

1 UNITED STATES OF AMERICA  
2 NUCLEAR REGULATORY COMMISSION

3  
4 PUBLIC MEETING

5 ON

6 REVISED ENFORCEMENT POLICY

7 - - -

8  
9 Sheraton O'Hare Inn  
10 6810 N. Mannheim Road  
11 Lancaster Room  
12 Rosemont, Illinois

13 Tuesday, December 2, 1980

14 The Commission met, pursuant to notice, at 1:00 p.m.

15 BEFORE:

16 JAMES G. KEPPLER, Chairman

17 DUDLEY THOMPSON

18 JAMES LIEBERMAN

19 CHARLES NORELIUS  
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P R O C E E D I N G S

1  
2 CHAIRMAN KEPPLER: Good afternoon, ladies and  
3 gentlemen. I am Jim Keppler, Director of the Nuclear  
4 Regulatory Commission's Region III Office, and I would  
5 like to welcome you to Chicago and this meeting.

6 We appreciate the opportunity to meet with  
7 you here today in the second of five regional conferences  
8 that are being held to explain and discuss the proposed  
9 revision of the NRC Enforcement Policy.

10 Before beginning the meeting, there are a  
11 few administrative matters which I would like to call  
12 to your attention.

13 We have three administrative people from my  
14 office here today. They will be here throughout the  
15 afternoon session.

16 Messages of any incoming calls will be posted  
17 on the bulletin board outside. If you need any assistance  
18 from them, please feel free to call on them.

19 The meeting is scheduled to run from 1:00 p.m.  
20 to 10:00 p.m. with a break from 5:00 p.m. to 7:00 p.m.  
21 for dinner.

22 We have a prepared presentation I would like  
23 to give in its entirety before honoring questions or  
24 requests to comment. We believe this approach will  
25 answer a number of questions ahead of time.

1           Copies of the prepared presentations, including  
2 the slides, will be made available during the break.

3           We have received advanced requests to comment  
4 from sixteen people so far. We have allocated as much  
5 as fifteen minutes per person. Others wishing to speak  
6 can register on the list outside the room and they will  
7 be taken in turn after those individuals making ad-  
8 vanced requests to speak are finished.

9           This meeting is being transcribed. A copy  
10 of the transcript will be filed in the NRC's public  
11 document room in Washington, D. C., and a copy will also  
12 be on file in our regional office in Glen Ellyn.

13           To help make the record clear it is requested  
14 to those asking questions or making comments identify  
15 themselves and the organization they represent.

16           I hope each person attending this meeting has  
17 received a copy of an inquiry card from the receptionist  
18 outside. If you didn't get a card as you entered, please  
19 pick up one at the reception desk as you leave.

20           The Nuclear Regulatory Commission has tried  
21 a broad outreach type program to inform citizens,  
22 organizations, and licensees of this series of meetings  
23 on the enforcement policy and we are interested in  
24 learning which of these methods reached you.

25           We would appreciate your filling out the

1 card to tell us whether your interest in this meeting  
2 was prompted by a letter mailed to you, by a newspaper  
3 ad, or other means. You do not need to sign the card  
4 if you do not want to. Please leave the card at the  
5 reception desk when you leave.

6 Lastly, coffee or soda will be made available  
7 during the afternoon break which will be about 2:30.

8 For the past year now an effort has been  
9 underway to revise the Nuclear Regulatory Commission's  
10 Enforcement Policy to reflect the Congress and the  
11 Commission's mandate to be firmer regulators of the  
12 nuclear industry and to incorporate legislation passed  
13 by Congress and signed by the President last summer  
14 providing the NRC with increased civil penalty authority.

15 An important milestone was reached on  
16 September 4, 1980, when the Commission approved issuance  
17 of the policy for public comment and interim use of the  
18 policy by the staff during the comment period.

19 The policy was published in the Federal  
20 Register on October 7, 1980, and is presently being used  
21 by the NRC staff.

22 This series of regional conferences is being  
23 held with licensees and the general public to explain  
24 how we are implementing the policy so that you will be  
25 in a better position to comment on the policy.

1           Comments can be provided orally at this meeting  
2 or in writing to the Secretary of the Commission,  
3 Attention: Docketing and Service Branch, by no later  
4 than December 31, 1980.

5           It is the intent of the Commission that the  
6 disposition of public comments be made a matter of  
7 record. It is also the intent that this policy, as  
8 finally adopted by the Commission, will be codified in  
9 the Code of Federal Regulations.

10           With me today to explain the revised Enforce-  
11 ment Policy are the NRC officials selected by Mr. Victor  
12 Stello, Director of the Office of Inspection and  
13 Enforcement, to accomplish this effort.

14           On my left is Dudley Thompson, Director of the  
15 Enforcement and Investigation staff in the NRC's Office  
16 of Inspection and Enforcement.

17           To his left is Jim Lieberman, Deputy Chief  
18 Counsel for Enforcement and Rulemaking of the NRC's  
19 legal staff.

20           To his left is Chuck Norelius, Assistant to  
21 the Director and Enforcement Coordinator, Region III.

22           In discussing the revised Enforcement Policy  
23 today, we thought it would be helpful to briefly sum-  
24 marize the background relative to the NRC's Enforcement  
25 Program.

1           Prior to 1969 the NRC's Enforcement Program  
2 did not include civil penalties. Enforcement actions in  
3 that era were primarily Notices of Violations supplemented  
4 by the occasional use of Orders for the more serious  
5 safety and chronic noncompliance cases.

6           In 1969 Congress granted the NRC, then the  
7 AEC, authority to levy civil penalties for items of  
8 noncompliance. Civil penalties of up to \$5,000 per  
9 item of noncompliance with a maximum civil penalty  
10 of \$25,000 for all violations occurring within a monthly  
11 period were permitted.

12           In August 1971 a rule was published to  
13 implement the statute, and in October 1972 the Commission  
14 first published its Enforcement Policy in the Federal  
15 Register.

16           The next important milestone was December 31,  
17 1974, when the staff provided all licensees an update  
18 and further clarification of its enforcement criteria.

19           Another key milestone occurred in early 1978  
20 when the Commission, recognizing that \$5,000 civil  
21 penalties did not represent a serious financial dis-  
22 incentive to larger licensees, submitted a request to  
23 Congress to increase the maximum civil penalty from  
24 \$5,000 per item of noncompliance to \$100,000. Congress  
25 enacted legislation and it was signed into law on

1 June 30, 1980.

2 While civil penalties and other escalated  
3 enforcement actions were used cautiously during the early  
4 and middle '70's, there has been increasing emphasis  
5 on enforcement actions over the past few years, with a  
6 significant increase in the number and severity of  
7 enforcement actions since Three Mile Island.

8 As I stated earlier, this increase is a  
9 clear reflection of the mandate given to the NRC to  
10 be strong regulators.

11 In December 1979, NRC further visibly displayed  
12 this posture when it published tough enforcement  
13 criteria for noncompliances associated with the trans-  
14 portation of nuclear materials.

15 During the past year the staff has been working  
16 to revise its Enforcement Policy to implement the new  
17 civil penalty authority. In this regard, the goals of  
18 the NRC's revised Enforcement Program can be stated to  
19 be as follows:

20 Can I have the first slide, please?

21 We wanted to ensure compliance with NRC  
22 regulations and license conditions; to obtain prompt  
23 correction of licensee weaknesses; to deter future non-  
24 compliance through strong enforcement measures; and  
25 to encourage improvements of licensee performance, thus

1 enhancing the degree of protection of public health and  
2 safety, common defense and security, and the environment.

3 Mr. Norelius next will be providing a des-  
4 cription of the revised Enforcement Program. Before he  
5 does, I would like to briefly repeat what the NRC hopes  
6 to get from these meetings, and we would urge you to  
7 focus on these matters in providing comments. Specifically,  
8 as we see in the next slide, we are seeking comments on:

9 First of all, is the policy fair and equitable?

10 Is the policy understandable?

11 Are the severity levels appropriate?

12 Are the different types of activities well  
13 enough defined? Should there be others?

14 Are the distinctions among various types of  
15 licensees shown in Table 1 appropriate?

16 Are the factors for determining the level of  
17 enforcement actions appropriate? Should there be others?

18 Is the degree of discretion allowed to Office  
19 Directors appropriate? Should there be more flexibility  
20 permitted? Less?

21 Are the levels of civil penalties that require  
22 Commission involvement appropriate? Should they be  
23 higher? Lower?

24 Are the provisions for escalated action set  
25 forth in Table 2 appropriate?



1 We would, of course, also welcome questions and  
2 comments on any other aspect of the NRC's Enforcement  
3 Program which is of interest to you.

4 I would now like to turn the meeting over to  
5 Mr. Norelius who will describe the basic elements of the  
6 revised Enforcement Policy.

7 MR. NORELIUS: Thank you, Jim.

8 In revising the NRC Enforcement policy we  
9 established six specific objectives as shown on the  
10 next slide.

11 First, we wanted to establish criteria for  
12 utilizing the increased civil penalty authority.

13 Second, we wanted to make the Enforcement  
14 Program tough, yet fair.

15 Third, we wanted to achieve greater uniformity  
16 in the treatment of licensees by taking equivalent  
17 actions against similar licensees having similar problems.

18 Fourth, we wanted to better define our enforce-  
19 ment capabilities with respect to NRC licensed activities  
20 other than operating reactors. In particular, we  
21 wanted to give more definitive guidance concerning  
22 enforcement in the areas of construction and safeguards  
23 and for taking enforcement actions against licensed  
24 operators.

25 Fifth, we wanted to focus escalated enforcement

1 actions on the specific event or problems which led to  
2 the decision to take escalated enforcement, rather than  
3 focus on the total number of noncompliance items  
4 identified.

5 Lastly, we wanted to articulate clearly our  
6 enforcement policy and define more clearly the criteria  
7 for taking various enforcement actions.

8 To further explain how these objectives were  
9 incorporated into the revised enforcement policy, I  
10 intend to discuss severity categories, including their  
11 application to the different functional areas regulated  
12 by NRC; Notices of Violation; enforcement actions  
13 against licensed operators; civil penalties; Orders,  
14 and the combination of enforcement sanctions for recurring  
15 significant noncompliances.

16 Let me begin with the severity categories.

17 We have had for the past several years three  
18 categories of noncompliances -- violations, infractions,  
19 and deficiencies.

20 While we have found that having different  
21 severity categories is beneficial in judging the  
22 significance of noncompliances, our experience has shown  
23 that more categories were needed to capture the differing  
24 thresholds of noncompliance. In defining severity  
25 categories, we wanted to relate them to the fundamental

1 problem or event involved, rather than solely to items  
2 of noncompliance. We established six severity categories.

3 Let me explain these categories in the  
4 context of reactor operations.

5 We considered the worst type of situation is  
6 one where safety systems are called upon to work and  
7 are not operable, for example, Three Mile Island. This  
8 was considered to be Severity Level I.

9 The next worse situation, Severity Level II,  
10 is one where a safety system is not capable of performing  
11 its intended safety function, but fortuitously was not  
12 called upon to work. An example would be a loss of  
13 containment integrity without a concurrent accident.

14 Severity Level III violations were established  
15 to cover situations where a safety system is not capable  
16 of performing its intended safety function under certain  
17 conditions. An example would be where the high pressure  
18 emergency core cooling system was inoperative under loss  
19 of power conditions.

20 The next lower level, Severity Level IV,  
21 involves a condition where a safety system is operational,  
22 but degraded. An example would be a situation where the  
23 sodium hydroxide additive was valved out of the con-  
24 tainment spray system, but the containment spray system  
25 itself was otherwise fully operable.

1           Severity Level V violations involve other  
2 procedural items which have other than minor safety  
3 significance. An example might be the failure to perform  
4 a required test on a timely basis.

5           Lastly, Severity Level VI violations involve  
6 items of minor safety significance, such as documentation  
7 inadequacies.

8           The same general principles were applied to  
9 other licensed activities.

10           The next slide shows the relative ranking of  
11 the new severity levels as compared with the ones that  
12 we have been using -- violations, infractions, and  
13 deficiencies.

14           You will see that the old violations now may be  
15 categorized as Severity Levels I, II, or III; the old  
16 infractions may now be categorized as Severity Level  
17 III in some cases, IV, or V. The old deficiencies  
18 will be equivalent to the new Severity Level VI violations.

19           In general we believe the Severity Levels I,  
20 II, and III are serious violations that should occur  
21 infrequently if appropriate attention is being given to  
22 NRC requirements. We believe the Severity Level IV  
23 violations also should not occur often, and we view the  
24 Severity Level V violations to be equivalent to most of  
25 the infractions that we have had in the past.

1           The different severity levels are defined  
2 separately for each of the seven different program areas  
3 which we regulate. The program areas are shown in the  
4 next slide.

5           While the severity levels show the relative  
6 importance of violations within the same program area,  
7 it is important to recognize that severity levels are not  
8 equatable in terms of safety importance from one program  
9 area to another. Said another way, the severity level I  
10 is the most significant violation in each of the seven  
11 different program areas shown, but a severity level I  
12 violation in the area of reactor operations obviously  
13 does not have the same safety significance as a  
14 severity level I in facility construction, for example.

15           As I mentioned earlier, the determination of  
16 severity categories is event oriented. By that I mean  
17 that any particular violation may, in one instance, be  
18 a severity level II violation while in another instance,  
19 the same violation may be of a lower severity level.

20           Two examples will help to explain this.

21           At a reactor construction site if numerous  
22 violations of the quality assurance criteria in Appendix  
23 A of Part 50 are found, and there are multiple examples  
24 of these violations in several different construction  
25 areas, the items collectively would demonstrate that

1 there has been a breakdown in quality assurance.

2 Based on such a determination, all the violations  
3 related to that particular situation would be categorized  
4 as severity level II violations. Any one of these  
5 violations identified separately in a more isolated  
6 sense may be a lower severity level violation.

7 A second example is in the area of radiation  
8 safety. If an overexposure occurs which exceeds five  
9 rems, and there are other violations such as the  
10 failure to conduct surveys, the failure to follow pro-  
11 cedures, and the failure to properly control access to  
12 an area, all of which contributed to the overexposure,  
13 all of these violations would be categorized as severity  
14 level II violations.

15 On the other hand, any one of these violations  
16 identified separately in a more isolated sense, would  
17 probably have a lower severity level.

18 The policy also stresses the importance that  
19 the Commission attaches to the accurate and timely  
20 reporting of events. Material false statements made  
21 to the Commission will be categorized as severity  
22 level I, II, or III violations, depending on their  
23 relative significance.

24 The failure to make a required report, unless  
25 otherwise specified in one of the supplements, will

1 normally be classified at the severity level of the event  
2 which has not been reported. The failure to make a  
3 required report will be classified as a separate event in  
4 addition to the event not reported.

5 At this point, I would like to address a  
6 comment that we have heard that this Enforcement Policy  
7 may result in required information not being provided  
8 to the NRC. Let me confront that concern by saying that  
9 NRC will consider the conscious failure to provide  
10 required information to the NRC a willful act that may  
11 result in not only civil penalties, but also referral to  
12 the Department of Justice for consideration of criminal  
13 prosecution.

14 One last point on the severity categories.  
15 Due to the general nature of the policy guidance, we  
16 recognize it may be difficult to apply the policy to  
17 certain specific situations which arise, and judgement  
18 will have to be exercised in selecting the proper  
19 severity caregory. We would especially welcome any  
20 comments you may have on clarifying the guidance in this  
21 area.

22 Next, I would just like to give you a couple  
23 of comments concerning Notices of Violations.

24 It is expected that Notices of Violation will  
25 continue to be sufficient enforcement action for greater

1 than ninety percent of the violations which are  
2 identified during inspections. Two changes to the Notice  
3 of Violation should be noted.

4 One, the Notices now reflect the new severity  
5 categories. Secondly, they will not normally require  
6 that responses must be submitted under oath or affirma-  
7 tion as provided for in Section 182 of the Atomic  
8 Energy Act. This latter step was instituted as an  
9 additional assurance of the accuracy of information  
10 provided in response to written Notices of Violation.

11 With respect to licensed operators, as you  
12 may be aware, the previous Enforcement Policy was silent  
13 on enforcement actions against licensed operators. The  
14 present policy provides that Notices of Violation will  
15 normally be issued to operators licensed under the  
16 provisions of 10 CFR Part 55, for severity level I, II,  
17 or III violations.

18 For serious violations which are recurrent,  
19 the probable course of escalated action against licensed  
20 operators will be license suspension or revocation. It  
21 is also possible that civil penalties may be issued  
22 to licensed operators. The policy does not preclude such  
23 action.

24 It should also be noted that enforcement  
25 action against a licensed operator will likely also



1 result in escalated enforcement action against the  
2 facility at which the particular violation occurred.

3 Let me now turn to a discussion of civil  
4 penalties.

5 As shown in the next slide, there are four  
6 general areas that are likely to lead to assessment of  
7 a civil penalty.

8 The first is for severity level I, II, or  
9 III violations which have occurred.

10 Secondly, it is possible to assess civil  
11 penalties for recurring severity level IV and V  
12 violations.

13 Thirdly, the knowing and conscious failure to  
14 report a defect by a responsible official of a licensee  
15 or vendor organization may result in the assessment of a  
16 civil penalty against that particular individual as  
17 provided for in Section 206 of the Energy Reorganization  
18 Act.

19 Fourthly, willful violations may result in  
20 civil penalties.

21 I want to go back and make some additional  
22 comments on the first two items shown on this slide. We  
23 recognize that some technical judgement will enter into  
24 the categorization of severity levels I, II, and III,  
25 and whether they warrant a civil penalty. Normally,

1 however, if it has been determined that a severity  
2 level I, II, or III violation existed, it is the  
3 Commission's intent to issue a civil penalty.

4 Civil penalties will generally be assessed  
5 for recurring severity level IV and V violations which  
6 are similar in nature to those which were the subject of  
7 an enforcement conference and which occurred within  
8 two years following the enforcement conference.

9 An enforcement conference is a meeting  
10 specifically designated as such between NRC and licensee  
11 management for the purpose of discussing specific  
12 violations, the planned corrective action, and the en-  
13 forcement options available to the NRC.

14 If similar violations occur after such an  
15 enforcement conference, and it is concluded that their  
16 occurrence resulted from ineffective licensee action, a  
17 civil penalty will generally be assessed.

18 The next slide shows a table of base civil  
19 penalties for different types of licensed programs and  
20 for different severity levels of noncompliance. In  
21 determining the civil penalty values, primary considera-  
22 tion was given to the severity level of the violation  
23 and potential hazard involved with the licensed operation,  
24 and to a lesser degree, general ability to pay.

25 In general, those programs which present a

1 greater potential hazard and those where licensees  
2 have a greater ability to pay are toward the top of  
3 the table.

4 Let me stress that this is generally the case.  
5 We recognize that isolated instances may not fit the  
6 general pattern. If a large disparity occurs, adjustments  
7 may be made on a case-by-case basis. Again, we would  
8 welcome your comments on the equitable distribution of  
9 civil penalties.

10 You will note from the table that the base  
11 civil penalty values for severity levels I and II are  
12 the same. This is because the same basic noncompliance  
13 act occurred.

14 However, as you will see later in our dis-  
15 cussion, if a severity level I violation occurs; the  
16 licensee will normally be subject to an Order in  
17 addition to the civil penalty, such that the total  
18 enforcement sanction will generally be more severe for  
19 a severity level I than for a severity level II  
20 violation.

21 It is also noteworthy that while the law  
22 provides that a civil penalty of \$100,000 may be assessed  
23 for each violation, the policy provides that for  
24 severity level I, II, and III violations the civil  
25 penalty will be assessed for each event irrespective of

1 the number of violations associated with the event.  
2 Whether more than one event arises out of a series of  
3 violations will be determined on a case-by-case basis.

4 Let me elaborate. For example, referring back  
5 to an example I gave earlier, if several violations were  
6 identified at a reactor construction site which led to  
7 the conclusion that a breakdown in quality assurance  
8 occurred in multiple phases of construction, each of  
9 the violations would be categorized as severity level II.

10 However, the civil penalty would be assessed  
11 for the event; that is, a cumulative civil penalty  
12 of \$80,000 would be assessed for all the violations  
13 which constituted that event, regardless of the number  
14 of specific violations. We believe that such an  
15 approach will help to focus licensee and public attention  
16 on the significance of events as opposed to the  
17 individual violations which may be identified.

18 The mechanics for assessing civil penalties  
19 remain the same; that is, the proposed Notice of  
20 Imposition of Civil Penalties and Notice of Violation  
21 must clearly state which violation occurred, and which  
22 violations civil penalties are being assessed for.

23 For example, if eight violations constitute  
24 a severity level II event, the \$80,000 base civil  
25 penalty may be equally assessed for all eight items

1 which make up the event, or the entire civil penalty  
2 may be assessed against only one violation. The actual  
3 distribution will be determined on a case-by-case basis.

4 There are several factors which enter into  
5 the determination of the civil penalty, some of which I  
6 have already touched on. These factors are shown on  
7 the next slide.

8 The first factor is the gravity or severity of  
9 the violation. This factor is taken into consideration  
10 in the structure of the table itself, in that more  
11 serious violations get higher civil penalties. Also,  
12 those licensees whose programs present a greater  
13 potential health and safety risk are toward the top of  
14 the table, and will be assessed the higher civil  
15 penalties.

16 The next factor is financial impact. This  
17 also is taken into consideration in the structure of the  
18 table, in that generally those licensees who have a  
19 greater ability to pay are in the groups near the top of  
20 the table, and smaller licensees with lesser ability to  
21 pay are generally near the bottom of the table.

22 Next, the duration of the violation will also  
23 impact upon the civil penalty which is assessed. Each  
24 day that a violation continues may be considered as a  
25 separate violation, and therefore subject to a separate

1 civil penalty. We expect to utilize that provision as a  
2 general practice. It is not possible to define before-  
3 hand how this will be applied, because the requirements  
4 and situations differ greatly.

5 As an example, if a required safety system is  
6 valved out so that it cannot perform its function, the  
7 Commission will likely issue a civil penalty for each  
8 day such a condition occurs. On the other hand, if an  
9 overexposure has occurred, that will be considered a  
10 single event where the duration of the violation does not  
11 come directly into play.

12 The policy provides that civil penalties may  
13 be reduced up to fifty percent of the base value if  
14 the noncompliance which led to the civil penalty was  
15 identified by the licensee, reported if required, and  
16 corrective action promptly initiated.

17 This self-identification does not apply to  
18 noncompliance disclosed by incidents such as over-  
19 exposures or accidents. The policy also provides that  
20 if the licensee has acted in good faith, an additional  
21 twenty-five percent reduction in addition to that  
22 already provided for self-identification may be applied.

23 Good faith is not precisely defined in the  
24 policy, but a reduction for good faith will be con-  
25 sidered in those cases where the licensee has taken

1 extraordinarily prompt and comprehensive corrective  
2 action.

3 On the other hand, the policy provides that if  
4 the licensee could reasonably have been expected to  
5 have taken preventive action, or if the violations are  
6 particularly serious, including cases involving will-  
7 fulness, the civil penalty may be increased up to  
8 twenty-five percent over the base value in the table.

9 We plan to review some specific cases in a  
10 little while to better demonstrate how these factors  
11 would influence the determination of actual civil  
12 penalty values.

13 The next slide shows the types of orders which  
14 may be issued by the Commission. There are orders to  
15 modify, suspend or revoke a license, and orders to  
16 cease and desist any particular operation. These orders  
17 may affect all or part of a license activity.

18 Normally, orders for modification, suspension,  
19 or revocation, will be issued with the show cause  
20 provision; that is, they will require a licensee to  
21 show cause why such action as proposed should not be  
22 taken. Such orders always provide a licensee opportunity  
23 for a hearing on the issues.

24 However, if a determination is made by the  
25 Director of the Office of Inspection and Enforcement

1 that the public health and safety, common defense and  
2 security, or public interest so demands, the order may be  
3 made effective immediately.

4 It is possible for orders to be issued which  
5 combine these provisions, that is, an order may require  
6 the immediate suspension of a particular operation,  
7 and may at the same time include a show cause provision  
8 as to why the license should not be revoked.

9 The last slide in this segment of the  
10 presentation shows a progression of escalated enforce-  
11 ment action which may be taken for repetitive serious  
12 violations.

13 This table is not intended to prohibit the  
14 NRC from taking a different action if the case warrants.  
15 The degree to which this progression should be followed  
16 in practice is a subject on which the Commission has  
17 explicitly sought comment.

18 Let me run through an example of how this  
19 table might be applied. If a severity level II violation  
20 occurred, its first occurrence would result in a civil  
21 penalty. A second similar violation within a two-year  
22 period would result in a civil penalty and an order to  
23 either suspend affected operations until the Office  
24 Director is satisfied that there is reasonable assurance  
25 that the licensee can operate in compliance, or to



1 modify the license to impose additional requirements to  
2 provide equivalent assurance. If a third similar violation  
3 occurred within a two-year period, then in addition to  
4 the actions taken the previous time, additional action  
5 to show cause for further license modification or for  
6 license revocation would be the next step.

7 You will note that the table applies to viola-  
8 tions in the same activity area. This means that if  
9 a severity I, II, or III event occurs in the area of  
10 safeguards, a subsequent significant event in the  
11 area of radiation safety would not be considered the  
12 same activity area, and this table would not be  
13 followed.

14 On the other hand, a personnel error leading  
15 to the misvalving of a safety system at a reactor on  
16 one occasion, followed by personnel error which mis-  
17 valved out another safety system would be considered  
18 as the same activity area, and this table would normally  
19 be followed.

20 While we have been discussing the enforcement  
21 actions normally taken by the NRC, it should also be  
22 noted that the policy also provides for criminal  
23 sanctions.

24 Chapter 18 of the Atomic Energy Act provides  
25 that certain violations of regulatory requirements may

1 be criminal offenses. All alleged or suspected criminal  
2 violations are required to be referred to the Department  
3 of Justice for possible investigation and prosecution.

4 I will now turn the meeting over to Mr. Dudley  
5 Thompson who will present a few sample cases demon-  
6 strating how this policy will be applied.

7 MR. THOMPSON: To illustrate application of  
8 the revised enforcement criteria, we have prepared a  
9 few hypothetical enforcement cases, based somewhat on  
10 actual experience. The examples are intended to  
11 demonstrate how the criteria might be applied, so some  
12 of the factual material has been altered from actual  
13 cases.

14 The first case involves a situation in which  
15 a power reactor licensee legitimately removed an  
16 emergency core cooling system from service to perform  
17 maintenance. When the maintenance was completed, a  
18 procedural error, coupled with a personnel error, led  
19 to the system remaining inoperable by virtue of valves  
20 remaining in the closed position.

21 Four days later, routine surveillance on the  
22 system disclosed the inoperable condition, which was  
23 immediately corrected by the licensee and reported  
24 to NRC.

25 The enforcement action is calculated as shown

1 on the slide. This is a severity level II violation of  
2 Supplement I in that a safety system was incapable of  
3 performing its intended safety function.

4 A base civil penalty of \$80,000 as shown in  
5 table I is reduced by fifty percent because the  
6 licensee identified the condition, promptly corrected it,  
7 and reported in a timely fashion. Since the violation  
8 continued for four days, the resulting adjusted \$40,000  
9 civil penalty is multiplied by four, resulting in a  
10 cumulative civil penalty of \$160,000.

11 The second case as shown in the next slide  
12 also involves a power reactor licensee who shipped  
13 radioactive waste to a burial ground. On arrival  
14 at the burial site, a state inspector surveyed the  
15 truck and found radiation levels at the surface of the  
16 truck substantially exceeded DOT limits.

17 The appropriate supplement is Supplement V.  
18 The severity level is II because the radiation level  
19 exceeded three times DOT limits without a breach in  
20 containment. Since this involved a power reactor, the  
21 base civil penalty is \$80,000. No adjustments upward  
22 or downward are applied.

23 Case number three as shown in the next slide  
24 is an example of a situation for which a civil penalty  
25 is of limited value because of the nature of the

1 problem. Instead, more severe sanctions are called for.

2 Over a two-year period, technicians at a  
3 hospital routinely administered double the prescribed  
4 doses of radioisotopes to patients undergoing diag-  
5 nostic procedures. Their motivation was apparently  
6 based on a desire to reduce the amount of time required  
7 for scanning, thus reducing the discomfort and in-  
8 convenience of the patients, most of whom were elderly  
9 and very ill.

10 When it was proposed to follow the same  
11 improper dosage procedure for a teenage patient, one  
12 of the technicians involved became sufficiently con-  
13 cerned that he blew the whistle to NRC. Our investi-  
14 gation confirmed the facts of the case and the actions  
15 shown on this slide ensued.

16 We immediately suspended the license and  
17 issued a show cause revocation order. In addition, the  
18 willfulness aspects of the case dictated that the  
19 matter be referred to the Department of Justice for a  
20 determination of the desirability of criminal prosecution.

21 The final case as shown in the next slide  
22 is one that occurs not infrequently among radiography  
23 licensees -- a classic radiography overexposure.  
24 Following a routine field shot, the radiographer failed  
25 to retract the source before entering the area to set

1 up film for the next shot. No surveys were made;  
2 personnel dosimetry was not carried; and the area of  
3 the shot had not been properly posted.

4 The radiographer and his helper both received  
5 overexposures; the radiographer's whole-body exposure,  
6 based on reenactments, was estimated to have been  
7 twelve rem; the helper's was seven rem. This was a  
8 severity level II event under Supplement IV, because  
9 of the amount of the exposure. This calls for a base  
10 civil penalty under table 1 of \$8,000.

11 There have been numerous notifications to  
12 radiographers concerning similar previous events like  
13 this one. Thus, there is a basis for concluding that  
14 the licensee could reasonably have been expected to  
15 have had prior knowledge and have instituted preventive  
16 measures. This means that the base civil penalty for  
17 this severity level II violation is increased by  
18 twenty-five percent, leading to a cumulative civil  
19 penalty of \$10,000.

20 Considerable flexibility is required and  
21 provided in implementation of the revised Enforcement  
22 Policy. Responsibility for this exercise of technical  
23 judgement is vested in Office Directors who are senior  
24 managers in NRC.

25 For most cases the principal enforcement

1 officer of the NRC is the Director of the Office of  
2 Inspection and Enforcement, although other Office Directors  
3 may, and in some cases do, issue enforcement actions  
4 in their own spheres of responsibility.

5 For example, the Directors of the Office of  
6 Nuclear Reactor Regulation or Nuclear Materials Safety  
7 and Safeguards issue license modification orders which  
8 restrict operation relatively often.

9 Similarly, the Director of the Office of  
10 Administration is authorized to issue license revoca-  
11 tion orders for nonpayment of required fees.

12 Fundamentally, however, we find that public  
13 interest and licensee concern focuses most strongly  
14 on those retrospective enforcement actions associated  
15 with noncompliance with regulatory requirements.

16 Enforcement actions associated with noncompliance  
17 are taken almost exclusively by the Director of In-  
18 spection and Enforcement and the discussion which  
19 follows is based on those cases.

20 Could we have the lights, please?

21 The Director's discretion is exercised both  
22 in his decision regarding which type of enforcement  
23 action to take -- notice of violation, civil penalty,  
24 or order.

25 In the case of a civil penalty, the deter-

1 mination of an appropriate amount to be assessed.  
2 Furthermore, as noted in the previous presentation,  
3 combinations of enforcement sanctions may be used for  
4 higher severity level matters or for repetitive non-  
5 compliance.

6 The choice of enforcement sanctions in such  
7 cases is a responsibility of the Director, based of  
8 course on staff recommendations and consistent with  
9 the general principles in the revised enforcement policy  
10 and the technical merits of each case.

11 The factors considered in reaching these  
12 decisions are those presented earlier and repeated here  
13 associated with determining the amount of a civil  
14 penalty to be applied; that is, gravity of the violation,  
15 duration of noncompliance, method by which the non-  
16 compliance was identified, financial impact on the  
17 licensee, good faith, prior enforcement history, and  
18 consideration of willfulness aspects.

19 The Director notifies the Commission; that is,  
20 the collegial body of the five Commissioners, in  
21 writing of each application of elevated enforcement  
22 sanctions such as civil penalties or orders.

23 In addition, for certain especially sig-  
24 nificant actions, the Commission is consulted prior to  
25 taking the action unless the urgency of the situation

1 requires immediate action to prevent or mitigate an  
2 imminent threat to public health or safety.

3 Prior consultation with the Commission is  
4 required for four types of situations.

5 First, when the action requires a balancing  
6 of the implications of not taking the action against  
7 the hazards to be eliminated by taking the action.

8 Second, proposed imposition of civil penalties  
9 exceeding either three times the value of a severity  
10 level I violation, or the maximum civil penalty for  
11 the next higher severity level for the type of  
12 licensee involved.

13 Third, actions for which the Commission has  
14 requested prior consultation.

15 Fourth, any action the Director believes  
16 warrants Commission attention.

17 An example of the first type of situation  
18 might involve a contemplated license suspension order  
19 for a facility providing products or services crucial  
20 to national defense and security. If the staff  
21 determines that shutdown of the facility might deny  
22 the needed product or service, and thus adversely  
23 effect the nation's interests, prior consultation with  
24 the Commission is required.

25 A second example occurred recently when serious



1 noncompliance involving patient care at a hospital  
2 dictated issuance of a license suspension order. This  
3 is basically the Case 3 example discussed earlier.  
4 Before taking the action, however, the staff made an  
5 explicit determination that needed health services to  
6 the community would not be denied by the order, since  
7 a neighboring hospital was also licensed to perform the  
8 same procedure. Had such a loss been a possibility,  
9 prior Commission approval would have been required for  
10 the suspension.

11           The dollar limits on civil penalties requiring  
12 prior consultation with the Commission can be reached  
13 by either a continuing violation, or by a combination  
14 of events.

15           For example, the inability of a reactor  
16 safety system to perform its intended safety function,  
17 a severity level II event, that continues over a period  
18 of a week might lead to a civil penalty of from \$210,000  
19 to \$700,000, depending on the extent to which adjust-  
20 ments were applied to the base values of table I. If  
21 the adjusted figure exceeds \$300,000, prior Commission  
22 consultation is required.

23           In the case of a continuing severity level III  
24 violation, for example unavailability of a reactor  
25 safety system if offsite power were lost, the civil

1 penalty for a week-long violation might vary from  
2 \$105,000 to \$350,000. Any such civil penalty proposal  
3 would require prior Commission consultation, since  
4 the maximum civil penalty for the next higher severity  
5 level violation at a power reactor is \$100,000.

6 The Commission has already identified  
7 one aspect of implementation of the revised Enforcement  
8 Policy on which it wishes to be consulted under the  
9 third criterion; that is, the first few cases for which  
10 the staff proposes to apply good faith as a basis for  
11 reduction of a civil penalty.

12 Finally, the fourth criterion for prior  
13 Commission consultation provides the mechanism by which  
14 the Director may solicit Commission guidance on new or  
15 unique applications of the policy, particularly for  
16 cases the Director believes to be watershed decisions  
17 establishing precedent.

18 As Mr. Keppler mentioned earlier, copies of  
19 these prepared remarks will be available at the back  
20 of the room at the break, which will occur at about  
21 2:30.

22 This concludes our prepared presentation, and  
23 I believe Mr. Keppler will take the chair now to  
24 handle the questions and comments.

25 CHAIRMAN KEPPLER: Thank you, Dudley.

1 We have approximately twenty people who have  
2 signed up to comment and ask questions concerning the  
3 Policy. I am going to take them in the order that  
4 they have signed up, and the only limitation I would ask  
5 at this time is that you restrict your comments or  
6 questions to a period no more than fifteen minutes.

7 I would also ask that you use the microphone  
8 in the center, and identify yourself and your affiliation.

9 The first on the list is Peter Marquart. Is  
10 he here?

11 MR. MARQUART: My name is Peter Marquart; I am  
12 an attorney. The comments that I am giving are those of  
13 Wayne Jens, Vice-President of Nuclear Operations on  
14 behalf of the Detroit Edison Company.

15 The Detroit Edison Company wishes to thank  
16 the Commission for this opportunity to comment on the  
17 Commission's revised proposed Enforcement Policy.

18 The company is an investor-owned public  
19 utility generating and distributing electrical energy  
20 in southeastern Michigan.

21 The company is impacted by the Commission's  
22 Enforcement Policy because it is constructing a  
23 nuclear facility, the Enrico Fermi Atomic Power Plant,  
24 Unit 2, and because the company is the holder of  
25 several material licenses issued by the Commission.

1           At this time the company wishes to endorse  
2 the comments which are to be filed in this rulemaking  
3 by the Nuclear Utility Group on Enforcement, NUGOE, of  
4 which the company is a member.

5           In providing separate comments, the company  
6 is not in disagreement with the comments to be provided  
7 by NUGOE, but rather to amplify the concern the company  
8 believes may be an unintended result of this revised  
9 Enforcement Policy.

10           The NRC has stated that one of the goals of  
11 this Enforcement Policy is to insure compliance with  
12 the NRC's regulations of license conditions. The  
13 company believes it is the Commission's goal to also  
14 improve the safety of nuclear facilities.

15           This goal, coupled with the apparent mechanistic  
16 approach of the entire Enforcement Policy, has every  
17 possibility of being counterproductive to safety.

18           This will happen if in applying the Enforcement  
19 Policy NRC second-guesses operator actions during  
20 emergency situations, which although violating an  
21 NRC regulation or a license condition, resulted in  
22 safer operation of the facility.

23           While the company does not suggest that  
24 anyone would condone a violation of any regulation or  
25 license condition, it does recognize that despite the

1 best training of operators and the installation of  
2 approved equipment, during emergency conditions the  
3 operators may be confronted with a situation not  
4 adequately addressed in either NRC regulations or plant  
5 licensing conditions.

6 In that situation, the best protection for  
7 the public is knowledgeable operators who are not fearful  
8 of taking that action needed to control the emergency  
9 because they would automatically be subject to sanctions  
10 for violating an NRC regulation or plant licensing  
11 condition.

12 Rather, the operator should know that their  
13 actions will be reviewed in light of the circumstances  
14 they faced at the time, and the NRC will make a judgement  
15 in view of those circumstances of whether or not to  
16 seek sanctions.

17 In short, the company believes that the  
18 Enforcement Policy should reflect and set forth to a  
19 much greater degree that discretion will be exercised  
20 by the agency in determining enforcement actions.

21 The company realizes that the NRC must be --  
22 it must be perceived to be a strong, effective enforcer  
23 of its regulations. However, the Commission must  
24 realize that an Enforcement Policy which, in the  
25 Commission's words, is marked by an aggressive enforcement

1 strategy that seeks more frequent use of stronger en-  
2 forcement measures poses the real probability of  
3 driving qualified people away from the nuclear industry.

4 This would be particularly true if the  
5 people involved perceived enforcement actions to be  
6 unfair.

7 While the Commission has no obligation to  
8 the nuclear industry, it does have an obligation to  
9 the nation. Policies which tend to drive people away  
10 from the nuclear industry can only lead to less safe  
11 operations, and exacerbate the nation's energy problems.

12 Therefore, Detroit Edison believes that the  
13 Commission should review its Enforcement Policy, and  
14 that Policy's implementation, to assure itself that this  
15 Policy is not unnecessarily influencing people's  
16 decisions not to remain in the nuclear industry, or  
17 for others to join it.

18 Once again, the company thanks the Commission  
19 for the opportunity to participate in this rule.  
20 Although these comments are not in a form to be sub-  
21 mitted today, it is our intention to file them before  
22 the close of the docket.

23 CHAIRMAN KEPPLER: Thank you very much.

24 Next on the list is Mr. Ted Fields. Is he  
25 present?

1 MR. FIELDS: I am Ted Fields, a partner of  
2 Fields-Griffiths and Associates. We are a consultant  
3 firm in the Midwest area.

4 I have a number of comments over here that  
5 are not necessarily in a prepared form that I would like  
6 to present at a further date for your benefit, and for  
7 ultimate submission, but these are comments that I  
8 have assembled over here in reviewing the literature  
9 that was sent out to us recently.

10 We are quite concerned in our practice and  
11 consulting of radiation safety programs for over 500  
12 clients in the Midwest in the nuclear-medical field,  
13 primarily.

14 We are quite concerned in the section on  
15 Supplement IV which has to do with health physics. A  
16 few preambles to this which I would like to mention  
17 before getting into some specifics, and specifically,  
18 we would like to at least bring to your attention as  
19 to whether there has been any type of economic impact  
20 statement or any kind of other presentation that the  
21 NRC has done in terms of what the effect would be of  
22 these fines or civil penalties on such carriers that  
23 are in back of us or maybe in front of us in our  
24 practice, in terms of the insurance carriers that we  
25 are very much concerned with at the present time, that

1 practitioners, at least in the health physics society,  
2 are having difficulty attaining.

3           These are people who will be definitely very  
4 much effected in terms of providing this type of  
5 coverage in the future.

6           We are also concerned whether we in our practice,  
7 and as we know we have seen in growth in years past, of  
8 whether we are going to be turned into really a bookkeeper  
9 or accountants, etc., and certainly we have noticed this  
10 in our own practices in the last few years, whereby not  
11 only are we being encouraged to be, let us say accountants,  
12 etc., but we are noticing that there is, as was brought  
13 up by the previous speaker -- that there has been an  
14 encouragement on the part of the NRC, maybe not to  
15 their intent, etc., but they are driving people away  
16 from nuclear energy procedures and back to the x-ray  
17 field.

18           Specifically, I might mention this has happened  
19 -- has had a technological impact, but when we go  
20 ahead and implement procedures or regulations that makes  
21 operators, or smaller operators, very difficult to  
22 operate, and we force them to go into other x-ray  
23 procedures.

24           These x-ray procedures use very much more  
25 radiation, cause much more radiation exposure than



1 similar types of nuclear-medical procedures, and we  
2 have seen this, and maybe an insidious type of slow  
3 progression where we are encouraging less usage of  
4 nuclear energy procedures because of the regulations  
5 and of the penalties that are involved.

6 We are very much concerned, too, about the  
7 regulations that we have seen on Supplement IV over  
8 here and the language being very, very vague, specifically  
9 let me get down to this.

10 You say under Supplement IV, Severity I, which  
11 has to do with the concept of exposure. Now, we have  
12 been involved with dozens of -- or even hundreds -- of  
13 instances where for one reason or another either ex-  
14 posures have to be reported instantaneously, twenty-  
15 four hours later, twenty-five, whatever numbers you  
16 want to come up with, and the NRC bases -- or at least  
17 it has been our experience -- that the concept of  
18 exposure is based primarily on the reading of a film  
19 badge.

20 Now, nothing could be worse, really, than  
21 basing it on the film badge. 99.9% of the exposure  
22 readings were false readings. These are things --  
23 if these are things that are going to have to be  
24 reported in "X" number of minutes or days, etc., this  
25 offers a real large area for future legal manipulations

1 malpractice suits, or whatever you want. I could go  
2 into this for hours. We have investigated all of  
3 these instances that have been brought to our attention,  
4 and the concept of exposure just is not indicated  
5 that tightly in the regulations.

6 The exposure should be, really, at least  
7 according to our evaluation, a real exposure that has  
8 brought -- that has been evaluated as a combination of,  
9 let us say the film badge company, the person in charge  
10 of the facility, and a qualified physicist to evaluate  
11 in fact that exposure, or overexposures, are based on  
12 a film badge reading is nothing but nonsense in our  
13 opinion.

14 We would also like to bring to the attention  
15 that perhaps the NRC should, in implementing these  
16 regulations or civil penalties, perhaps enforce them  
17 according to the level of activities of the individual --  
18 at least a medical facility.

19 It seems to us that in terms of the accounting,  
20 the bookkeeping, the follow-up, etc., that would have  
21 to done by the single small, half-person nuclear-  
22 medical facility out in somewhere away from the big  
23 towns is about the same amount of bookkeeping, quality  
24 control, and whatever you have, for people who have a  
25 half a dozen or a dozen cameras, and this really

1 imposes a tremendous load upon these facilities.

2 I am rather amused here, incidentally, on  
3 some of the speakers, not to perhaps pat us on the back,  
4 etc., but I see that in our year past over here we try  
5 to get ourselves out of business. As a professional,  
6 we try to make it safe for people to do their own work,  
7 and I think the NRC is encouraging dozens of companies  
8 now being set up on a semi-technical, etc., level for  
9 carrying out the regulations, and there is a horrendous  
10 expense, and there's no way around it.

11 We see the new devices, and the personnel  
12 getting into it, and it's been the small user which  
13 really doesn't have that much radiation exposure in-  
14 volved to go ahead and have to follow these regulations.  
15 Somebody has to pay for it.

16 So, in general, it gets down to the fact that  
17 we think the language here is definitely vague. We  
18 would like to have more consideration put into the  
19 economic impact all the way down the line, not only  
20 to the user, but what avenues could be opened up in  
21 terms of the insurance, the accounting, the legal  
22 responsibilities.

23 We would like to have some evaluation or  
24 some consideration made in terms of an appeal process  
25 that when penalties are imposed we would like to see

1 some efforts made in that or another area similar with  
2 what we have with the IRS, etc., that some appeal be  
3 possible before we get really involved with the fines  
4 that can be assessed -- that there be some type of  
5 appeal process that would be simple to apply that can  
6 be enforced at the same moment.

7 I want to thank you for your attention, and  
8 we will submit these comments at a later date.

9 CHAIRMAN KEPPLER: Let me just ask you,  
10 in submitting comments if you could come up with some  
11 language to take out the vagueness of the things you  
12 are referring to it would be helpful to us.

13 I would also say that with respect to your  
14 comments about film badge as a mechanism of determining  
15 overexposures, this document doesn't say that, and the  
16 determination of how much dosage an individual got  
17 would be determined the same way it has been in the  
18 past, irregardless of this policy.

19 What we are interested in is the exposure to  
20 the individual -- the real exposure. If it's determined  
21 the film badge isn't an accurate reading, we will  
22 review what the dose is through other means.

23 MR. FIELDS: I might just add to that, it's  
24 been our experience where badges have come back with  
25 high readings that we were gigged -- or we weren't,

1 but let's say the people we work for were gigged on  
2 the fact that they didn't report this immediately, and  
3 it was our judgement that some of these readings were  
4 just impossible when you run off twenty-five or fifty  
5 rads minimum for years.

6 So, this has come up before, and the NRC has  
7 been using film badge readings from the suppliers as  
8 the means for coming up with this judgement that they  
9 did have an overexposure that was not reported within,  
10 let's say a twenty-four hour period. It's worthy of  
11 discussion in any event and should be spelled out.

12 MR. THOMPSON: I would like to add a couple  
13 comments in this area.-- work backwards through your  
14 comments.

15 There is nothing in this policy that denies  
16 or institutes any changes to the appeal procedure  
17 which has been and continues to be available to all  
18 licensees for all elevated enforcement actions. The  
19 right of appeal is available and is availed by many  
20 licensees when they seek to have appeal of the imposition  
21 of an elevated enforcement action. That is a decision --  
22 that is a right of the licensee involved. They use  
23 it sometimes, and they don't use it sometimes, but it  
24 is available, and nothing in this policy changes it.

25 Secondly, for the first time this afternoon,

1 and I suspect not for the last time, I need to point  
2 out two things. First, this policy in no way can  
3 create regulatory requirements. Enforcement, by its  
4 nature is retrospective in character based on violations  
5 of existing regulatory requirements imposed by other  
6 means. This does not impose requirements.

7 This is the means by which we take action to  
8 prevent recurrence of violations of requirements  
9 imposed through other mechanisms. We don't impose  
10 new requirements in retrospect enforcement actions.

11 There are, of course, some conditions where  
12 we need to impose license conditions that are prospective  
13 in nature, but the vast bulk of what we are talking  
14 about in the Enforcement Policy is retrospective and  
15 does not establish requirements. It only takes action  
16 when noncompliance is identified.

17 I don't think I have any other comments.

18 CHAIRMAN KEPPLER: The next person on the  
19 list is Mr. Robert S. Hunter from Indiana and Michigan  
20 Electric Company.

21 MR. HUNTER: Good afternoon, and thank you  
22 for this opportunity to make a few comments before this  
23 group.

24 I am Robert S. Hunter, Vice President of  
25 Indiana and Michigan Electric Company, and also

1 Executive Vice President of the American Electric  
2 Power Service Corporation.

3 Indiana and Michigan Electric Company owns  
4 the Donald C. Cook Nuclear Power Plant, and the  
5 American Electric Power Service Corporation provides  
6 management and engineering services to that plant.

7 My remarks will be limited to several of the  
8 questions that you have raised in your invitation to  
9 this meeting. There are more extensive comments that  
10 are being made through the Nuclear Utility Group on  
11 Enforcement of which we are a member.

12 Let me first state that the challenge that  
13 you have undertaken to develop a program, an enforcement  
14 program, is commendable but very difficult.

15 We support the development and the use of  
16 a coherent, fair, and equitable policy which provides  
17 all concerned, the NRC staff, the licensees, and the  
18 public, with an understanding of how enforcement will  
19 be utilized by the Commission.

20 We agree with the NRC that the thrust of  
21 such a policy should be to further heighten safety  
22 and not retribution. Such a policy should provide for  
23 great flexibility and discretion so that it is not  
24 artificially and blindly applied.

25 We all should recognize though that violations

1 are going to occur. You must keep in mind that from the  
2 multiplicity of regulations, technical specifications,  
3 and procedures, stem literally thousands of requirements  
4 that must be met. At best, an enforcement program  
5 can serve only to reduce the frequency, and perhaps  
6 the severity, of violations.

7 Therefore, an enforcement program should  
8 provide strongest encouragement for licensees to take  
9 prompt corrective action and substantially reduce the  
10 likelihood of future violations.

11 We believe that the potential for avoidance  
12 of civil penalties is one form of such encouragement  
13 which will help the policy's laudible goals to be  
14 more rapidly achieved.

15 Let me comment on some of the specific  
16 questions. Is the policy fair and equitable? To be  
17 fair and equitable, an enforcement policy must be  
18 understandable, it must define the standards of be-  
19 havior and criteria for punishing violators, and it  
20 must provide for impositions of sanctions in a reasonable  
21 sense and manner on a case-by-case basis.

22 For the proposed policy to be fair and  
23 equitable, its standards and criteria must be more  
24 clearly articulated, and it should provide for greater  
25 recognition of those licensees who willingly undertake



1 to detect, and correct, and report violations.

2 Accordingly, our strongest recommendation  
3 today is that you provide for the reduction of the base  
4 civil penalties by as much as seventy-five percent, not  
5 fifty percent, and provide further that if a licensee  
6 takes extraordinary and comprehensive corrective action  
7 -- your definition of good faith -- it should not be  
8 fined at all.

9 Can you imagine a press release in which  
10 NRC commends a licensee for its exemplary corrective  
11 action and determines that no civil penalties will be  
12 assessed? This whole industry needs that kind of  
13 recognition, is hungry for such recognition.

14 Ultimately, of course, the answer to this  
15 question lies not in the reading of the policy, but  
16 in its application. If sanctions are judiciously  
17 applied and tailored to assure safe operations of  
18 reactors, then such sanctions and the underlying  
19 policy can be characterized as fair and equitable.

20 The next question -- are the severity levels  
21 appropriate? The severity levels and the supplements  
22 raise many question.

23 What criteria were used to place particular  
24 violations in their various levels? Why in Supplement I  
25 does satisfaction of the action statement prevent a

1 violation in Severity 3-1 but in no other category?

2 For example, if the action statement for  
3 assistance covered by Severity Level 2-1 is satisfied,  
4 why is there a violation?

5 Without going to the criteria, it is impossible  
6 to determine how an as yet unidentified violation  
7 would be placed in a particular severity category.

8 Additionally, it is not clear how the  
9 supplements are to be applied. What is the definition  
10 of the term violation? Are there degrees of violations,  
11 and how does the proposed policy differ from the present  
12 one?

13 Will the present policy of categorizing  
14 noncompliances into deficiencies, infractions, and  
15 violations be retained, or must all violations be  
16 placed in the severity levels?

17 Are the supplements for guidance only, or  
18 are they mandatory, and what is the definition of  
19 the word system? Does it include redundant systems  
20 or sub-systems?

21 What is the purpose -- or what purpose is  
22 served by having Severity Levels V and VI? No  
23 explanation is given what violations fall under these  
24 categories, and no penalty is stated for Level VI  
25 violations, and if the present categories of non-

1 compliance are to be retained, then we suggest that V  
2 and VI should be deleted for lack of definition.

3 If, however, all violations must be fitted  
4 into a level, then these examples should be given so  
5 that a degree of certainty is added to the supplements.

6 There should be a clear distinction between  
7 Severity Levels I and II, and it should be at least  
8 reflected in a lower base civil penalty for the  
9 second level.

10 In Supplement I that relates to release of  
11 radioactivity offsite greater than ten times the  
12 specification falls into Severity Level I, while  
13 exceeding the level by five times falls into Level II,  
14 yet the fine would be the same for either case. This  
15 doesn't make any sense.

16 I return to question seven. Is the degree of  
17 discretion allowed to Office Directors appropriate?  
18 Should there be more flexibility permitted or less?  
19 I said at the outset, and will repeat it here, that the  
20 policy should be flexible and discretionary.

21 The proposed policy provides for some  
22 flexibility, but we would like to see more flexibility  
23 and for downward adjustments of fines and less for  
24 imposing higher fines. We believe the present scheme  
25 does not allow the Director enough flexibility to

1 provide incentives, such as minimal fines to find and  
2 correct violations.

3           Additionally, although the policy speaks in  
4 terms of discretion, it prevents the discretionary  
5 decisions of not imposing of fines at all by limiting  
6 reductions to specific percentages. I expressed our  
7 view on this earlier.

8           There should be enough flexibility to reduce  
9 the fine by seventy-five percent, and in some cases  
10 by one hundred percent.

11           However, if the present scheme is retained  
12 with additional reduction for good faith, your proposal  
13 should be twenty-five percent of the original base civil  
14 penalty and not the adjusted value.

15           You should also consider flexibility by  
16 recognizing in the policy the authority to reduce the  
17 civil penalty by some or all of the costs incurred  
18 by a licensee to correct a violation. This would  
19 augment the efforts to encourage improvements of  
20 licensee performance and reduce the likelihood of  
21 punishment for punishment's sake.

22           As for the discretion to impose large fines,  
23 we think the Commission should become involved sooner  
24 than the proposal now provides, although you have  
25 explained it here that perhaps they will.

1 We did find the present trigger mechanism  
2 for Commission involvement a bit confusing.

3 We believe that the base civil penalties should  
4 be the point of reference rather than the maximum  
5 civil penalties. We suggest that a fine for continuing  
6 Severity Level III, IV, or V violations which exceeds  
7 the base civil penalty for a single violation of the  
8 next higher severity level should be approved by the  
9 Commission, and a fine for continuing Severity Level I  
10 or II violation which exceeds the respective base  
11 civil penalty also should be approved by the Commission.

12 We think early Commission involvement is  
13 important when such large sums of money may be extracted  
14 from the licensee. The prospect of early Commission  
15 involvement will provide a degree of even-handedness  
16 necessary to assure appropriate use of such large fines.

17 Another point to be made involves the  
18 potential increase by twenty-five percent where a  
19 licensee could have been expected to take preventative  
20 measures.

21 It concerns us that the policy identifies  
22 information notices, circulars, and other means as  
23 sources of knowledge which may put a licensee on  
24 notice of a problem. We think information notices and  
25 circulars are too informal and indefinite to be used

1 as notice mechanisms, and we do not know what other  
2 means might be used.

3 Accordingly, the NRC should clarify the basis  
4 for determining that a licensee was on notice of a  
5 problem and should therefore have corrected it.

6 Finally, we wish to comment on the responsibility  
7 section. First, language in the footnote puzzles us.  
8 It says: "IE will normally confine use of its authority  
9 to actions based on violations of existing requirements."  
10 This raises the question of what is the Enforcement  
11 Policy? If it is not to enforce only existing require-  
12 ments, what is it?

13 What, other than violating an existing  
14 requirement, would justify IE's use of its authority?  
15 Should not your statement that civil penalties are  
16 imposed only for violations of existing requirements  
17 be in this on the civil penalty section?

18 Second, we would like to see the delegation  
19 of authority placed into the text of this policy and  
20 limit the delegation of authority to issue civil  
21 penalties to only the Director of IE.

22 Question nine, are the provisions for  
23 escalated actions set forth on table II appropriate?  
24 We agree that repetitive violations of the same type  
25 over a period of time may call for escalated enforcement

1 action. However, we think the conditions for taking  
2 such action require clarification.

3 Our first comment is define what a repetitive  
4 violation is. Were the violations similar enough to  
5 merit escalated action?

6 For example, if over a given period of time  
7 a licensee first exceeds one safety limit and then  
8 another, is the second violation considered similar?  
9 Is it more than one safety limit was violated, or does  
10 it have to be the same safety limit? This question  
11 also is important when considering civil penalties for  
12 Severity Levels IV and V.

13 The stated policy is to impose penalties only  
14 after repetitive violations have occurred. In the  
15 case of not following procedures, is it not following  
16 a series of procedures, or not following the same  
17 procedure more than once?

18 This leads us to our second comment. Escalated  
19 enforcement action for repetitive violations should  
20 only be applied where there exists a pattern of non-  
21 compliance or willful disregard.

22 As I said earlier, because of the thousands  
23 of requirements violations will occur, but where a  
24 licensee strives to prevent that, or detects and  
25 corrects those that do occur, it should not be punished

1 more than once for isolated rather than programmatic  
2 concerns.

3 With regard to the less serious violations  
4 in Severity Levels V and VI, the time frame for  
5 enforcement action should be six months rather than  
6 two years. Again, there are many, many requirements  
7 that must be met.

8 Additionally, it is not clear whether table II  
9 is mandatory, although I think you explained it, and  
10 we suggest that it be identified as guidance only.  
11 Its examples should be those that could be taken, not  
12 those that would be normally prescribed.

13 Finally, we suggest for the reasons mentioned  
14 earlier, escalated enforcement actions for Levels I,  
15 II, and III require consultation with the Commission  
16 prior to taking any action.

17 I would close my remarks by emphasizing two  
18 points. First, you need to provide greater incentives  
19 to licensees to correct violations.

20 Knowing that detecting and correcting  
21 violations will not result in harsh punishment will  
22 provide the needed encouragement to take the proper  
23 action.

24 Second, you need to clarify certain portions  
25 of the policy to eliminate as many questions as



1 possible. It must be made more understandable.

2 I thank you for this opportunity, and I hope  
3 that my comments have been constructive.

4 CHAIRMAN KEPPLER: Thank you. I would say  
5 that I noticed you were a little late coming in, and  
6 I think several of the points that were raised in your  
7 questions are contained in the remarks that will be  
8 handed out during the break period.

9 I appreciate your comments.

10 The next person who signed up is Mr. Lincoln  
11 Hubbard.

12 MR. HUBBARD: First, I would also like to  
13 thank the NRC for this opportunity to speak on this  
14 important matter.

15 The American Association of Physicists in  
16 Medicine, Midwestern Chapter, is the professional  
17 organization of medical physicists in Illinois and  
18 parts of Indiana and Wisconsin.

19 Our members are trained scientists, most  
20 holding advanced degrees, and most having specialized  
21 clinical training in the medical use of radiation.  
22 Our members supply almost all the radiation therapy  
23 physics in our area, and most of the radiation protection  
24 in the medical facilities.

25 As such, our members represent the largest

1 fraction of medical radiation expertise in this area.  
2 The major professional activity of the members of the  
3 AAPM - MC is the efficacious and safe application of  
4 ionizing radiation for medical diagnosis and therapy.  
5 Through education and other voluntary programs we work  
6 to enhance these goals.

7 We recognize that although voluntary means  
8 can be very effective in most situations, mandatory  
9 efforts such as the NRC's and the State's is needed  
10 to eliminate unskilled and careless operations.

11 We feel that regulation and enforcement  
12 should encourage programs which are safer, more  
13 efficacious and more cost effective. This includes  
14 the attraction and retention of high quality pro-  
15 fessionals in medical radiation fields.

16 The AAPM - MC notes with considerable dis-  
17 appointment certain trends within the NRC in the last  
18 year or two which may lead to an estrangement between  
19 professional medical radiation workers and the NRC.

20 The NRC seems to have embarked on a series  
21 of initiatives in rule making which excludes or runs  
22 in the face of judgement in the fields they regulate.  
23 First, contrary to the requirements of publishing  
24 rules and the public hearings before final rule  
25 promulgation, the NRC issued its edict on ALARA.

1 Through heavy protest this was temporarily withdrawn  
2 only to be reissued by edict'.

3 Although the ALARA concept is probably the  
4 most generally accepted principle of radiation safety,  
5 the NRC did not attempt to obtain an endorsement or  
6 even understanding from professionals or the professional  
7 societies of its ALARA program. The residual program  
8 is a paper-work pretense.

9 Second, without comment or endorsement of any  
10 major professional group, the NRC issued as an emergency  
11 an immediate gamma-beam teletherapy license change  
12 requiring radiation monitors with many questionable  
13 properties.

14 The AAPM - MC, questioning several particulars  
15 of this emergency rule, has requested a hearing on this  
16 rule. The NRC, although seeing fifteen days as a  
17 suitable implementation time for this rule, has not  
18 in six months seen fit to formally acknowledge the  
19 hearing request, to say nothing of responding to the  
20 request. We believe this rule is counterproductive to  
21 safety in several details.

22 To quote the NRC on its recent misadministration  
23 rule: "Ninety percent of the comments were opposed  
24 to the rule." Many significant questions were raised  
25 in these comments, but they have been brushed aside

1 with "unless Congress should expand NRC's authority,  
2 the NRC must operate under the presumption that  
3 Congress intended that a disproportionate degree of  
4 federal regulatory control be exercised."

5 This rule is highly counterproductive. An  
6 announced "misadministration of radiation therapy"  
7 could do enormous damage to an institution, even when  
8 the actual patient treatment is professionally sound.  
9 Several examples of such misadministrations are des-  
10 cribed in the "clarifying" document issued by the  
11 NRC in November, 1980.

12 Thus, institutions, particularly radiation  
13 therapy facilities, must do everything in their power  
14 to avoid misadministrations by changing their modality.  
15 For example, if possible use less-safe radium for  
16 brachytherapy rather than cesium by simplifying their  
17 prescriptions, for example back to milligram hours  
18 and given dose from the clinically more meaningful  
19 tumor dose, and not discovering errors, for example,  
20 no checks at or near the end of treatment.

21 Unfortunately, the less efficient the operation,  
22 the less likely that a misadministration will be dis-  
23 covered, and virtually all misadministrations must be  
24 self-discovered.

25 In addition to the generation of rules and

1 license conditions of questionable validity, we  
2 question the wisdom of the Commission's intent that  
3 its enforcement program be marked by an aggressive  
4 enforcement strategy that seeks more frequent use of  
5 stronger enforcement measures.

6 The NRC, with its liberal use of strong en-  
7 forcement methods is expanding its power over the  
8 economic and professional status of employees of  
9 licensees. Hospitals and other medical institutions  
10 are not accustomed to fines and similar measures; they  
11 are not in a position to do much more than pick out  
12 a scapegoat, one or more to the satisfaction of the NRC.

13 Most hospitals feel constrained against  
14 entering a noisy legal battle. These aggressive  
15 enforcement activities without any prior safeguards, such  
16 as hearings, etc., to imposition exert a force dis-  
17 proportionate to any financial penalty, and most of  
18 the impact of this enforcement will be borne by  
19 individual employees of the licensees. Several examples  
20 of this at local institutions have occurred.

21 Many of the severe offenses as designated by  
22 the NRC are, in fact, paperwork hazards. For example,  
23 at one institution where I assisted in producing some  
24 of the licensing documents, the paperwork got lost by  
25 the NRC. The NRC's thirty-day letter stimulated

1 several phone calls which lead to the discovery of the  
2 paperwork and the over-hasty issuance of a renewal.

3 One radionuclide which had been the subject  
4 of much of the back and forth paperwork was overlooked  
5 in the Washington office. Since there was no comment,  
6 we assumed that a full renewal had been received.  
7 Technically, for about a year this institution had a  
8 severity III violation, item two in severity III,  
9 supplement VII. For this, or the majority of the  
10 violations written up at inspection, stiff fines are not  
11 justified.

12 Suppose this problem had been discovered by  
13 an inspector who may have been disturbed by not having  
14 immediate access to the physicist? And supposing the  
15 physicist had clearly explained to the inspector that  
16 it really was the NRC's oversight not his? For this  
17 lack of cooperation that physicist may be categorized  
18 as not interested in radiation safety or in eliminating  
19 problems with the licensee's program.

20 Will a fine for the hospital and a pink slip  
21 for the physicist be an anticipated sequel? As a conse-  
22 quence of the power the inspector has, the licensee personnel  
23 must take a more or less degrading approach with in-  
24 spectors. Only at several professional peril would  
25 licensee personnel naively express vexation at an

1 inspector monopolizing time or facilities.

2 The inspectors are obviously very important  
3 in any enforcement program, but particularly in a  
4 very aggressive one. Many of the NRC inspectors have  
5 given considerable professional support to the licensee  
6 programs. However, we note that there is no uniformity  
7 of training and no standards for inspection. That is,  
8 there is no internal quality control in the NRC to  
9 insure a uniform quality inspection. The inspectors  
10 are under pressure to maximize the number of non-  
11 compliances found.

12 The AAPM - MC agrees with the NRC that strong  
13 measures are required when the potential of real  
14 hazard exists, but penalties should only be levied  
15 when the licensee has permitted a serious hazard to  
16 exist or a real overexposure which has a significant  
17 risk has occurred.

18 In general, the goals and purpose of the  
19 NRC are widely applauded. We feel that these will be  
20 enhanced by making the NRC rules and enforcement  
21 policies practical and sound. Continued progress in  
22 radiation safety requires the cooperation between  
23 professional experts actually working in the field and  
24 the regulatory bodies.

25 CHAIRMAN KEPPLER: Thank you very much.

1 I suggest we take a coffee break for about  
2 fifteen minutes. I suggest we be back here at five  
3 minutes to 3:00.

4 (Short recess taken)

5 MR. THOMPSON: The next speaker identified  
6 wishing to make a statement is Mr. George Schultz. Is  
7 Mr. Schultz in the audience?

8 (No response)

9 MR. THOMPSON: In his absence, the next  
10 individual identified is Mr. Richard Blaisdell, who  
11 is appearing as a private citizen.

12 MR. BLAISDELL: Thank you, gentlemen. My  
13 name is Richard Blaisdell, and I am an employee of  
14 Black and Beach Consulting Engineers in Kansas City,  
15 Missouri.

16 We are involved in the consulting aspects of  
17 nuclear power plant design.

18 I find that I am somewhat left out of your  
19 policy, because I am not a licensee, I am not license  
20 holder, nor am I an employee of a license holder.  
21 The only aspects that seem to apply to me are those  
22 in Part 21.

23 In referring to the policy in II, the very  
24 last sentence that was clarified by Mr. Thompson,  
25 indicates that the NRC imposes civil penalties only on



1 the basis of violations of existing requirements. I  
2 hope that is interpreted to mean on requirements that  
3 exist when the time of the act occurs.

4 Design sometimes is four and five years in  
5 the making, and requirements change over that time period,  
6 and I hope that would be judged in the relationship to  
7 the requirements at the time the act occurs.

8 At the end of roman three, there is a sentence  
9 that indicates that part twenty-one -- failure to make  
10 a part twenty-one report can be assigned a severity  
11 level of I, II, or III. I look at Supplement II, Item D,  
12 and I find it is considered a severity level IV for  
13 failure to make a review or make a report. There  
14 appears to be some conflict there, at least as I read  
15 the words now.

16 In referring to table 1, I am assuming, and  
17 clarify me if I am wrong please, that the last category  
18 of all licensees or other persons subject to civil  
19 penalties is the category for those individuals con-  
20 sidered directors or officers of companies regulated  
21 by part twenty-one.

22 MR. LIEBERMAN: That is correct.

23 MR. BLAISDELL: That part twenty-one falls  
24 under that particular area?

25 MR. LIEBERMAN: And licensed operators, too.

1 The responsible officer under 206 of the Act would  
2 fall under this last category.

3 MR. BLAISDELL: Therefore, my actions in  
4 relationship to design of construction of a facility are  
5 governed by this last category, and not by the  
6 severity levels for the construction of that facility?  
7 I will leave that subject to later interpretation.

8 MR. THOMPSON: I don't understand the comments.

9 MR. BLAISDELL: Well, I can take an action in  
10 a design organization that may cause some problem in  
11 a construction of a facility -- an error in a drawing,  
12 an error in calculating, something. My actions would  
13 be governed by the last category, and not necessarily  
14 the consequence of that safety system in the facility.

15 We may need to deal with that later, and  
16 hopefully -- I don't need a response to that. I will  
17 leave that comment with you, and we will go from there.

18 I would encourage you to consider issuing  
19 a NUREG or some other document very similar to what  
20 you did on part twenty-one after the series of part  
21 twenty-one meetings that you held some two to three  
22 years ago, where many of the comments and questions were  
23 put forward and the responses recorded by the NRC.

24 I have found that document to be very useful  
25 and worthwhile, and refer to it on many occasions.

1           Someplace in roman four, under enforcement  
2 actions, just above Item C, there's a sentence that  
3 reads: "A greater civil penalty is imposed if a  
4 violation continues for more than one day." Because  
5 of the time lapse between when a design decision is  
6 made and when it may be discovered as a problem under  
7 part twenty-one, I hope that per day penalty does not  
8 apply in those particular cases.

9           The examples provided by table 2 indicate an  
10 increase in severity in terms of civil penalties and  
11 in actions to suspend licenses. Obviously, since I do  
12 not have a license, and am not a licensed entity, that  
13 option is not available, and I am assuming it doesn't  
14 apply. I would hope that in your review of this policy,  
15 gentlemen, that you deal a little more in depth with  
16 the requirements of part twenty-one, since they are  
17 dispersed through procurement actions through many lower-  
18 tier organizations and widely utilized throughout the  
19 United States.

20           Many of these organizations that fall under  
21 part twenty-one are not directly licensed, nor are  
22 they directly inspected. I happen to fall under the  
23 licensee, contractor, vendor inspection program, and  
24 as such, I am directly inspected by the inspectors in  
25 Region IV, but there are many people in the United States

1 who fall under part twenty-one as a lower-tier procurement  
2 that do not receive direct inspections, and I think  
3 that their role and their liability under this need a  
4 little more clarification for those of us in that aspect  
5 of the industry.

6 I have no other comments, gentlemen.

7 CHAIRMAN KEPPLER: Thank you.

8 The next speaker is Ms. Catherine Quigg.

9 MS. QUIGG: Thank you for this opportunity to  
10 make comments on your proposed policy.

11 My name is Catherine Quigg; I am research  
12 director of Pollution and Environmental Problems, Inc.  
13 On behalf of the members of my non-profit public interest  
14 organization in Pallatine, Illinois, I have the  
15 following comments on the proposed Enforcement Policy.

16 It is unsettling to realize that even perfect  
17 licensee conformance to existing and proposed NRC  
18 regulations and license conditions will not ensure  
19 public health and safety.

20 The NRC identified seventeen unresolved safety  
21 issues in 1978 and assigned twenty-two generic tasks  
22 to resolve them. These unresolved safety issues  
23 include, but are not limited to, water hammer, generator  
24 tube integrity, anticipated transients without scram,  
25 nozzle cracking, and pipe cracks.

1 To date, only three of these generic tasks  
2 have been completed, and the public safety continues  
3 to be jeopardized. An unresolved safety issue is a  
4 matter affecting a number of nuclear power plants that  
5 poses important questions concerning the adequacy of  
6 existing safety requirements for which a final resolu-  
7 tion has not yet been developed and that involves  
8 conditions not likely to be acceptable over the lifetime  
9 of the plants affected.

10 The NRC's schedule for releasing a staff  
11 report on most of these issues has been delayed due  
12 to NRC staff shortages. As a result, an examination  
13 of these serious safety problems has been postponed  
14 longer than a year in some cases.

15 We in Illinois are particularly concerned with  
16 the unresolved safety issue called "anticipated transient  
17 without scram." We have two operating boiling water  
18 reactors at Quad Cities and two at Dresden with this  
19 defect involving failure of control rods to properly  
20 insert into the reactor after detection of trouble by  
21 reactor safety instruments.

22 We believe that it is negligent of the NRC  
23 to allow the licensees to operate these reactors with  
24 this serious defect and believe that this example  
25 illustrates our case that a licensee can fulfill the

1 letter of NRC's law and still jeopardize the public  
2 health and safety.

3 We submit that a more active, aggressive, and  
4 objective organization than the NRC is needed to license,  
5 monitor, investigate, and regulate nuclear facilities  
6 in the United States.

7 The activities described under safeguards in  
8 your proposed regulations are not sufficiently com-  
9 prehensive. Most nuclear facilities rely on security  
10 guards to provide security. The background and quali-  
11 fications of these guards are intrinsic to the measure  
12 of security and safety they can provide.

13 We believe that prevention of the types of  
14 violations listed under safeguards is best achieved by  
15 strict requirements for guard personnel, some of whom  
16 will be supplied with firearms.

17 To this end, we believe there should be a  
18 regulation requiring a thorough security check, including  
19 FBI clearance, for each guard now in service at every  
20 nuclear facility and for every guard hired in the  
21 future. Violation of this requirement should be  
22 considered a severity I violation. All allegations  
23 regarding security violations should be given top  
24 priority and investigations should be conducted by  
25 experienced personnel.

1           Our concern in this area stems from our  
2 awareness of lax guard hiring practices in the past at  
3 the Zion Nuclear Station where at least one ex-convict  
4 has been hired as a guard. The ex-convict in this case  
5 was subsequently re-imprisoned for another non-nuclear  
6 offense.

7           While imprisoned he made allegations about  
8 security at Zion. His allegations were investigated  
9 by an NRC intern who visited the prison-ensconced guard  
10 and quizzed him about the specific details and dates  
11 of his complaints.

12           The NRC's investigatory report on the guard's  
13 allegations indicates a vice president of RSS, the  
14 contracted guard service, was also contacted for his  
15 records and observations on the background of the  
16 allegor. The RSS records were incomplete, and the  
17 vice president said the ex-convict must have been a  
18 short-timer.

19           The NRC investigation of the ex-convict's  
20 charges concerning serious security lapses at Zion  
21 turned into an investigation of the man himself,  
22 rather than the hiring practices of the licensee and the  
23 conduct of guards on the job. We agree this should have  
24 been part of the investigation, but not the whole.

25           One who reads the allegations and then the

1 NRC's follow-up report is left with a realization of  
2 the inadequacy of NRC investigations, and that the  
3 protection of the licensee rather than public safety  
4 seems of paramount concern.

5 In this case an opportunity to improve security  
6 was missed because more emphasis was placed on proving  
7 the allegor wrong than on doing a first rate job of  
8 uncovering security violations.

9 We submit the proposed regulations are de-  
10 ficient because they do not provide a description of  
11 NRC inspection obligations. Sound inspection practices  
12 would act as a deterrent to safeguards violations in  
13 our opinion.

14 Licensee should be obliged to report all  
15 violations of its technical specifications, even if it  
16 plans or has completed corrective action. This pro-  
17 cedure will notify the NRC of possible problems generic  
18 to a specific kind of reactor or facility.

19 Contrary to the proposed NRC policy for notice  
20 of violation, we believe the NRC should issue notices  
21 of violation even for those violations identified by  
22 the licensee and corrected. In these situations  
23 licensee identification of violations might be con-  
24 sidered a mitigating circumstance in determining  
25 severity of penalties.



1           The NRC's proposed increases in civil  
2 penalties is an action we approve. The ceiling on fines  
3 has been much too low. In October, 1977, TRW's study  
4 reported that monetary amounts for a civil penalty  
5 precludes their having any noticeable effect on the  
6 utilities' profitability.

7           Some industry spokesmen believe that licensees  
8 should not be punished if they take immediate corrective  
9 action after identification of violations. This is  
10 ridiculous. If a valve is incorrectly closed, and the  
11 emergency core cooling system rendered inoperable for  
12 four days, those are four days of horrendous risk to  
13 the public.

14           Just because the licensee takes immediate  
15 corrective action and opens the valves does not make  
16 him less guilty of serious neglect.

17           The phrasing of the last paragraph in column  
18 two on Federal Register page 66756 suggests reduction of  
19 civil penalties by as much as fifty percent. This  
20 seems more a bribe than an incentive. We recommend  
21 this paragraph be reworded to read: "If prior to  
22 NRC discovery a licensee identifies, immediately  
23 corrects, and reports a violation in a timely fashion,  
24 a reduction in civil penalty will be considered."

25           It is necessary to insert the word

1 "immediately" before the word "corrects" to indicate  
2 that licensee will not benefit by a delay in reporting  
3 in order to correct violations.

4 It seems naive for the NRC to think that a  
5 multi-billion dollar public utility would consider the  
6 saving of a few thousand dollars an incentive, es-  
7 pecially when the utility is accustomed to passing on  
8 its losses by charging higher rates to consumers. The  
9 NRC should be specific as to what exact time period  
10 constitutes timely fashion for each offense.

11 It offends common justice for electricity  
12 rate payers to be assessed for civil penalties imposed  
13 on utilities for malfeasance or violations. We recommend  
14 an NRC instruction to state utility commissions advising  
15 that civil penalties be paid by licensee investors  
16 and not passed on to rate payers.

17 The financial impact should not be included in  
18 the determination of the amount of civil penalty.  
19 Abating risks to the public should be the overriding  
20 consideration of the NRC in its imposition of civil  
21 penalties, not the financial health of a given licensee.

22 The NRC should issue notices of violations for  
23 violations and penalties at all severity levels. This  
24 policy will assist the NRC in analyzing patterns of  
25 violations which cumulatively might have safety

1 significance. Realization of the adverse public  
2 reaction to violations may provide utilities with greater  
3 incentive to prevent violations than increased civil  
4 penalties. However, we would like the record to show  
5 that we approve of the increase in civil penalties. It  
6 is a long needed reform.

7 Civil penalties should be imposed for  
8 Severity Level IV, V, and VI violations. These penalties  
9 are lesser amounts for lesser infringements. They will  
10 have no impact if the possibility of their imposition is  
11 reduced by unnecessary and time-consuming restrictions  
12 such as enforcement conferences and legalistic red  
13 tape. Licensee adherence to rules preventing Severity  
14 IV, V, and VI violations will help avoid more serious  
15 violations.

16 The words "reasonably foreseen," last paragraph  
17 on column three of page 66755 of the Federal Register,  
18 could allow the licensee a weasel out of almost every  
19 situation. We would delete this paragraph in its  
20 entirety.

21 If licensee cannot reasonably foresee serious  
22 violations resulting in risks to the public health and  
23 safety, he should not be in such a risky business, and  
24 we should not be at his mercy.

25 The NRC cites an example of equipment failures

1 that are not foreseen by the licensee. We suggest  
2 that the licensee must anticipate equipment failure and  
3 avoid this potential failure by constant and careful  
4 surveillance, inspection, repair, replacement, and  
5 other preventive maintenance procedures.

6 If the NRC is referring to sabotage, natural  
7 disasters, and acts of war as unforeseen circumstances  
8 leading to violations, then these situations should be  
9 specifically described and notice should be given to  
10 the public that the licensee has no liability for losses  
11 incurred in accidents stemming from these kinds of  
12 unforeseen circumstances.

13 The NRC should not set a time limit on  
14 imposition of civil penalties. In certain cases, for  
15 example the unreported tritium releases at Zion,  
16 recognition of a violation comes years after the actual  
17 violation occurred because of subterfuge or evasion.  
18 This kind of dishonesty should occasion a higher  
19 penalty, not a waiver of penalty.

20 The section describing referrals to the  
21 Department of Justice for alleged criminal violations  
22 should be expanded to include violations of the NRC  
23 or the NRC in collusion with a licensee.

24 In the case of allegations of NRC-VEPCO  
25 collusion in withholding seismic information, the

1 Department of Justice claimed it did not have juris-  
2 diction over a federal agency, and therefore, they  
3 could not prosecute. Revised rules to cover this  
4 situation should be presented in the proposed regulations.

5 The NRC proposed rules should apply to  
6 nuclear facilities under construction, in addition to  
7 existing facilities. This application should be  
8 explicitly stated in the regulations. I gather that  
9 I missed that, because from your prior comments it  
10 seems that that is the case.

11 Finally, the following deficiencies in the  
12 NRC inspection program must be corrected if the proposed  
13 regulations are to be effective:

- 14 1. A routine inspection program of older  
15 plants to assess ability of safety components and  
16 systems to service an accident must be established.
- 17 2. Uniform NRC quality assurance programs  
18 are needed.
- 19 3. The NRC should expand its quality assurance  
20 inspection staff. Competent quality control and re-  
21 liability experts in the various technical disciplines  
22 are required to enable more direct testing and in-  
23 spection by the NRC.

24 This should be over and above the on-site  
25 resident inspector who, by the way, I think should be

1 around the clock. It shouldn't just be an eight-hour  
2 job. I believe there should be teams of inspectors who  
3 arrive unannounced at nuclear facilities to perform  
4 their inspections, and they should be experts in  
5 the various disciplines.

6 4. It should be mandatory for an NRC in-  
7 spector of licensee facilities to make a formal written  
8 recommendation following each inspection. In the event  
9 of disapproval, either in the region or headquarters,  
10 there should be an automatic provision for submitting  
11 the case in question to the next level of management  
12 for a decision.

13 The inspector should have the right to  
14 insist on management review of a controversial case  
15 to the highest level of inspection-enforcement management.

16 To conclude, the proposed regulations imposing  
17 increased civil penalties are a step in the right  
18 direction. However, without corresponding changes  
19 in attitude among NRC inspection personnel, they will  
20 be of no avail. NRC inspectors must assume their  
21 intended role as vigorous, independent regulators,  
22 without concern for the impact of their actions on the  
23 profitability of the nuclear industry.

24 All NRC roadblocks to the effectiveness of  
25 inspectors should be removed so they can fulfill their

1 vital function as independent guardians of the public  
2 interest.

3 Thank you very much.

4 CHAIRMAN KEPPLER: Ms. Quigg, I am going to  
5 let the rest of the panel comment if they wish, but  
6 I have two points I would like to make to you.

7 One is with respect to the resident in-  
8 spection program. I think you should be aware that the  
9 resident inspection program is not a substitution for  
10 our past program, but an augmentation of our existing  
11 program.

12 We continue to send out inspectors unannounced  
13 from the regional office to the sites, and these are  
14 inspectors that are skilled in various disciplines of  
15 reactor operation, construction, and so forth.

16 So, I think we do what you have asked in that  
17 regard. Probably at a given facility during the course  
18 of a year there may be as many as twenty-five different  
19 people getting to that facility.

20 So, it's not just the resident inspector.

21 The other point, and I am not sure whether I  
22 have got the gist of your concern, but when an inspector  
23 does have a concern, and that concern isn't shared by  
24 his immediate supervision, there is recourse in our  
25 system to escalate the concern to the top level.

1           So, we have a built-in system that all  
2 inspectors are aware of and can use if need be.

3           MS. QUIGG: Is this something that happened  
4 recently?

5           CHAIRMAN KEPPLER: Well, I think it's been  
6 formalized probably within the last year.

7           MS. QUIGG: I see.

8           CHAIRMAN KEPPLER: If you would like a copy  
9 of that I can see that you get one.

10          MS. QUIGG: Thank you.

11          MR. THOMPSON: I would like to make one general  
12 comment. First, I appreciate your comments. I  
13 recognize that your comments reflect a degree of  
14 concern and skepticism that is shared by many people,  
15 particularly with regard to the degree to which ob-  
16 jectivity can be exercised by NRC staff members in  
17 general.

18                 I think it is appropriate to note for the  
19 record that every instance of allegation of misconduct  
20 on the part of NRC employees is investigated by in-  
21 dependent officer -- independent inspector auditor  
22 which is not part of I & E, or NSS, or NRR, but is  
23 answerable directly to the Commissioners.

24                 To my knowledge, and I am not privy to all  
25 those investigations, I know of no cases in which



1 allegations of such misconduct have not been fully  
2 investigated and appropriate disciplinary action taken  
3 where it had been substantiated. I recognize that a  
4 degree of skepticism and doubt will continue to  
5 prevail because of the technical nature of the business  
6 we regulate.

7           The professional qualifications of our staff  
8 in large measure parallels the kind of professional  
9 qualifications sought by the industry we license, and  
10 I recognize that creates a climate that lends itself  
11 very readily to skepticism and doubt about the independence  
12 of the agency. We are very sensitive about that, and  
13 we do our very best to make sure that objectivity is  
14 maintained.

15           In my opinion, we do a pretty good job of  
16 it, but I do recognize and accept your concerns. We  
17 will certainly do our best to continue to address that  
18 problem, and I hope at some stage we can provide the  
19 kinds of assurances that will alleviate the concerns  
20 you identify.

21           MS. QUIGG: I think some of it might be  
22 alleviated if the NRC would be more skeptical itself  
23 and place less reliance on the licensee and more on  
24 itself as far as inspection and as far as examination  
25 of the licensee.

1 MR. THOMPSON: Thank you for your comments.

2 CHAIRMAN KEPPLER: Any other panel member  
3 want to comment?

4 (No response)

5 CHAIRMAN KEPPLER: Thank you very much.

6 Our next speaker is Thomas Plunkett from  
7 the Illinois Power Company.

8 MR. PLUNKETT: My name is Thomas Plunkett,  
9 and I am an employee of the Illinois Power Company.  
10 I am the plant manager for their Clinton power station.

11 Like others, I would also like to thank you  
12 for giving me the opportunity to comment on these  
13 proposed changes to 10 CFR 2.

14 Although I am speaking as an Illinois Power  
15 Company representative, my background has been in the  
16 area of nuclear power plant start-up and operation.  
17 Thus, I would hope that I am also speaking for some of  
18 my colleagues in the utilities who are working in the  
19 power plants today and usually have little or no  
20 opportunity to comment on regulations.

21 My remarks are as follows:

22 Item One. The NRC needs to provide true  
23 incentives for accurate, honest, prompt reporting.  
24 Consequently, there should be no punitive or regulatory  
25 actions associated with such reporting.

1 I doubt very much if the reduction of a  
2 civil penalty by as much as fifty percent for licensees  
3 reported violations will have the effect intended.  
4 Furthermore, the proposed reduction in fines as in-  
5 centive is not clearly defined, and places reliance  
6 on subjective decisions of I & E relating to the good  
7 faith of licensees, the promptness of the reporting,  
8 the comprehensiveness of corrective action.

9 Subjected decisions are not acceptable in the  
10 light of the large fines being proposed. Punitive or  
11 regulatory actions are only appropriate when there is  
12 a failure to report or a failure to identify the  
13 violation.

14 Secondly, the proposed base civil penalties  
15 are discriminatory when based on ability to pay.  
16 Potential public consequences, for example the true  
17 public consequence of accidents at a fuel facility, can  
18 be greater than that at a power reactor.

19 Moreover, many of the violations relate to  
20 non-public incidents such as radiation exposure to  
21 workers. The seriousness of an overexposure is equal  
22 at all licensees. The civil penalties should be equal  
23 as well.

24 Item three. Imposing civil penalties for  
25 every day that a violation occurs is contrary to the

1 approach that should be taken to improve performance.  
2 It is fairly well recognized that rewards and incentives  
3 are more effective than punishment. Yet, the tone of  
4 this proposed regulatory change is purely punitive.

5 I would suggest the authors of this document  
6 may want to investigate other types of motivation  
7 techniques. I would also recommend that all fines  
8 must be approved by the Commission, and you have  
9 addressed the appeal path which was going to be another  
10 one of my comments.

11 Item four. The proposed rule change refers to  
12 adherence to informal obligation, informal agreements,  
13 etc. It would clear the air considerably if the  
14 word written would be placed in front of the word informal.

15 Item five. I can understand the need for  
16 progressive escalation of actions with respect to  
17 unresponsive licensees.

18 However, I feel that table 2  
19 eventually would result in a shutdown of most operating  
20 units. I am particularly referring to severity  
21 of violation categories II and III.

22 I could easily postulate equipment failures  
23 which could occur over a two-year period, thereby resulting  
24 in suspension of operations.

25 I believe you need to quality this table

1 somewhat to ensure that equipment, which is subject to  
2 some probability of failure true of all equipment, is  
3 not subject to punitive enforcement action.

4 This comment also applies to a considerable  
5 number of severity category supplements. A brief  
6 comment pertaining to a couple of the severity category  
7 supplements are as follows:

8 Reactor Operations. "A system designed to  
9 prevent or mitigate a serious safety event not being  
10 able to perform its intended function under certain  
11 conditions," may not represent a violation due to the  
12 redundancy of safety systems. In any event, if the  
13 matter is within the bounds of technical specifications  
14 limiting conditions for operations, there should be no  
15 penalty.

16 Health Physics. I could find no allowance  
17 made for the one time emergency exposures where  
18 possible harm to human life is concerned. I really  
19 do not believe that you gentlemen would subject punitive  
20 enforcement action to somebody who has received greater  
21 than twenty-five rem exposure to save a human life.

22 Item two under health physics. I am not  
23 aware specifically of any NRC standard related to  
24 decontamination. In general, I found the severity  
25 categories were poorly defined and considered prone

1 to subjective judgement of the NRC.

2 Finally, and this is the real reason I came  
3 up here today, I am personally tired and offended with  
4 the use of the word criminal and criminal offenses, etc.  
5 which appears throughout this document and which was  
6 used by at least two of you gentlemen today.

7 The NRC is mistaken if they believe that by  
8 using fear tactics such as threat of investigation by  
9 the FBI and involvement of the Department of Justice,  
10 compliance with all regulations can be achieved.

11 The only effect those types of threats have  
12 is to eventually disgust good, dedicated employees  
13 who feel that life is too short to work in this type  
14 of industry or environment. When they leave, usually  
15 less experienced people take their places.

16 This does not achieve the stated goal of  
17 "to encourage improvement of the licensee performance."

18 Thank you, gentlemen, for giving me the  
19 opportunity to comment.

20 MR. THOMPSON: I would like to make a couple  
21 of comments on a couple of your points, I think partly  
22 for clarification.

23 The first reply I will offer is not only to  
24 a comment of yours, but was echoed by an earlier  
25 commentor. I think it's important to clarify where we

1 anticipate this policy statement is going.

2 An earlier commentor had referred to this  
3 meeting as some sort of a hearing, and referred to the  
4 policy statement as a rule. It is the intent of the  
5 Commission to publish the revised Enforcement Policy  
6 following the public comment period as an appendix to  
7 part two of its regulation, but it will appear there as  
8 a general statement of policy, and not as a rule.

9 There are some legal distinctions aside from  
10 the fact that it does not make a requirement, but rather  
11 a statement of policy.

12 Secondly, I would like to respond to your  
13 comment about ability to pay, the discriminatory  
14 aspects of the ability to pay, and in order to do that  
15 I would point out that the diversity of activities  
16 regulated by NRC is very, very wide.

17 Most of us working in this area tend to look  
18 at NRC from our own perspective. There are a large  
19 number of utility representatives here today. There  
20 are also a fair number of representatives from the  
21 medical community. There are some 9,000 NRC licensees,  
22 and comparable numbers of state licensees that are  
23 very small firms.

24 We have, in our prepared text, commented about  
25 the differentiation between large companies and small

1 companies, and pointed out that the primary differentia-  
2 tion among these different types of activities is  
3 associated with the hazards, but there is also a  
4 secondary consideration that what may not be technically  
5 difficult from a financial point of view for a large  
6 company to handle in the way of civil penalties, could  
7 very well bankrupt a small operation.

8 Now, we are not particularly sympathetic to  
9 whether it would bankrupt a small organization or not  
10 if the hazard is severe enough, then the action should  
11 be appropriate to the hazard. Nevertheless, if we  
12 are so concerned about the activities of a small  
13 licensee that we believe he should not engage in the  
14 activities he was licensed to do, the way to get him  
15 out of that business is not to run him into bankruptcy,  
16 but to restrict his license.

17 That is also an enforcement tool available  
18 to us, and we would exercise and have exercised that  
19 in the past.

20 I recognize that question of ability to  
21 pay is a very difficult one. It is among the factors  
22 to be considered in assessing enforcement actions  
23 against licensees by virtue of the legislative history  
24 of the authorization for civil penalties.

25 There are determinations in the legislative



1 history that tell us what we must consider, and Congress  
2 has dictated what we must consider -- including ability  
3 to pay.

4 The next item I would like to comment on is  
5 to point out, as an earlier commentor had noted, and  
6 I believe you noted as well, on table 2 there is some  
7 rather strange wording in the Federal Register.

8 It's there by design; it was added at the last  
9 minute. There are two alternative possibilities on  
10 table 2, and the Commission in its announcement of these  
11 meetings explicitly asked for expressions on how table  
12 2 should be used. You will notice that it parenthetically  
13 uses the verb could and will normally be. That was  
14 by design.

15 We have had some comments in the past by  
16 people who didn't understand what it meant, and we  
17 have commented on that in the past.

18 The next point I would like to comment on is  
19 in each of the supplements we have preceeded the  
20 identification of the samples to is the severity levels  
21 by the violations. The examples that appear in the  
22 supplement are not necessarily in themselves violations.

23 You must first have noncompliance with a  
24 regulatory requirement, and I responded to your  
25 comments about actual statements on LCO.

1 MR. PLUNKETT: You stated that previously. I  
2 think you may want to include that.

3 MR. THOMPSON: We have had the comments before.  
4 I think it is a point we will consider in the rewriting  
5 of the policy.

6 Your final comments concerning the offensive  
7 nature of the term criminal offenses is also dictated by  
8 terms of the Atomic Energy Act.

9 It is the Atomic Energy Act that provides that  
10 all alleged or suspected violations of federal statute  
11 will be investigated by the FBI. That is not our rule.

12 MR. PLUNKETT: I guess I am questioning the  
13 continued use of that rule, both verbally and in your  
14 written document, and the impact it is having on the  
15 personnel that are working in these power plants.

16 That is the point I was trying to make.

17 MR. THOMPSON: I understand your concern. In  
18 our prepared comments, you will notice one of the goals  
19 we had was to articulate as clearly as we could what  
20 the policy would be. The alternative you propose is  
21 to remain silent on a requirement of the law and then  
22 when it comes, hit the vendor with it with surprise.

23 We are trying to be up front with this.  
24 Those provisions are there. They are requirements of  
25 statute, and if we remain silent on it to avoid

1 offense, we are not being candid and forthright with  
2 the individual.

3 MR. PLUNKETT: I know the provisions are there,  
4 I guess it's your use of those provisions is what I  
5 am questioning, and I am just hoping that you may  
6 take a look at the impact it's having on the people that  
7 are working in the plants when you do use this.

8 MR. THOMPSON: I can understand your concern.

9 CHAIRMAN KEPPLER: You raised a point about  
10 the word systems and its use in the table -- in the  
11 supplements.

12 MR. PLUNKETT: I think that was a previous  
13 speaker.

14 CHAIRMAN KEPPLER: Okay, I'm sorry, I thought  
15 you did.

16 MR. PLUNKETT: No, I used the words failure  
17 being used as a punitive action, and you do allude to  
18 that, you touch on it by stating that the NRC considers  
19 violations of severity levels, etc., licensees are not  
20 ordinarily cited for violations, and then you touch on  
21 equipment failures, but then I go to the severity  
22 categories and I see severity category I where it  
23 talks about a system not being able to perform its  
24 intended function.

25 MR. THOMPSON: Again, it's noncompliance that

1 causes that.

2 MR. PLUNKETT: That doesn't come out in this  
3 document.

4 MR. THOMPSON: I think that's a point we need  
5 to address.

6 CHAIRMAN KEPPLER: Because it is our view that  
7 the severity levels I, II, and II should be very in-  
8 frequent.

9 MR. PLUNKETT: Okay.

10 CHAIRMAN KEPPLER: One other comment, because  
11 you and several others have brought it up here,  
12 and it was a dominant theme in the meeting at Atlanta  
13 yesterday.

14 That is the strong plea from the industry to  
15 not incriminate or self-identify noncompliances. The  
16 other side of the coin that we have to deal with is  
17 that it is our view that the conditions which led to  
18 the violations of I, II, and III shouldn't happen  
19 either, and I think that as you comment formally, those  
20 of you that are commenting in writing, you should  
21 recognize that that side of the coin is of much concern  
22 to the Commission as well.

23 MR. PLUNKETT: Thank you.

24 CHAIRMAN KEPPLER: The next speaker listed  
25 is Adaline Mather. Is she here?

1 (No response)

2 CHAIRMAN KEPPLER: Dr. John Weir -- is he present?

3 DR. WEIR: I represent the American College of  
4 Nuclear Physicians which joins the other commentors  
5 in welcoming this opportunity to respond to the  
6 Commission.

7 The College represents more than a thousand  
8 physicians and scientists using radioactive materials  
9 in pharmaceutical form or diagnostic and therapeutic and  
10 research applications.

11 These studies represent a large area for the  
12 use of radioactivity, provides clear benefits with  
13 immeasurably small risks.

14 Nuclear medicine physicians are trained in the  
15 biological effects of radiation exposure, and routinely  
16 evaluate the benefit versus risk, both for the individual  
17 patient and for society in general.

18 The policy statement is welcomed as a  
19 mechanism of establishing the position of the Commission  
20 prior to inspections which we undergo. In general,  
21 it is clear and fair, although with some areas that we  
22 believe need change.

23 Paragraph four D-2 and 3 represent areas of  
24 continuing difficulty to many of us, both from an  
25 inability to understand them and from a use of words

1 which do not seem to mean what we were taught they meant.

2           Recommendations are not requirements. Many  
3 provisions in Commission standards, and particularly  
4 in the guides, are stated to be suggestions or a  
5 method of solution, but not necessarily the only  
6 method.

7           A licensee should not be obliged to follow  
8 "a type of activity that a class of licensees has been  
9 encouraged to follow." The Commission should clearly  
10 delineate the difference between encourage and ob-  
11 ligatory measures between requirements and suggestions,  
12 and should adhere to the difference, as well as  
13 expecting the licensee to do so.

14           Comments on specific violations include  
15 the following:

16           Supplement I, Severity I, category I and II  
17 violations seem considerably less dangerous than  
18 categories III and IV, and their grouping together  
19 does not seem particularly logical.

20           In Supplement IV, Severity II, this area  
21 seems to establish -- to effectively establish ex-  
22 posure limits less than those currently imposed by  
23 established standards. We do not think this policy  
24 statement is the place or the mechanism to establish  
25 new limits.

1 Exposure slightly in excess of these limits  
2 would provide only slight risks, and the penalties are  
3 clearly in excess of the violation and would probably  
4 not be enforced for minimal overexposures, but that  
5 isn't at all clear when you read it.

6 We think extensive revision of this area is  
7 needed.

8 In Supplement IV, Severity III, violation  
9 number four seems of lesser magnitude than the others  
10 in the section, and is difficult to interpret.  
11 Downgrading, at least to Severity IV is recommended.

12 In Supplement V, Severity I and II violations,  
13 in general they seem very harsh in comparison to the  
14 magnitude of the violations -- in comparison to the  
15 magnitude of the violations, the penalties seem harsh.  
16 Downgrading of at least one step is recommended.

17 It also is not quite clear where medical  
18 licensees fit in the supplements as listed. We assume  
19 that any violation by a medical licensee would fall  
20 under Supplement IV, but that is not clearly delineated.

21 Again, we thank you for this opportunity.  
22 We believe the proposed policies are good, but we hope  
23 that these changes can be made.

24 CHAIRMAN KEPPLER: Thank you. I would just  
25 comment -- I'm sorry, go ahead.

1 MR. NORELIUS: I was going to address some of  
2 the comments that you made which I think might be  
3 helpful for clarification purposes.

4 The first one had to do with regulatory  
5 guides and how they apply in the licensing process --  
6 whether they are guidance or regulatory requirements.

7 I think this has been an area of some con-  
8 fusion. You are correct in saying that the Commission  
9 prepared regulatory guides as a means of meeting  
10 requirements, but in practice if a person applying for  
11 a license has said I will adhere to that guide as a  
12 part of their license application, then the Commission  
13 has normally turned around in that sense and made  
14 that a part of the license condition. That, in turn,  
15 does really make the guide a requirement through the  
16 specific license condition.

17 So, that may be helpful in just clarifying  
18 the procedure that the Commission has normally followed.

19 There are other ways that a licensee could  
20 address a particular problem, and if they address it  
21 in a different way in their license application, then  
22 the Commission would probably endorse that method.

23 Whichever method is a part of the application  
24 is normally made a requirement as a license condition.

25 DR. WEIR: That's very clear after you have



1 your license, but it's not always clear when you are  
2 applying, and many of us may apply only once every  
3 five years, and not have enough familiarity with  
4 your process to know that we're permitted to try to  
5 work out other ways.

6 Also, it has been our experience, that in  
7 many instances during inspections that what was a  
8 suggestion last year is a requirement this year without  
9 clear delineation of the change.

10 MR. THOMPSON: I think there is an inter-  
11 pretation. Perhaps I will let counsel comment on  
12 this, but from my position on the staff, a regulatory  
13 requirement is a statute, a rule, a licensing condition,  
14 or the result of Orders.

15 Those impositions of agreements between  
16 licensees and the NRC that come about by virtue of  
17 bulletins, circulars, information notices, needed  
18 action letters, or commitments otherwise made by a  
19 license do not constitute strict regulatory requirements.

20 Noncompliance with those are the deviations  
21 we were talking about in Section 4 and that's why we  
22 do not put it in the formal enforcement action.

23 An inspector cannot impose a requirement,  
24 he can only suggest or point out where the requirement  
25 exists -- the statute, rule or license.

1 I recognize the problem that you face, because  
2 there are occasions where inspectors' suggestions or  
3 recommendations convey to the licensee the idea that  
4 it's a prudent thing to do -- to go along with what he  
5 suggests, but in the strict legal sense, they are  
6 not requirements.

7 MR. NORELIUS: Let me address a couple other  
8 areas that you brought up. You mentioned certain areas  
9 which are unclear, and I would encourage you if you  
10 plan to submit more detailed written comments, if you  
11 can give us words that would make it more clear, we  
12 would appreciate that help.

13 That would be helpful to us in better defining  
14 the policy.

15 You made a general comment that the levels  
16 of violations for Supplement V, Transportation, seemed  
17 rather severe. I guess I would just make the point  
18 that for some of the supplements there are rather low  
19 thresholds of compliance which have been established by  
20 this policy. They are not equatable one to the other  
21 in terms of their absolute severity, and transportation  
22 is one that you have identified.

23 This was brought about, I think, by the  
24 problems that occurred at waste disposal sites, and  
25 there was the threat by the governors of three of the

1 states which have such sites stop receiving wastes, and  
2 of course, that would be a very significant problem  
3 from an operational standpoint, and it would be  
4 significant from a safety standpoint if you had to  
5 store waste at your facility because of the unavailability  
6 of a waste site.

7 So, for that reason, the threshold for  
8 compliance was really lowered in that area.

9 DR. WEIR: We clearly recognize the dangers of  
10 closing the waste sites, but I wonder if a more  
11 suitable method of preventing that would be to punish  
12 the people that cause the problem rather than impose  
13 new rules on people who met the old rules anyway.

14 MR. NORELIUS: Let me clarify that the policy  
15 does not impose any new rules. It establishes the  
16 threshold at which certain actions would be taken. So,  
17 it may give more importance to what is done on a  
18 violation under existence.

19 Let me just clarify one more point. You  
20 ask where medical licensees would fit. They ob-  
21 viously do fit in the supplement which you mentioned,  
22 the Part 20, health physics radiation exposure.

23 Also, the Supplement VII relating to materials  
24 licensees would also apply to medical licensees.

25 DR. WEIR: Thank you.

1 CHAIRMAN KEPPLER: Thank you very much, Dr. Weir.  
2 The next speaker is Erik Zickgraf.

3 MR. ZICKGRAF: My name is Erik Zickgraf, and  
4 I am a medical physicist at St. Francis Hospital in  
5 Evanston, Illinois.

6 I wish to thank the NRC for the opportunity to  
7 express my comments on the proposed rules.

8 If the NRC decides to become aggressive  
9 in its search for violations, I can foresee many  
10 situations in which a paper mistake could lead to an  
11 apparent violation and a fine, when in fact no violation  
12 had occurred -- especially under the new ALARA  
13 restrictions.

14 Up until this time our hospitals and regulatory  
15 agencies have enjoyed very good relationships. I do  
16 not wish to see this altered due to a change to an  
17 unduly aggressive agency trying to maximize the number  
18 of violations and violators cited.

19 Thank you.

20 CHAIRMAN KEPPLER: Thank you  
21 Dr. Lynn Miner?

22 DR. MINER: Before beginning my remarks  
23 this afternoon, I would like to observe that my  
24 appearance here today, in contrast to what is on your  
25 list of scheduled participants, is here in connection

1 with Marquette University. It probably was a typo, where  
2 somebody got the names Miner and Meir crossed. I am  
3 here today on behalf of Marquette University.

4 Marquette University welcomes this opportunity  
5 to comment briefly on the NRC's proposed General Policy  
6 Statement.

7 In our judgement, the statement as described  
8 in the October 7, 1980, Federal Register has a  
9 potentially deleterious and perhaps even unanticipated  
10 impact upon the scholarly conduct of research at  
11 Marquette and perhaps most other college and universities.

12 That is the primary conclusion based upon our  
13 preliminary analysis. The remarks presented today on  
14 behalf of the Marquette University incorporate the views  
15 of a number of central administrators and senior  
16 faculty members, including the Vice President for  
17 Governmental Relations, the Associate Vice President  
18 for Academic Affairs, the Graduate Dean, the Radiation  
19 Safety Officer, the Radioisotope Safety Committee,  
20 and the Director of the Office of Research and Support.

21 I cite these individuals to communicate how  
22 seriously we take this matter to be in the university-  
23 wide context.

24 Not so incidentally, Marquette has an ex-  
25 tremely active governmental relations antenna, perhaps

1 more extended and searching than most institutions.  
2 Nevertheless, this NRC matter comes as an eleventh hour  
3 surprise.

4 During the course of my formal remarks, I  
5 want to address four issues briefly.

6 1. The Marquette academic environment under-  
7 lying our grave reservations about the statement.

8 2. The specific Marquette objections to the  
9 statement.

10 3. Specific proposed modifications of the  
11 language of the statement which will alleviate our  
12 concerns.

13 4. Direct answers to the nine questions  
14 posed in the October 17th Notice.

15 First, the Marquette academic environment.

16 The use of radioactive isotopes at Marquette  
17 dates back to the late 1940's. At that time, the  
18 Marquette Medical School, which is now known as the  
19 Medical College of Wisconsin, provided diagnostic and  
20 treatment services to their patients.

21 With the 1970 departure of the medical school,  
22 our institutional use is primarily restricted to  
23 scholarly research projects in the bio-medical sciences.

24 We are currently operating under a Class B  
25 License, as well as several special-use licenses.

1 By any reasonable definition, we are a small user of  
2 radioactive isotopes. Our research needs can be  
3 satisfied through nominal quantities of hydrogen 3,  
4 carbon 14, phosphorus 32, calcium 45, iodine 121, and  
5 iodine 135.

6 At present we have twenty-one professors  
7 designated as authorized users by our Radioisotope  
8 Safety Committee. Two brief examples will illustrate  
9 our research use of isotopes.

10 One research laboratory follows the  
11 formation of immune complexes in the lungs of animals  
12 undergoing inflammatory reactions subsequent to the  
13 inhalation of foreign organic particles.

14 This animal reaction will provide insights  
15 into the mechanism of the diseased condition known as  
16 hypersensitivity pneumonitis.

17 Another research laboratory is looking at  
18 the role of protein in normal and diseased muscles.  
19 Radioisotope studies are essential for understanding  
20 activation mechanisms.

21 Do these studies with RAVIS require rigid  
22 federal edicts? We are small, but our concerns are not.  
23 One cannot vigorously pursue the scientific process  
24 of asking perceptive questions, making controlled  
25 observations, and interpreting results while harboring

1 fears of civil penalties, a rubric for heavy fines, or  
2 a laboratory lockout for that matter.

3 We have no qualms about accountability, we  
4 demand it of ourselves, in many respects more stringently  
5 than what could be externally imposed. In fact, we take  
6 special pride in our character as urban, Jesuit institu-  
7 tion deeply committed to matters of ethics and value  
8 to human welfare.

9 Now, accountability is not at issue, rather  
10 the issue is potential regulatory encroachment which  
11 might sabotage our three part institutional mission  
12 of teaching, research, and public service.

13 We welcome NRC's monitoring of activities, as  
14 long as it does not obstruct the university's welfare  
15 by over-intrusiveness.

16 Next, let me identify six specific policy  
17 statement objections we have and suggest the proposed  
18 changes.

19 First, we are concerned about the timeliness  
20 of your policy statement. It was issued twenty-nine  
21 days after President Carter signed the Regulatory  
22 Flexibility Act. Although this legislation does not  
23 become effective until January 1, 1981, and applies  
24 only to Notices of Proposed Rulemaking which this  
25 clearly is not, it's legislative intent and spirit



1 should not go unheeded by NRC.

2 It provides a measure of protection for "small  
3 entities," which includes public and private universities  
4 relative to the potential economic impact of rule  
5 issuance. Among other things, it provides time for  
6 the clarification of compliance of reporting require-  
7 ments, essential time which Marquette has not had for  
8 two reasons.

9 First, the Director Thompson memo, dated  
10 October 28 came to my attention just six days ago which,  
11 unfortunately, spanned a four-day holiday period.  
12 This memo makes reference to twelve major sections  
13 of the 1954 Atomic Energy Act, three sections of the  
14 1974 Energy Reorganization Act, Public Law 96-295,  
15 six sections of 10 CFR, three sections of the Federal  
16 Register, plus numerous subsections and related cross  
17 reference material. Egyptian mummies are not the only  
18 ones pressed for time.

19 Our situation at Marquette may not be totally  
20 unique. So far we have identified four other universities  
21 each actively engaged in radioisotope research who  
22 were unaware until our phone call of the policy state-  
23 ment and regional hearings.

24 The matter at hand is too important to be  
25 trapped in a communication clog, especially for

1 academic administrators who are simultaneously  
2 monitoring regulatory agency requirements relative to  
3 human subjects, animal welfare, new drugs, state radiation  
4 matters, EPA, OSHA, recombinant DNA, A-21 time and  
5 effort reporting requirements, and OMB fiscal concerns.

6 With this plethora of must do's, it's no  
7 wonder there is so much adverse comment from institu-  
8 tions seeking relief from regulatory burdens. Ac-  
9 cordingly, we recommend the NRC delay further action  
10 on this statement for at least six months. The comment  
11 period should be extended.

12 NRC should expand their university comment  
13 network through such academic base publications as  
14 Higher Education and National Affairs, Higher Education  
15 Daily, and the Chronicles of Higher Education.

16 In the last month these three publications  
17 generated over thirty issues. None contained a state-  
18 ment or story regarding the proposed Enforcement Policy.  
19 If NRC wishes to communicate with the academic  
20 community, they should use the communication channels  
21 designed specifically to reach the academic community.

22 In the meantime, pursuit of policy changes  
23 should be characterized by gradualism, not abruptness.

24 Second, Marquette is concerned about the  
25 language used in the introduction and purpose. More

1 specifically, it says that the NRC programs should be  
2 marked by "an aggressive enforcement strategy that  
3 seeks more frequent use of stronger enforcement measures,"  
4 and implementation that assures "that noncompliance is  
5 more expensive than compliance."

6 The question is how aggressive is aggressive?  
7 Webster's Dictionary cites these synonyms for aggressive:  
8 "hostile, belligerent, assailant, vicious, tending to  
9 attack, contentious, and zealous."

10 Is this really the intent of the Nuclear  
11 Regulatory Commission? Is this their desire of an  
12 agency-user relationship? What happened to the  
13 partnership relationship where sharing of expertise  
14 was commonplace?

15 Terms like aggressive and related synonyms are  
16 antithetical to the conduct of scholarly research, and  
17 an environment for free uninhibited inquiry is essential.

18 Accordingly, we recommend that NRC change the  
19 tenor of their statement of purpose. Instead of  
20 erecting adversarial barriers, the program should be  
21 marked by a "compliance management strategy that  
22 seeks more frequent agency-user interaction," and  
23 implementation that assures "that compliance is more  
24 beneficial than noncompliance."

25 Third, we note with astonishment that

1 corrective enforcement actions may be taken in the  
2 absence of any violations of NRC requirements. That is  
3 to say, universities may be forced to take corrective  
4 actions, even if no violations exist.

5 We are concerned about maintaining compliance.  
6 If this language is adopted, how would universities know  
7 if they are in compliance? How will they know a model  
8 program when they see one? Which distinctive features  
9 separate a good from a bad program?

10 What is our yardstick? This language invites  
11 continuing internal uncertainty about compliance status.  
12 Further, it invites no trust, no risk, no progress.

13 Accordingly, we recommend that NRC delete  
14 this provision. If a standard is important, it should  
15 be promulgated. If it is not important, users should  
16 not be guilty of relying on their own resourcefulness  
17 and administrative control techniques which may or  
18 may not conform to NRC expectations -- the lantern  
19 carrier should go ahead.

20 Fourth, we cautiously note that violations  
21 not specifically identified by a severity level will  
22 be placed at the level best suited to the significance  
23 of the particular matter.

24 This sounds fuzzy to our ears. Who determines  
25 the best-suited level? In such a subjective judgement,

1 differences of opinion are inevitable. What review and  
2 appeal processes are available?

3 Accordingly, we recommend that NRC defuzzify  
4 this statement by initially encouraging the field  
5 officer to resolve the issues informally at the local  
6 level. If this fails to produce a mutually acceptable  
7 solution, the regional director should establish and  
8 implement an appeals protocol.

9 Fifth, table 1 reports the base civil  
10 penalties. NRC application of this table presumes  
11 five severity levels that may in reality exist along  
12 a continuum rather than cluster discretely.

13 Nevertheless, we understand the need to draw  
14 boundaries. What we can't clearly determine from this  
15 table is the limit of a university's financial  
16 liability.

17 The fines apparently can be increased or  
18 decreased on a discretionary basis. This table 1,  
19 for example, applied to a severity level I violation  
20 for universities, while potentially an \$8,000 fine,  
21 may actually range from \$4,000 to \$10,000 per violation,  
22 and if continued uncorrected, could run as high as  
23 \$24,000.

24 If this represents administrative flexibility,  
25 okay. If this represents a masquerade for gray-zone

1 judgement calls, then no.

2 Accordingly, we again recommend NRC delay  
3 adoption of the civil penalty schedule until universities  
4 have had opportunity to assess its economic impact.

5 At Marquette, a single violation could cost  
6 more than a two-year supply of radioisotopes. We  
7 don't know the impact on our sister institutions, but  
8 we hold special concern for colleges and universities  
9 which have a small NRC-related activity and a large  
10 non-NRC related scholarly effort.

11 These potential financial liabilities could  
12 well put them out of the radioisotope research business,  
13 thereby leaving such research only within the reach  
14 of major research universities.

15 Six, we are expected to adhere scrupulously  
16 to informal obligations and commitments such as  
17 bulletins, circulars, information notices, and generic  
18 letters. We regard these obligations too significant  
19 to be classified as informal.

20 It may not be fully appreciated by NRC that  
21 universities, too, have an elaborate infrastructure.  
22 These casual communications may well be delayed, or  
23 even not reach the appropriate administrator in time  
24 to make the appropriate modifications in order to  
25 effect compliance.

1 NRC then has two options -- either allow more  
2 lead time in the communication process, or attempt to  
3 more precisely target essential information within the  
4 organization. Here the concern is for the channel of  
5 communication, not the content. You can't fix it if  
6 you don't know it's broke.

7 Finally, responses to the nine questions.

8 Is the policy fair and equitable? No,  
9 because its statement of purpose invites an antagonistic  
10 relationship, at least on the part of universities.

11 Further, it increases uncertainty about  
12 self-judgement of compliance.

13 Number 2, is the policy understandable?  
14 Marginally so. Change egregious to flagrantly bad.  
15 The seven supplement categories need examples, specifi-  
16 cally at the lower severity levels.

17 Number 3, are the severity levels appropriate?  
18 Only if you could really segment a continuous variable.  
19 We anticipate substantial problems in differentiating  
20 between levels IV, V, and VI for universities.

21 Number 4, are the different types of  
22 activities well enough defined? No, additional examples  
23 like the type that were presented earlier would be  
24 very helpful.

25 Five, are the distinctions among the various

1 types of licensees appropriate? No, either exempt  
2 small users, or by use of footnotes specify who was  
3 included in that phrase "all other licensees and  
4 persons subject to civil penalties."

5 Number 6, are the factors for determining  
6 the level of enforcement action appropriate? No.  
7 Again, clarify by use of examples. Describe the  
8 appeal process.

9 Number 7, is the degree of discretion  
10 allowed to the Office Directors appropriate? Yes.

11 Number 8, are the levels of civil penalties  
12 that require Commission involvement appropriate? Again,  
13 yes.

14 Number 9, are the provisions for escalated  
15 action appropriate? No. Why are Levels IV through VI  
16 omitted?

17 In conclusion, I recognize that I may have  
18 committed the cardinal public speaking sin of insulting  
19 the crocodile before crossing the river. Nevertheless,  
20 it was felt to be a necessary risk in order to em-  
21 phasize our concerns and the need for extensive review  
22 by a much larger array of colleges and universities.

23 We ask that these remarks be made a part of  
24 the public record for this hearing. We plan to present  
25 additional comments by the December 31, 1980, deadline.



1           CHAIRMAN KEPPLER: Thank you very much.  
2 Being with the government, we have good thick skins,  
3 and you haven't offended the crocodile.

4           I guess one comment we would have is the  
5 amount of money that we intend for fines for universities.  
6 I think it would be appropriate to comment on that  
7 when you do.

8           I think another thing is that you should know  
9 that in addition to the policy being out for public  
10 comment, we stated in the beginning of the meeting that  
11 the Commission has approved the policy for interim  
12 use during this period and it is so being used.

13           Dudley, do you want to make any comments?

14           MR. THOMPSON: Yes. First, I would like  
15 to express my appreciation for Dr. Miner's comments,  
16 and particularly the tone. I think we are dealing  
17 with a serious subject, there is no question about  
18 that, but unfortunately in these marathon meetings,  
19 sometimes we get ourselves so wrapped up around the  
20 axle that we need a little bit of levity from time  
21 to time.

22           I was particularly interested in your quoting  
23 synonyms from the dictionary, and with apologies to  
24 some members of the audience, I should note that having  
25 recently undergone some sensitivity training on how to

1 sexually discriminate, I am very conscious these days  
2 of the difference between the word aggressive and  
3 assertive.

4 Women in careers today are counseled to  
5 be assertive but not aggressive. Perhaps we should  
6 take a lesson.

7 I would point out, however, in that dimension  
8 that the extracts that were cited are directions to the  
9 staff from the Commission. It is a recognized,  
10 legitimate purpose of the collegial body that heads  
11 this organization to provide guidance to the staff,  
12 which they have done in the extracted, footnoted  
13 document on policy, programming, and planning guidance.

14 The statements that are extracted there are  
15 explicit statements presented to the staff by the  
16 Commissioner that this is where we expect this agency  
17 to go.

18 Nevertheless, I do appreciate the allusion  
19 to hostility and some of these other synonyms, and  
20 the only comment I would reply, and it does help to  
21 have the thick skin that Jim referred to, but over the  
22 years in working on this side of the table, I have  
23 taken great refuge in recognition that one can never  
24 be hurt when you are on the side of the angels.  
25 We'll let that sit for a while.

1 CHAIRMAN KEPPLER: The next listed speaker  
2 is Dr. Eugene Pitts.

3 DR. PITTS: Thank you. I am Dr. Eugene Pitts,  
4 and I am a Radiation Safety Officer of the Victory  
5 Memorial Hospital in Waukegan, Illinois, and I appear  
6 before you in that position.

7 It would be repetitive and unnecessary  
8 imposition of the time of you gentlemen, as well as  
9 those to my right, to repeat or emphasize material  
10 which has been brought before you in the last hour or  
11 two, particularly the remarks of Dr. John Weir and  
12 recently Dr. Lynn Miner.

13 The only thing that comes to mind above  
14 all is the severity levels of the punishment which is  
15 outlined in this proposed regulation which I feel are  
16 not indicated or appropriate.

17 Victory Hospital will have a full, written  
18 response before the December 31 deadline.

19 Thank you.

20 CHAIRMAN KEPPLER: Thank you.

21 Dr. Meir?

22 (No response)

23 CHAIRMAN KEPPLER: Mr. Gibbs?

24 MR. GIBBS: Thank you for this opportunity.

25 I am Jim Gibbs, United Technologies Corporation, Packett

1 Instrument Company. I am speaking for the corporation,  
2 which is a manufacturer of radioactivity measuring  
3 instruments and a user of small quantities of radio-  
4 activity.

5 I'm also speaking in the interests of our  
6 customers who are primarily medical and research  
7 institutions.

8 We offer at this point negative answers  
9 to all nine questions posed in the notice of this  
10 meeting. A formal communication will be submitted  
11 later.

12 These enforcement proposals do not appear  
13 to be adjusted to the level of radioactivity in use.  
14 The proposals appear to be an attempt to provide an  
15 umbrella applicable to all licensees without regard to  
16 the nature or the extent of operation.

17 These comments are intended to suggest that  
18 such an umbrella is not possible with fairness to all.  
19 The distinctions among the licensees indicated in table 1  
20 are vague with regard to medical licensees, industrial  
21 and institutional research laboratories, and industrial  
22 suppliers of radioactive materials, although the  
23 potentials for unsafe conditions are not equivalent.

24 Cumulative penalties may be appropriate in  
25 some cases, but appears too stringent in others. It

1 would be helpful if NRC could make available historical  
2 data on the severity and frequency of violations.

3 The economic impact of these proposals is  
4 likely to be excessive. There are two possibilities.  
5 One, added expense to licensees; and two, flight from  
6 use of nuclear materials by licensees unwilling to  
7 absolve additional expense. Neither of these descriptions  
8 is desirable by the NRC or by the licensees.

9 We think extensive review and revision of  
10 the proposals is desirable, despite the fact that they  
11 are now in interim use.

12 I suggest the involvement of health physics  
13 societies, trade associations, professional societies,  
14 consulting organizations, and others.

15 Thank you again for this opportunity.

16 CHAIRMAN KEPPLER: Thank you very much.

17 Ben Margulo?

18 (No response)

19 CHAIRMAN KEPPLER: James Rhodi?

20 MR. RHODI: I am James Rhodi, Plant Manager,  
21 Combustion Engineering. We wish to thank you for  
22 the opportunity to comment.

23 The plant under C. E. ownership has cooperated  
24 fully with Region III inspectors. We have operated  
25 much tighter internal controls than those required

1 by the regulations for licensing conditions. We have  
2 been responsive to every suggestion from Region III.  
3 We shall continue to cooperate in the future to the  
4 extent practical.

5 The proposed regulations, however, could only  
6 result in a deterioration of our relations with the  
7 NRC by creating barriers to communication between the  
8 NRC and the inspectors. This cannot enhance the  
9 protection of public health and safety, common defense  
10 and security, and the environment.

11 I acknowledge a need for civil penalties for  
12 violations having substantial potential impact on the  
13 public and for chronic offenses of less serious nature,  
14 but the proposed regulations are not limited to  
15 violations of this type.

16 A substantial fraction of the deficiencies  
17 normally reported from fuel cycle facilities such as  
18 our own, result from problems in the interpretation  
19 of license conditions and the regulations.

20 Violations of this type result from vague  
21 wording, not intent to subvert the rule. Resolution  
22 of language problems will be hindered by the threat  
23 of imposition of civil penalties.

24 Specific problems with proposed regulations  
25 include the following:

1           Severity categories for safeguards of viola-  
2 tions show no differentiation between low enriched and  
3 high enriched materials. Entry of unauthorized in-  
4 dividual into a material access area of low-enriched  
5 fuel plant does not have the same potential for com-  
6 promising the public safety as entry into a high-enriched  
7 plant where bomb-grade specialty nuclear material  
8 could be diverted.

9           Particulary this could be the case if you  
10 were dealing with a facility where the primary containers  
11 are three ton units which could not be carried out.

12           However, both acts would be severity I  
13 violations carrying a fine of \$40,000 under the proposed  
14 regulations. The proposed regulations do not take into  
15 consideration the gravity of the violation involved  
16 in determining the severity levels for safeguard  
17 violations.

18           There is no attempt to differentiate between  
19 operations in the case of utilizing unauthorized or  
20 unqualified personnel. The use of an authorized porter  
21 for the container containing one gram of uranium could  
22 result in a severity III violation, \$20,000 fine and  
23 fuel-cycle operation.

24           A severity II violation in the transportation  
25 category could result from surface contamination on

1 a package which was not the result of breach of the  
2 package. A severity III violation, \$20,000, could  
3 result from improper labeling of a package or improper  
4 packaging, and this is very difficult to determine  
5 without going through extensive cross files of regula-  
6 tions.

7 In general, the penalties appear to be unduly  
8 harsh for the violations, particularly in categories IV,  
9 V, and VI, where there are a few examples given.

10 The probable result of the proposed changes  
11 to 10 CFR Part II will be an escalation of litigation,  
12 development of an adversarial relationship between  
13 licensees and inspectors, and a reluctance to generate  
14 thorough internal audit reports.

15 Thank you.

16 CHAIRMAN KEPPLER: Mr. Rhodi, just a couple  
17 of comments. In my recollection of your operation at  
18 Combustion Engineering, I am not aware of any instance  
19 where Combustion Engineering has experienced a severity  
20 category I, II, or III violation.

21 MR. RHODI: That is correct.

22 CHAIRMAN KEPPLER: I think you are aware from  
23 our discussion that the only time escalated enforcement  
24 action would be taken for a severity IV or V type  
25 violation is when it has been of a chronic nature and



1 that has led me to have a management conference and  
2 enforcement conference with a licensee.

3 MR. RHODI: I guess I said that to make my  
4 point.

5 CHAIRMAN KEPPLER: I don't understand your  
6 comment why it leads to such an adversarial relationship.

7 MR. RHODI: We hope it will not. Our ex-  
8 perience on new regulations in the past has been that  
9 we must comment at the time they come out, though we  
10 really don't know what the effect of the regulations  
11 will be until we see how they are interpreted by IAE  
12 and how they are used, and this also goes back to  
13 Washington and how they impose additional conditions  
14 upon us.

15 CHAIRMAN KEPPLER: Again, I would make the  
16 point it is the intent of the Commission that categories  
17 I, II, and III type violations would not occur at a  
18 high frequency, and I realize your concern is in the  
19 interpretation of policy.

20 MR. RHODI: Thank you.

21 CHAIRMAN KEPPLER: Anybody else have a  
22 comment?

23 (No response)

24 CHAIRMAN KEPPLER: The next speaker is Stan  
25 Huber.

1 MR. HUBER: I am Stan Huber, President of Stan  
2 A. Huber Consultants, Inc., New Lenox, Illinois.

3 We are a consulting firm specializing in  
4 health physics, radiation safety, regulatory compliance,  
5 record systems, quality assurance, continuing education,  
6 etc. This proposed NRC policy could be considered  
7 fantastic for my consulting business, but we do not  
8 have such a selfish or short-sighted viewpoint.

9 I believe it can safely be said I am re-  
10 presenting at least our 200 client hospitals involved  
11 in nuclear medicine and thirty industries involved with  
12 the use of radioactive materials throughout a seventeen  
13 state area.

14 As soon as I received and read the NRC notice  
15 in early November, we made a mass mailing to all of  
16 our clients urging them to read this important policy  
17 and to attend these hearings, or at least submit  
18 their written comments.

19 We received a tremendous feedback from that  
20 mailing. There was not one single positive statement  
21 in favor of not only the policy itself, but also  
22 serious objections to the methods used in developing  
23 the policy.

24 From a personal note, I have been in the  
25 business of full-time nuclear consulting services for

1 fifteen years and, although I have written comments  
2 to the NRC before, this is the first time I have  
3 attended a public hearing, because this proposed  
4 policy represents the most potentially serious impact  
5 in the history of the AEC-NRC and in the use of nuclear  
6 materials in this country.

7 First, the answers to the nine questions  
8 the NRC asks in the purpose of the Enforcement Policy  
9 section of the October 17, 1980, Federal Register notice  
10 are no -- double underlined.

11 Obviously, if I were to use just about one  
12 minute per item to attempt expanding on the reasons  
13 for those nine no answers, my time for comment would be  
14 up. Reasonable response cannot be given in that short  
15 a time.

16 Although the questions asked by the NRC  
17 are important, there are even more important consi-  
18 derations about questions the NRC has not asked.

19 One question deals with whether laws are more  
20 important than regulations meant to enforce laws. The  
21 NRC apparently believes its regulations and policies  
22 are more important than the intent of Congress in its  
23 passage of the Regulatory Flexibility Act of 1980  
24 which was signed into law the month before the NRC  
25 announced these proposed policies.

1 Under the provisions of the "reg-flex" law,  
2 federal agencies should:

- 3 1. Prepare regulatory feasibility analyses  
4 of proposed regulations before publishing them.
- 5 2. Develop less burdensome alternatives for  
6 small entities.
- 7 3. Mention review of major regulations every  
8 ten years to determine whether they can be revised to  
9 minimize impact on small entities.
- 10 4. Publish semi-annual agendas of proposed  
11 regulations so that small entities can have the time  
12 and opportunity to comment on them.

13 The NRC did none of these items. Congress  
14 no doubt assumed that regulatory agencies would have  
15 enough respect for laws of the land whereby Congress  
16 would not have to inspect and punish any agencies that  
17 did not comply. Was Congress wrong?

18 Do regulatory agencies have the right to  
19 disregard laws while expecting the people they regulate  
20 to pay attention to fine and meticulous detail of  
21 their regulations, dealing with only one particular  
22 law the regulatory agency chooses to enforce?

23 The second question deals with the amount of  
24 time and personnel the NRC had to develop this policy  
25 versus the amount of time given to the licensees and

1 public to respond to the notice.

2 Again, it is obvious in the October 7, 1980,  
3 Federal Register Notice the NRC had been working on this  
4 proposed policy at least six months or more than a  
5 year before Congress passed the law in June, 1980, to  
6 raise the maximum civil penalty from \$5,000 to \$100,000  
7 and to eliminate the provision limiting civil penalties  
8 in any thirty day period to \$25,000.

9 It took the NRC five additional months, from  
10 June, 1980, to develop the October 7 and October 17  
11 Federal Register Notices and the October 28 Notice to  
12 licensees and others about the public hearings.

13 Thus, the NRC, with considerable staff at its  
14 disposal which specialize in regulations, had probably  
15 over eighteen months on this project. Yet, the NRC is  
16 giving only one month to licensees, officials, and  
17 citizens to comment on all that ground work.

18 These latter organizations or individuals  
19 do not have such staffs of specialists, nor did most  
20 of the licensees we contacted even realize that the  
21 table 1 category of "all other licensees," which was  
22 buried in the text of this proposed policy, really did  
23 affect them.

24 With this additional background, let me ask  
25 the question: "Is that fair?"

1           A third question deals with the real reasons  
2 why these punitive measures are being adopted. If  
3 the nuclear industry, or even a small percentage of  
4 it, is in that bad a shape to require a policy of this  
5 type, why did not the NRC consult with the nuclear  
6 licensees and the nuclear medicine and other trade  
7 associations in the development of a fair and under-  
8 standable policy?

9           Is the purpose of this policy really to  
10 solve problems, or is it simply to provide the NRC  
11 with numbers and statistics to impress certain pressure  
12 groups who will never be satisfied until the entire  
13 nuclear industry, including the NRC, is eliminated?  
14 Has someone joined and/or been appointed to the NRC  
15 with a willful purpose of destroying it?

16           A fourth and most important question deals with  
17 the economic impact of this proposed policy. I will  
18 start off with the NRC's own figures used in a recent  
19 value impact assessment and report justification for  
20 deletion of 10 CFR 20.304 regarding burial of small  
21 quantities of radionuclides.

22           The economic impact of that proposal is  
23 nothing compared to the impact of this proposed NRC  
24 policy we are discussing today. At any rate, that  
25 NRC impact statement indicates there is a total of

1 about 10,745 radioactive material licensees in the  
2 United States.

3 Let me round that figure off to 11,000 and  
4 assume this proposed policy of NRC fines will only  
5 effect about five percent of the licensees. That means  
6 about 550 fines per year among twenty categories in  
7 Table I dealing with five severity levels among four  
8 categories of licensees, including the "all other  
9 licensees" category.

10 That breaks down to only about twenty-eight  
11 fines per category for a year's time, or just over  
12 two fines per month per category nationwide. I am  
13 sure someone in the NRC has higher goals than that,  
14 but I want to be ultra-conservative.

15 Adding up all the numbers in the twenty  
16 categories of fines and multiplying that number by  
17 twenty-eight fines per category, you arrive at \$12  
18 million for the year. If there are four fines per month  
19 per category, the annual figure is \$24 million. Those  
20 are conservative figures, but do not even begin to  
21 consider the real economic impact.

22 Let's assume this policy goes through as is  
23 and just ten other federal agencies, practically all  
24 of which make the NRC look like small potatoes, see  
25 what the NRC has created for iteself. These other

1 agencies say: "Hey, we need better enforcement of  
2 our regs, too."

3 Still, based on the very conservative as-  
4 sumption that only five percent of the regulated  
5 businesses are affected by this progression, all of  
6 a sudden we could easily have at least a billion dollar  
7 per year direct negative impact on our national economy.

8 If ten percent of the businesses are affected,  
9 or if any of the larger agencies really get carried  
10 away with themselves, we can be talking in the \$2 to  
11 \$5 billion per year range.

12 This, gentlemen, is still considering just  
13 the direct revenue to the government from fines against  
14 five to ten percent of the public that is being  
15 protected against itself. That is still just scratching  
16 the surface of economic impact.

17 The third step is a very reasonable consi-  
18 deration that for every average fine of \$8,000 at least  
19 one \$16,000 per year employee will leave or not enter  
20 a given field impacted upon by regulations enforced  
21 in this manner. Then the \$2 to \$5 billion impact  
22 becomes \$6 to \$20 billion per year.

23 A fourth step is the consideration that the  
24 category of "all other licensees" in this proposed NRC  
25 policy will obviously curtail nuclear research, the



1 offering of nuclear medicine services, and the develop-  
2 ment of nuclear industry which is involved in paper and  
3 plastic production, oil, electricity, and everything  
4 that makes this country operate.

5 The impact of the other regulatory agencies  
6 which will mimic the NRC in its policy will again  
7 easily double the aforementioned third step impact of  
8 \$6 to \$20 billion per year to a total of \$12 to \$40  
9 billion per year. What is \$40 billion per year?  
10 Well, gentlemen, it is a percentage of our Gross National  
11 Product and would be one hell of a percentage of our  
12 inflation rate.

13 If anyone from any regulatory agency disagrees  
14 with this scenario, I suggest their credentials in  
15 economics should be examined and I propose that  
16 someone of the stature of Milton Friedman or William  
17 Simon, former Secretary of the Treasury, be asked for  
18 their opinion on who is closer to the truth.

19 At the very least, this type of economic  
20 impact must certainly be examined by the GAO, Government  
21 Accounting Office, just as the much lower economic  
22 impact of the NRC ALARA program was examined before it  
23 was finalized.

24 Someone may ask: "Well, what is any regulatory  
25 agency supposed to do about those five to ten percent

1 of incompetents or criminals who are endangering  
2 public health and safety?" The obvious answer is to  
3 put them out of business or in jail if the situation  
4 is, indeed, more than an individual inspector's inter-  
5 pretation of attention to fine and meticulous detail.

6 The equipment, materials, and facilities are  
7 not at fault -- it is the people who manage them.  
8 By putting incompetents out of business, the economic  
9 wealth is simply distributed to those who can properly  
10 do their jobs within the regulations. Either that or  
11 a closed down facility is reopened under new management  
12 who can run it properly.

13 In this way national productivity is actually  
14 increased compared to the highly inflationary and  
15 punitive fines mechanism being proposed by the NRC.

16 In case anyone seriously questions the  
17 aforementioned rough economic impacts, I will reference  
18 an analysis in 1974 performed by General Motors, when  
19 that single company reported it cost them \$1.3 billion  
20 to comply with government regulations. Those costs were,  
21 of course, passed on to the consumer, just as the  
22 costs of this proposed policy would be. God knows what  
23 General Motors is spending today, six years later.

24 Even more frightening is the question what is  
25 this country spending this year for protection against

1 itself in attention to fine and meticulous detail?  
2 What are the costs versus risks and the risks versus  
3 benefits ratios? Or, simpler still, are there any real  
4 benefits at all to the country from this proposed  
5 policy?

6 In conclusion, and before even attempting to  
7 pursue this proposed NRC policy any further, I have  
8 the following recommendations:

9 1. The NRC, all licensees, public officials  
10 and interested citizens should read William E. Simon's  
11 book A Time for Truth published by Berkeley Publishing  
12 Corporation. That reference, plus Friedrich von  
13 Hayek's dissertation The Road to Serfdom, for which he  
14 became Nobel Laureate in Economics in 1974, specifically  
15 addresses the control over all life that economic  
16 control confers and the roles of responsible government  
17 therein.

18 The conclusion after reading those two  
19 references must be that the NRC needs to reexamine its  
20 management philosophy and systems that could possibly  
21 have permitted this proposed policy to be put into  
22 print in the first place.

23 2. Examine why the "Reg-Flex Act of 1980"  
24 was ignored or overlooked.

25 3. Examine the reasons for the rush of this

1 proposed policy.

2 4. Ask why the nuclear industries and trade  
3 associations were not consulted in the formative stages  
4 of this proposed policy.

5 5. Evaluate the total economic impact and  
6 risk/benefit ratios of this proposed policy through  
7 the Government Accounting Office, Small Business  
8 Administration, and other groups affected by this  
9 proposed policy. The GAO route in this case is not  
10 an option, but a mandate.

11 6. Realize that another recently passed  
12 law called Equal Access to Justice allows courts to  
13 award legal fees to small businesses that prevail  
14 against regulatory actions the courts deem unreasonable.

15 Practically all the hospitals, industries,  
16 and others at this hearing can classify as a small  
17 business. In other words, the government will pay you  
18 to take it to court if any of its regulatory agencies  
19 does anything ridiculous.

20 With all these serious concerns, I urge the  
21 NRC to totally revamp this proposed policy and consider  
22 the items expressed in this presentation.

23 Thank you.

24 CHAIRMAN KEPPLER: I have one comment, Mr.  
25 Huber. Going back to the point I tried to make earlier

1 that it was the intent when we set up this policy  
2 to put those categories, or those violations that fit  
3 the categories of civil penalties, are those that  
4 were viewed to be of such importance that they shouldn't  
5 occur very frequently.

6 Is it your view that the threshold that we  
7 have for Severity Levels I, II, and III is too low?

8 MR. HUBER: I think the economic approach  
9 itself is wrong. I think that's been evidenced really  
10 by the lady from PEP, as well as all the other comments  
11 I have heard today. The economic impact is simply  
12 passed on to the consumer, and that's not the approach  
13 to take.

14 If someone is really endangering the public  
15 health and safety, they should be put out of business,  
16 and that eliminates both the public's problem and the  
17 NRC's problem.

18 CHAIRMAN KEPPLER: Thank you.

19 Our next speaker is Jerry Niles.

20 MR. NILES: My name is Jerry Niles. I am  
21 employed by New York State Power Company as the General  
22 Manager. However, I do not speak representing my  
23 company, but rather as a private citizen who has  
24 dedicated twenty-two years of my working career to  
25 nuclear operations and nuclear safety, all of which

1 time has been involving responsible positioning of  
2 reactor operations, operations engineering, nuclear  
3 reactor operations management.

4 The reason I rise to make a statement at  
5 this occasion is a very deep underlying concern as to  
6 substance and potential negative impact on nuclear  
7 reactor safety as a consequence of this Enforcement  
8 Policy.

9 Just as government ultimately relies on the  
10 consent of the governed, in this case because nuclear  
11 safety regulations as it has evolved and exists today,  
12 is largely a matter of a subjective process requiring  
13 a great deal of interpretation of rules, regulations,  
14 technical specifications.

15 Nuclear safety regulations does rely to a  
16 great extent on a consent of the regulated and the  
17 mutual objective of nuclear safety. Let me illustrate  
18 the aspect that I am most concerned about, and that is  
19 the proposed Enforcement Policy has the potential to  
20 destroy nuclear safety regulations as we know it today.

21 The consent of the regulated thus far I  
22 think can be shown by the fact that rare indeed is the  
23 case that the regulated entity has ever exhausted the  
24 administrative processes of unreasonable regulations  
25 and sought relief through the courts.

1           This policy, I think, has a large potential  
2 to change that environment and force the regulated  
3 licensees to seek relief through the court system after  
4 exhausting the administrative remedies of appeal.

5           The magnitude of the penalties offered will  
6 compel many licensees to litigate for relief. In the  
7 litigation for relief it can be anticipated that the  
8 defense in most cases will be a constitutional challenge  
9 to the regulation that lies behind the citation for  
10 nonconformity and noncompliance.

11           I think there is a long and instructive  
12 history, not necessarily related to AEC and NRC  
13 regulations, but many regulators of other governmental  
14 entities wherein the constitutional challenge is based on  
15 a requirement that to be enforceable and constitutional  
16 a regulation should be subject to the same inter-  
17 pretation as to its intent on requirements by two  
18 independent knowledgeable parties.

19           Now, that is not the history of nuclear safety  
20 regulations, which can be illustrated very clearly by  
21 the circumstance that a few pages or a few paragraphs  
22 or a few lines of amendments to regulations result  
23 thereafter in the issuance of a NUREG document of  
24 a hundred or more pages to interpret the intent of the  
25 regulation, thereafter followed by regulatory guides

1 that are laid upon licensees in an "I got you"  
2 circumstance, often in the environment of a renewal  
3 application or other similar conditions once the plant  
4 is down.

5 Now, the nuclear safety regulation is indeed  
6 a subjective process, and I think all of us that have  
7 spent any part of our careers in the nuclear business,  
8 either on the regulated side or on the regulator side,  
9 are quite aware of that.

10 The process works, even though it is sub-  
11 jective by the mutual consent of regulated and regulator,  
12 with the mutual objective of enhancement of safety.

13 I think what is proposed here has a very,  
14 very real hazard of destroying the regulatory objective  
15 of nuclear safety through the ligatory process of  
16 appeals for relief in the courts. I don't want to  
17 see that happen.

18 Thank you.

19 CHAIRMAN KEPPLER: Thank you very much, Jerry.

20 Let me run back through just briefly the  
21 people that I called before that weren't present.

22 Is Mr. Schultz here?

23 (No response)

24 CHAIRMAN KEPPLER: Ms. Mather?

25 (No response)



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CHAIRMAN KEPPLER: Dr. Meir?

(No response)

CHAIRMAN KEPPLER: Mr. Margulo?

(No response)

CHAIRMAN KEPPLER: That completes the list of speakers who signed up to comment. We have five minutes. Do you have another comment you want to make, Jerry?

MR. NILES: As long as there is still five minutes, I would like to take a minute or two of that five. I would like to point out a statement that you yourself made to us in the management conference, Mr. Keppler, a couple of years ago as to how the regulatory process works in one respect.

You mentioned to us, and I think I recall this correctly, that I & E had done an internal study to ascertain some estimate of the requirements of regulations on licensing conditions, technical specifications, program commitments for a typical operating reactor licensee with the conclusion that those commitments approached 18,000 for a typical reactor, and that it was not humanly possible for any licensee at any one instant in time to be assured that every one of those commitments was up to snuff.

We add to that the Enforcement Policy

1 discussed here today, and I think we have on our hands  
2 an impossible situation.

3 CHAIRMAN KEPPLER: Let me ask, are there any  
4 others who wish to make a comment before we wrap this  
5 up?

6 MR. BROADBENT: I have been sitting here  
7 debating whether or not to say anything. My name is  
8 Michael Broadbent, B-r-o-a-d-b-e-n-t, a partner with  
9 the firm of Fields-Griffiths and Associates.

10 I have some comments out of the presentation.  
11 It appears that the regulatory -- or the regulators  
12 penalize all people or institutions if one person or  
13 institution makes an error.

14 It's unfortunate that the NRC has taken, or  
15 has been directed to take, an adversarial position  
16 rather than one of assistance and cooperation.

17 It is not the intent of most people with  
18 whom I work to circumvent regulations, but assistance  
19 is appreciated in making suggestions which will help  
20 make a safer program to operators, patients, and the  
21 general public.

22 With all I have spoken with about this  
23 hearing, they have all said about the same thing --  
24 these fines will lead to hiding of facts and making  
25 inspectors trying to find them, such as not wearing

1 film badges so that they don't exceed established levels.

2 Some questions which have come up concerning  
3 this: Are the fines mandatory? Is there any concern  
4 for the very small users, such as if they are fined  
5 they will have to close?

6 The severity levels are much too high, the  
7 civil penalties making inspectors the judge and the  
8 jury. This calls for self-incrimination and confession.  
9 In other words, all are guilty until proven innocent.

10 With the government and public outcry for  
11 lower cost for health care, how do you justify the  
12 inevitable increase for cost of medical care to  
13 cover the inevitable fines which will be assessed?

14 Thank you.

15 MR. HUBBOLTZ: My name is Mark Hubboltz,  
16 General Manager of Medex. We provide a high quality  
17 heat reducing nuclear medicine service. We utilize gamma  
18 cameras and appropriate radiopharmaceuticals.

19 Our specific marketplace is in rural en-  
20 vironments, where either no tests were previously done,  
21 or diagnosis was often done posthumously, or patients  
22 often aged and infirm were subjected to ambulance  
23 or automobile trips of considerable distance with  
24 associated expense and risk, higher than those of the  
25 tests to be regulated.

1           Although we provide all health physics  
2 support for our client hospitals, they indeed are  
3 the license holders. If, in spite of our best efforts  
4 to comply, a fine should be imposed, would the hospital  
5 be responsible, or in light of the fact that the  
6 registered technologist is our employee, would we  
7 be responsible for such fine?

8           With a typically unsophisticated administration  
9 associated with rural medicine, the nuclear medicine  
10 itself is an unknown and often feared entity. I am  
11 sure that many hospitals dread the day that the technetium  
12 generator goes into meltdown, leveling a forty-bed  
13 hospital, and a good portion of the neighboring  
14 grain elevator, too.

15           If we add the additional burden of the hint  
16 of financial penalty, I fear that we will drive  
17 potential hospitals from accepting nuclear medicine,  
18 therefore requesting the expensive movement of patients.

19           If we offer to pay such potential fines, I  
20 can assure you that the bottom line would be the same --  
21 higher patient costs, which is counterproductive to yet  
22 another regulatory agency whose major concern is cost  
23 containment.

24           The fear of being shut down awhile, the fear  
25 of loss of license and its perception of our lack of

1 professionalism, has been more than enough incentive for  
2 us to want to do quality nuclear medicine, and a system  
3 of fines will only increase individual costs to each  
4 patient, most probably through a higher test rate  
5 as insurance against a possible fine.

6 Thank you.

7 CHAIRMAN KEPPLER: Ms. Quigg?

8 MS. QUIGG: Yes, I would like to comment  
9 that it isn't at all assuring to hear industry's  
10 comments today complaining about the increased civil  
11 penalties under the proposed regulations.

12 I would have thought from the industry press  
13 that the nuclear technology was almost fail-safe, and  
14 I would like to know why they are so concerned about  
15 fines when they have told the public constantly for  
16 many years that accidents and negligence just won't  
17 happen -- that this is a near-perfect technology run  
18 by nearly-perfect people.

19 We recognize that that is not the case, but  
20 we didn't know that you did.

21 CHAIRMAN KEPPLER: Any other comments?

22 Mr. Thompson would like to make a couple of  
23 remarks.

24 MR. THOMPSON: I would like to comment in  
25 a general fashion on the character of many of the

1 comments we have heard this afternoon, both pro and con.

2 To begin with, I believe that it's appropriate  
3 to note that in a meeting that deals with a narrow  
4 subject such as this one, tends to emphasize the subject  
5 matter of the meeting to the exclusion of the context  
6 in which it appears.

7 It is appropriate to note that the subject  
8 matter we have today is involved in about two percent  
9 of the cases involving enforcement action of one form  
10 or another.

11 The emphasis has been on the elevated enforce-  
12 ment action of civil penalties and Orders, and they do  
13 constitute a very small number of cases. It's  
14 appropriate to note for the entire audience that when  
15 we conduct inspections, there are only a few things  
16 that can happen on the inspector's findings.

17 He can find that those items he inspected are  
18 clear; that is, that there are no violations of  
19 regulatory requirements. He can find that there is  
20 sufficient question about the compliance of a particular  
21 item that it remains unresolved and requires further  
22 examination; or he can find that the item is an item  
23 of noncompliance.

24 What we are dealing with today is the latter  
25 class. It does not constitute the majority of our

1 inspection findings, and I think it's important to keep  
2 that in mind as we begin to approach a break point in  
3 the session.

4 I think these meetings have been of particular  
5 value to those of us who have worked on articulating  
6 NRC's Enforcement Policy for the future. All the  
7 comments that we receive will be considered when the  
8 policy is revised to accommodate the public comments.

9 Obviously, not all will be accommodated,  
10 because they are at opposite ends of the spectrum,  
11 but all of them will be considered and all of them  
12 will be helpful in clarifying the Policy as it's been  
13 promulgated for comment.

14 I think there is one specific comment I  
15 want to make that is conveyed by a number of commentators  
16 today who have implied that by some means we establish  
17 a ticket quota. That is not the case. An inspector  
18 is explicitly not sent out to find noncompliance.  
19 He is sent out to find the status of compliance of  
20 licensee activities, and there is no quota.

21 If we find items of noncompliance, I don't  
22 believe the most ardent supporter of the nuclear  
23 industry would advocate that we not address those  
24 items of noncompliance and take appropriate action  
25 to be sure they are corrected, and steps are taken to

1 prevent their recurrence. That's what we are dealing  
2 with today, and you have to keep the context of the  
3 entire performance in the back of your mind as you  
4 deal with this necessarily negative and retrospective  
5 function that we are trying to articulate policy on  
6 in this statement.

7 I wanted to make that statement because I  
8 suspect as we break for the dinner break there will be  
9 a somewhat smaller group of people here in the evening  
10 session.

11 There may be new people here; there may be some  
12 of you who chose to return for the evening session, but  
13 inasmuch as many of you may be leaving, I felt it  
14 appropriate to make the comment about enforcement in  
15 the total picture of the industry.

16 CHAIRMAN KEPPLER: I would like to just make  
17 one additional remark before closing. There is a  
18 feeling I have that has come from the first two meetings  
19 that I guess I would like to focus on.

20 When we developed the policies, it was the  
21 intent to try to create the image that we would have  
22 very strong enforcement action for very serious violations  
23 or for violations which were chronic in nature and  
24 which were not receiving management attention.

25 We did not set this up with the idea that



1 there would be a significant increase in the numbers  
2 of fines or a significant increase in escalated actions  
3 by themselves. The tone that comes back is that you  
4 anticipate that there will be a large number of fines  
5 and you will be subjected to fines for almost every  
6 inspection, and I guess that translates into the  
7 feeling that the severity categories or the examples  
8 that we have given in the back, that the threshold is  
9 too low for those things, and I have laid out to you  
10 what our intent was, and I think if you can be very  
11 specific in your comments as to those functional areas  
12 that you feel the threshold is too low, and to comment  
13 forthrightly, and they will be considered.

14 It is a very clear intent that we will come  
15 down hard on the serious safety related problems that  
16 occur.

17 With that, I guess I would like to thank  
18 you for coming today. It was a miserable day outside,  
19 but it is very warm in here. The comments made it warmer,  
20 and we do appreciate the input from all the commentators.

21 The comments will be considered very care-  
22 fully in reviewing the policy, and we will reconvene  
23 at 7:00 p.n. for those of you who will be staying  
24 for the evening session.

25 (Whereupon, at 5:05 p.m. the hearing in the

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above-entitled matter recessed, to reconvene at  
7:00 p.m. this same day.)

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E V E N I N G S E S S I C N

(7:00)

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2  
3 CHAIRMAN KEPPLER: We have three people that  
4 were not here this afternoon. You were not here, is  
5 that correct?

6 SPEAKER: Right.

7 CHAIRMAN KEPPLER: Oh, here comes some more.  
8 Let me ask you this. We made a prepared  
9 presentation that was about an hour in length this  
10 afternoon, and I believe you got copies of it when  
11 you came in.

12 SPEAKER: Yes.

13 CHAIRMAN KEPPLER: I guess what I would like  
14 to ask you is do you want us to repeat that presentation,  
15 or would you like us to summarize it very briefly, or  
16 would you like to just go into commenting on it? I  
17 will leave it up to you. We will gladly do whatever  
18 would be helpful.

19 SPEAKER: Summarization.

20 SPEAKER: A summary would be fine.

21 CHAIRMAN KEPPLER: Summarization, okay. Does  
22 that sound okay to you?

23 SPEAKER: Yes.

24 CHAIRMAN KEPPLER: I will let Mr. Norelius  
25 give you the summary.

1 MR. NORELIUS: We may use some of the slides,  
2 Jean. Let me try to summarize rather briefly what the  
3 Policy is about and hit some of the highlights that I  
4 think will be of interest to you.

5 First, let me run through some specific  
6 objectives that we had in writing the Policy that I  
7 think will be helpful in giving you a basic under-  
8 standing of where we have come from.

9 Just by way of further background, the  
10 Congress and our own Commission really has given us  
11 a mandate to come up with a tougher enforcement policy,  
12 if you will, and also the Congress passed a law ef-  
13 fective June 30, 1980, which increased the civil  
14 penalty authority where before the maximum civil  
15 penalty was \$5,000 per item, not to exceed \$25,000  
16 for a thirty-day period, the new authority raised that  
17 to \$100,000 civil penalty per item of noncompliance  
18 with no upper cap.

19 Maybe we should show Slide 3, Jean, just to  
20 give you six specific objectives that we started with  
21 in establishing -- in writing the policy.

22 First, we wanted to establish criteria  
23 for utilizing this increased civil penalty authority.

24 Secondly, we had a mandate to make the  
25 enforcement program tough, yet we wanted to be fair.

1 Third, we wanted to achieve greater uniformity  
2 in the treatment of licensees by taking equivalent  
3 actions against similar licensees having similar  
4 problems.

5 Fourth, we wanted to better define our  
6 enforcement capabilities with respect to our NRC  
7 license activities other than operating reactors.

8 Fifth, we wanted to focus escalated enforce-  
9 ment actions on the specific event or problems which  
10 led to the decision to take the enforcement actions,  
11 rather than to focus on the specific items of non-  
12 compliances.

13 Last, we wanted to clearly articulate our  
14 Enforcement Policy and define more clearly the criteria  
15 for taking the various enforcement actions.

16 So, that is just a little background. In  
17 developing the policy, we came up with six categories --  
18 six severity levels of noncompliance -- and I think  
19 this will be of some interest to you.

20 In the past we have had three categories of  
21 noncompliance which we called violations, infractions,  
22 and deficiencies. Now, in the new policy, rather than  
23 those three designations, we have six severity levels  
24 of noncompliance or violations -- six severity levels  
25 of violations.

1 I think it will be helpful to show Slide 4, Jean,  
2 which shows the relative ranking of the old terms that  
3 we used with the new severity levels, and I think this  
4 will help you to get an understanding of how they  
5 relate.

6 What we used to call violations, we now would  
7 probably call either a Severity Level I, II, or  
8 possibly a III.

9 What were formerly infractions, may now be  
10 a III, but would more likely be a IV or a V; and VI  
11 would be equivalent to the old deficiencies.

12 One thing that is new, and seems to present  
13 some difficulty in getting the thought across, is that  
14 the new severity categories are related in a sense to  
15 the seriousness of the event.

16 There is a series of supplements at the end  
17 of the policy which describes severity levels for  
18 seven different program areas which we regulate, and I  
19 believe that's shown on the next slide.

20 There is a separate supplement for each of  
21 these seven areas, and in each of those areas, there is  
22 a description of six different severity levels.

23 An important point to remember is that within  
24 any program, for example in the materials program,  
25 if you hold a by-product materials license, the

1 seventh supplement describes the six severity levels.  
2 The safety significance of those are not equatable  
3 from one supplement to another; that is, the severity I  
4 item in a materials program is not equatable in its  
5 absolute safety significance to severity I say in reactor  
6 construction. So, they are relative in each of those  
7 groupings.

8 Now, this presents a change also from the  
9 past policy in that if, for example, you were to have an  
10 overexposure which exceeded five rems at your facility,  
11 and if that was -- resulted from the failure to follow  
12 a procedure, or the failure to do a survey, maybe  
13 there were those three items of noncompliance.

14 Under the new policy, we would call all three  
15 of those severity level II violations. In another  
16 instance, where you might just have the failure to  
17 do a survey in an isolated instance, it may be a  
18 lower severity level -- a IV or a V.

19 So, the attempt is to make the severity  
20 level commensurate with the problem, and we think  
21 that will help both licensees and the public to attain  
22 a better focus on what the seriousness of the problem  
23 is, and as we will see later, that has a direct bearing  
24 on the enforcement action which we might take.

25 Before addressing the subject of civil

1 penalties, let me make one comment that you will  
2 notice as a change when you get routine Notices of  
3 Violation.

4 First of all, they will carry the new  
5 severity category designations -- Severity I through VI.

6 Secondly, the responses to the Notices of  
7 Violations will in the future be required to be  
8 submitted under oath or affirmation as provided in  
9 Section 182 of the Atomic Energy Act.

10 So, that will be a change from the past  
11 way of doing business.

12 Let's go to Slide 6 and talk a little bit  
13 about the civil penalties.

14 There are four general ways that would lead  
15 to assessment of a civil penalty. The first one is  
16 if you were to have violations in the severity levels I,  
17 II, or III categories. These are considered to be the  
18 more serious events, and we feel from past experience  
19 and from working in these areas that there should not  
20 be many of these, assuming proper attention is given  
21 to the requirements.

22 So, it's considered that they are the  
23 more serious kinds of problems, and they would occur  
24 it would lead to a civil penalty.

25 Severity categories IV and V are the ones



1 that are most similar to the infractions that you may  
2 have had in the past. These may subject a licensee  
3 to a civil penalty if they are recurring in nature.  
4 They would be assessed only after an enforcement con-  
5 ference had been held to discuss their significance  
6 with you.

7 Let me just stop there a minute and say that  
8 in practice we would probably only have an enforcement  
9 conference with you if we found that these were pro-  
10 grammatic type of problems. If we found isolated  
11 instances of noncompliance -- maybe the failure to cali-  
12 brate survey meters, failure to do prescribed tests, or  
13 whatever that occurred here or there -- we would  
14 probably just issue a Notice of Violation, but if we  
15 found that there was not a program to perform those  
16 required tests or whatever, then we would probably  
17 have an enforcement conference.

18 An enforcement conference is a meeting  
19 between NRC and the licensee management in which we  
20 would address the specific items of noncompliance, to  
21 plan corrective action, and we would tell you what the  
22 enforcement options are that we might take.

23 Now, following such an enforcement conference  
24 if we found continued violations at that level, then  
25 we may also assess a civil penalty for these

1 lower severity level IV's or V's.

2 Maybe I should make the point that what we  
3 envision is that most of the infractions -- most of  
4 the items of noncompliance that have been cited in the  
5 past would probably fall into the severity V category,  
6 some in IV, and would not routinely lead to civil  
7 penalties unless they were programmatic problems  
8 pervasive in nature.

9 The last two ways that civil penalties can  
10 be assessed -- one is the failure to report an item,  
11 and this specifically relates to Part 21 and has to  
12 do with vendors primarily, and the last if there are  
13 willful violations that have occurred they also may  
14 result in the issuance of civil penalties

15 Taking a look at the next slide, this is  
16 the table of civil penalties. There seems to have  
17 been some confusion from this afternoon as to what the  
18 latter grouping meant -- "all other licensees and  
19 persons subject to civil penalties."

20 That means primarily materials licenses, and  
21 the persons subject to civil penalties are licensed  
22 operators at nuclear power plants and individuals who  
23 fail to report under the provisions of Part 21, which  
24 primarily relates to vendors in the nuclear program.

25 I could answer other specific questions

1 about this, but I think I won't make any other comments  
2 on it at this point.

3 Maybe we should take a look at Slide 10, which  
4 is another table. The question had come up previously  
5 as to how many times should the Commission issue  
6 civil penalties to a particular licensee before  
7 taking a stronger enforcement action, and this table  
8 is an attempt to show some sort of a roadmap of how  
9 we would proceed for serious violations which are  
10 repetitive.

11 A severity level II, just to use an example --  
12 well, I gave you an example before of an overexposure  
13 exceeding five rems being a severity level II. If  
14 that were the case, the first time it occurred, we would  
15 issue a civil penalty as shown by the little "a"  
16 designation.

17 If a similar violation occurred within a  
18 two-year period, the second such instance would  
19 result in a civil penalty plus an Order.

20 If a third such violation occurred which was  
21 similar in nature, that would include a civil penalty  
22 plus a more severe Order which may include a show  
23 cause for license revocation.

24 Now, this table is not absolutely binding on  
25 the Commission. In fact, I should point out that the

1 Commission made a specific request to get comments on  
2 this table as to whether it should be the one normally  
3 applied or it's one we could apply, and so we welcome  
4 comments on that. This is a way we could do it, and  
5 probably the one we would normally follow all else  
6 being equal, but it does not restrict us from doing  
7 something else.

8 If a situation is quite severe, we could issue  
9 an Order the first time to suspend operations if that's  
10 what was required.

11 Well, that's a very brief summary. I think  
12 I have hit the major highlights, unless some of the  
13 other panel members wish to elaborate. If not, maybe  
14 we can stop there and turn the lights back on and  
15 take questions or your comments of things you are  
16 specifically interested in. This is a rather fast  
17 summary.

18 CHAIRMAN KEPPLER: I believe you indicated  
19 you had some questions you would like to ask us  
20 concerning the Policy?

21 SPEAKER: Not at this time. It seems to  
22 be pretty clear.

23 CHAIRMAN KEPPLER: Is there any comment you  
24 wish to make for the record or for the Commission?

25 SPEAKER: No.

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CHAIRMAN KEPPLER: How about you?

MR. EMROLL: My name is Lawrence Emroll, E-m-r-o-l-l, I am Assistant Manager, Department of Nuclear Medicine, Holy Cross Hospital here in Chicago.

I was here this afternoon and heard the comments and spent a couple hours digesting everything, and just before we walked in I was talking to one of the panel members, and I thought I might make some comments to help in understanding for anybody that's here from the medical profession that would be effected by the Nuclear Regulatory Commission's proposals here.

In getting those Notices, it's very difficult to go through them, read them, and understand them all. All we do is come up with some dollar signs that show us we are going to be fined when we are inspected. Whether we will get fined for every little thing or whatever, it's hard to understand.

Just talking a few minutes ago, it seemed like we weren't going to get fined for every little thing. I would be willing to comment out loud here as to our recent inspection.

There were six areas of noncompliance. We received notification from the office that all we had to do was send them a letter indicating how we were going to correct this. We were under the impression

1 upon receiving this notice that we might be fined for  
2 all these little things that we did.

3 The question of whether they are really little  
4 things or not is in the mind of somebody else. In  
5 my mind I feel they are certainly not life threatening,  
6 and the question that always occurs to me is when do  
7 we do our patients with all the documentation we have  
8 to do, all the things we have to keep records for --  
9 when do we find time to do all our patients? That  
10 seems to be something that some people always forget --  
11 that we are in the business of diagnosing and treating  
12 patients medically through the use of radioisotopes.

13 The items that I had, and I wrote them down  
14 as I could remember them, we were in noncompliance --  
15 for instance, over the course of the last two or three  
16 years, there were about eight weeks where we didn't do  
17 our weekly survey. The isotope committee did not  
18 meet quarterly as it was supposed to by virtue of the  
19 license.

20 I realize these are technically areas of  
21 noncompliance because your license says, or your  
22 request for renewal says you must do these things.  
23 Annual in-service, for instance, for the ancillary  
24 groups; the housekeeping, security, and nursing  
25 personnel was not done.

1           200 microcuries, the standard for use in the dose  
2 calibrator was not white tested and recorded -- well,  
3 it was white tested, but it was not recorded in  
4 microcuries annually or semi-annually as required.

5           When we switched from buying from a manufacturer  
6 to a radiopharmacy, it became unclear to me how we  
7 were to report the material as it was being returned  
8 to the pharmacy, since when you get a manufacturer's  
9 product you take a survey meter reading on the box,  
10 open it, make sure there's nothing leaking, visually  
11 inspect it, open it, survey it, and record it, and then  
12 turn around and record the empty box -- take the survey  
13 meter again to show that it's backgrounded and discard it.

14           On the other hand, now we are sending unused  
15 materials or empty syringes back to our pharmacy --  
16 to the central radiopharmacy. What do you record?  
17 How do you record it?

18           To me the inspection was a matter of a  
19 learning process also. The question comes up are we  
20 going to be fined for each of those six items, or do  
21 they all come together to form one big fine?

22           You know, what is the value and the level  
23 placed on it? Is there going to be one? That was  
24 hard to determine from the information as presented  
25 in the brochure that came to the department.

1 I think it would be helpful to anybody here  
2 that is in a medical facility to know whether that is  
3 true, or they are going to be fined, or whether we  
4 are going to maintain the same instance, which is what  
5 we were discussing earlier.

6 CHAIRMAN KEPPLER: I think the specific  
7 items of noncompliance that you mentioned -- none of  
8 them fall into the category levels of severity I, II,  
9 or III, and the case would be handled basically the  
10 same way as it was this last time.

11 If I felt there was a problem, I would have  
12 called you in for a meeting and put you on notice for  
13 a fine for the next time. So, obviously, we did not  
14 treat the matters as warranting anything more than a  
15 Notice of Violation, and that's the same way it would  
16 be handled under the new policy.

17 Let me just add, the intent, again, of the  
18 new Policy is to come down very hard on noncompliance  
19 situations that are threatening the public health and  
20 safety and that's what we intended by the language  
21 we used where complete losses of safety occurred or  
22 losses of management control occurred.

23 For cases where there was more of a degradation  
24 in the safety boundaries or other procedural type  
25 violations, they would be handled by your normal



1 routine enforcing program.

2 MR. NORELIUS: In the past, of all our in-  
3 spections, only about two percent I think result in an  
4 escalated civil penalty or order, and we don't envision  
5 that changing a whole lot under the new Policy.

6 MR. EMROLL: I can appreciate that, but I  
7 would like you to understand that you are talking to  
8 somebody that works out of a community hospital -- no  
9 staff physicist, nobody to sit there and interpret  
10 what the verbiage is in that brochure, and it's very  
11 difficult. That's why I came here today, and am taking  
12 the day from work with the approval of the hospital,  
13 even after the legal counsel there had had a chance to  
14 go through it, which wasn't very much time I might add,  
15 and the administrator -- one of the vice presidents had  
16 it in his hands for about a week -- and nobody gave  
17 me any direction, other than I was authorized to come  
18 down here and listen.

19 Now, at least, I have a better understanding,  
20 but reading that brochure it's murderous to try to  
21 sit down and try to go through the verbiage of something  
22 like that.

23 CHAIRMAN KEPPLER: I appreciate the comments.  
24 I guess I would say we have wrestled with that language  
25 for the better part of a year now, and it's very hard

1 to come up with language that will be -- will have the  
2 same meaning to all people involved in this business,  
3 both directly involved and through the industry, or  
4 people in the public domain.

5 I guess I would just tell you that we would  
6 welcome your input and others as to how that might  
7 be clarified so that it would take some of the ambi-  
8 guity out of it.

9 Would you two gentlemen like to comment at  
10 all or ask any questions while you are here?

11 (No response)

12 CHAIRMAN KEPPLER: Does anybody have any  
13 questions to ask?

14 (No response)

15 We will stay around as long as there is  
16 interest in discussing anything. We would be glad to  
17 do that.

18 I am going to officially close the meeting.  
19 Thank you all for coming.

20 (Thereupon, at 7:35 p.m. the hearing in the  
21 above-entitled matter was closed.)

22 - - -

