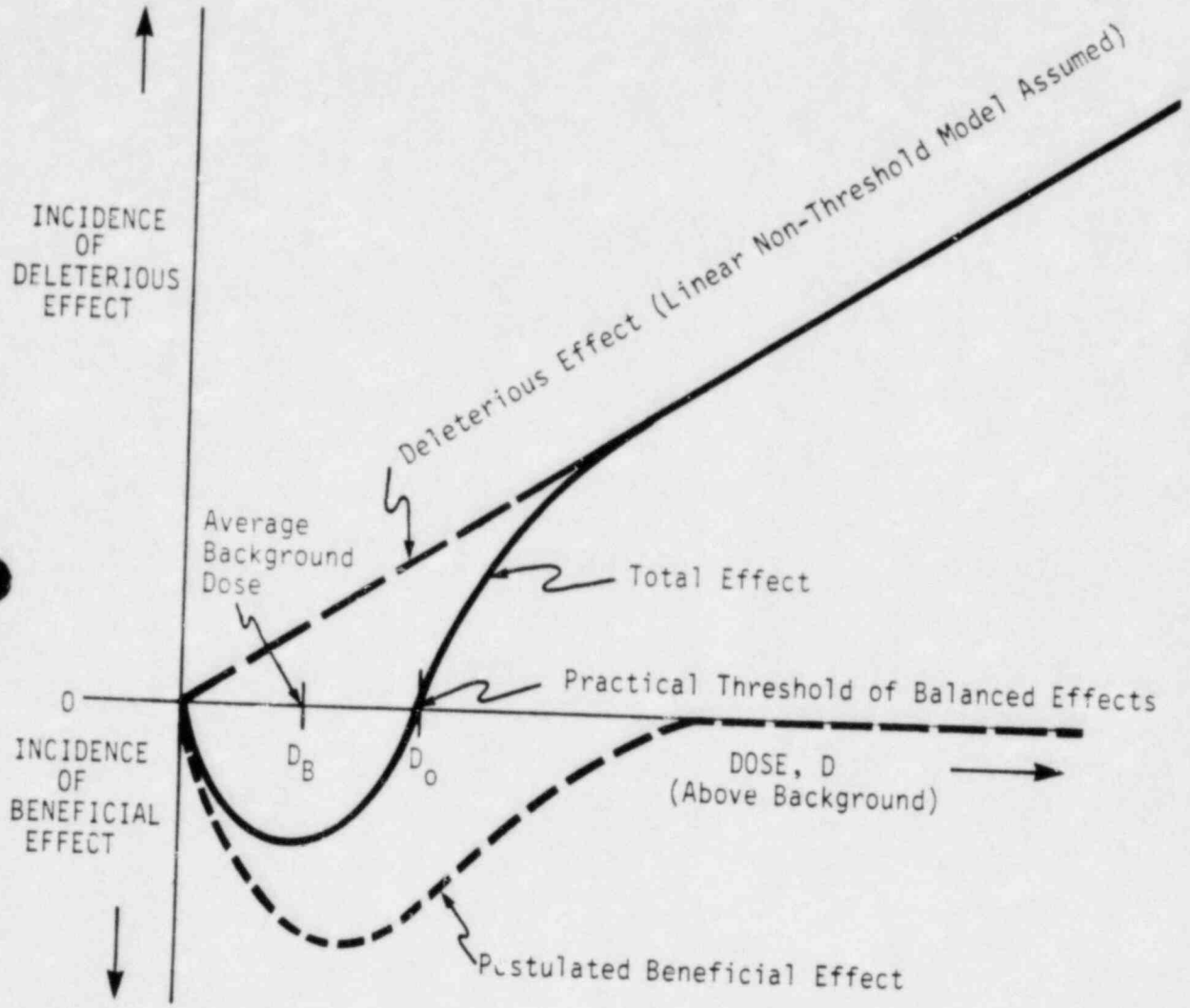
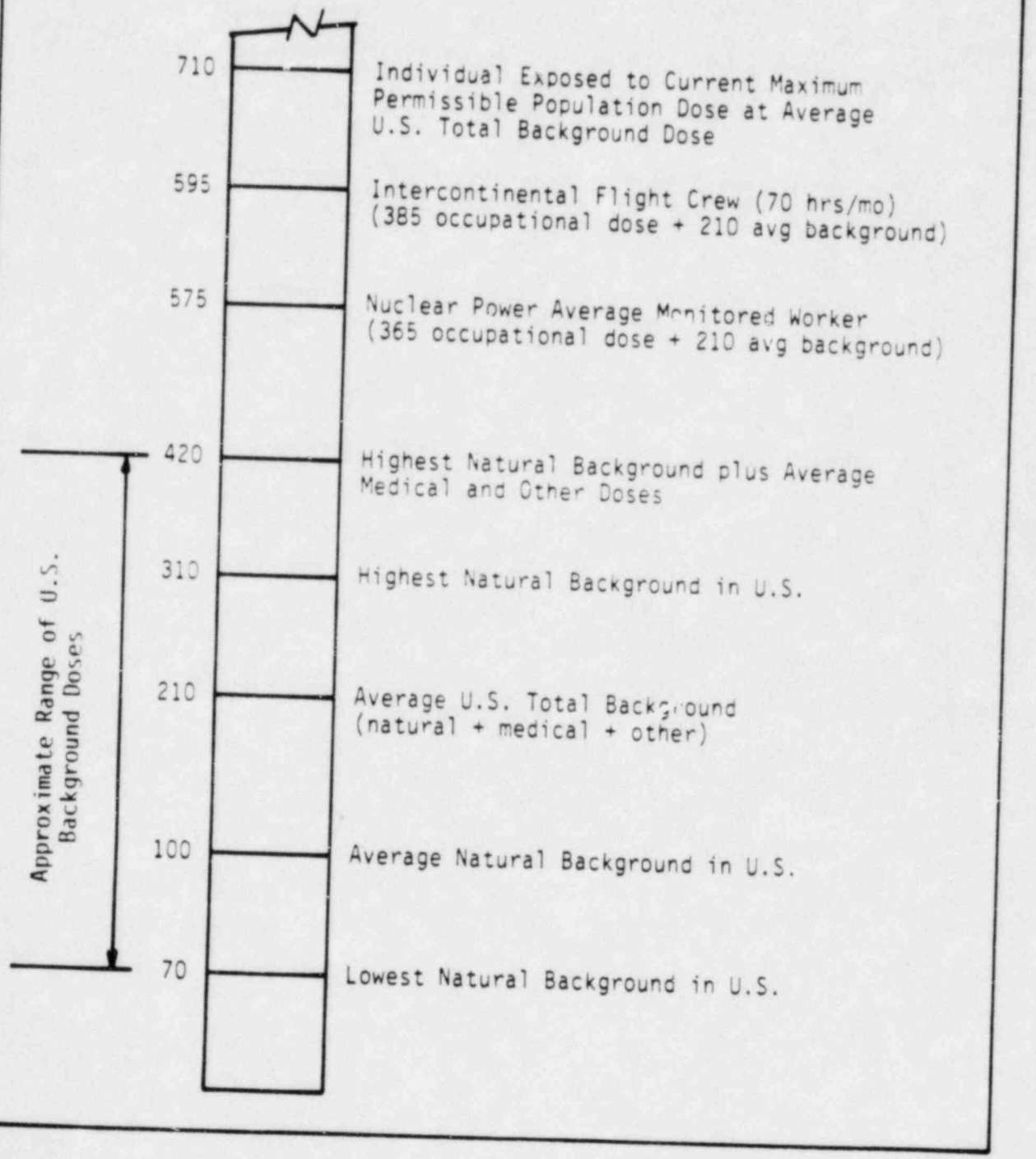

INCIDENCE OF DELETERIOUS EFFECT
Deleterious Effect (Linear Non-Threshold Model Assumed)
Average Background Dose
Total Effect
Practical Threshold of Balanced Effects
0
INCIDENCE OF BENEFICIAL EFFECT
$D_B$
$D_o$
DOSE, D (Above Background)
Postulated Beneficial Effect

Fig. (c) Examples of Estimated Annual Doses to Individuals in the United States (mrem)



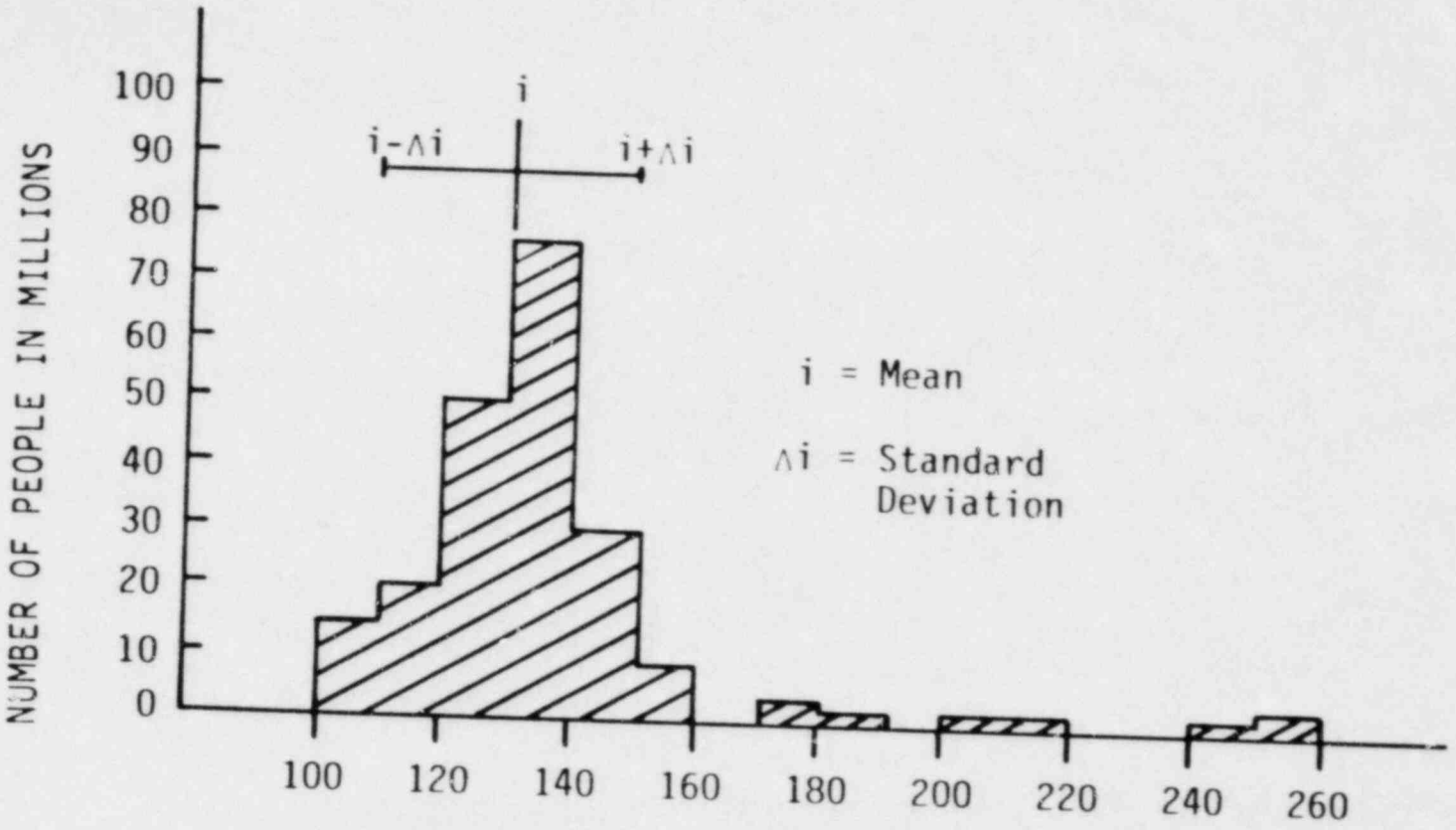

Relative Levels of Radiation Exposure

## Natural Background Levels and Variability

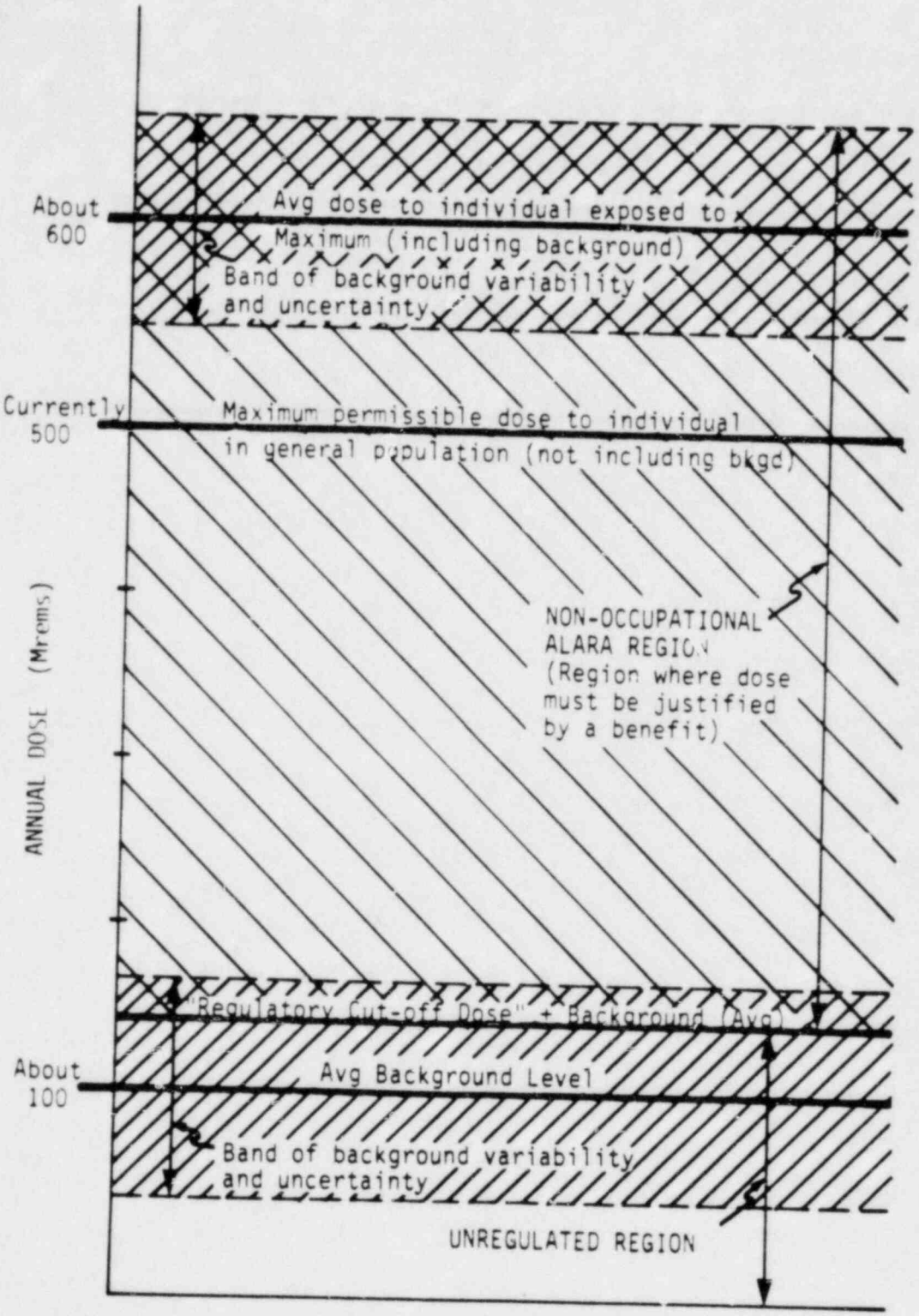
| Area | Population Included | Background Level (mrem/yr)* |
|---|---|---|
| U.S. (Atlantic & Gulf Coast) | 6,760,000 | 65 - 70 |
| U.S. (Non-coastal Plains) | 46,780,000 | 80 - 95 |
| U.S. (Colorado Plateau) | 1,070,000 | 125 - 160 |
| U.S. (Leadville, CO) | 10,000 | 235 |
| U.S. (Central Florida & New England Areas) | ? | 200 |
| Brazil (Coastal Strips) | 30,000 | 500 |
| France (Granite Rock Areas) | 7,000,000 | 180 - 350 |
| India (Kerala & Madras States) | 100,000 | 1300 |
| Niue Island (Pacific) | 3,000 | 1000 |
| Egypt (Northern Nile Delta) | Densely Populated | 300 - 400 |
| World (Calculated Average) | 2 billion | 80 - 90 |

*Note: Levels given are for external radiation only. Internal doses not included.

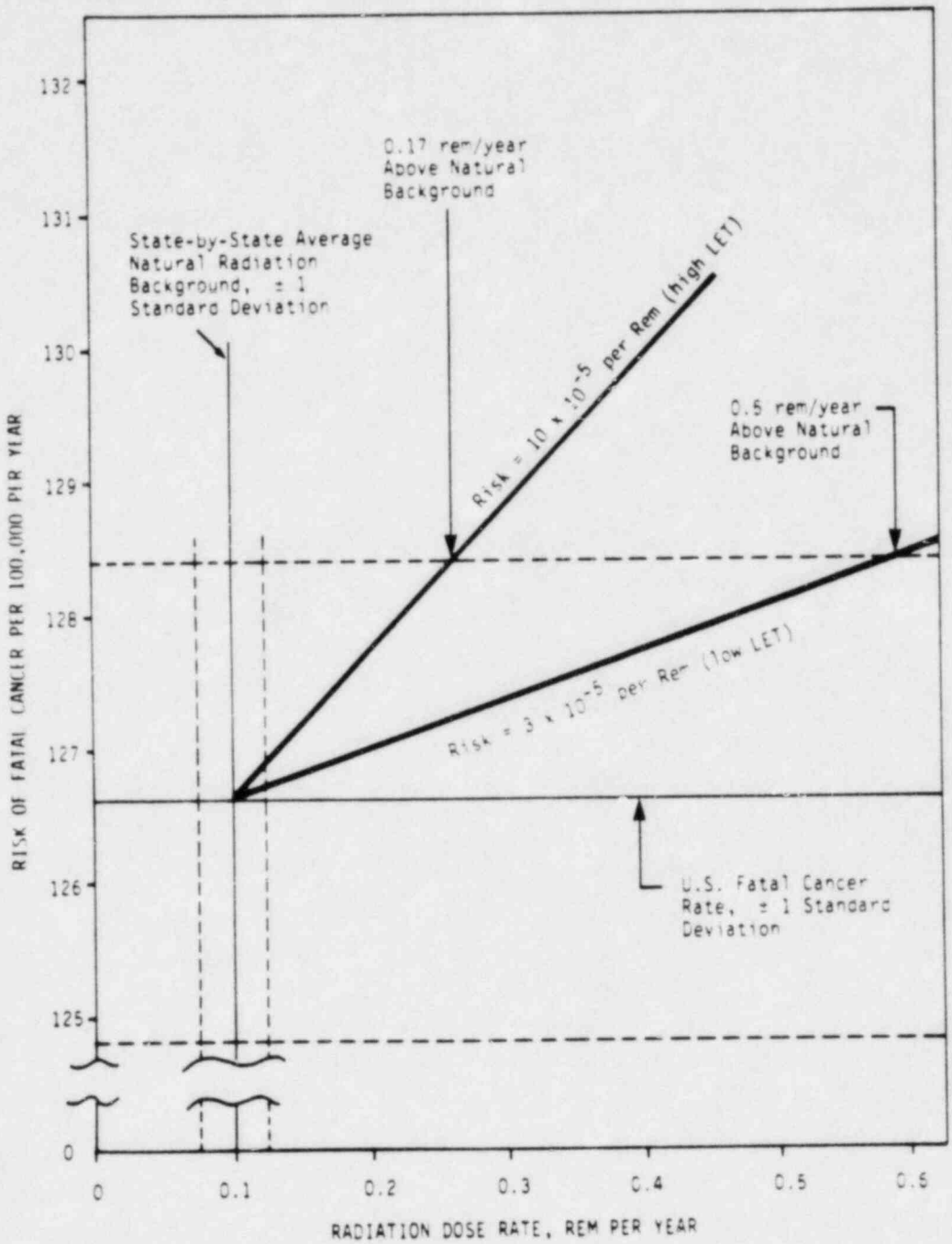
From: NIH Publication No. 80-2087




Variability of State-by State Average Natural Backgrcund Levels (Adapted from Adler and Weinberg "An Approach to Setting Radiation Standards", 34 Health Physics, pp 719-720, 6/78)




Schematic Diagram of Application of a Regulatory Cut-Off Level for Non-Occupationally Exposed Individuals Based on Background Variability




Calculation of De Minimis Doses Based on Comparison with Background Cancer Risk (Adapted from "A Practical Threshold for Radiation" by G. H. Whipple)

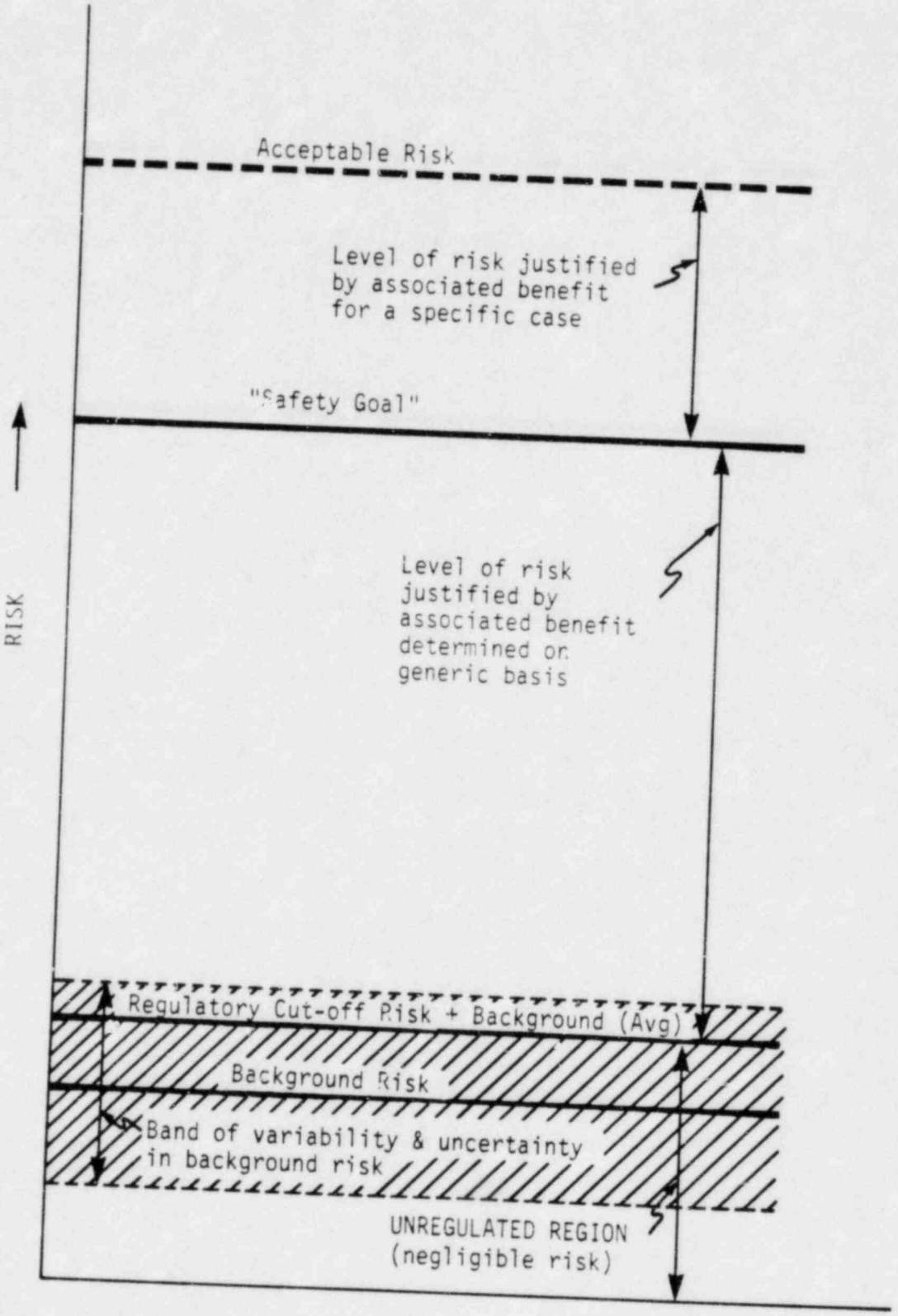
Numerical Dose Values - Possible Bases for Regulatory Cut-Off Levels

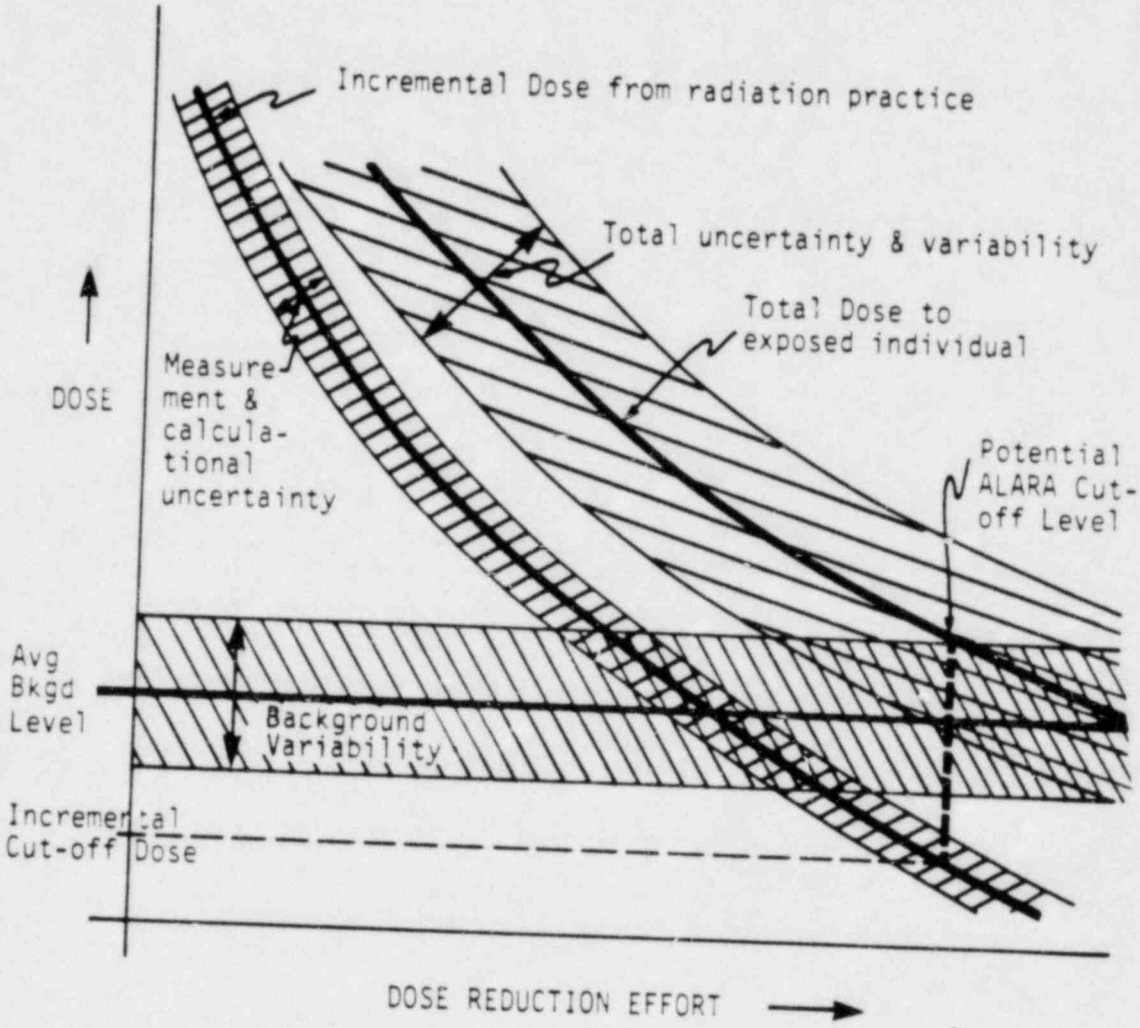
| Application | Cut-Off Level |
|---|---|
| Individual Dose Limit (general population) | 500 mrems/yr |
| Grand Junction, Co. Cut-Off for Remedial Action | 440 mrems/yr |
| Monitoring Threshold for Radiation Workers | 1200 mrems/yr<br>250 mrems/yr |
| Indoor Contamination Cut-Off for Remedial Action - Cleanup of Inactive Uranium Mill Sites | 180 mrems/yr (including background) |
| Regulatory Cut-Off Level - Negligible Dose | 100 mrems/yr |
| Population Exposure ALARA Guidance for NRC Licenses | 100 mrems/yr (proposed) |
| Guidance for Disposal or Storage of Uranium and Thorium from Past Operations | 90 mrems/yr |
| Dose Limits (general population) | 25 mrems/yr |

| Application | Cut-Off Level |
|---|---|
| Contamination Level Limit for Decommissioning | 25 mrems/yr (suggested) |
| Population Exposure Reporting Cut-Off for NRC Licensees | 25 mrems/yr (proposed) |
| Dose from Mill Tailings Disposal | 14 mrems/yr |
| Limits on Exposure from Reactor Effluents (general population) | 8 mrems/yr |
| Nuclear Facilities Decommissioning Residual Radioactivity | 5 mrems/yr (proposed) |
| Nuclear Facilities Decommissioning Residual Radioactivity | 1 mrem/yr (proposed) |
| Allowable Dose from Solid Waste Requiring No Regulatory Control or Surveillance | 1 mrem/yr (suggested) |
| Dose with no Significant Environmental Impact | 0.2 mrems/yr |

Numerical Dose Values - Possible Bases for Regulatory Cut-Off Levels

| Application | Cut-Off Level |
|---|---|
| Cut-Off Dose for Environmental Analyses | 0.1 mrems/yr (proposed) |
| "De Minimis" Level for NEPA Cost/Benefit Balancing | 1.12 mrems/yr (average over population) |
| Cut-Off Level for Regulatory Concern | Somewhere between 0.01 mrems and 10 rems. |


Acceptable Risk
Level of risk justified by associated benefit for a specific case
"Safety Goal"
RISK
Level of risk justified by associated benefit determined on generic basis
Regulatory Cut-off Risk + Background (Avg)
Background Risk
Band of variability & uncertainty in background risk
UNREGULATED REGION
(negligible risk)




ALARA Limited by Background

## BENEFITS

- PUBLIC ASSURANCE
- ECONOMIC SAVINGS
- OPTIMUM USE OF RESOURCES

# HEALTH PHYSICS POLL

| Q1 | Q2A | Q2B | Q3 | Q4A | Q4B | Q4C | Q5 |
|---|---|---|---|---|---|---|---|
| PHD | 4.0 | NO | UNIV | . | . | . | . |
| PHD | 5.0 | YES | DOE-LAB | 500 | 170.00 | 170.00 | YES |
| PHD | 6.0 | YES | UNIV | 100 | 100.00 | 100.00 | NO |
| PHD | 8.0 | NO | DOE-LAB | 25 | 5.00 | 5.00 | NO |
| PHD | 10.0 | NO | UTILITY | 25 | 25.00 | 25.00 | NO |
| PHD | 11.0 | NO | DOE-LAB | 125 | 125.00 | 125.00 | YES |
| PHD | 12.0 | NO | DOE-LAB | 20 | 5.00 | 5.00 | NO |
| PHD | 15.0 | NO | UNIV | 25 | 5.00 | 1.00 | NO |
| PHD | 15.0 | NO | UNIV | 25 | 25.00 | 25.00 | NO |
| PHD | 15.0 | NO | DOE-LAB | 5 | 5.00 | 5.00 | NO |
| PHD | 17.0 | YES | INDUSTRY | 10 | 5.00 | 5.00 | NO |
| PHD | 20.0 | YES | DOE-LAB | 15 | 5.00 | 5.00 | NO |
| PHD | 20.0 | NO | DOE-LAB | 500 | 100.00 | 10.00 | YES |
| PHD | 23.0 | NO | UNIV | 8 | 8.00 | 8.00 | NO |
| PHD | 24.0 | YES | UNIV | 5 | 5.00 | 5.00 | NO |
| PHD | 25.0 | YES | UNIV | 100 | 10.00 | 1.00 | NO |
| PHD | 25.0 | YES | DOE-LAB | 1 | 1.00 | 1.00 | YES |
| PHD | 27.0 | YES | UNIV | 30 | 10.00 | 10.00 | NO |
| PHD | 28.0 | YES | UNIV | 170 | 15.00 | 3.00 | NO |
| PHD | 28.0 | NO | INDUSTRY | 30 | 15.00 | 5.00 | NO |
| PHD | 30.0 | YES | UNIV | 5 | 5.00 | 5.00 | NO |
| PHD | 32.0 | YES | DOE-LAB | 20 | 10.00 | 5.00 | NO |
| PHD | 34.0 | NO | OTHER | 500 | 170.00 | 170.00 | NO |
| MS | 1.5 | NO | UTILITY | 1 | 1.00 | 1.00 | NO |
| MS | 2.0 | NO | UTILITY | 200 | 0.01 | 0.01 | NO |
| MS | 4.0 | NO | DOE-LAB | 1000 | 100.00 | 50.00 | NO |
| MS | 5.0 | NO | UTILITY | 25 | 25.00 | 25.00 | NO |
| MS | 6.0 | YES | UNIV | 25 | 25.00 | 25.00 | YES |
| MS | 6.0 | YES | UTILITY | 10 | 3.00 | 1.00 | NO |
| MS | 6.0 | NO | DOE-LAB | 300 | 100.00 | 50.00 | NO |
| MS | 7.0 | YES | UTILITY | 10 | 5.00 | 1.00 | NO |
| MS | 7.0 | NO | UTILITY | 5 | 1.00 | 0.10 | NO |
| MS | 7.0 | NO | UTILITY | 10 | 1.00 | 0.10 | NO |
| MS | 7.0 | NO | UTILITY | 100 | 10.00 | 0.00 | NO |
| MS | 9.0 | NO | DOE-LAB | 20 | 10.00 | 5.00 | NO |
| MS | 10.0 | NO | DOE-LAB | 100 | 100.00 | 100.00 | NO |
| MS | 10.0 | NO | DOE-LAB | 500 | 170.00 | 170.00 | NO |
| MS | 10.0 | NO | UTILITY | 100 | 1.00 | 0.10 | NO |
| MS | 12.0 | YES | UTILITY | 20 | 2.00 | 0.20 | NO |
| MS | 15.0 | YES | DOE-LAB | 100 | 50.00 | 25.00 | NO |
| MS | 15.0 | YES | UTILITY | 500 | 170.00 | 5.00 | NO |
| MS | 15.0 | NO | DOE-LAB | 250 | 125.00 | 125.00 | NO |
| MS | 15.0 | NO | UTILITY | 100 | 1.00 | 0.10 | NO |
| MS | 17.0 | YES | DOE-LAB | 10 | 2.00 | 2.00 | NO |
| MS | 20.0 | YES | UNIV | 20 | 5.00 | 5.00 | NO |
| MS | 20.0 | YES | UTILITY | 5 | 1.00 | 0.10 | NO |
| MS | 20.0 | NO | OTHER | 100 | 100.00 | 100.00 | NO |
| MS | 25.0 | YES | UNIV | 200 | 200.00 | 200.00 | YES |
| MS | 25.0 | YES | DOE-LAB | 10 | 1.00 | 1.00 | NO |
| MS | 25.0 | NO | DOE-LAB | 5 | 5.00 | 1.00 | NO |
| MS | 27.0 | YES | DOE-LAB | 10 | 5.00 | 3.00 | NO |
| MS | 28.0 | YES | UTILITY | 10 | 1.00 | 0.10 | NO |
| MS | 30.0 | YES | UNIV | 50 | 50.00 | 50.00 | NO |
| MS | 30.0 | YES | DOE-LAB | 500 | 100.00 | 100.00 | NO |
| MS | 32.0 | YES | DOE-LAB | 100 | 10.00 | 1.00 | NO |
| BS | 3.0 | NO | UTILITY | 10 | 5.00 | 2.50 | NO |

# HEALTH PHYSICS POLL

| Q1 | Q2A | Q2B | Q3 | Q4A | Q4B | Q4C | Q5 |
|---|---|---|---|---|---|---|---|
| BS | 5 | NO | DOE-LAB | 500 | 50 | 50.0 | NO |
| BS | 5 | NO | UTILITY | 5 | 1 | 0.1 | NO |
| BS | 5 | NO | UTILITY | 50 | 20 | 10.0 | NO |
| BS | 7 | NO | DOE-LAB | 5 | 1 | 1.0 | NO |
| BS | 8 | NO | UTILITY | 25 | 25 | 25.0 | YES |
| BS | 15 | NO | UTILITY | 10 | 1 | 1.0 | NO |
| BS | 15 | NO | UTILITY | 10 | 10 | 10.0 | NO |
| BS | 20 | NO | UTILITY | 50 | 5 | 5.0 | YES |
| BS | 20 | NO | UTILITY | 50 | 5 | 5.0 | NO |
| BS | 22 | YES | DOE-LAB | 100 | 10 | 5.0 | NO |
| BS | 22 | NO | INDUSTRY | 500 | 170 | 170.0 | NO |
| BS | 23 | YES | DOE-LAB | 100 | 100 | 50.0 | NO |
| BS | 24 | YES | DOE-LAB | 300 | 100 | 50.0 | NO |
| BS | 25 | YES | OTHER | 170 | 17 | 3.0 | NO |
| BS | 28 | NO | DOE-LAB | 50 | 15 | 5.0 | NO |
| BS | 29 | NO | DOE-LAB | 30 | 10 | 10.0 | NO |
| BS | 30 | NO | DOE-LAB | 200 | 100 | 25.0 | NO |
| BS | 30 | NO | DOE-LAB | 500 | 200 | 100.0 | NO |
| BS | 31 | YES | DOE-LAB | 50 | 10 | 10.0 | YES |
| BS | 31 | NO | DOE-LAB | 250 | 250 | 250.0 | YES |
| BS | 35 | YES | DOE-LAB | 10 | 0 | 0.0 | NO |
| BS | 35 | YES | DOE-LAB | 10 | 3 | 1.0 | NO |
| MS | 15 | NO | UTILITY | 25 | 25 | 25.0 | NO |
| MS | 28 | NO | UTILITY | 650 | 65 | 6.5 | NO |

PERCENT RESPONDING

TABLE OF Q1 BY Q4A

| Q1 PERCENT | DEGREE Q4A \| | 1-19 | 20-50 | MAXIMUM EXPOSED INDIVIDUAL 51-250 | >250 | TOTAL |
|---|---|---|---|---|---|---|
| PHD | 1.27 | 7.59 | 10.13 | 5.06 | 3.80 | 27.85 |
| MS | 1.27 | 12.66 | 7.59 | 12.66 | 6.33 | 40.51 |
| BS | 0.00 | 8.86 | 8.86 | 6.33 | 5.06 | 29.11 |
| HS | 0.00 | 0.00 | 1.27 | 0.00 | 1.27 | 2.53 |
| TOTAL | 2<br>2.53 | 23<br>29.11 | 22<br>27.85 | 19<br>24.05 | 13<br>16.46 | 79<br>100.00 |

PERCENT RESPONDING

TABLE OF Q1 BY Q4C

| Q1 DEGREE / Q4C POPULATION W/IN 50 MILES<br>PERCENT | <1 | 1 | 2-19 | 20-50 | 51-250 | TOTAL |
|---|---|---|---|---|---|---|
| PHD | 0.00 | 3.80 | 16.46 | 2.53 | 5.06 | 27.85 |
| MS | 11.39 | 7.59 | 6.33 | 7.59 | 7.59 | 40.51 |
| BS | 2.53 | 3.80 | 12.66 | 6.33 | 3.80 | 29.11 |
| HS | 0.00 | 0.00 | 1.27 | 1.27 | 0.00 | 2.53 |
| TOTAL | 11<br>13.92 | 12<br>15.19 | 29<br>36.71 | 14<br>17.72 | 13<br>16.46 | 79<br>100.00 |

PERCENT RESPONDING

TABLE OF Q2A BY Q4A

| Q2A / PERCENT | Q4A: 1 | 2-19 | 20-50 | 51-250 | >250 | TOTAL |
|---|---|---|---|---|---|---|
| <5 | 1.27 | 1.27 | 0.00 | 1.27 | 1.27 | 5.06 |
| 5 TO 9 | 0.00 | 7.59 | 7.59 | 2.53 | 3.80 | 21.52 |
| 10 TO 19 | 0.00 | 6.33 | 7.59 | 7.59 | 2.53 | 24.05 |
| 20 TO 29 | 1.27 | 10.13 | 8.86 | 8.86 | 5.06 | 34.18 |
| 30 AND OVER | 0.00 | 3.80 | 3.80 | 3.80 | 3.80 | 15.19 |
| TOTAL | 2 | 23 | 22 | 19 | 13 | 79 |
| | 2.53 | 29.11 | 27.85 | 24.05 | 16.46 | 100.00 |

Q2A YEARS OF EXPERIENCE Q4A MAXIMUM EXPOSED INDIVIDUAL

PERCENT RESPONDING

TABLE OF Q2A BY Q4C

| Q2A PERCENT | YEARS OF EXPERIENCE Q4C POPULATION W/IN 50 MILES | | | | | |
|---|---|---|---|---|---|---|
| | <1 | 1 | 2-19 | 20-50 | 51-250 | TOTAL |
| <5 | 1.27 | 1.27 | 1.27 | 1.27 | 0.00 | 5.06 |
| 5 TO 9 | 5.06 | 3.80 | 3.80 | 6.33 | 2.53 | 21.52 |
| 10 TO 19 | 3.80 | 2.53 | 7.59 | 5.06 | 5.06 | 24.05 |
| 20 TO 29 | 2.53 | 5.06 | 20.25 | 2.53 | 3.80 | 34.18 |
| 30 AND OVER | 1.27 | 2.53 | 3.80 | 2.53 | 5.06 | 15.19 |
| TOTAL | 11 | 12 | 29 | 14 | 13 | 79 |
| | 13.92 | 15.19 | 36.71 | 17.72 | 16.46 | 100.00 |

PERCENT RESPONDING



TABLE OF Q2B BY Q4A

Q2B CERTIFIED HEALTH PHYSICIST? Q4A MAXIMUM EXPOSED INDIVIDUAL

| PERCENT | 1 | 2-19 | 20-50 | 51-250 | >250 | TOTAL |
|---|---|---|---|---|---|---|
| YES | 1.27 | 16.46 | 8.86 | 11.39 | 5.06 | 43.04 |
| NO | 1.27 | 12.66 | 18.99 | 12.66 | 11.39 | 56.96 |
| TOTAL | 2 | 23 | 22 | 19 | 13 | 79 |
| | 2.53 | 29.11 | 27.85 | 24.05 | 16.46 | 100.00 |

PERCENT RESPONDING

TABLE OF Q2B BY Q4C

Q2B CERTIFIED HEALTH PHYSICIST? Q4C POPULATION W/IN 50 MILES

| PERCENT | <1 | 1 | 2-19 | 20-50 | 51-250 | TOTAL |
|---|---|---|---|---|---|---|
| YES | 5.06 | 8.86 | 17.72 | 6.33 | 5.06 | 43.04 |
| NO | 8.86 | 6.33 | 18.99 | 11.39 | 11.39 | 56.96 |
| TOTAL | 11<br>13.92 | 12<br>15.19 | 29<br>36.71 | 14<br>17.72 | 13<br>16.46 | 79<br>100.00 |

PERCENT RESPONDING

TABLE OF Q3 BY Q4A

| Q3 | FACILITY Q4A MAXIMUM EXPOSED INDIVIDUAL | | | | | |
|---|---|---|---|---|---|---|
| PERCENT | 1 | 2-19 | 20-50 | 51-250 | >250 | TOTAL |
| UNIV | 0.00 | 3.80 | 7.59 | 5.06 | 0.00 | 16.46 |
| DOE-LAB | 1.27 | 11.39 | 8.86 | 11.39 | 11.39 | 44.30 |
| OTHER | 0.00 | 0.00 | 0.00 | 2.53 | 1.27 | 3.80 |
| INDUSTRY | 0.00 | 1.27 | 1.27 | 0.00 | 1.27 | 3.80 |
| UTILITY | 1.27 | 12.66 | 10.13 | 5.06 | 2.53 | 31.65 |
| TOTAL | 2 | 23 | 22 | 19 | 13 | 79 |
| | 2.53 | 29.11 | 27.85 | 24.05 | 16.46 | 100.00 |

PERCENT RESPONDING

TABLE OF Q3 BY Q4C

| Q3 | FACILITY Q4C | | POPULATION W/IN 50 MILES | | | |
|---|---|---|---|---|---|---|
| PERCENT | <1 | 1 | 2-19 | 20-50 | 51-250 | TOTAL |
| UNIV | 0.00 | 2.53 | 7.59 | 3.80 | 2.53 | 16.46 |
| DOE-LAB | 1.27 | 7.59 | 16.46 | 8.86 | 10.13 | 44.30 |
| OTHER | 0.00 | 0.00 | 1.27 | 0.00 | 2.53 | 3.80 |
| INDUSTRY | 0.00 | 0.00 | 2.53 | 0.00 | 1.27 | 3.80 |
| UTILITY | 12.66 | 5.06 | 8.86 | 5.06 | 0.00 | 31.65 |
| TOTAL | 11 | 12 | 29 | 14 | 13 | 79 |
| | 13.92 | 15.19 | 36.71 | 17.72 | 16.46 | 100.00 |

# HEALTH PHYSICS POLL ON DEMINIMIS

1. Highest Academic Degree _____

2. (a) Years of Experience _____

   (b) ABHP Certified Yes _____ No _____

3. Type of Faciiity (University, DOE Lab or Plant, Utility, Other Industry and Other _____) _____

4. Suggested Safe DeMinimis for Off-site for:

   a) Maximum exposed individual (fence post) _____

   b) Representative population within 5 miles _____

   c) Average to total population to 50 miles _____

5. Should person-rems be the governing factor? Yes _____ No _____

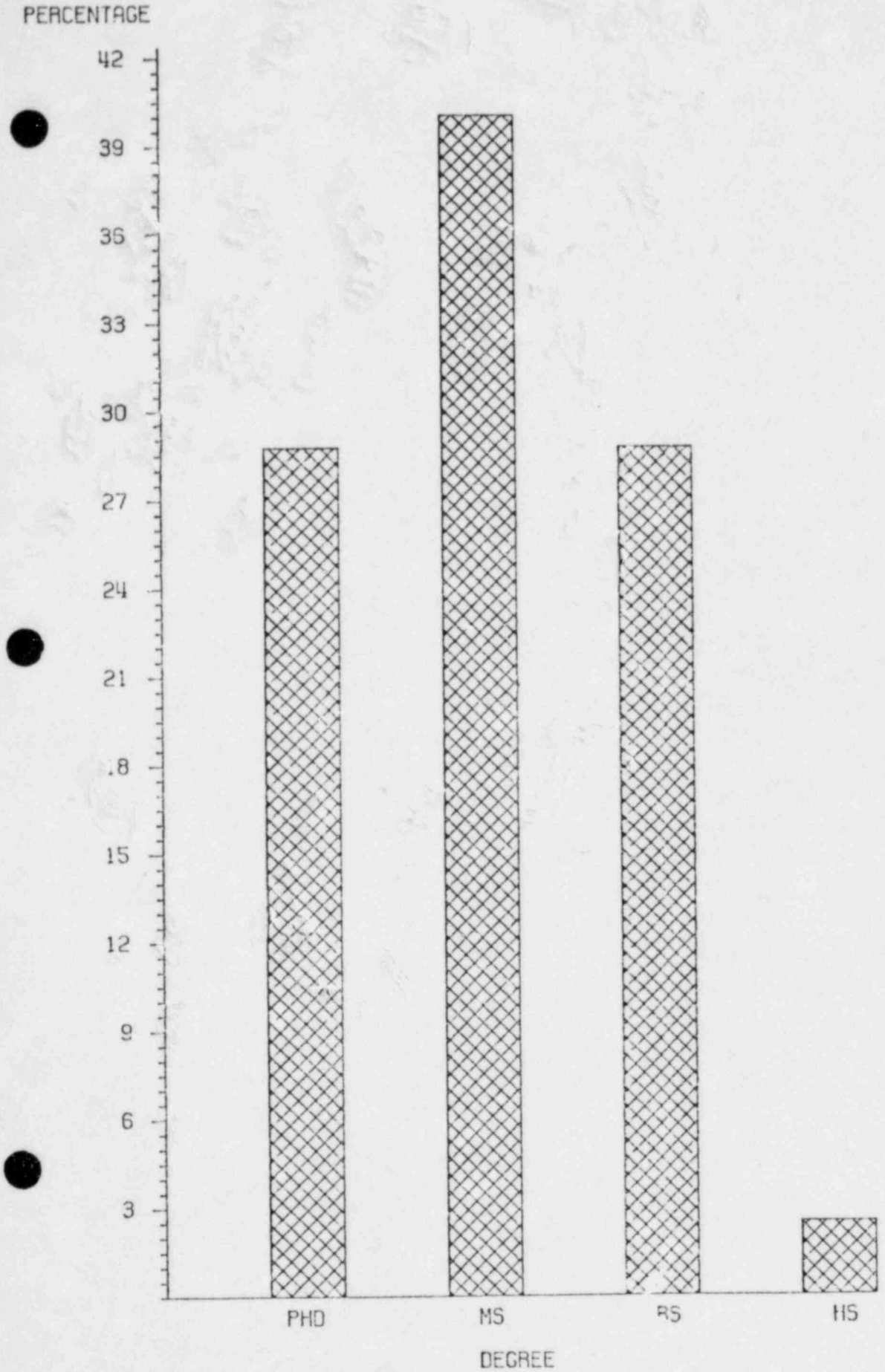
Comments: _____

_____

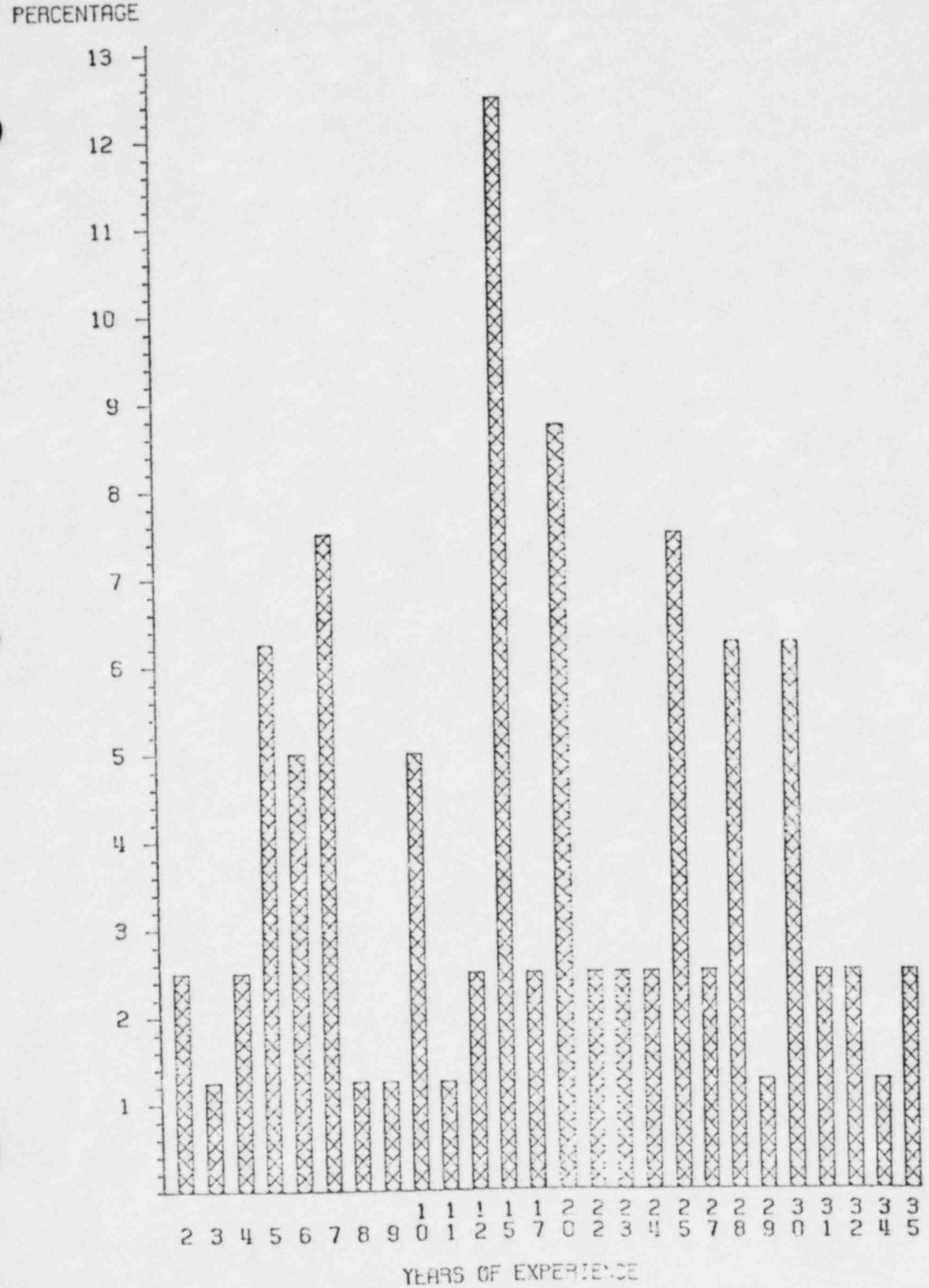
_____

_____

# DISTRIBUTION OF RESPONSES



# DISTRIBUTION OF RESPONSES



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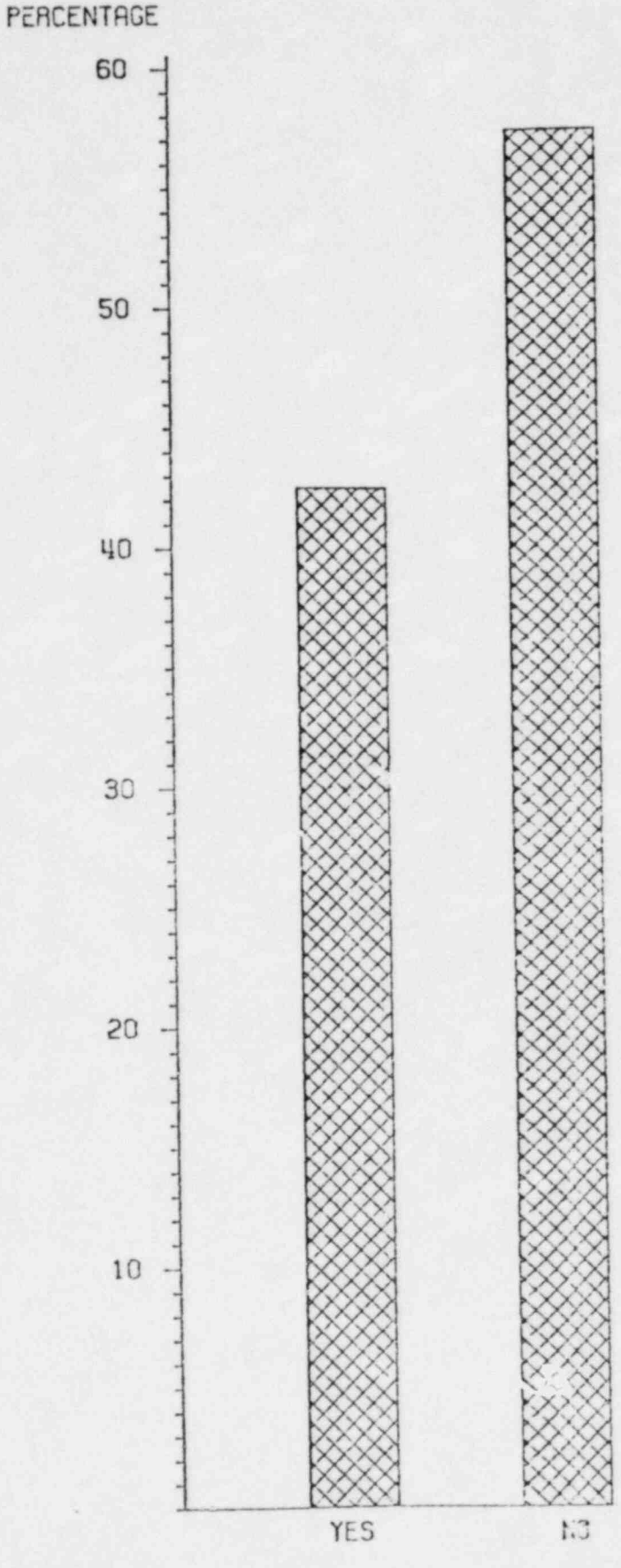

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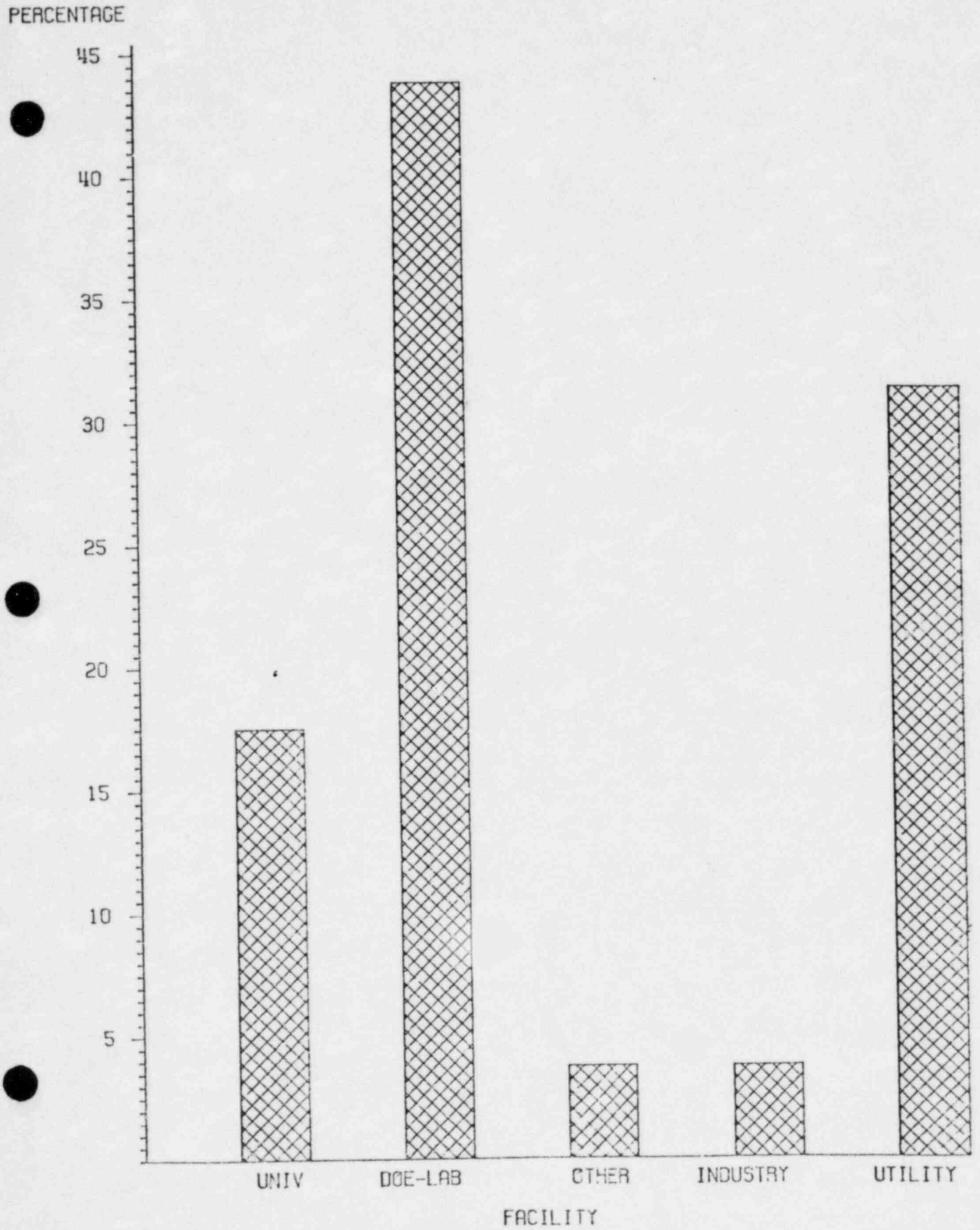
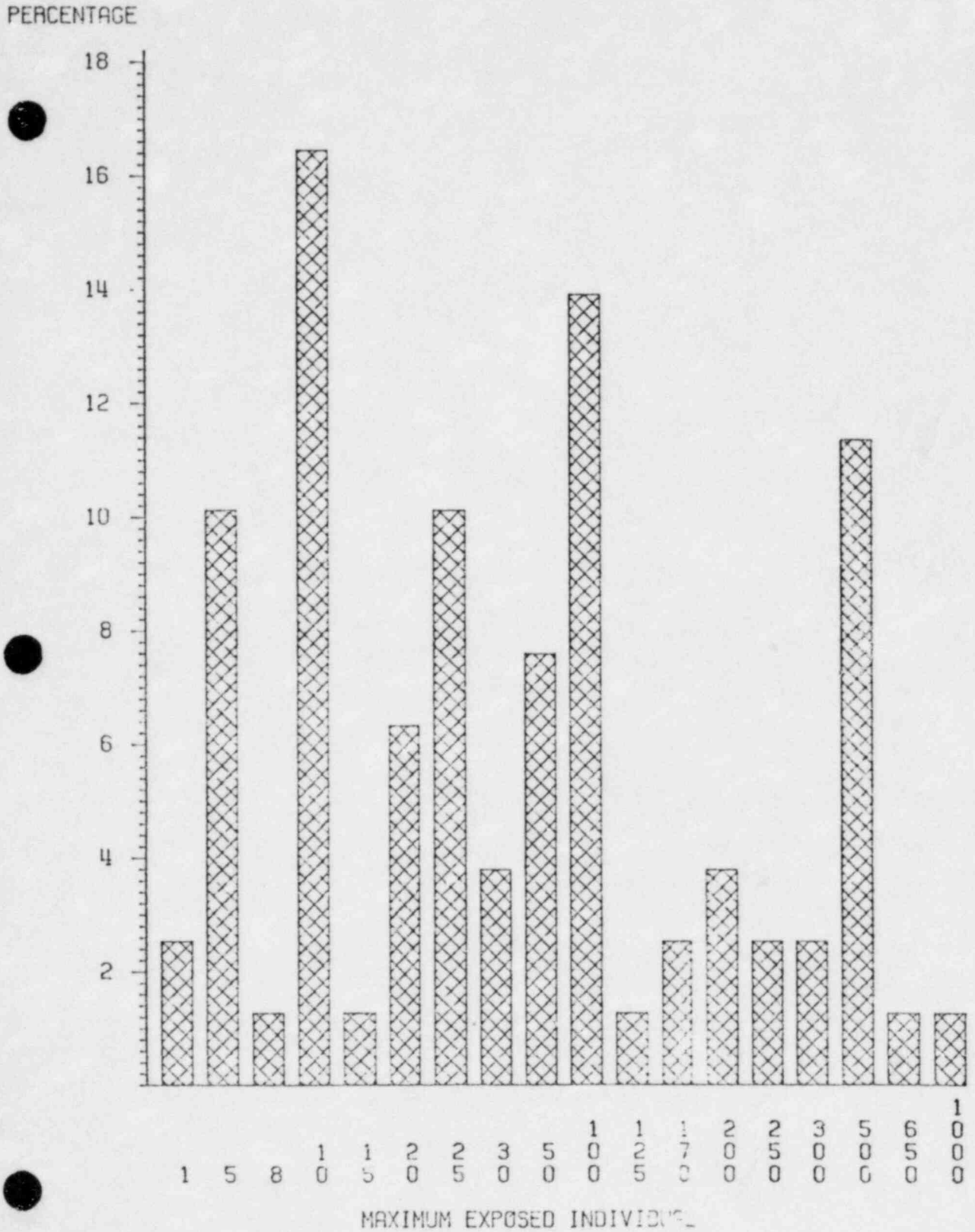
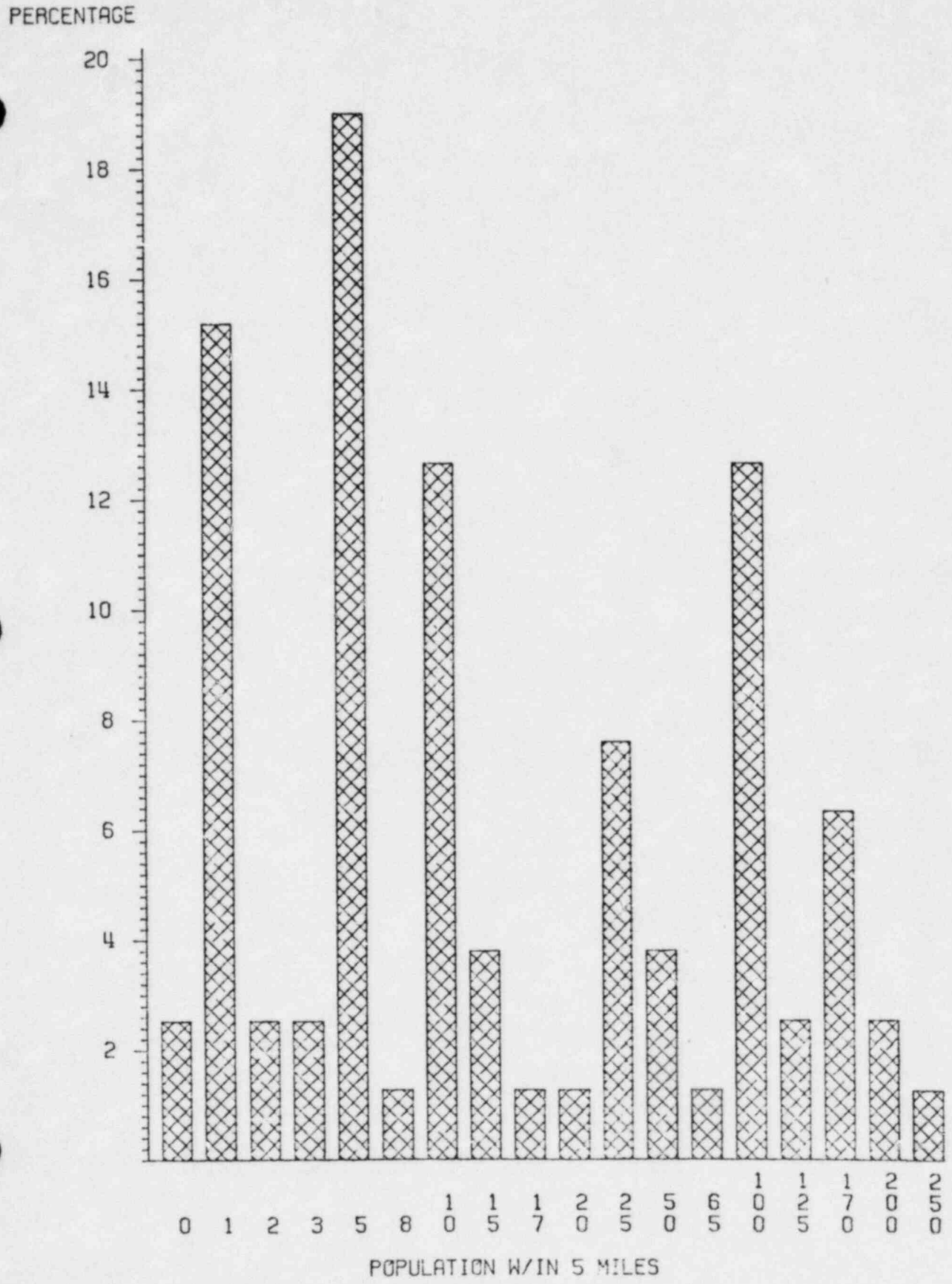


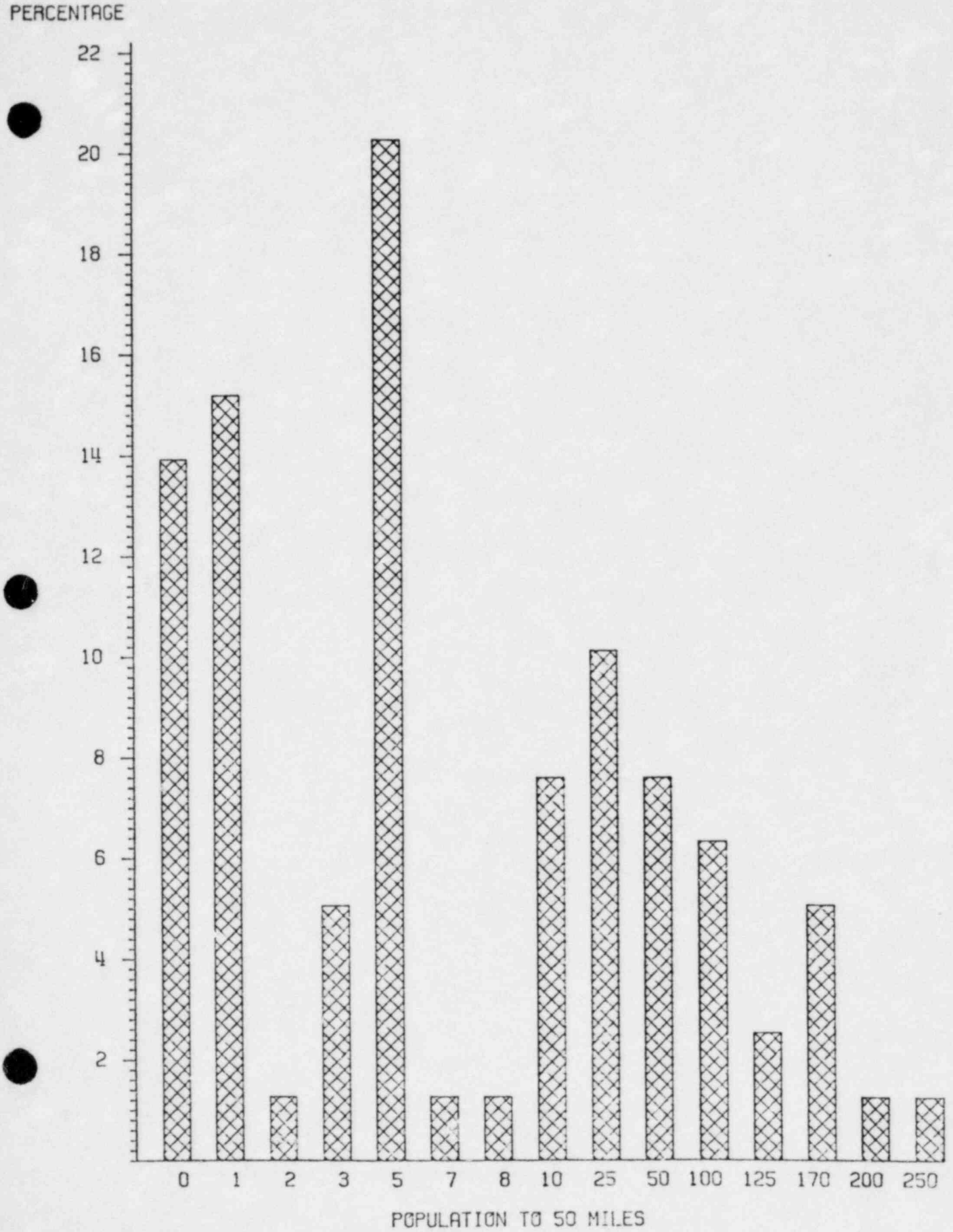
# DISTRIBUTION OF RESPONSES



# DISTRIBUTION OF RESPONSES



# DISTRIBUTION OF RESPONSES



# DISTRIBUTION OF RESPONSES