UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D C 20555

October 19, 1990

OFFICE OF THE
INSPECTOR GENERAL

MEMORANDUM FOR: Chairman Carr

FROM: David C. Williams
Inspector General

SUBJECT: ALLEGED IMPROPER STAFF ASSISTANCE TO PETITIONERS TO AMEND 10 C.F.R. PART 35

Enclosed is an Office of the Inspector General (OIG) Report of Investigation concerning an allegation that NRC staff from the Office of Nuclear Material Safety and Safeguards (NMSS), Division of Industrial & Medical Nuclear Safety improperly solicited and assisted in preparing a petition for rulemaking to amend 10 C.F.R. Part 35 (Part 35). The American College of Nuclear Physicians and the Society of Nuclear Medicine (ACNP/SNM) submitted a petition to amend Part 35 on June 5, 1989. The petition was developed by [redacted] on behalf of the ACNP/SNM.

The OIG investigation determined that NMSS staff advised [redacted] to submit a petition after they concluded that the medical community had legitimate concerns with Part 35. The OIG investigation further determined that a staff member provided [redacted] with substantial assistance in drafting the petition and in reviewing subsequent revisions. This individual and another staff member also reviewed the final petition for [redacted] before it was officially submitted to the Commission.

The investigation did not substantiate wh her the staff had violated criminal statutes, NRC regulations or internal policies. However, we concur with the Office of the General Counsel (OGC) in an opinion obtained during the investigation, that the staff

FREEDOM OF INFORMATION/PRIVACY ACT EXEMPTION (b)(6)(7)(C) + 7F

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in accordance with the Freedom of Information
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conduct raises significant policy issues and that the staff needs additional guidance concerning assistance which may be provided to potential rulemaking petitioners. We also concur with OGC, that if the staff participates in developing a petition, the assistance should be accurately acknowledged to the Commission and to the public when the petition is published for comment.

Enclosure:
Report of Investigation

cc: J. Taylor, EDO
W. Parler, OGC

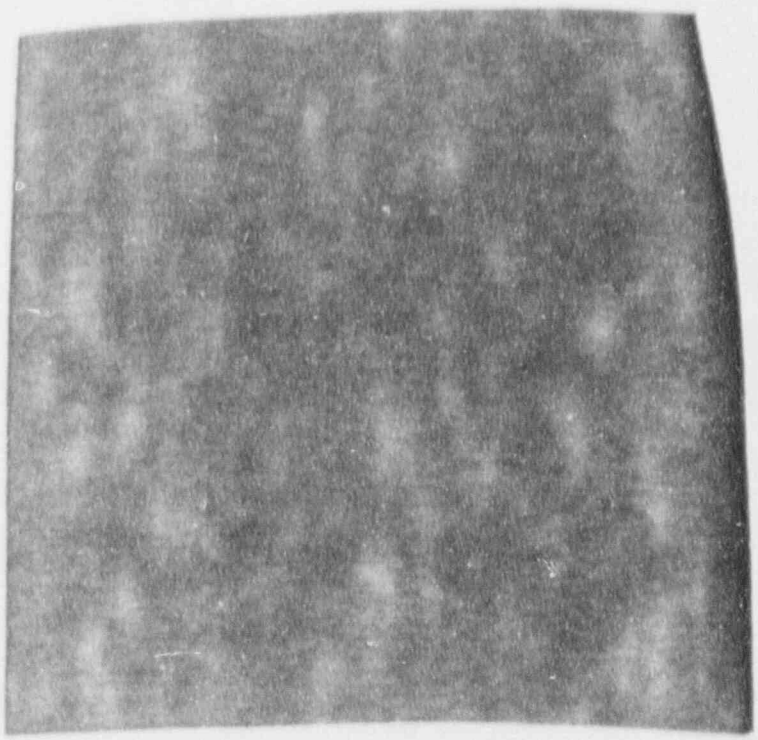
[redacted]

OFFICE OF THE INSPECTOR GENERAL

REPORT OF INVESTIGATION

ALLEGED IMPROPER STAFF ASSISTANCE TO PETITIONERS
TO AMEND 10 C.F.R. PART 35

CASE NO.: 90-20A



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SUBJECTS

STATUTES

10 C.F.R. Part 0.735-49a(f) - Other Proscribed Actions

18 USC 208 - Conflict of Interest

SYNOPSIS

This investigation was initiated based on information received from a U.S. Nuclear Regulatory Commission (NRC) employee. It was alleged that NRC staff, from the Office of Nuclear Material Safety and Safeguards (NMSS), Division of Industrial & Medical Nuclear Safety improperly solicited and assisted in preparing a petition for rulemaking to amend 10 C.F.R. Part 35 (Part 35). Part 35 regulates the medical use of byproduct material.

The American College of Nuclear Physicians and the Society of Nuclear Medicine (ACNP/SNM) submitted a petition for rulemaking to amend Part 35 on June 5, 1989. The "Petition to Correct Regulatory Incompatibility and Permit the Traditional Practice of Nuclear Medicine and Nuclear Pharmacy" was developed by [redacted] on behalf of the ACNP/SNM.

From August 1988 to March 1989, NMSS staff and [redacted] had several discussions concerning problems the medical community was having with Part 35. As a result of these discussions, NMSS staff advised [redacted] to submit a petition after they concluded that the medical community had legitmate concerns with Part 35. The investigation determined that a staff member provided substantial assistance in drafting the petition and in reviewing subsequent revisions. This individual and another staff member also reviewed the final petition before it was officially submitted to the Commission.

The Office of the General Counsel (OGC) was requested to review the extent of assistance that staff may provide to a prospective petitioner in connection with a petition for rulemaking. OGC advised that relevant statutes do not address whether it is appropriate for agency staff to assist petitioners and do not define the nature of such assistance. OGC noted that 10 C.F.R. Part 2.802 encourages petitioners to confer with the staff. However, OGC advised that neither NRC regulations nor NRC internal policies define the staff role or level of assistance that may be provided to potential petitioners. OGC stated that if the staff participates in drafting a petition, their role should be brought to the Commission's attention. Moreover, NRC should acknowledge the staff role when the petition is published.

The investigation did not substantiate whether the staff had violated criminal statutes, NRC regulations or internal policies. However, we concur with OGC that the conduct of the staff raises significant policy issues and that the staff needs additional guidance concerning assistance which may be provided to potential rulemaking petitioners. The investigation determined that while the staff maintained that the assistance provided to petitioners was in accordance with Part 2 rules, the extent of staff assistance was never fully disclosed to the Commission.

BASIS

This investigation was initiated based on information received from an NRC employee. It was alleged that NRC staff from the Division of Industrial & Medical Nuclear Safety (NMSS/IMNS), improperly solicited and assisted in preparing a petition for rulemaking to amend 10 C.F.R. Part 35 (Part 35). The employee noted that the petition stated in part, that it resulted from an NRC staff determination to change Part 35. Part 35 regulates the medical use of byproduct material. NMSS is charged with reviewing proposed rule changes and for preparing, advising and providing information to the Commission. The Office of Nuclear Regulatory Research (RES) has lead responsibility in reviewing petitions (Exhibit 1).

DETAILS

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM), submitted a petition for rulemaking to amend Part 35 on June 5, 1989. A letter to Chairman ZECH, dated May 19, 1989, advised him of the forthcoming petition. It stated that the petition resulted after extensive discussions with [redacted]. According to [redacted] the petition was requested by NRC after the NRC staff determined that the best course of action was to change Part 35. [redacted] stated that the petition was written, with equal participation, by the most knowledgeable individual on the subject at NRC. This individual was assigned to help write the document by the NRC official who initially requested the petition (Exhibits 1, 2, and 3).

From approximately August 1988 to March 1989, NRC staff and [redacted] had several telephone conversations and meetings to discuss problems that the nuclear medical community was having with Part 35. According to [redacted] after NRC made changes to Part 35 in 1987, nuclear physicians and pharmacists were effectively precluded from practicing nuclear medicine. [redacted] commented that NRC may not have understood the impact of the rule changes and may not have intended the resultant effect (Exhibits 4, 5, 6, 7 and 8).

NRC staff members indicated that the idea of a petition evolved during the course of several meetings with the medical community. They further indicated that the issues were complex and the staff did not initially understand the medical community's problems concerning Part 35 regulations (Exhibits 9, 10 and 11).

[redacted] stated that during an August 1988 conference call with [redacted] and [redacted] told [redacted] that NRC had decided there should be a petition because the only way to address the

[redacted]

problem and take care of the needs of the medical community was through a rule change. According to [redacted] did not think NRC could provide the medical community with what they wanted with the current regulations. Further, [redacted] wanted [redacted] to submit a petition which would be endorsed by the ACNM/SNM. [redacted] told [redacted] that it was customary for NRC staff to work with petitioners and that [redacted] would assist [redacted] (Exhibit 4 at 2).

[redacted] stated that [redacted] did not specifically recall when [redacted] was advised to submit the petition or who so advised [redacted] although it may have been [redacted] or [redacted] advised that [redacted] and/or [redacted] may have told [redacted] to submit a petition. According to [redacted] told [redacted] to write a petition and that [redacted] would assist [redacted]. Both [redacted] and [redacted] stated that [redacted] was the logical choice for assisting [redacted] because [redacted] was most familiar with medical regulations and [redacted] was largely responsible for rewriting Part 35 in 1987 (Exhibits 9, 10, 12 and 12a).

[redacted] and [redacted] met with [redacted] in September 1988. [redacted] had planned to work on petition issues with [redacted] during these meetings, but instead, [redacted] assigned [redacted] of [redacted] staff to assist [redacted]. After several hours of discussion, [redacted] concluded that [redacted] could not work with [redacted]. [redacted] commented that [redacted] wanted to control nuclear medicine and would not allow physicians to make judgmental decisions. [redacted] stated that [redacted] and [redacted] had several conversations concerning the petition (Exhibits 4, 6, and 11).

[redacted] and [redacted] met with [redacted] and [redacted], in November 1988. According to [redacted] and [redacted] threatened to seek a court injunction against NRC if it continued to impede the practice of nuclear medicine. [redacted] notes, dated November 8, 1988, reflect that among the options being discussed were "injunction, petition, badger Congress, work it out." The notes also reflect that [redacted] wanted the medical community to define the problem and that "if the rulemaking was flawed we can republish (if it accidently dropped the scope of permission) and state that we won't enforce until clarified." According to [redacted] members of the ACNM/SNM subsequently formed a committee to work with NRC staff to develop a petition (Exhibits 4, 8 and 10).

[redacted] conducted a radiopharmacy workshop with the medical community, Food and Drug Administration representatives and NRC staff on January 25, 1989. A notice of the meeting was published in the Federal Register. Part 35 and changes that the medical community wanted in the regulations were discussed. [redacted] advised that the staff was still identifying and reviewing the

problems with Part 35 and had not yet made a decision to amend the regulations (Exhibits 10 and 13).

Several memorandums reflect the ongoing discussions between the medical community and NMSS staff. On December 2, 1988, [redacted] advised the Regional Directors, Division of Radiation Safety and Safeguards, that because of several questions concerning the human application of by-product material, NMSS was reexamining the regulations and policy statements. Further, NMSS was considering exemptions and the advisability of amending the regulations. Subsequently, a staff memorandum entitled: "EDO Problem Issues," dated March 3, 1989, reflected that amendment of the regulations was "one of the least restrictive alternatives." Also, a March 17, 1989, memorandum delegated [redacted] to assist [redacted] in preparing a letter to the Commission explaining the medical community's regulatory concerns. [redacted] assistance resulted in the May 19, 1989, letter to Chairman ZECH. (Exhibits 14, 15, 16, 17 and 17a).

During March 20-26, 1989, [redacted] was in California on official business. After attending scheduled conferences, [redacted] met with [redacted] at the UCLA Harbor Medical Center. [redacted] stated that on Saturday, March 25, 1989, [redacted] assisted [redacted] in preparing a detailed outline of the petition and part of the introductory text. [redacted] stated that [redacted] knew what [redacted] wanted in the petition and [redacted] provided technical assistance in drafting the document. According to [redacted] [redacted] clarified the issues, explained NRC regulations and advised [redacted] on the type of language and information [redacted] had to provide. [redacted] travel voucher reflected that [redacted] conducted official government business on March 25, 1989. Review of [redacted] time and attendance records indicated that [redacted] did not request compensation for working on Saturday with [redacted] (Exhibits 12, 18 and 19).

[redacted] stated that after the experience with [redacted] it was clear to [redacted] that if a petition was going to be written, it would have to be done by [redacted] and [redacted]. [redacted] stated that [redacted] assisted [redacted] in preparing a detailed outline of the petition. [redacted] guided [redacted] through NRC regulations; told [redacted] to provide background information and specific examples of the problems confronting nuclear medicine. [redacted] stated that [redacted] did not write the petition and [redacted] was careful not to offer [redacted] personal opinion. [redacted] asked "what if" questions concerning the language to use, and [redacted] told [redacted] how to state the information without contradicting other sections of NRC rules. [redacted] commented that [redacted] could not have written the petition without [redacted] assistance because [redacted] lacked familiarity with NRC's regulatory language (Exhibit 4).

[redacted] advised that there were five or six drafts of the petition which was finalized during the six week period following their March 1989 meeting. Throughout this period, [redacted] had numerous

[redacted]

conversations with [redacted] either discussed the petition changes during telephone conversations, in correspondence or sent [redacted] pages of the draft via facsimile transmission for [redacted] comments and advice. [redacted] stated that the ACNM/SNM committee reviewed the petition and after making revisions to ensure that it was legally correct, forwarded the petition to [redacted].

[redacted] provided [redacted] the completed draft petition on April 18, 1989, and additional revisions on June 5, 1989. A letter dated April 19, 1989, forwarded the completed draft petition to [redacted]. [redacted] stated in the letter that [redacted] was returning [redacted] original notes so [redacted] could see the changes that had been made and that [redacted] might rest easier knowing [redacted] had the notes. [redacted] advised the OIG that the letter had been written in jest and was not intended to be serious. [redacted] stated that [redacted] has always acknowledged [redacted] assistance and never considered that the assistance might be viewed as improper. According to [redacted] never implied that [redacted] assistance was improper. The ACNM/SNM officially submitted the petition to NRC on June 5, 1989 (Exhibits 4, 4a, 4b, 20, 21, 22, and 23).

According to 10 C.F.R. Part 2.802(b), a petitioner is encouraged to confer with the staff prior to filing a petition. Questions regarding regulations, procedures and requests for meetings are to be addressed to the Director, Division of Freedom of Information and Publications Service (Exhibits 24).

Both [redacted] and [redacted] stated that they did not know the extent of the assistance [redacted] provided to [redacted]. However, a staff memorandum, dated June 8, 1989, noted that the staff had provided technical assistance to ACNP/SNM during the development of the petition pursuant to 10 C.F.R. Part 2.802(b) (Exhibits 9, 10 and 25).

[redacted] said that [redacted] did not recall when or how the petition was written. [redacted] stated however, that [redacted] told him in the spring/summer of 1989, that [redacted] had met with [redacted] and they had worked on the petition; that it "had been developed," and that it was "something we (NRC) could deal with." According to [redacted] may have indicated that [redacted] met with [redacted] while attending a conference in California. [redacted] stated that he asked [redacted] whether [redacted] was assisting [redacted] in accordance with NRC rulemaking regulations. According to [redacted] he may have told [redacted] to "check with the lawyers," or asked [redacted] "is this okay with the lawyers to do this" (Exhibit 9).

[redacted] stated that [redacted] was aware that [redacted] was assisting [redacted] with the petition and that [redacted] had regular communications with [redacted]. [redacted] stated that [redacted] told [redacted] wrote "parts or some" of the petition, but [redacted] did not ask [redacted] what [redacted] meant by this. [redacted] also stated that after [redacted] returned

[redacted]

from California, [redacted] "alluded to something about writing or marking up some aspect of the petition." According to [redacted], [redacted] told [redacted] to be careful about the amount of interaction [redacted] had with [redacted], that [redacted] should not write the petition for [redacted] and that Part 2 limited the amount of assistance staff could provide to petitioners (Exhibits 7, 8).

[redacted] stated that [redacted] did not recall reviewing changes to the petition after it was drafted in March 1989. According to [redacted], [redacted] provided [redacted] with technical drafting assistance, in accordance with NRC regulations. [redacted] stated that [redacted] never received guidance concerning Part 2 and was never told to be careful about the amount of assistance given to [redacted]. [redacted] further stated that [redacted] never told [redacted] to check with NRC attorneys and never said the regulations limited the amount of assistance staff could provide to petitioners (Exhibit 12a).

[redacted] stated that after the petition was submitted to NRC, [redacted] assisted the staff in analyzing and clarifying the petition issues. In January 1990, [redacted] recused himself from actively participating in the resolution of the petition. Although [redacted] stated that [redacted] was generally involved in petition meetings, [redacted] did not recall [redacted] involvement in the petition review process. [redacted] stated that [redacted] reviewed the staff's work on the petition. [redacted] further stated that [redacted] directed several changes which the Office of the General Counsel (OGC) disagreed with because they did not have adequate checks and balances (Exhibits 11, 12 and 12a).

On May 17, 1990, OIG requested legal advice from OGC concerning the extent of assistance that staff may provide to a prospective petitioner. OGC reviewed the issue of whether the assistance, provided by the staff, tainted the NRC rulemaking process contrary to the Administrative Procedures Act, NRC regulations and internal policies. Also addressed was whether the staff engaged in conduct that violated acceptable standards of conduct.

OGC concluded that the rulemaking process was not tainted by the staff participation in the petition. However, OGC stated that the "staff conduct raised significant policy issues and that additional guidance needs to be provided to the NRC staff on what constitutes appropriate assistance to potential rulemaking petitioners." OGC also concluded that if the staff is permitted to participate in drafting petitions, the participation should be acknowledged and should be a matter of public record.

OGC advised that the Administrative Procedures Act, which established the procedures governing the rulemaking process, does not address whether staff may assist potential rulemaking petitioners. Additionally, according to OGC, neither NRC's regulations, 10 C.F.R. Part 2.802, nor agency policy define

the staff's role or level of assistance that may be given to prospective petitioners.

OGC concluded the law did not require that the staff be disqualified from further advising NRC on the Part 35 rulemaking petition. OGC advised that disqualification had to be established on clear and convincing evidence that the staff providing the assistance had an "unalterably closed mind" on the issues raised in the petition. OGC doubted that such a high threshold could be met. Moreover, OGC noted that the staff involved were not in a position of authority to commit the agency and were not the agency's decision makers.

Concerning whether the staff violated acceptable standards of conduct, OGC stated that employees are generally to refrain from conduct that adversely affects the efficiency of the agency. Employees accordingly, may not engage in conduct that has an effect on the credibility of the employee and/or the agency.

OGC noted that while 10 C.F.R. Part 2.802 encouraged prospective petitioners to confer with staff, it provided that requests to meet with staff be channeled through the Director, Division of Freedom of Information and Publication Services (DFIPS). Similarly, the NRC Regulations Handbook indicates that any office receiving a request to meet with prospective petitioners should coordinate with the DFIPS Director. The handbook also provides that meetings are to be summarized by DFIPS and included in the official file on the petition. OGC advised that the handbook is not a mandatory directive, however, the staff is obliged to comply with the regulations (Exhibit 26).

Interviews conducted and documents reviewed did not disclose any evidence that the staff informed DFIPS of the ongoing meetings between staff and the medical community concerning problems with Part 35; or that the staff channeled requests for meetings through DFIPS. Hugh THOMPSON, Deputy Executive Director, Nuclear Safety Safeguards & Operations Support stated that program offices typically work with licensees, or in this instance, the medical community, to resolve problems within their area of responsibility. THOMPSON advised that he would not expect the staff to be familiar with Part 2 rulemaking provisions. According to THOMPSON, he would not have expected the staff to advise the DFIPS of the staff's effort to assist the medical community in developing a petition to amend Part 35 (Exhibit 27).

Several staff members stated that most rule changes have been initiated by NRC. [redacted] said that in the past, [redacted] reviewed a draft petition submitted by a pharmaceutical manufacturer and pointed out items in the petition that had been omitted, left unclear or were repetitive. The company subsequently submitted the final petition and NRC revised the regulatory language that the petitioners had objected to (Exhibits 9, 10 and 12).

[redacted] and [redacted] stated that licensees are typically directed to submit a petition when they have problems with NRC regulations. [redacted] stated that unlike the indoctrination staff received concerning assistance to a license applicant, the issue of how much assistance may be provided to a petitioner has not been addressed by management. Further, [redacted] stated that [redacted] has never requested assistance or advice concerning this issue from OGC (Exhibits 9 and 10).

According to [redacted] there are no prohibitions on the staff in assisting petitioners. [redacted] stated that the type of assistance given to a petitioner would vary depending on the complexity of the petition. In [redacted] opinion, the assistance given to [redacted] by [redacted] while in California was not inappropriate. [redacted] stated that if the staff assisted in writing the petition, [redacted] did not view the assistance as a significant problem because the document would be reviewed by many individuals before final approval by the Commissioners (Exhibit 9).

[redacted] stated that the Administrative Procedures Act dictated once the rulemaking process is initiated, all communications that may influence the contents of a petition must be on record. Accordingly, [redacted] would not have approved the staff's reviewing the petition before it was officially submitted to NRC. [redacted] stated that the branch should not get too involved in a petition because it could lose some objectivity and would not be able to review the petition from an independent perspective (Exhibit 10).

In providing their opinion, OGC inquired whether the Part 35 petition was a joint petition between the staff and petitioners; or whether the staff may have used petitioners as the vehicle to submit a petition, bypassing the customary process for staff generated rulemaking proposals. Interviews with staff members determined that the petition was submitted after the staff concluded the medical community had legitimate problems with the regulations. According to one staff member, the medical community was best equipped to amend Part 35 and [redacted] would not have known how to change Part 35 to accomplish what they wanted (Exhibits 9, 10 11 and 12).

[redacted] advised that when Part 35 was changed in 1987, NRC had not intended to make the rule more restrictive or to impede the practice of medicine. Further, if the medical community was correct that the regulations impeded patient health care, NRC was obligated to deal with the issues as quickly as possible. According to [redacted] the staff would have initiated a petition given the safety issues raised by the medical community. However, [redacted] undated handwritten note reflects direction [redacted] received from [redacted] "ask [redacted] to define practice of med, practice of pharm, keep [redacted] to the single issue, the greater the

support, ex AC SNM...the better the chances have SNM submit" (Exhibits 9, 12a and 12b).

[redacted] stated that the staff recognized the need for a rule change, but whether the staff could initiate it and justify doing so, was another matter. According to [redacted] the Commissioners clearly wanted strong oversight of the medical community. In [redacted] view, a staff initiated rule change would have lacked the necessary consensus and would have been a long protracted effort. During the January 1989 workshop, [redacted] advised the medical community that a petition submitted by them would have a better chance of succeeding because it would be viewed as having a broad consensus. Also, the Commission would have to respond to the petition (Exhibit 10).

FINDINGS

The investigation determined that there was insufficient evidence the staff had violated criminal statutes, NRC regulations or internal policies. However, we concur with OGC that the staff conduct raises significant policy issues. We also concur that the staff needs additional guidance concerning assistance which may be provided to potential rulemaking petitioners.

The investigation determined that while the staff maintained the assistance to petitioners was in accordance with Part 2 rules, the level of staff assistance provided was never fully disclosed to the Commission. According to THOMPSON, the assistance provided to [redacted] would not have changed the outcome of the staff's review of the petition. However, THOMPSON stated that if the staff participated in developing the petition, their role should have been disclosed.

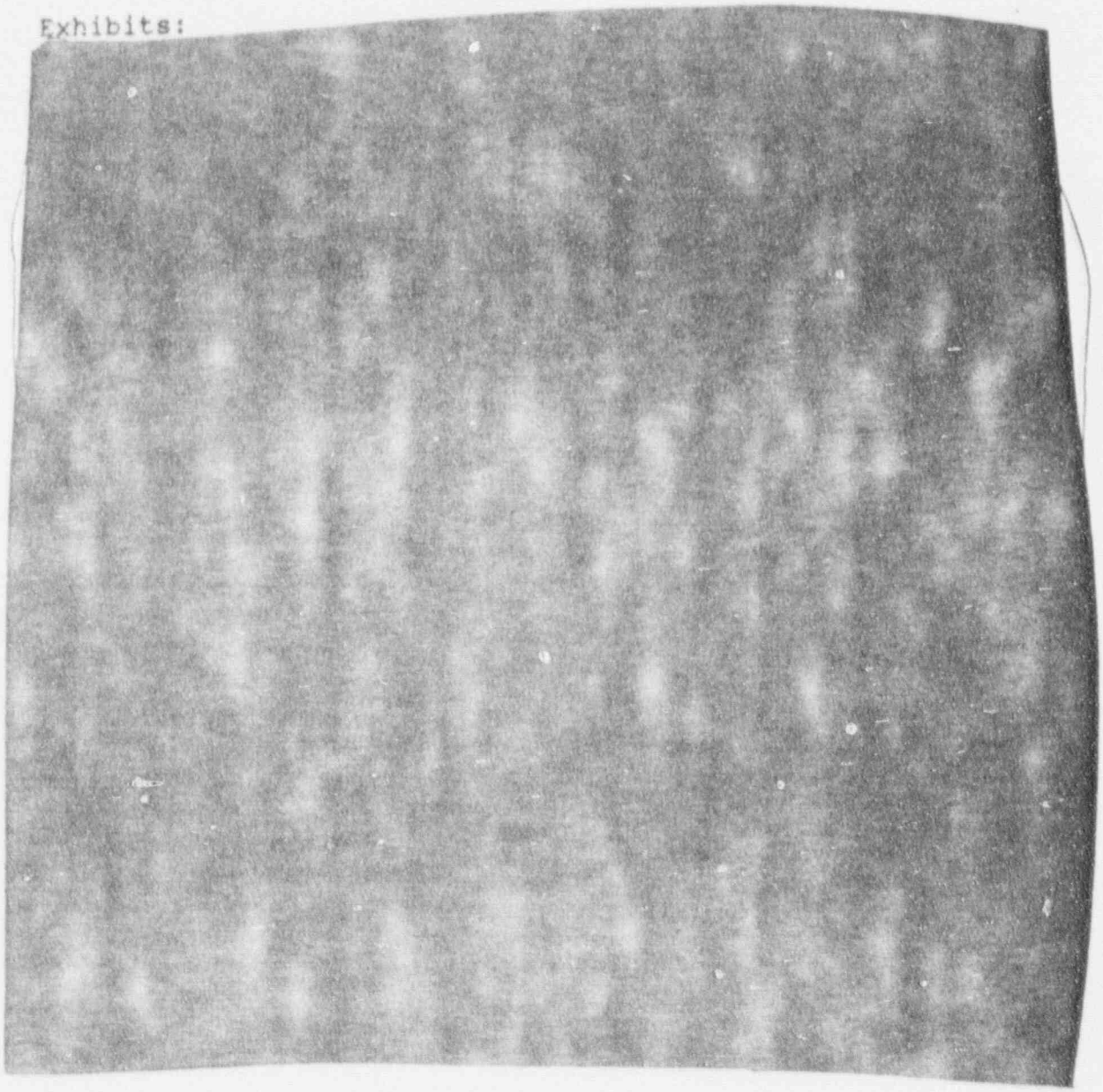
In addition, [redacted] and [redacted] statements that [redacted] was cautioned regarding the amount of assistance being provided to [redacted] is not consistent with [redacted] contention that there are no prohibitions concerning what staff may do in assisting petitioners (i.e., why caution someone if there are no restrictions on their level of assistance).

NMSS management was aware that [redacted] was working with the medical community to develop a petition. [redacted] stated that [redacted] and [redacted] were given a fair description of the assistance [redacted] had provided. In March 1989, [redacted] reported orally to [redacted] after returning from assisting [redacted] in California. According to [redacted] was not given "any signal that [redacted] was doing too much" to assist [redacted] and [redacted] had the opportunity to ask questions regarding [redacted] participation in the petition but did not. Also, [redacted] advised that [redacted] would not have devoted that much time to a project without [redacted] and [redacted] knowledge. Therefore, it appears that [redacted] assumed [redacted] actions were in accordance with

the wishes of NMSS management, especially in view of [redacted] declarations that there are no prohibitions on staff participation.

The investigation revealed that the staff requested the medical community to submit the petition to amend Part 35 and that the ACNP/SNM may not have otherwise done so. Staff members advised that the medical community was most familiar with the relevant issues they confronted on a day to day basis and knew what changes they wanted in the rules. Accordingly, the medical community was better able than the NRC to initiate the rule change.

Exhibits:



Outside Group O/S