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UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the matter of:

BRIEFING ON INTERIM ACTIONS ON
PERFORMANCE TESTING FOR PERSONNEL
DOSIMETRY

Place: Bethesda, Maryland

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BRIEFING ON INTERIM ACTIONS ON PERFORMANCE TESTING FOR PERSONNEL DOSIMETRY

Room 550
East-West Towers 4850 East West Highway
Bethesda, Maryland

Tuesday, April 15, 1980

The Commission met, pursuant to notice, for presentation of the above-entitled matter at 2:00 p.m., John F. Ahearne, Chairman of the Commission presiding.

BEFORE:

JOSEPH HENDRIE, Commissioner

STAFF ATTENDANCE

Speaker: R. Alexander

C. Goller

R. Minogue

N. Dennis

E. Hanrahan

Dr. Phillip Plato, University of Michigan

M. Ehrlich, National Bureau of Standards

CHAIRMAN AHEARNE: The Commission starts its afternoon agenda. A Briefing on interim actions for improving personnel dosimetry... Mr. Alexander, Kevin, senior officials of the agency.

MR. CORNELL: I'd like to refer to Carl Goller.

CHAIRMAN AHEARNE: Thank you Kevin. Mr. Chairman in response to Section 80 44 dated January 23, 1980, the Commission approved publication of advanced notice of rulemaking on the certification of personnel dosimetry processes. This advance notice was published in the Federal Register on March 28. The advance notice addresses the problem of lack of consistency and accuracy in dosimeter processing and invites comments on how a test and certification program of dosimetry processors should be established and conducted. Subsequently the Commission requested a briefing to focus on what might be done immediately or in the interim to ameliorate this problem. We suspect this request on the part of the Commission was the result of a combination of concerns, particularly the perceived seriousness of the problem and the relatively long time it usually takes to complete an entire rulemaking process. We will in the course of this briefing be speaking to both of these points. We welcome what has already been done, what will be done and what else could be done on an interim basis to help this problem. Bob Alexander, the chief of the

Occupational Health Standards Branch in the Office of Standards Development will provide further briefing. Bob.

MR. ALEXANDER: Thank you. Mr. Chairman, we have two guests today, our contractor from the University of Michigan which conducted a pilot study that I'll talk about later is here. Dr. Phillip Plato and would be willing to answer any questions you might have and our other guest is the chairman of the Health Physics Society Standards Committee that prepared the standard that we are using in this program, Dr. Greta Ehrlich from the National Bureau of Standards. This problem has been around for quite awhile. Battele, Northwest published studies in 1967 and 1965 indicating a problem of consistency and accuracy in the area of personnel dosimetry. However, not much happened until ...

CHAIRMAN AHEARNE: Were both of those studies focused on the processing..

MR. ALEXANDER: They..

CHAIRMAN AHEARNE: Or were they focused on the instruments or what?

MR. ALEXANDER: They focused simply on the results that the processors obtained. Badges were irradiated to known doses and sent to the processors...

CHAIRMAN AHEARNE: One is focused upon...in both cases what was done is focused on the processors.

MR. ALEXANDER: Yes.

CHAIRMAN AHEARNE: Now did anything happen? There is an interim period there?

MR. ALEXANDER: Not much. I really know of very little of a constructive program that was started during that period. Things started happening in 1973 and strangely enough the states called our attention to the situation in 1973.

CHAIRMAN AHEARNE: Now were both studies done by the AEC?

MR. ALEXANDER: The 1957 study was funded by the AEC and the 1975 study was funded by the Bureau of Radiological Health. Things really started happening when the Health Physics Society standards committee published a standard to go by in this area. A draft became available in November of 1973 and we in the next month held a public meeting in which all of the processors and most of the ...many of the users --principal users--of dosimetry services were invited.

CHAIRMAN AHEARNE: And you say that they were requested to develop new standards?

MR. ALEXANDER: That -- feel free to correct me. If you look back at the record, it appears to have been sort of a consensus of many different state governements and Federal governments that a new standard was needed.

MS. EHRLICH: That's right. It started actually with the states. The request came directly from the states.

MR. ALEXANDER: The pilot study--the public meeting was very well attended and people seemed to be very much in favor of a performance testing program to be conducted by the government, but they gave us one more. They said you should conduct a pilot study to make sure that standard is a good one one that is stringent enough, but not so stringent that it puts everybody out of business. So we accepted that advice and held a pilot study which took considerable time. We had to award the contract and then we had to get all the radiation equipment and sources set up and then we had two rounds of testing for the processors that took about two and a half years to complete. The pilot study was conducted by the University of Michigan

CHAIRMAN AHEARNE: What part of the University?

MR. ALEXANDER: The school of Public Health?

VOICE: Yes

MR. ALEXANDER: The School of Public Health. The participation was entirely voluntary. We had 59 processors to process about 90% of the dosimeters in our country, not all of which incidentally are NRC licensees. There are many other people who wear those badges. The processors were tested in 8 different radiation categories such as gamma radiation, neutrons, and a combination of radiations. The testing procedure

CHAIRMAN AHEARNE: It covered all sources.

MR. ALEXANDER: Yes. All significant types of expo-

sures. The testing procedure...in

MR. GOLLER: Mr. Chairman, the various categories that were considered are these. It's the slide that we now have displayed.

CHAIRMAN AHEARNE: That's the draft standard and the --our study covered all of the elements of the draft standard?

MR. ALEXANDER: Yes. (Pause) The testing procedure involved receiving a number of badges from each participant Dr. _____irradiated those badges to known doses. The accuracy of his work was attested to by the National Bureau of Standards. His radiations were within 2 percent of the actual dose. The badges were then sent to the processors to try to determine the dose and then their results were sent back to the University of Michigan where they were prepared against the statistical criteria of the standard. The results were not extremely encouraging. Many of the processors did rather poorly as we expected. The standards came out very well. Some changes were indicated to be necessary. Those have been made.

CHAIRMAN AHEARNE: What? How when you say they indicated the standard was generally acceptable it came out well. What kind of criteria were you using to judge the acceptability of the standard?

MR. ALEXANDER: Well, the NRC staff pretty much left that to the working group that had been established to develop the standard. We didn't try to guide them in the words of the

statistical criteria that should be used. It was rather obvious that these standards were too strict. Some changes had been made in the standards to make it more reasonable.

CHAIRMAN AHEARNE: In what sense?

MR. ALEXANDER: All right. Could I have the backup viewgraph for those standards?

MR. GOLLER: Mr. Chairman as I understood the thrust of your first question, I think the ultimate answer to that is that it was found that some processors were able to satisfy all parts of the standard so that the standard was achievable in all aspects.

CHAIRMAN AHEARNE: But then...

MR. GOLLER: And some processors were able to pass all components of the standard.

MR. ALEXANDER: The statistical test was changed. The tolerance limits which were variable depending on the dose were changed to a constant which was independent of dose so that you...all badges have to meet the same criteria even for low doses as well as high doses. The revised standard has been submitted back to the Health Physics Society to approve. An approval is expected this summer. Those were the major changes that were made in the standard th we looked particularly at.

CHAIRMAN AHEARNE: The last item ...cobalt cesium what is that?

MR. ALEXANDER: A cobalt source was used in the pilot study was called for in the standard. That's a rather high energy proton above 1MEV that causes some secondary electron difficulties at the point of the irradiation of the bags... interactions of protons with .r. Cesium is considerably softer gamma and considered to be more suitable for calibration of high energy protons.

CHAIRMAN AHEARNE: (inaudible)

MR. ALEXANDER: I just wanted to say that the ...although the study was conducted primarily to test the standard th . we were also looking at the performance of the processors and as you may be aware the performance of the processors doesn't look very good if you look at the first issue of the standard as the criteria. If you look at the second issue of the standard as the criteria the performance becomes somewhat better and if you look at it on the basis of just percentage badges that got the dose right, it doesn't look nearly as bad as the first issue of the standard made the situation look.

CHAIRMAN AHEARNE: What is that second percentage that you cite?

MR. ALEXANDER: We have a backup viewgraph with that information. For example that plus or minus 50 percent..you use that as a tolerance limit. In the first round of testing 77.6% of the badges came within plus or minus 50 percent and 86.4 percent came that close in the second round.

CHAIRMAN AHEARNE: What was the differnce between round 1 and round 2?

MR. ALEXANDER: There were no differences in the radiation procedures I believe. The difference was that the processors had an opportunity to improve their process before they participated in the second round. Unfortunately only a very few did. That as you can see. I think considerable judgment is required in evaluating these data and saying how good the American dosimetry processes really are. A lot depends on the criteria we use to evaluate them. The..that's all I wanted to say about the pilot study results. The regulatory action.

CHAIRMAN AHEARNE: Well let me ask another question. I have never studied the badges ..so I'm not...how accurate are the badges? Because you are getting a testing by doing an accurate measurement of the dose that's given to a badge. Then you have a processor check the badge. What are the normal tolerances that you'd expect from the badge manufacturer

MR. PLATO: From the badge itself, not including the processor?

COMMISSIONER HENDRIE: Suppose the processor were 100 percent _____

MR. PLATO: From my experience about a 10 percent variability is probably reasonable. But given a large number of dosimeters, there's about a plus or minus 10 percent spread

just in the way the badges are manufactured, assembled and so on.

CHAIRMAN AHEARNE: Thank you.

MR. GOLLER: I'd like to add to that. That is somewhat a function of the care that is taken in selecting the TRV chips that are used. Some processors do this we are aware and some do not. One of the objectives of this entire program is to encourage real processors to do that. To examine the chips that they receive and reject any defective ones. Those processors that have done this have reported to us rejection rates as high as 25 percent. This is encompassed within the program that we have underway and would be one of the ways of --but only one of the ways of improving this dosimetry process.

CHAIRMAN AHEARNE: I guess I didn't quite follow you Carl in the sense that ...are you saying that the processors are the same as the manufacturers of the badges or are you asking that ...

MR. GOLLER: Well, either of the two could conduct this quality program.

CHAIRMAN AHEARNE: Are you talking about the quality program focused on manufacturers, as well as processors or?

COMMISSIONER HENDRIE: I think Carl is talking in the word processor in this sense in the sense of the guy that assembles the badge.

MR. GOLLER: No. In either one. The processor could

perform that function if the processor, as I understand it... the processor could so write in his specification and of course increasing price to him, purchase the badges from the manufacturer of the badges, with that examination and additional QA already applied. Alternately, he could apply it. Another alternative might be the manufacture of the chips themselves. I don't think that we would be specifying who would actually do this. It could be done anywhere in the line.

CHAIRMAN AHEARNE: Now is your comment though that you would hope to be able to decrease the plus or minus 10 percent or is your comment that there are some badges that clearly fall way outside the plus or minus 10 percent.

MR. ALEXANDER: No these. Many of these kits fall way outside plus or minus.

CHAIRMAN AHEARNE: Not due to the quality. I'm trying to draw a distinction between the quality processing of the badge.

MR. ALEXANDER: We are talking about the materials now.

CHAIRMAN AHEARNE: I'm talking about the materials myself. You say many would fall way outside that. Do you have any way or the study of any way of estimating how much of this would do that?

MR. ALEXANDER: Our contractor gave us an estimate that as many as 25 percent of these chips would be outside of

reasonable tolerance levels.

CHAIRMAN AHEARNE: Your contractor in Reston.

MR. PLATO: Well, from what we saw, a processor who very carefully screened his dosimeter..the sensitive element of the dosimeter, where it was film or thermoluminescent material. If he put forth a very good effort, still about the best he could do is somewhere on the order of 7 or 8 or 10 percent, right in there. And if the processor doesn't screen the sensitive elements, in some cases, you see sensitive elements that don't respond to radiation at all. I don't know what ... it's a factor of infinity.

CHAIRMAN AHEARNE: In the results that you have there it shows that you have 78-86 percent plus or minus 50. How much of that is due do you think to faulty dosimeters and how much of that is due to bad reading and bad processing of the dosimeter?

MR. PLATO: I suppose about the first 10 percent of the 77. That's probably about as good as you are going to get the dosimeter and the rest of that has something to do with the processor's procedures.

CHAIRMAN AHEARNE: Then it could be either bad badge as well as bad reading practices?

MR. PLATO: That's correct. Including such things that have nothing to do with the physics of dosimetry, it's just that you incorrectly copy a number.

CHAIRMAN AHEARNE: And there's a mixture...an undetermined mixture of those?

MR. PLATO: That's right.

COMMISSIONER HENDRIE: Is there a ...With regard to the material variability including some of those that are well outside the range. Is the distribution more or less symmetrical about the correct dose or do you preferentially read those?

MR. PLATO: Yes, I've seen it go both ways. Yes, I would think it is fairly normal to distribute it. When you consider all of the error.

COMM. HENDRIE: In which case when you run 23,000 badges why, those bummers that are giving you very anomalously low dose are balanced by some bummers that are giving you anomalously high doses.

MR. PLATO: With the one exception, the lowest dose you can report is 0 but there is no upper limit on the upper.

COMM. HENDRIE: Hard to beat that.

MR. GOLLER: I'm curious about what you meant Commissioner about balance?

Well, so they are not balanced by the standard. The standard is on an absolute basis and a low reading is just as bad as a high.

COMMISSIONER HENDRIE: In terms of this, for instance I'm looking at..trying to look at badge data cumulative exposure at a station over a year or something like that. What I

can say is that I pick up any badge reading that has a swing in it but this suggests it is fairly substantial. But if the error distribution is fairly symmetrical, it probably means the station man rem for the year is to first order, not

MR. GOLLER: As far as that consideration, yes there is balance obviously.

MR. ALEXANDER: We found that to be true for photons but not for neutrons or beta particles. The badges tended to underestimate the neutron dose and to overestimate the beta dose. So what you say for photons is absolutely correct. Well the regulatory action that the staff is planning concerns an amendment to part 20 which we will prepare to send to the Commission, which would state that personnel dosimetry results would only be acceptable to the NRC if they are acquired by a processor who has successfully passed the performance testing program using this HPSSC standard. I think the most difficult problem we have in this program is the fact that the NRC's authority extends only to our licensees and not to the processors who do the dosimetry. So that's the reason for our The revision of the standard has been completed I'm informed by Dr. Ehrlich the chairman and has been submitted to the Health Physics Society for approval and that is expected in May. After we have had a chance to analyze the comments from the advance modus we hope to be able to come back to the Commission and discuss in more detail the alternative approaches

that we can take to the operation of a test and certification laboratory this summer. Then we want to accelerate our schedule for getting the rule in place. This we intend to...the Commission willing... to publish the proposed rule this fall and the effective rule the following summer to get the program into place.

CHAIRMAN AHEARNE: Why do you believe it would take that long?

MR. GOLLER: Actually as Bob indicated that schedule compared to the usual rulemaking process has been considerably shortened.

COMMISSIONER HENDRIE: Sounded precipitous to me.

MR. GOLLER: And I might add we had specifically done that in response to the Commission's apparent concern about this problem and it's request for this briefing.

CHAIRMAN AHEARNE: Done which?

MR. GOLLER: Accelerated the schedule.

CHAIRMAN AHEARNE: Can it be accelerated?

MR. GOLLER: It can and we will certainly try, but I think the one that's scheduled now indicated is an expedited optimistic schedule which we will try

CHAIRMAN AHEARNE: But it has gone through as you pointed out at least the basic standard

MR. GOLLER: The problem has been identified. I think we would just point out going back to 1967. The stan-

dard was discussed as to when should you in your briefings have a ----------and a lot of comment on it. Alex then recommended it's gone through pilot study, revised standards developed.

MR. GOLLER: Well the advance notice went out the very end of March and we certainly wanted to have the benefit of the comments ..

CHAIRMAN AHEARNE: Oh yes. I understand that.

MR. GOLLER: So that I think to develop a proposed rule by fall of 80 is optimistic but reasonable.

CHAIRMAN AHEARNE: When did the advance notice... when did they....when did the public comments end?

VOICES: 60 days...May 27.

CHAIRMAN AHEARNE: May 27?

VOICE: Yes.

MR. GOLLER: Mr. Chairman, if I may. This discussion is focused on a technical question. And there's another aspect to this rulemaking. We are really hacking a lot of new ground with this business of a certification program for processors and many of the questions of advance notice really deals with that issue...how the government should best come at a program of certification of processors and that's a relevant split between private industry and that's going to raise some very complex issues and a very optimistic schedule, accelerated with those issues is not practical as indicated here.

COMMISSIONER HENDRIE: It goes beyond the technical issues that we have been discussing.

CHAIRMAN AHEARNE: You just shot down; I was about to say but since it seems to be a very technical rule that perhaps under the delegation of standards that it could be handled that way but I think we just pointed out that it has the nature of policy.

MR. MINOGUE: I think this is a general problem, Mr. Chairman. A real tendency nowadays and a good tendency to think in terms of programs of certification and use of some of these third party systems. But they all involve some very complex policy issues.

CHAIRMAN AHEARNE: I will take your word Bob based on your long experience and the chairman's uh Joe's point about being precipitous. But it doesn't look too accelerated to me.

MR. GOLLER: There's another nontechnical aspect to this Mr. Chairman that we should all be familiar with and that is that only 30 percent or less of the dosimeters being processed are actually for NRC licensees. In the process of the NRC taking these steps we will very likely be correcting this problem which certainly exists for all those other dosimeters also and for other regulatory organizations.

MR. ALEXANDER: Let me speak to that. The ..back after the standards graph first became available to us, many other agencies were interested in the problem and the NRC

simply took the lead and we formed a policy committee in a formal way which involves all of these other agencies and we meet periodically to review the NRC progress and to give advice to them and I think as a result of that effort when we come to you with a proposed rule we will be able to say that we have the concern of the staff people at the other agencies.

CHAIRMAN AHEARNE: Who are the other places involved?

MR. ALEXANDER: The National Bureau of Standards, the Bureau of Radiological Health, Department of Labor, OSHA, Department of Energy, Department of Defense, EPA and representatives of the states.

CHMN. AHEARNE: How is that latter individual chosen?

MR. ALEXANDER: Greta, do you know how he is chosen?

MS. EHRLICH: The organization...The Conference of Radiation controlled probably this approach and they selected.

MR. ALEXANDER: Now, getting to the interim actions the Commissioner has requested us to focus on, we feel that the foregoing actions, interim actions have already been taken to effect improvement and we have some evidence that some improvement has taken place. The pilot study itself caused many processors, unfortunately not all of them, but many of them, to make improvements in their processing. We asked our contractor to visit 8 of the largest commercial processors to go over the process with them and try to point out to them why they did poorly in the test if they did poorly. That was

done and a number of corrections were made as a result of that study. We were very pleased with that. We feel that the advance notice of rulemaking which the Commission has just approved will do a great deal toward getting the attention of the dosimetry processors and we had indications from our contractor that many of the processors did not take the pilot study seriously, did not really make an effort to be better in the second round, not believing that the government was really going to do something about this problem. Now that the advance notice has been published, NRC has stated to the world that action is going to be taken on this problem, we feel that corrective measures would be taken very readily. In this connection this week we are in the process of mailing a letter to all of the licensees discussing with them the causes of queer performance that were identified in the pilot study and in the limited side visits and suggesting to them that they get busy making corrections before a regulatory program is put into place. Now with respect to the corrective interim actions to be taken, these are actions that we have already decided to take. Additional site visits are in progress to all of the other processors, not just the 8 big ones so that Dr. Pluto can work with them in identifying their problems.

CHMN. AHEARNE: Do you know how many processors?

MR. ALEXANDER: Well there were 59 participants

so he has about 50 to go. That project has already been funded. Then we are planning a third round of testing. Now the principle reason for the third round of testing is to test the standard revisions because we don't like the idea of coming to the commission with an untested standard in any way and asking you to make it regulatory. This project has been accelerated at the time of supplemental funding was suggested. We plan to do it in Fiscal year 80 if these get started in FY 80 if the supplemental funds become available. If they don't become available then we plan to conduct this as originally planned in FY 81.

CHMN. AHEARNE: So that whatever date that you have for the final completion is certainly tied

MR. ALEXANDER: Tied, proposed to the rule? The way we are planning to do that is to have the third round completed before we come to you asking you to make the rule effective so that the result of the third round would be a go - No go result sort of thing. If we were satisfied with them, we would be able to come to you and say we believe that the time has come for this regulation. If not, they would have to come to you and say that. The third round of testing would in no way slow down the regulatory process.

CHAIRMAN AHEARNE: If the third round of testing shows that they are doing even worse than the first and second rounds does that lead you to conclude the standard is too tough

or that its absolutely meaningless.If the third round of testing shows that they all did magnificently that leads you to conclude the standard isn't needed or it's not tough enough.

MR. ALEXANDER. I think that there is a very limited probability that either one of those eventualities will take place.

CHMN. AHEARNE: Then if its clear

MR. ALEXANDER: The only thing I'm really worried about Mr. Chairman is that one of these changes in the standard will be something impractical and we want to identify that.

MR. MINOGUE: Mr. Chairman, you need the ..

CHMN. AHEARNE: Well I was trying to see how closely linked they are coupling everything.

MR. MINOGUE: Well the standard should be seen I think as the basis for the _____program. It's a pre-requisite.

CHMN. AHEARNE: Is the action to be taken in May on the standard to be one that is intended or is it on approval by the Health Physics Society?

MS. EHRLICH: Final approval

MR. ALEXANDER: To continue, as a result of the communication from the Commission regarding the advance notice of rulemaking and expression of interest by the commmission in interim measures to take while waiting for the rule to take place, we put our heads to work trying to think of additional

things that we could do and came up with the idea of which we've adopted of holding a public meeting out of here, but in this final meeting, the type that we've often held in standards development..on the subject of personnel dosimetry processes in which we would bring the processors together and discuss problems and the lessons learned in the pilot studies and let them share what they've learned the new procedures that they've been able to take to solve their own problems in their own shops and we think that a workshop like that which is almost no expense to the government can be very effective to these technical people. Turning now to some other interim actions that we have considered but rejected as impractical and inappropriate, these have to do with imposing as quickly as possible quality assurance requirements on the processors. Now, assurance to the current quality assurance to deal with inhouse procedures that they might follow to check their own process as opposed to a testing program which involves an outside testing lab. Such court requirement could be placed on the licensing by the various ways that NMSS and NMR have in dealing with their licenseees. We should investigate possibility of imposing quality assurance programs on the processors themselves in a manner similar to the way I&E does quality assurance inspections where we have component manufacturers who are not really our licensees. There is some question about the regulatory base with that approach. And the third

one, let me emphasize again we are not recommending an immediate effective regulation which would impose a specified quality assurance program. That concludes our formal briefing.

COMMISSIONER HENDRIE: In the course of your pilot study in your contacts with some of the processors and so on, what sense do you get from what I will characterize as more progressive members of that group? Do they sound like they are going to drag foot, scream and holler, or are they going to move forward and pick up these leads and look for a certifying laboratory. What sense do you get from ..I'd say the good side of the industry.

MR. ALEXANDER: I think we can put that question to Dr. Pluto directly. My impression as a regulator is that they seem to be divided into two groups. One group which is very scientifically oriented, very health protection oriented people who want to do a good job and who do a good job and a few who don't do a very good job at all. Is that about right?

DR. PLUTO: I think the vast majority approve of this and in fact, the hesitation has come in part because over the years, there have been a number of efforts at creating standards and implementing testing programs and I think some of the hesitation by a lot of processors is this yet one more standard. Why should we put any special effort on this and I think they are beginning to realize that this is the way things are moving.

COMM. HENDRIE: This one, hopefully by virtue of the testing grounds that had been made and will be made often have a better basis I would think than the results of the best intentions to me, working over a series of meetings to try to evolve some standards.

MR. WEISS: What I was going to say is that based on the past history, this standard now has with all of the ones back in 1963, an incentive. It was never there before and it was a standard at the University of Michigan. The National Sanitation Foundation had a standard It was well accepted. It was sponsored by DHEW. But there was no incentive, no sanctions and people saw no need to pass it and it kind of dropped by the wayside. And now its down to four companies that participate in that program. And so the standard that has been from has been the intent of sanctions that we now have had and I think the majority of the job is done once you get their interest and they start calibrating and providing for it too.

COMM. HENDRIE: Well I should think the responsible operators in the field would be grateful for a competent agreement with standards mandated by the government. In effect, it allows them to do a quality job without the commercial risk of being undercut by a sloppy operator who just runs a slapdash cheap operation and then offers it to a guy's customers. If everybody has to tow a reasonable quality line, you can at

least work to that level and in effect you are commercially protected.

MR. WEISS: And they think that they can pass and they are not too sure about the others small guys can.

MR. ALEXANDER: It's interesting. I think that it's the largest problem dosimetry processor visited us out at Nicholson Lane a few months ago and encouraged us to not change the standard at all but to leave it exactly as it was. He saw all of h s competition and he figured that he had a way to meet it and nobody else did.

MR. MINOGUE: One of the motives for publishing this advance notice that way which is to deliver this message broadly

COMM. HENDRIE: I don't have any more questions.

CHMN. AHEARNE: Bob you mentioned that about 30 percent of the dosimeters are from

MR. ALEXANDER: Thirty percent or less.

CHMN. AHEARNE: Is there any other large bulk that are regulated?

MR. ALEXANDER: Yes. I think the largest number of people would be the users of X-ray machines which are generally regulated by the individual state. They are a much larger group than our group.

CHMN. AHEARNE: And, do you get the sense, that I gather you had sensed this original effort seemed to be precipitated by state request. Do you think the states will

follow the strictures that ------

MR. ALEXANDER: Absolutely. The only way that would fal to happen is that if we just do a lousy job of it. I And don't really do anything that would be helpful. Then I think they will find another way. But they are very interested in this program.

CHMN. AHEARNE: Well thank you all.

Interim Actions For Improving Personnel Dosimetry Performance

OUTLINE

I. Purpose of Briefing

II. Statement of Problem

III. Status of NRC Efforts to Resolve Problem

- A. Regulatory Action Completed
- B. Regulatory Action Planned

IV. Interim Actions

- A. Corrective Actions Taken
- B. Corrective Actions To Be Taken
- C. Other Possible Interim Actions Considered and Rejected

STATEMENT OF PROBLEM

- First Battelle Study - 1967
- Second Battelle Study - 1975
- Results indicated significant problems with consistency and accuracy of Dosimeter Processing

REGULATORY ACTION COMPLETED

- HPSSC REQUESTED TO DEVELOP NEW STANDARD - 1975
- DRAFT STANDARD AVAILABLE NOVEMBER, 1976
- PUBLIC MEETING HELD DECEMBER, 1976
  - IDEA OF PERFORMANCE TESTING WELL ACCEPTED
  - PILOT STUDY TO TEST STANDARD STRONGLY RECOMMENDED
- PILOT STUDY CONDUCTED 1977 - 1979

Pilot Study

- Conducted by the Univ. of Mich. under NRC Contract
- Voluntary participation
- Confidentiality of Processor Performance
- 59 processors participated
- Participants process about 90% of US personnel dosimeters
- 8 radiation categories
- Testing procedure

Results of the Pilot Study

- Confirmed the HPSSC/ANSI Standard as generally acceptable
- Indicated necessary changes in Standard
- Confirmed significant problems with consistency and accuracy of dosimeter processing

Regulatory Action Planned

- Regulatory requirement for Dosimetry Processor Certification
- Revision of HPSSC Standard - Summer 1980 (Eventual issue by ANSI)
- Meeting with Commission To Discuss Comments and Issues - Summer 1980
- Publication of Proposed Rule - Fall 1980
- Publication of Effective Rule - Summer 1981

Corrective Interim Actions Taken

- Pilot Study Completed
  - Discovery of problems, voluntary corrections
  - Draft Standard Tested and Evaluated
  - Impact of Standard
- Limited Site Visits by Contractor
  - Identification of causes for poor performance
  - Methods of correction
- Advance Notice of Rulemaking
  - Proposed Rule to Require Certification
  - Indicates Adoption of Revised HPSSC Standard
  - Impact of the Advance Notice
    - . Promote management approval for expenditures
    - . Positive impact on third round of testing
    - . Increase impact of current site visits by UM
- Letters to Licensees and Processors
  - To accompany Advance Notice Mailing (voluntary action)
  - Discuss causes of poor performance

Corrective Interim Actions To Be Taken

- Additional Site Visits by Contractor
- Third Round of Testing
  - Significant changes in the Standard
  - Test the revised Standard
  - Permit adoption of best criteria if choices arise
  - Allow test of processors after site visits
- Workshop
  - Technical dosimetry problems
  - Elements of a quality assurance program
  - Comments on Advance Notice

Other Possible Interim Actions

(Considered and Rejected)

- Dosimetry QA Requirements
  - On Licensees
    - Letter,
    - IE Circular or Bulletin,
    - License Amendment, or Tech Spec
    - Order
  - On Processors
  - Immediately Effective Regulation

10 CFR Part 20

Advance Notice of Rulemaking on Certification of Personnel Dosimetry Processors

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Advance notice of rulemaking to improve accuracy in personnel dosimetry.

SUMMARY: Tests have indicated that a significant percentage of personnel dosimetry processors may not be performing with an appropriate degree of accuracy. Alternatives for action to correct this situation are presented. Interested persons are invited to submit comments on these alternatives.

DATES: Comment should be received by May 27, 1980.

ADDRESSES: Comments or suggestions for consideration in connection with these alternatives may be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Mr. Robert E. Alexander, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301–443–5975.

SUPPLEMENTARY INFORMATION: Recent tests indicate that a significant percentage of the personnel dosimetry processors in the United States are not performing with a degree of accuracy acceptable to the NRC when compared against a consensus standard prepared under the auspices of the American National Standards Institute.* To the extent that these test results are representative of routine field conditions, the results indicate that the dose received by occupationally exposed personnel may often be considerably different from the dose reported by the dosimetry processor. Where complete reliance for individual dose determinations is placed on personnel dosimeters, control of individual radiation exposures may not be accomplished as well as is indicated, and compliance with regulatory dose limits may not, in fact, be achieved. The test results indicate that individual doses may be over or understated. Further, these incorrect measurements could become a source of error when the dosimetry data are used in epidemiological studies intended to investigate the does-effect relationship.

The principal causes of the inconsistent test measurements that have been observed are not well understood. There is some evidence that the inconsistencies are due primarily to differences between the dosimeter irradiation techniques used by the tester and the calibration methods used by the processors; this possibility is discussed in the following paragraph. However, actual inaccuracies may arise because of inadequate quality control in dosimeter manufacturing or in a few cases because of ineptitude on the part of the processor. These different problems would require different solutions, so that appropriate regulatory corrective action is very dependent on a better understanding of the causes of the problem.

Regarding the adoption of methods for correcting this problem, it is evident from at least two important considerations that caution should be exercised. First, as previoulsy mentioned, the inconsistent test measurements refer to differences between the amount of radiation delivered to a dosimeter, under highly controlled laboratory conditions, by the individuals conducting the test, and the amount of radiation subsequently reported by the processor. These tests do not necessarily measure the difference between the radiation delivered to a dosimeter worn by a worker and the radiation subsequently reported by the processor. For example, the radiation source used by the processor to calibrate the dosimeter may emit radition of the same or very similar quality as the radiation to which the worker is exposed, but may be quite different from the radiation used by the tester to irradiate the processor's test dosimeters. Thus, standardization of calibration techniques among U.S. processors, which may be essential for achieving good performance in a test program, could in some cases produce apparent improved accuracy while actually introducing greater errors in the personnel dose measurement process.** This consideration is an integral part of the personnel dosimetry problem and must receive full consideratton in corrective action planning.

Secondly, any regulatory action taken must be handled in a manner to ensure that sufficient personnel dosimetry services remain available. Unnecessarily severe or improper corrective action could reduce the number of available processors to the extent that the dose determinations for some workers could be adversely affected.

* Pilot study conducted for the NRC by the University of Michigan.

** For example, a processer may calibrate beta dosimeters for workers at a uranium fuel fabrication plant using a uranium slab; the tester may use a strontium-90 source. The processor could then measure the workers' doses accurately but could fail the performance test.

One of the major sources of error in personnel dosimetry is known to be the potential difference between the actual dose received by the dosimeter and the actual dose received by the wearer. Such differences can, for example, be due to shielding of the dosimeter by the body when the worker is not facing the source of radiation or due to different irradiation of the part of the body on which the dosimeter is worn than of other parts of the body. These sources of error are recognized but are not part of the dosimeter processing problem that is being considered for correction.

A Federal Interagency Policy Committee on Personnel Dosimetry Performance has been formed to guide and coordinate correction of the dosimetry processor performance problem. Represented on this Committee are: the Bureau of Radiological Health (HEW), the Department of Defense, the Department of Energy, the Environmental Protection Agency, the National Bureau of Standards (NBS), the Nuclear Regulatory Commission, the Occupational Safety and Health Administration (DOL), and the Conference of Radiation Control Program Directors (States). Dosimetry processors and users have indicated agreement that some corrective action is appropriate. A working group of the Health Physics Society Standards Committee (HPSSC) has developed and the American National Standards Institute (ANSI) has published a draft standard for dosimetry performance (N13.11, July 1978). This standard is considered to be the most important element in a corrective program. An industry committee (Personnel Dosimetry Overview Committee) has been formed to assist in ensuring that any proposed regulatory action is effective and appropriate to the need. However, agreement has not been reached as to the specific action that should be taken. Alternative corrective actions under consideration are discussed below.

Recent Federal Government Action

Some time ago, on November 30 and December 1, 1976, the Nuclear Regulatory Commission and other Federal agencies conducted a public meeting at which the personnel dosimetry performance problem was discussed in an open forum by personnel dosimetry processors, dosimetry users, and representatives of State governments and Federal agencies. Other co-sponsors of this meeting were the Energy Research and Development Administration (now the Department of Energy) and the Bureau of Radiological Health. These discussions revealed general agreement that a personnel dosimetry problem does exist and that the problem is sufficiently broad in scope that it should be addressed by the Federal government. However, many of the attendees cautioned against precipitous action and strongly recommended a pilot study (1) to evaluate the draft HPSSC/ANSI standard and (2) to provide precessors the opportunity to take any necessary corrective actions in their operations prior to the implementation of new Federal regulations on the dosimetry performance problem. These recommendations were accepted, and the Nuclear Regulatory Commission (NRC) subsequently issued a contract to the University of Michigan (UM) to conduct a two-year pilot study. The objectives of this study were:

(1) To determine whether the draft HPSSC/ANSI standard provides an adequate and practical test of dosimetry performance;

(2) To give processors an opportunity to correct any problems that are uncovered;

(3) To develop operational and administrative procedures to be used later by a permanent testing laboratory.

The study was completed December 31, 1979.

Conditions of the contract included a provision that any personnel dosimetry processor in the United States would be allowed to participate in the study on a strictly voluntary basis, provided only that the dosimeters tested be restricted to those used to provide the permanent record of occupational exposures. Processors were told that the UM would keep test results confidential (i.e., that no organization other than the UM would be able to associate specific results with the name of a processor), that all results would be published (in coded form), that the UM would charge no fee for participation, that the new HPSSC/ANSI standard would be used to evaluate their performance, that each participant would be given the opportunity to be tested twice and would also be given an opportunity to discuss with UM personnel the possible reasons for any poor performance prior to the second round of tests, and that the accuracy of the irradiations provided by the UM would be verified by the NBS, and that UM facilities and equipment would be open to inspection by the participants prior to the beginning of the tests. An open house was conducted for the latter purpose by the UM on April 20, 1978. Fifty-nine processors participated in the study; it is believed that very few U.S. processors did not participate. During the course of this study, the UM submitted monthly progress reports to the NRC. These reports are available for inspection or copying in the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. Copies may also be obtained by contacting the Public Document Room, (202) 634-3273. The final report for the study, NUREC/CR-1064, may be purchased from National Technical Information Service, Springfield, Virginia 22161.

The draft standard allowed processors to be tested in eight different radiation categories. The term "category" refers to the type of radiation being measured. For example, Category 1 is gamma radiation, Category 2 is high energy X-radiation, Category 3 is low energy X-radiation, etc. Within each category of the draft standard were several dose ranges called intervals. The consensus standard used in the pilot study evaluated a processor's ability to consistently and accurately perform within a specific tolerance limit for each interval. Failure to pass one interval within the category would cause a processor to fail the entire category test. A performance index, P, was calculated for each dosimeter as (reported dose minus the delivered dose) divided by the delivered dose. For each interval, the average performance index, P, and its standard deviation, S, were calculated. The draft standard incorporated a statistical test, $P + 2S$ equal to or less than a specific tolerance value. The tolerance value for any given interval was a function of the average delivered dose and varied from 0.3 to 2.0. A processor could only pass a given category if all intervals of a respective category were passed.

At the conclusion of the first round of testing, the results were examined by the NRC staff, by the Interagency Policy Committee on Personnel Dosimetry Performance, and by the industry's Personnel Dosimetry Overview Committee. The results indicated poor performance on the part of many processors. Only 23% of the category tests attempted by the processors were passed, using the criteria in the HPSSC/ANSI standard. None of the processors passed all of the tests attempted in the first round, but every category test was passed by at least one processor. These facts indicate that the standard is achievable and suggest that the problem may lie with the processor and/or with differences in irradiation techniques used by the UM and those used by the processors during their calibration procedures. The participants' performance in the first round was also evaluated used a simple percentage-

passed basis (as opposed to the more complicated statistical formula of the standard). Again, generally poor performance was indicated. Using a simple ±30% pass-fail criterion for each and every dosimeter in a category during the first round of tests, the weighted average of all the processors reveals 7% of the category tests were passed (i.e., all dosimeters tested in all intervals of the category fell within the ±30% criterion). Using a ±50% criterion in the same manner, 21% of the category tests were passed. Thus, the results using the draft standard are similar to those using the ±50% criterion.

It had been anticipated at the beginning of the pilot study that processors who performed poorly during the first round of testing would be able to take corrective action prior to the second round and would improve their performance. The second-round results did indicate improvement over the first round. Approximately 35% of the category tests were passed. Using a simple ±30% pass-fail criterion for each dosimeter in a category during the second round of tests, the weighted average of all the processors reveals 19% of the category tests were passed (i.e., all dosimeters tested in all intervals of the category fell within ±30% criterion). Using a ±50% criterion in the same manner, 32% of the category tests were passed.

Processor performance was not based on the percentage of dosimeters that individually passed the criteria set forth in the standard. Of the 23,000 individual dosimeters evaluated during the pilot study, 85% of the dosimeters tested passed round one of the tests and 90% of the dosimeters passed in the second round. Failure of the 15% and 10% of the dosimeters tested, to meet minimum tolerances established by the HPSSC/ANSI in the standard is an unsatisfactory level of performance when determining individual dose assessments. In the pilot study, for example, high doses (i.e., 600 rads) delivered to some of the test dosimeters were actually undetected by some of the processors.

One processor, whose results in the first round were very poor, worked with UM personnel to identify and effect the necessary changes in the process and then performed very well during the second round, passing all categories attempted but one. Another processor passed all eight of the categories. These facts provide rather strong indications that conformance with the standard is attainable, but that many processors have not made the necessary changes in their operations.

After considering this situation, the Interagency Committee on Personnel Dosimetry Performance made the following recommendations:

(1) The actual causes of the poor performance should be determined with a greater degree of certainty before finalizing plans for corrective action;

(2) A notice should be published in the **Federal Register** for the purpose of notifying all personnel dosimetry processors and the public that the Federal Government is determined to take action as necessary to correct the personnel dosimetry problem.

Subsequently, the NRC staff authorized the UM to conduct a series of site visits with eight of the largest processors to try to determine the causes of poor performance. At the conclusion of these site visits, the UM personnel prepared a report which indicates four major causes:

(1) Inadequate calibration sources,

(2) Variability in the thermoluminescent dosimeter chips,

(3) Clerical errors,

(4) Lack of effort on the part of the processors to make the changes necessary to pass the tests.

This report, dated May 1979, is available in the Commission's Public Document Room in the file on personnel dosimetry performance testing.

Future Action

The pilot study was completed by the UM on December 31, 1979. Future action will be based in part on the final report. However, it is possible at this time to identify the following actions that the NRC has under consideration.

Processor Certification

According to this plan, the NRC would issue new regulations stating that personnel dosimetry results would be acceptable only if provided by a processor who is certified by a testing (i.e., certifying) laboratory approved by, or specified by, the NRC.

These processors would have to obtain and maintain their certification by passing, at a specified frequency, performance tests conducted by the certifying laboratory. The certifying laboratory(s) would use performance criteria published by the American National Standards Institute (ANSI) and referenced in the new regulations. These regulations: (1) Would adopt, possibly in modified form, the final ANSI standard evolving from draft ANSI standard N13.11; (2) would specify how frequently processors would have to demonstrate, through testing, their ability to comply with this standard; (3) would establish the procedure to be used by the NRC to let its licensees know which processors have been certified as well as those who have lost their certification; (4) would (except for one possibility noted below) name the testing and certification laboratory(s) required to be used; (5) would stipulate that the laboratory(s) would be monitored for technical competence by the National Bureau of Standards; and (6) would specify the procedure to be used for reinstating processors who have lost their certifications and have appealed.

Subsequently, other affected Federal and State agencies would be likely to consider adopting similar regulations. Although it is estimated that only about 15% of U.S. personnel occupationally exposed to measurable ionizing radiation (e.g., above 30 mrems per month) are engaged in NRC-licensed activities, it should be recognized that any NRC regulations in this area would affect a much larger percentage. This is true because most commercial processors serve customers other than NRC licensees, and any improvements in their operations would be likely to benefit all of their customers rather than just the NRC licensees.

Several alternatives are possible as to the operation of the testing and certification laboratory(s):

(1) *Unspecified Laboratory(s).* This alternative would require an amendment to the NRC regulations as described above but without naming the testing laboratory(s). The processors and users would thereby be left to their own initiatives to establish one or more laboratories, which would have to be monitored by the NBS. The NRC would have no control over the laboratory(s), except through regulations applying to its licensees. However, if it is stipulated that the licensee must obtain personnel dosimetry results under conditions as described above (except for naming the testing and certification laboratory(s)), NRC licensees could only use a processor who complies with these conditions, including monitoring by the NBS.

(2) *NRC-Operated Laboratory.* This alternative would also require an amendment to the NRC regulations as described above, but the testing laboratory would be a Government facility managed and operated by NRC employees. By charging an appropriate testing fee, costs for establishing, maintaining, and operating the laboratory could be recovered.

(3) *NRC-Contracted Laboratory.* Similar regulation amendments would be needed for this alternative, but the laboratory would be operated by an NRC contractor, using the contractor's facilities. Funding would be provided by testing fees.

(4) *Federal Government (non-NRC) Operated Laboratory.* Similar regulatio amendments would be needed for this alternative, but this testing laboratory would be operated by an agency of the Federal Government other than the NRC, preferably by one of the agencies experienced in laboratory testing work. Existing expertise could be utilized, or qualified personnel could be employed. The facilities would be Government-owned; funding would be provided by testing fees.

Invitation To Comment

Information pertaining to the personnel dosimetry problem discussed in this notice is invited, including comments on the alternative solutions described, suggestions of other alternatives, and estimates of costs anticipated in the process modifications necessary to permit successful passing of the ANSI standard criteria. Comments should be received by May 27, 1980.

Dated at Washington, D.C., this 21st day of March 1980.

For the Nuclear Regulatory Commission.

William J. Dircks,

Acting Executive Director for Operations.

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