



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
476 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

April 25, 1990

MEMORANDUM FOR: James Lieberman, Director, Office of Enforcement
FROM: Thomas T. Martin, Regional Administrator, Region I
SUBJECT: REGION I COMMENTS ON SECTIONS OF THE DRAFT ENFORCEMENT
GUIDANCE MEMORANDUM CONCERNING THE IDENTIFICATION AND
PAST PERFORMANCE ESCALATION AND MITIGATION FACTORS

Enclosed are specific Region I comments on the subject draft EGM sent to us with your memorandum dated March 27, 1990. My primary concern with the draft guidance is that it creates a policy whereby if the NRC identifies a number of Severity Level IV and V violations, and concludes that the number and nature of the violations represent a management breakdown, then that single conclusion will result in

1. the violations being classified in the aggregate at a higher Severity Level, namely, Level III;
2. the resultant penalty being escalated because the NRC identified the violations (another symptom of the management breakdown); and
3. a prohibition on mitigation of the resultant penalty, regardless of whether the licensee's past performance, prior to and during the previous inspections, was good or mediocre.

Such an approach, in my opinion, does not demonstrate a "firm but fair" policy on enforcement. In fact, the licensee with the mediocre past (as measured by the prior NRC inspections) will be treated the same as the licensee with the good past.

If you have any questions on these comments, please contact me or D. Holody of my staff.

Thomas T. Martin
Regional Administrator

Enclosure: As stated

James Lieberman

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cc w/encl:
Regional Administrators
 RII, RIII, RIV, RV
J. Partlow, NRR
J. Goldberg, OGC
Enforcement Directors, RII-RIII
Enforcement Officers, RIV-V

ENCLOSURE 1

COMMENTS ON DRAFT EGM ON IDENTIFICATION AND PAST PERFORMANCE

COMMENT 1 (Reference: Page 1, Paragraph 1, Concerning Changes to Existing Enforcement Guidance)

It appears that the only existing NRC guidance for applying the two referenced escalation/mitigation factors is the specific guidance set forth in the enforcement policy (10 CFR 2, Appendix C). If this guidance needs to be revised (or clarified), then it would appear to constitute policy changes, and therefore, require Commission consultation prior to revision.

COMMENT 2 (Reference: Page 1, Paragraph 2, Concerning Escalation of Civil Penalties for an Aggregate Severity Level III Problem (based on NRC Identification))

The concept of a "management breakdown in the control" of a licensee's program seems rooted in the premise that a licensee's management has become ineffective, as evidenced by the fact that (1) a significant number of violations occurred, and (2) the licensee did not identify these violations, which were otherwise identifiable. Clearly, the NRC expects licensees to detect and correct problems in their own programs; the failure to do so is generally the staff's primary consideration in concluding that a management breakdown has occurred. Furthermore, the reason for a licensee's failure to recognize a breakdown in management control is generally due to the breakdown itself (i.e., management and supervision have not adequately monitored their staff's performance to ensure tasks are performed, as required). Therefore, once the NRC has decided to classify a number of NRC-identified Severity Level IV and/or V violations in the aggregate at Severity Level III based on the premise of a management breakdown, as frequently happens in the materials area, it would appear to constitute a "double bang" if the NRC also escalates the civil penalty for essentially the same reason. Every "bang" (be it a higher Severity Level classification or application of an escalation factor) should send a distinct message which can be clearly articulated in the letter to the licensee. Since a "double bang" serves no useful purpose other than to send the same message twice, we recommend that civil penalties in such cases not be escalated because the NRC identified the violations.

COMMENT 3 (Reference: Page 1, Paragraph 3, Concerning the Prohibition on Mitigation of a Civil Penalty for Good Past Performance When the Violations Represent a Management Breakdown)

If the licensee has demonstrated, during prior inspections, that it has established and maintained a good licensed program, that factor should be considered when determining enforcement action for any violations identified during the most recent inspection (just as that past performance would be considered if the prior inspections demonstrated that the licensee's program

was poor or mediocre). Otherwise, although penalties will be escalated for licensees with prior poor histories, there will be no distinction between the licensee who demonstrated a "good past" (as measured by the NRC inspections) and the licensee who demonstrated a "mediocre past."

COMMENT 4 (Reference: Page 2, Paragraphs 1, 2, and 3, Concerning Prohibition of Mitigation of Civil Penalties for Good Past Performance when the Violations are Willful)

Although the enforcement policy does state that a civil penalty is "normally" assessed for any willful violation at any severity level, the policy also states that civil penalties are "normally" issued for Severity Level I, II and III violations. In these latter cases, the NRC still applies the escalation and mitigation factors in determining whether to assess a civil penalty, and in some cases, no penalty is assessed. Clarification should be sought from the Commission to determine whether the reference to "normally issuing a civil penalty for willful violations" is meant to exclude any consideration of mitigating factors when willful violations are involved, or whether it should be interpreted to mean that a civil penalty is normally issued for willful violations "absent any mitigating factors." If the proper interpretation is the former, it would be inconsistent with the following cases in which mitigating factors, including past good performance, were considered in not issuing a civil penalty for willful violations:

- EA 90-005 Saint Mary's Hospital
- EA 90-007 Humana Hospital Greenbrier Valley
- EA 88-285 Cooper
- EA 88-216 South Texas

As an additional consideration, the NRC should encourage, to the maximum extent possible, licensee identification, investigation, correction, and reporting of all issues, including willful violations. If the NRC precludes the consideration of any mitigating factors simply because a violation was willful, that fact may undermine the licensee's incentive to root out and correct such problems at the various levels within its organization.

With respect to SECY 88-19 (Milford Hospital), the related Commission paper states that further escalation of the civil penalty in that case was inappropriate in consideration of the licensee's past good performance. Although that Commission paper does not describe whether any consideration was given to mitigating the penalty based on the licensee's past good performance, mitigation was not warranted since the RSO had been falsifying the Radiation Safety Committee meeting minutes for several years, and therefore, the facts of that particular case did not warrant mitigation. In its response, dated February 29, 1988, concerning the Milford Hospital case, the Commission did state that all violations of a similar nature [to the Milford case] should receive sanctions to the maximum extent possible. However, the Commission's response did not state, nor, in our opinion, did it imply that a willful violation may not be mitigated based on the licensee's good past performance.

Furthermore, since willful violations, by their nature, tend to be isolated to a specific incident or program area, and specific individuals, it would appear to be inconsistent with the intent of the enforcement policy to focus only on the specific willful violation and not consider the licensee's overall and past performance in determining an appropriate enforcement action. The Statements of Consideration for the revision to policy in October 1988 reflects an intent to permit greater consideration of overall licensee performance in assessing past performance. We agree that when considering good past performance for any willful violation, a factor in the assessment should be whether the past good performance is in some way attributable to previously undiscovered willful violations (such as falsification of records), as was the case at Milford Hospital. However, when the violations occurred subsequent to previous inspections which had demonstrated good performance, that prior good performance (as measured by the NRC inspections) should be considered in determining whether a civil penalty should be issued, or in determining the amount of the penalty.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

MEMORANDUM FOR: William T. Russell, Regional Administrator, Region I
Stewart D. Ebner, Regional Administrator, Region II
A. Bert Davis, Regional Administrator, Region III
Robert D. Martin, Regional Administrator, Region IV
Jack B. Martin, Regional Administrator, Region V
Dennis M. Crutchfield, Associate Director for Special
Projects, NRR

FROM: James Lieberman, Director
Office Of Enforcement

SUBJECT: DRAFT ENFORCEMENT GUIDANCE MEMORANDUM (EGM) ON
IDENTIFICATION AND PAST PERFORMANCE ESCALATION
AND MITIGATION FACTORS

Please review the enclosed draft EGM and provide comments by April 11, 1990.
Please plan on having your regional enforcement staff discuss their personal
views at the counterpart meeting.

James Lieberman, Director
Office of Enforcement

cc: H. Thompson, DEDS
J. Partlow, NRR
R. Cunningham, NMSS
J. Goldberg, OGC

DRAFT

EGM 90-

MEMORANDUM FOR: Thomas T. Martin, Regional Administrator, Region I
Stewart D. Ebnetter, Regional Administrator, Region II
A. Bert Davis, Regional Administrator, Region III
Robert D. Martin, Regional Administrator, Region IV
Jack B. Martin, Regional Administrator, Region V
Dennis M. Crutchfield, Associate Director for Special Projects, NRR

FROM: James Lieberman, Director
Office Of Enforcement

SUBJECT: ESCALATION AND MITIGATION FOR IDENTIFICATION AND PAST PERFORMANCE FACTORS

As a result of several recent cases that have been reviewed by the OE staff, it appears that the existing guidance on applying the escalation and mitigation factors for past performance and identification and reporting needs to be revised. I propose we adopt the following guidance:

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The previous position of not escalating a civil penalty for NRC identification when a number of Severity Level IV and V violations are considered collectively to represent a breakdown in the control of the program and are classified as a Severity Level III problem is being rescinded. The rationale for this change is that we expect licensees to detect and recognize breakdowns in the control of their programs. Our philosophy has been and continues to be that if the NRC can perform inspections on an audit basis and determine that a breakdown of significant regulatory concern has occurred, licensees should be able to reach the same conclusion. Therefore, a civil penalty for breakdowns in the control of a program may be escalated for NRC identification even though NRC identification may have been a consideration in categorizing the individual Severity Level IV violations as an aggregate Severity Level III.

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The mitigation of civil penalties for good past performance has come in to question for cases involving breakdowns in control over licensed activities or willful violations. For those cases that involve breakdowns in the control of licensed activities, past performance has been permitted as a mitigation factor under the present guidance. This has been reconsidered. This factor is intended to permit relatively isolated failures to be offset by good past performance. The issue that should be considered is whether the violation at issue is reflective of overall performance considering present and past activities. When there is a significant breakdown in control resulting in extensive violations, the violations are not isolated, but are reflective of overall performance. In those cases good past performance should not offset current unacceptable performance caused by management failures to take charge of their licensed activities. Therefore, if NRC identifies a significant breakdown in the control of licensed activities, the fact that in the past, management was effectively controlling or overseeing the program should not be a mitigating factor. It is still appropriate to consider escalation for poor past performance.

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For cases involving willful violations, OE has reviewed the case history for the past three years and found that for various reasons we have generally not mitigated the base civil penalty for good past performance. The Enforcement Policy in Section V.B states that, "Civil penalties will normally be assessed for knowing and conscious violations of the reporting requirements of Section 206 of the Energy Reorganization Act, and for any willful violation of any Commission requirement including those at any severity level. In addition, in SECY-88-19 (EA 87-189, Milford Hospital) the staff gave no mitigation to the licensee for its recognized good past performance because it was inappropriate. The Commission in response to SECY-88-19 stated that the actions taken in this case should be a guide for the future, and all violations of a similar nature should receive sanctions to the maximum extent permitted by the Commission's regulations.

Comm

The Statements of Consideration for the October 13, 1988, changes in the Enforcement Policy states that for past performance "... this factor has been changed to provide more flexibility in considering past performance in the assessment process. Currently past performance focuses on prior performance in the area of concern though overall performance can be considered. The effect of deleting the reference to general area of concern is to permit greater consideration of overall performance. With the change, both overall performance and performance in the area of concern may be considered."

In light of the above, OE has reconsidered past performance for willful violations. Since willful violations raise the issue of integrity and integrity goes to the heart of the regulatory process, willful violations are never acceptable. Therefore, it is not appropriate to mitigate civil penalties for good past performance when a willful violation is involved. Whether the base civil penalty should be mitigated based on the past performance factor will be handled on a case-by-case basis.

While we are applying the above guidance on a case-by-case basis, please provide comments, if any, to OE within 30 days.

James Lieberman, Director
Office Of Enforcement

cc: H. Thompson, DEDS
J. Partlow, NRR
R. Cunningham, NMSS
J. Goldberg, OGC

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME

11/26/90

11:00

☒ A.M.
☐ P.M.

☐ INCOMING CALL

☒ OUTGOING CALL

☐ VISIT

PERSON CALLING

OFFICE/ADDRESS

PHONE NUMBER

EXTENSION

PERSON CALLED

OFFICE/ADDRESS

PHONE NUMBER

EXTENSION

Dr Flesch COS

VA ALBANY

FTS 563-9211

CONVERSATION

SUBJECT

Inspection

SUMMARY

Called Dr Flesch and verified that the Cesium needles had been located in a storage room for nuclear medicine. He further stated that a letter will be forth coming describing the action taken after the inspection which include hiring a consultant to straighten out the program.

REFERRED TO:

ACTION REQUESTED

NWE

☐ ADVISE ME OF ACTION TAKEN.

INITIALS

df

DATE

11/26/90

ACTION TAKEN

INITIALS

DATE

G/2

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

Date: November 26, 1990
From: Acting Radiation Safety Officer (115)
Subject: Unscheduled NRC Inspection - 11/20/90
To: ACOS, Research and Development (151)

1. As you know, we were inspected by the NRC on November 20-21, 1990. The following is a list of items which were found to be in non-compliance in Research Service:

- A. Evidence of food and beverage consumption in several of the labs was found.
- B. Some personnel were not wearing film badges.
- C. Room 627B has been modified to a storage area and gamma counting room without prior notification of the Radiation Safety Officer. A microwave oven was also noted in this area.
- D. Inventory sheets posted on refrigerator doors are not up to date.
- E. Some researchers have not been surveying their hands before leaving the radiation work areas.
- F. There is a discrepancy of sewer disposal records for 1988. Figures reported by Research Service do not agree with those of RSO. (Suggestion was made by inspector that a log sheet posted in front of sewer drain would provide an instant record).

2. All principal investigators are responsible to take corrective actions immediately and report to the Radiation Safety Officer.

3. Your assistance in correcting these deficiencies is appreciated. As you know, the cooperation of all personnel is necessary to create a safe work environment. Please contact me if you have any questions.


S. A. KANG, M.D.



Veterans
Administration

Memorandum

Date: November 28, 1990

From: Min-Fu Tsan, M.D., Ph.D, Chief, ACOS/R&D

Subj: Result of Nuclear Regulatory Commission Inspection
of November 20, 1990

To: All Principal Investigators

1. The Research Service was inspected by the Nuclear Regulatory Commission on November 20 and 21, 1990. We have been cited for a number of deficiencies as indicated in the attached memo from the Acting Radiation Safety Officer, dated November 26, 1990. It is mandatory that you take corrective actions immediately and report to the Radiation Safety Officer no later than December 10, 1990.
2. I strongly urge you and your staff to strictly adhere to the Radiation Safety guidelines for the safety of your employees and your privilege to continue to use radioactive tracers in research.
3. Please let me know if you have any questions. Thank you for your cooperation.

Min-Fu Tsan, M.D., Ph.D.
ACOS/R&D

Attachment: Ltr Dated 11/26/90

DEPARTMENT OF
VETERANS AFFAIRS

Memorandum

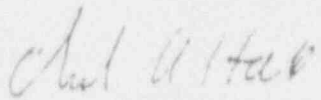
Date: December 5, 1990

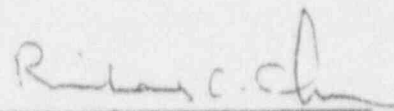
From: Dr. Charles A. Hall and Richard C. Chu

Subject: Inspection (11/20/90)

To: S.A. Kang, M.D., Chief Nuclear Medicine

1. Necessary corrective actions will be taken pertaining to our laboratory as you have indicated in your memo, 11/26/90.
2. Radiation safety guidelines will be strictly followed to ensure safety of our workers and others.


Charles A. Hall, M.D.


Richard C. Chu, Ph.D.



Veterans
Administration

Memorandum

Date: December 3, 1990

From: Chief, Neurology Service (127)

Subj: Your memorandum concerning the unscheduled NRC Inspection of
November 20, 1990

To: Acting Radiation Safety Officer (115)

1. The neurochemistry research laboratory is located in room 610A but does not occupy a segregated suite of rooms.
2. No infractions against the listed rules and regulations were identified in that area. However, we have no provision for "surveying hands". Also, the hospital does not provide an area for persons who wish to eat their "brown bag" lunches. The cafeteria in the basement is not intended for that purpose and at the usual lunch hour it is all far too crowded.
3. The neurochemistry staff wishes to be acknowledged for the high quality radiation safety measures. I wish to specially commend Mr. Andrew Dickson for his meticulous care in this matter. He came to this laboratory from the production plant of the Sterling Company in Rensselaer, New York, where he was used to weekly FDA inspections.


ARNULF H. KOEPPEN, M.D.

cc: ACCS/R&D (151)