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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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COMMISSIONERS:

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Ivan Selin, Chairman
Kenneth C. Rogers
Forrest J. Remick
E. Gail de Planque

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

In the Matter of)
)
ADVANCED MEDICAL SYSTEMS, INC.)
)
One Factory Row)
Geneva, Ohio 44041)
_____)

SERVED JUN - 9 1994

Docket No. 30-16055-SP

(Suspension Order)

EA-86-155

DECISION

CLI-94-06

I. Introduction

In this decision we deny the appeal of Advanced Medical Systems, Inc. (AMS), a licensee authorized to possess and use radioactive byproduct material, from a decision of an Atomic Safety and Licensing Board, LBP-90-17, 31 NRC 540 (1990), which granted the Nuclear Regulatory Commission (NRC) staff's motion for summary disposition of the issues in this enforcement proceeding. AMS's appeal was filed initially with the Atomic Safety and Licensing Appeal Board in accordance with the rules of practice then in effect. While AMS's appeal was pending before the Appeal Board, the Commission determined to abolish the Appeal Board and initiated a rulemaking to revise our appellate procedures. See Procedures for Direct Commission Review of Decisions of Presiding Officers, 56 Fed. Reg. 29,403 (June 27,

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1991). Although the Appeal Board retained jurisdiction over AMS's appeal under the interim appellate procedures in effect pending the conclusion of the rulemaking, the Appeal Board did not reach a decision on AMS's appeal prior to the Appeal Board's dissolution on June 30, 1991. By order dated June 28, 1991, the Appeal Board referred AMS's appeal to the Commission for determination.¹

The staff, the only other party to the proceeding, opposes AMS's appeal and urges us to affirm the Licensing Board's decision. For the reasons that follow, we affirm LBP-90-17.

II. Procedural Background

A. Prior History

AMS is authorized by NRC license to undertake a number of activities involving the use of radioactive byproduct material: e.g., the manufacture of sealed radioactive sources to be used in teletherapy and radiography units, the installation and removal of sealed sources from teletherapy machines, and the maintenance, service, and dismantling of such machines. This proceeding concerns AMS's challenge to an "Order Suspending License and Order to Show Cause (Effective Immediately)", issued by the NRC

¹ Because our review of AMS's appeal is governed by the same rules in effect when AMS filed its appeal, the transfer from the Appeal Board to the Commission has not affected AMS's right to an appeal of the Licensing Board's decision nor the nature of our consideration of AMS's appeal.

staff on October 10, 1986.² Based on an investigation of allegations about the licensee's service operations, the staff charged that the licensee's employees had been performing service and maintenance on teletherapy equipment at various medical facilities . en though the employees lacked required training, did not have radiation detection and monitoring equipment or the required service manuals, and had objected to performing maintenance without proper training. Given the circumstances of the alleged violations, the staff found that it lacked adequate assurance that AMS would adhere to the terms of its license. Moreover, the staff found that the conduct of maintenance and service activities by unauthorized and untrained personnel could have potentially serious adverse consequences to the public, hospital personnel, and AMS's employees. Consequently, the staff determined that immediate action was required to ensure protection of the public health and safety and, pending further order, the Director of the Office of Inspection and Enforcement summarily suspended AMS's activities under Byproduct Material License No. 34-19089-01 pertaining to installation, service, maintenance, or dismantling of radiography or teletherapy units.

² 51 Fed. Reg. 37,674 (Oct. 23, 1986). The order was signed by the Director of the Office of Inspection and Enforcement, then the principal staff officer responsible for administering the NRC's enforcement program.

AMS filed a timely request for hearing on the order and denied the alleged violations.³ AMS also sought relief from the staff from the immediate effectiveness of the order.⁴ When that relief was denied, AMS filed a motion to stay the effectiveness of the order.⁵ While its stay motion was still pending before the Licensing Board, AMS proposed to the staff a number of actions that AMS was willing to take to obtain a rescission of the effectiveness of the order pending completion of a hearing. Based on AMS's commitments, the staff permitted AMS by letter dated February 2, 1987, to resume licensed activities subject to

³ AMS's Answer to Order Suspending License and Order to Show Cause (Effective Immediately) (Request for Hearing Contained Herein) (Oct. 29, 1986).

⁴ Motion of Advanced Medical Systems, Inc. for Preliminary Hearing on Continuation of License Suspension During Pendency of Agency Adjudication (Oct. 30, 1986). Although AMS filed its motion with the Commission, the Secretary of the Commission informed AMS's counsel that relief should first be sought from the NRC Regional Administrator who was empowered by the terms of the order to relax or rescind any of its conditions. Letter from Samuel J. Chilk, Secretary, to Richard D. Panza, Esq. (Nov. 6, 1986). AMS thereafter filed a Brief in Support of Rescindment of Suspension Order (Dec. 22, 1986) with the Regional Administrator for NRC Region III and met with the staff on December 23, 1986 to discuss relief from the order. The staff declined to grant relief at that time. Letter to S. S. Stein, President, AMS, from James G. Keppler, Administrator, NRC Region III (Jan. 7, 1987) (Attachment 37 to NRC Staff's Motion for Summary Disposition).

⁵ Application of Advanced Medical Systems, Inc. for Stay of the Effectiveness of Decision (With Supporting Memorandum) (Jan. 16, 1987). Although filed with the Commission, the stay application was referred to the presiding officer for a ruling.

certain conditions.⁶ On February 10, 1987, AMS withdrew its motion for a stay.

In March 1987, at the request of the United States Department of Justice, the staff sought a stay of the proceeding pending the completion of a parallel criminal investigation of AMS. A stay of the proceeding was granted initially until August 15, 1987, and subsequently was continued until July 12, 1988. ALJ-87-4, 25 NRC 865 (1987); see LBP-89-11, 29 NRC 306, 310 n.7 (1989). On August 11, 1987, the staff amended AMS's license in response to applications filed by AMS to authorize certain persons to act as "licensed" service engineers.⁷ A few months later, the Regional Administrator revoked in their entirety the original order and the conditions in the February 2, 1987 letter that permitted resumed activities, because the license amendment superseded and apparently conflicted in some respects with the earlier order and letter.⁸

⁶ Letter to S.S. Stein, AMS, from James G. Keppler, Region III Administrator (Feb. 2, 1987).

⁷ Amendment No. 12 to License No. 34-19089-01, attached as Enclosure 1 to NRC Staff's Statement of Issues in Proceeding (Sept. 11, 1987).

⁸ Letter from A. Bert Davis, Regional Administrator, to S.S. Stein (Dec. 3, 1987). The staff had taken the position a few months earlier that the amendment to the license had in effect superseded the earlier order and the Regional Administrator's condition for rescission of the suspension. See NRC Staff's Statement of Issues in Proceeding at 2-3 (Sept. 4, 1987).

B. Issues Set for Litigation

After the stay of the proceeding expired, the Licensing Board requested the parties' positions as to whether any issues remained for litigation in the proceeding. Although the staff took the position that the proceeding was moot, AMS identified 7 issues it wished to litigate:

1. Whether or not there was a substantial basis for the NRC to conclude that it lacked the requisite reasonable assurances that AMS would comply with Commission requests in the future;
2. Whether or not there was a substantial basis for the NRC to conclude that continued conduct of certain licensed activities by AMS could pose a threat to the health and safety of the public, to wit: the performance of installation, service, maintenance or dismantling of radiography or teletherapy units;
3. Whether or not the NRC had a substantial basis for concluding that the public health, safety and interest required that AMS' License Number 34-19089-01 should be suspended;
4. Whether or not the NRC had a substantial basis for concluding that pursuant to 10 CFR Section 2.201(c) no prior notice was required as to its actions, and pursuant to 10 CFR Section 2.202(f) that the Suspension Order of October 10, 1986 should be immediately effective;
5. Whether or not the NRC had a substantial basis for the actions it took beyond and through its January 7, 1987 Declination to Rescind Immediate Effectiveness of October 10, 1986 Suspension Order;
6. Whether or not, and to what extent, all service, installation, maintenance and dismantling of radiography or teletherapy units at issue herein must be performed by licensed individuals (including hospital personnel);

7. Whether or not 10 CFR Section 2.202(f), et seq., is constitutional.⁹

In LBP-89-11, the Licensing Board determined that the proceeding was not moot and admitted the first four of AMS's issues for litigation.¹⁰ The Licensing Board declined to admit issue 5 because it merely echoed the challenge in issue 4 with respect to the immediate effectiveness of the order. The Board rejected issue 6 to the extent that it sought a generic determination of the scope of licensable activities, but the Board acknowledged that it could, and probably must, determine the legality of AMS's actions under AMS's license. The Board viewed issue 7 as beyond the scope of its authority and therefore precluded from litigation by 10 C.F.R. § 2.758(a).

On January 10, 1990, the staff filed a motion for summary disposition of the issues under 10 C.F.R. § 2.749. The staff's motion was supported by affidavit and other documentary exhibits, including statements from AMS employees obtained during the

⁹ AMS's Statement of Issues, at 6-7 (Aug. 5, 1988). AMS characterized the matters in controversy alternatively as raising seven, three, or two general issues. Id. at 7-8; AMS Response to NRC Staff Response, at 3 (Sept. 2, 1988); see also LBP-89-11, 29 NRC 306, 313 n.12 (1989). We have looked at the alternative characterizations to the extent that they helped us understand AMS's position.

¹⁰ 29 NRC 306, 313-17 (1989). In this decision the Licensing Board also determined, in response to AMS's request for an award of attorney fees and expenses under the Equal Access to Justice Act, 5 U.S.C. § 504 (1988), that the Board was empowered to grant such relief if the licensee prevailed on some or all of the issues set for litigation. 29 NRC at 310-13. The Licensing Board's determination on this score was reversed by the Appeal Board. ALAB-929, 31 NRC 271 (1990). The Commission declined to review the Appeal Board's decision. Memorandum for Board and Parties from S. J. Chilk, Secretary (June 13, 1990).

investigation of the alleged violations and purchase orders reflecting the transactions in question. AMS filed a "Brief in Opposition to NRC Staff Motion for Summary Disposition" (Mar. 1, 1990) (hereinafter "Brief in Opposition").

C. *The Licensing Board's Decision*

In LBP-90-17, the Licensing Board found that no material issues of fact remained in dispute with respect to the issues and, consequently, the Board granted staff's motion for summary disposition. The Board found that the admitted issues could be distilled to a single question: "Under Commission regulations, did the Director act lawfully when he issued the summary suspension order?" 31 NRC at 543. The Board confined itself to an examination of the information available to the staff when the Director issued the order on October 10, 1986. *Id.* at 542 n.5.

In reviewing the Director's decision to issue the suspension order the Licensing Board applied the criteria derived from the Commission's decision in Consolidated Edison Co. (Indian Point Units 1-3), CLI-75-8, 2 NRC 173, 175 (1975):

1. Whether the statement of reasons given permits rational understanding of the basis for his decision;
2. whether the Director has correctly understood the governing law, regulations, and policy;
3. whether all necessary factors have been considered, and extraneous factors excluded, from the decision;
4. whether inquiry appropriate to the facts asserted has been made; and

5. whether the Director's decision is demonstrably untenable on the basis of all information available to him.¹¹

With respect to the first criterion, the Licensing Board determined that the order adequately articulated the basis on which the Director based the decision to suspend temporarily AMS's service and maintenance operations; i.e., the alleged violations of license requirements pertaining to personnel authorized to conduct maintenance, training, and radiation monitoring. 31 NRC at 546. In analyzing the staff's application of the governing law and regulations, the Board found that the Director had relied on the appropriate statutory authority and procedural regulations for issuing an order and making it immediately effective. Id. at 547. Because the gravamen of the dispute between staff and AMS concerned the scope of service and maintenance work that requires a "licensed" service engineer, the Licensing Board reviewed the available affidavits, documentary evidence, and the contents of AMS's license to determine whether the alleged violations had an adequate foundation.

The Board found that the staff had sufficient evidence at the time that the order was issued to conclude that unlicensed

¹¹ See 31 NRC at 544-45. As the Board noted, the criteria in Consolidated Edison Co. had been articulated in the context of Commission review of a staff decision to deny an enforcement petition, i.e., a declination to issue an order. The Commission, however, later applied the criteria in a case involving a licensee's challenge, similar to the one here, to the issuance of an immediately effective order. Nuclear Engineering Co. (Sheffield Low-Level Radioactive Waste Disposal Site), CLI-79-6, 9 NRC 673, 676 (1979), reconsid. denied, CLI-80-1, 11 NRC 1 (1980).

persons were replacing timer mechanisms in teletherapy units, that unlicensed individuals were exposing the radioactive source in the units, and that individuals were conducting service and maintenance activities without following required safety procedures. Id. at 551. Under the terms of AMS's license, the Board concluded, work involving a teletherapy unit's timer must be carried out by "licensed" personnel and all individuals must use radiation monitoring devices. Id. at 553. Consequently, the Board determined that the Director had properly interpreted and applied the conditions of AMS's license. Moreover, in the Board's view, the Director reasonably concluded that "substandard or ill-planned" maintenance of teletherapy could have potentially immediate, adverse consequences on the general public and workers using the equipment. Id. at 554.

With respect to the remaining three Consolidated Edison Co. criteria, the Licensing Board also found that the staff had acted appropriately in issuing the suspension order. The Director had considered the appropriate factors in making the decision to issue the order and had made an appropriate inquiry into the facts that formed the basis for the order. Id. at 554-55. In assessing whether the Director's decision was "demonstrably untenable", the Licensing Board emphasized that the staff should be afforded flexible discretion to initiate administrative enforcement action. In the Board's view, the sufficiency of the information on which the staff relied in taking action should be assessed in the context of whether it was "reliable, probative,

and substantial -- within the context of reasonableness". Id. at 556. The Licensing Board concluded that the Director reasonably relied on the interviews of past and present AMS employees conducted by NRC investigators. Moreover, the information reasonably supported a conclusion that unlicensed technicians were performing maintenance on teletherapy machines in a manner inconsistent with the terms of AMS's license, that such activities could pose a safety risk to the public and workers, and that there was a disrespect for or conscious disregard of radiation safety on the part of AMS employees or management. Id. at 557. Consequently, the Board concluded the Director's actions were reasonable and not "demonstrably untenable". Id.

D. Issues on Appeal

AMS raises a number of issues on appeal challenging both the substance and the scope of the Licensing Board's decision.¹² AMS argues that the Board decided the case on the basis of an issue which the parties had never raised or briefed and ignored the issues that AMS had raised and were admitted for litigation. AMS maintains that the Board erroneously concluded that no material facts remained in dispute with respect to the activities of AMS technicians and AMS management's involvement. AMS contends that the Board employed an improper standard of review of the staff's actions by only assessing the facts available in

¹² Advanced Medical Systems, Inc.'s Brief in Support of Reversal of the Licensing Board's Order Granting NRC Staff Motion for Summary Disposition and Terminating Proceeding (July 20, 1990) (hereinafter AMS Appeal Brief).

October 1986 when the Director issued the suspension order, rather than looking to all the facts available up to the time that the order was revoked by the staff in December 1987. In AMS's view, the Board should have applied a "clear and convincing evidence" standard in assessing the facts.

AMS also maintains that the Director did not have the discretion to issue an immediately effective order and thus violated Commission procedures. At most, AMS contends, the Director could have issued a non-immediately effective show-cause order. AMS suggests that it was treated unfairly because other licensees did not receive a similar order. For these averred flaws, AMS asks that a full hearing on the merits of AMS's claims be ordered to determine the truthfulness of the witness statements on which the staff relies and to examine the motives and fairness of NRC management in suspending AMS's operations.

For its part, the NRC staff submits that the Licensing Board's order is well-founded and should be sustained.¹³ In the staff's view, the Board properly found that no genuine issues of material fact remained to be decided; AMS's assertions to the contrary rested on general denials and speculation and did not demonstrate that the essential factual bases for the staff's order were in dispute. The staff submits that the Board decided precisely the issues that AMS had raised and the Board considered an appropriate scope of evidence. The staff also contends that

¹³ NRC Staff Brief in Response to Appeal by AMS (Sept. 4, 1990) (hereinafter Staff Reply Brief).

the Board applied an appropriate standard of proof and properly found that the Director acted within his discretion in determining to issue a summary suspension order to AMS.

III. Analysis

A. *The Licensing Board's Characterization of the Issues*

At the outset, we deal with AMS's assertion that the Licensing Board did not decide the matters set for decision in the proceeding, but decided the case on the basis of an issue neither raised nor briefed by the parties. If AMS's assertion had merit, our inquiry might stop here. See Public Service Co. of New Hampshire (Seabrook Station, Units 1 & 2), ALAB-422, 6 NRC 33, 41 (1977), aff'd on other grounds, CLI-78-1, 7 NRC 1 (1978). AMS has not convinced us, however, that the Board failed to resolve the contested issues in this case and to articulate in reasonable detail the basis for its decision or that the Board decided the case on a basis which the parties did not have an opportunity to address.

AMS complains that the Board did not base its decision on the four issues adopted for litigation,¹⁴ but AMS does not explain why the Board erred in treating these issues as aspects of one overriding question: i.e., "did the Director act lawfully when he issued the summary suspension order?" 31 NRC at 543. Even in its earlier order admitting issues for litigation, the Board recognized that AMS's issues all bore on the general

¹⁴ AMS Appeal Brief at 21; see LBP-89-11, 29 NRC at 313, 317.

question of the legal and factual basis for the staff's suspension order.¹⁵

AMS gives no clue as to the matters that the Board decided which AMS avers were not briefed or raised by the parties. AMS's failure to illuminate the bases for its exception would in itself be sufficient grounds to reject it as a basis for appeal. The appellant bears the responsibility of clearly identifying the errors in the decision below and ensuring that its brief contains sufficient information and cogent argument to alert the other parties and the Commission to the precise nature of and support for the appellant's claims. General Public Utilities Nuclear Corp. (Three Mile Island Nuclear Station, Unit 2), ALAB-926, 31 NRC 1, 9 (1990); Wisconsin Elec. Power Co. (Point Beach Nuclear Plant, Units 1 & 2), ALAB-666, 15 NRC 277, 278 (1982).

In any event, the Licensing Board's analysis of the legal and factual matters in controversy leaves no doubt that the Board considered the issues which AMS had raised and that it determined the case on a fair consideration of those and other relevant matters. In structuring its analysis around the criteria set forth in our decision in Consolidated Edison Co., the Board dealt precisely with the issues that AMS had raised.

AMS's first issue challenges whether the staff had a substantial basis to conclude that AMS would not comply with

¹⁵ See LBP-89-11, 29 NRC at 314 & n.13. As the Board noted, AMS itself variously characterized the matters in controversy as raising seven, three or two issues. Id. at 313 & n.12.

Commission requirements in the future. The Board's analysis of the second, fourth, and fifth criteria in Consolidated Edison Co. deal essentially with that issue: i.e., whether the Director understood governing law, regulations, and policy; whether an appropriate factual inquiry has been made; and whether the Director's decision is demonstrably untenable on the basis of available information. With respect to AMS's second and third issues, the Board's consideration of the second through fifth Consolidated Edison Co. criteria discusses matters concerned with the basis for determining that AMS's activities could pose a threat to public health and safety and thus warranted suspension of the license. AMS's fourth issue, concerning the basis for dispensing with prior notice and making the order immediately effective, is analyzed primarily in the context of the Board's discussion of the second, fourth, and fifth criteria under Consolidated Edison Co.

Thus, we reject AMS's general complaint that the Licensing Board failed to address the issues raised by the parties or to decide the case on matters that the parties had no opportunity to address. We turn now to the more specific exceptions to the Licensing Board's decision.

B. *Authority for Immediately Effective Orders*

The Director's order was issued under section 2.202 of the Commission's regulations and relied on the exceptions specified in sections 2.201(c) and 2.202(f) as the basis for making the

order effective upon issuance. When the order was issued in October 1986, our regulations provided --

§ 2.201 Notice of Violation

(a) Before instituting any proceeding to modify, suspend, or revoke a license or to take any other action for alleged violation of any provision of the Act or this chapter or the conditions of a license, the Director, Office of Inspection and Enforcement, a regional Administrator, or the designee of either, will serve on the licensee or other person subject to the jurisdiction of the Commission a written notice of violation, except as provided in paragraph (c) of this section....

(c) When the Director, Office of Inspection and Enforcement, finds that the public, health, safety, or interest so requires, or that the violation is willful, the notice of violation may be omitted and an order to show cause issued.

§ 2.202 Order to Show Cause

(a) The ... Director, Office of Inspection and Enforcement, ... may institute a proceeding to modify, suspend, or revoke a license or for such other action as may be proper by serving on the licensee an order to show cause which will:

(1) Allege the violations with which the licensee is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for the proposed action;

(2) Provide that the licensee may file a written answer to the order under oath or affirmation within twenty (20) days of its date, or such other time as may be specified in the order;

(3) Inform the licensee of his right, within twenty (20) days of the date of the order, or such other time as may be specified in the order, to demand a hearing;

(4) Specify the issues; and

(5) State the effective date of the order....

(f) When the ... Director, Office of Inspection and Enforcement, ... finds that the public health, safety, or interest so requires or that the violation is willful, the order to show cause may provide, for

stated reasons, that the proposed action be temporarily effective pending further order.¹⁶

The Commission's regulations recognize that a licensee should be afforded under usual circumstances a prior opportunity to be heard before the agency suspends a license or takes other enforcement action, but that extraordinary circumstances may warrant summary action prior to hearing. Consumers Power Co. (Midland Plant, Units 1 & 2), CLI-73-38, 6 AEC 1082, 1083 (1973). Similar provisions have been in force since the early days of the regulatory scheme under the Atomic Energy Act of 1954.¹⁷

The Commission's regulations are consistent with the Administrative Procedure Act (APA) and the dictates of due process. Under section 9(b) of the APA, which is made specifically applicable to the Commission in section 186 of the Atomic Energy Act, an agency may dispense with prior notice of the withdrawal, suspension, revocation, or annulment of a license in cases of willfulness or those in which the public health,

¹⁶ We rely on the regulations as they were codified in Title 10 of the 1986 edition of the Code of Federal Regulations in effect at the time of issuance of the order. Our procedural rules for issuing orders have undergone significant updating and revision in the past few years, although the essential procedures for issuing orders and making them immediately effective have remained the same. See 10 C.F.R. §§ 2.201, 2.202, & 2.204 (1994); 56 Fed. Reg. 40,664 (Aug. 15, 1991); 57 Fed. Reg. 20,194 (May 12, 1992).

¹⁷ See 21 Fed. Reg. 804 (1956); Plaine, The Rules of Practice of the Atomic Energy Commission, 34 Texas L. Rev. 801, 806-807 (1956).

safety, or interest so requires.¹⁸ Moreover, summary administrative action to protect important governmental interests, particularly protection of public health and safety, has long been upheld under the Constitution.¹⁹

Due process does not require that emergency action be taken only where there is no possibility of error;²⁰ due process requires only that an opportunity to be heard be granted at a meaningful time and in a manner appropriate for the case.²¹ Our inquiry here concerns whether the Licensing Board properly decided, using summary procedures and without an evidentiary hearing, that the staff had an adequate basis for issuing an immediately effective suspension of AMS's license. An agency may ordinarily dispense with an evidentiary hearing in resolving a controversy when no dispute remains, as the Licensing Board found in this proceeding, as to a material issue of fact. See Veg-Mix,

¹⁸ 5 U.S.C. § 558(c); 42 U.S.C. § 2236(b). See Kodon v. Department of Justice, 564 F.2d 228, 234 (7th Cir. 1977); Wolf Corp. v. SEC, 317 F.2d 139, 142 (D.C. Cir. 1963); New England Air Express v. Civil Aeronautics Bd., 194 F.2d 894 (D.C. Cir. 1952).

¹⁹ Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc., 452 U.S. 264, 300-01 (1981); Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594, 599-600 (1950); North American Cold Storage Co. v. Chicago, 211 U.S. 306, 315-16 (1908). Contrary to the implication in AMS's brief (at 17), summary action prior to hearing has not been limited solely to circumstances requiring protection of the national interest in wartime.

²⁰ Hodel, 452 U.S. at 302.

²¹ Logan v. Zimmerman Brush Co., 455 U.S. 422, 437 (1982); Mathews v. Eldridge, 424 U.S. 319, 333 (1976). See also Union of Concerned Scientists v. AEC, 499 F.2d 1069, 1081 (D.C. Cir. 1974).

Inc. v. Department of Agriculture, 832 F.2d 601, 607-08 (D.C. Cir. 1987).

C. *The Appropriate Standard for Review of Staff's Order*

This proceeding was decided by the Licensing Board and comes before the Commission in an unusual posture. Unlike most licensing or enforcement proceedings, we are not called upon to make a decision that has any substantial future effect on AMS. Neither a reinstatement of the license suspension nor other enforcement sanction would be triggered by a decision affirming LBP-90-17. In deciding that issues remained for determination in this proceeding, the Licensing Board relied on an exception to the doctrine against issuing declaratory orders in otherwise moot cases when the party's injury is "capable of repetition, yet evading review." LBP-89-11, 29 NRC at 314 (quoting Southern Pacific Terminal Co. v. ICC, 219 U.S. 498, 515 (1911)). In the Board's view, this proceeding fell within that set of cases because the challenged suspension was too short to be fully litigated before its cessation and AMS could be subject to similar action again. LBP-89-11, 29 NRC at 314-15. To the extent that the Licensing Board found issues left for resolution, however, those issues centered on the basis for the immediate effectiveness of the staff's suspension order. Id. at 313, 316.

AMS contends that the Licensing Board applied an inappropriate evidentiary standard. Indeed, AMS maintains that the Board should have applied a "clear and convincing" standard to the evidence. AMS Brief at 19. Upon consideration of AMS's

arguments we conclude that the Licensing Board's decision reflects an appropriate analysis of the sufficiency of the evidence required to support the staff's threshold decision to order an immediately effective suspension. The standard by which the immediate effectiveness of the order is judged may differ from that ultimately applied after a full adjudication on the merits of an enforcement order. See Nuclear Engineering Co., 11 NRC at 4-5. In this proceeding, however, because the admitted issues concern only the threshold determination as to whether there was a sufficient basis for issuing an immediately effective order, the standard applied to review of matters after a full adjudicatory hearing on the merits of an order did not apply.

The Licensing Board applied the criteria in Consolidated Edison Co. and Nuclear Engineering Co. in its assessment of the adequacy of the staff's bases for an immediately effective order. As the Board noted, these criteria give substantial deference to the staff's decision to initiate enforcement proceedings. 31 NRC at 543-45. To the extent that the staff's order, and particularly its immediate effectiveness, rested on specific factual allegations, the Board measured the sufficiency of the evidentiary basis for the order under "the threshold evidentiary requirements associated with administrative proceedings under the Administrative Procedure Act -- that the information he bases his decision upon be reliable, probative, and substantial -- within the context of reasonableness." Id. at 556.

We agree with the Licensing Board that the standard for review of an order's immediate effectiveness under Nuclear Engineering Co. permits such orders to be based on preliminary investigation or other emerging information that is reasonably reliable and indicates the need for immediate action under the criteria set forth in section 2.202. See CLI-79-6, 9 NRC at 677-78, reconsideration denied, CLI-80-1, 11 NRC 1, 5-6 (1980). This standard does not suggest an absence of controversy over such evidence or over the need for immediate action. In a recent rulemaking to adopt procedural changes to our rules of practice to ensure a prompt review of challenges to the immediate effectiveness of orders, we characterized the basic test as one of "adequate evidence" for the order and noted the kinship of this test to one for probable cause for an arrest, warrant or preliminary hearing. See Revisions to Procedures to Issue Orders: Challenges to Orders That Are Made Immediately Effective, 57 Fed. Reg. 20,194, 20,195-96 (May 12, 1992). Under this test,

[A]dequate evidence is deemed to exist when facts and circumstances within the NRC staff's knowledge, of which it has reasonably trustworthy information, are sufficient to warrant a person of reasonable caution to believe that the charges are true and that the order is necessary to protect the public health, safety, or interest.

Id. at 20,196. The test "strikes a reasonable balance between the Commission's ability to protect the public health, safety, or interest on the basis of reasonably trustworthy information while still providing affected parties with a measure of protection

against arbitrary enforcement action by the Commission." Id. Although this rulemaking was adopted after the controversy in this proceeding arose, the "adequate evidence" test is consistent with the preliminary review of the available evidence under our earlier Nuclear Engineering Co. decision.

Thus, we reject AMS's argument that the staff was required to show that it had "clear and convincing evidence" of license violations before it issued its order.²² In the recent amendments to section 2.202, we rejected a similar comment that the Commission apply the "preponderance of the evidence" standard in assessing threshold challenges to the immediate effectiveness of an order, because of the potential adverse impact on the

²² As staff notes in its reply brief (at 12), AMS raises the applicability of the "clear and convincing" test for the first time on appeal, which would in itself be grounds for its rejection. See Georgia Power Co. (Vogtle Electric Generating Plant, Units 1 & 2), ALAB-872, 26 NRC 127, 133 (1987). The only authority cited for AMS's proposition is a Licensing Board decision adopting as a matter of discretion a "clear and convincing" test in a special hearing on falsification of data related to operation of the Three Mile Island Unit 2 reactor. Inquiry into Three Mile Island Unit 2 Leak Rate Data Falsification, LBP-87-15, 25 NRC 671, 690-91 (1987), aff'd on other grounds, CLI-88-2, 27 NRC 335 (1988). Notwithstanding a licensing board's discretionary application of the standard in a single case, the Commission has never adopted a "clear and convincing" standard as the evidentiary yardstick in its enforcement proceedings, nor are we required to do so under the AEA or the APA. Typically, NRC administrative proceedings have applied a "preponderance of the evidence" standard in reaching the ultimate conclusions after hearing in resolving a proceeding. See, e.g., Radiation Technology Inc., ALAB-567, 10 NRC 533, 536 (1979); Revisions to Procedures to Issue Orders; Deliberate Misconduct by Unlicensed Persons, 56 Fed. Reg. 40,664, 40,673 (Aug. 15, 1991). The "preponderance" standard is also the one generally applied in proceedings under the APA. See Steadman v. SEC, 450 U.S. 91, 101-02 (1981) (preponderance of evidence standard governs APA on-the-record proceedings).

public safety or interest that could occur if additional time were required to collect evidence necessary to sustain immediate action under such a standard. 57 Fed. Reg. at 20,196.

We acknowledged in our rulemaking that the "adequate evidence" standard is not a test for determining the ultimate merits of an order, but is intended only as a preliminary procedural safeguard against the staff's ordering immediately effective action based on "clear error, unreliable evidence, or unfounded allegations." Id. at 20,197. Likewise, the Licensing Board's assessment of the information available to the Director should be understood in a similar context. As the Board recognized, AMS's admitted issues for litigation concentrated on the legitimacy of the Director's invocation of the grounds for making an order immediately effective and initiating such action. Thus, we believe the Licensing Board correctly considered in assessing the evidence available to the staff whether that evidence was probative and a reasonably reliable basis on which to impose an immediately effective suspension. No more stringent test need be considered in addressing the threshold adequacy of such an order.

In reviewing the record in light of the criteria in Nuclear Engineering Co., the Board concluded in response to the staff's motion for summary disposition under 10 C.F.R. § 2.749 that no material facts remained in dispute regarding whether the staff had sufficient evidence on which to base an immediately effective order. See LBP-90-17, 31 NRC at 542 and n.5. Thus, we have also

reviewed the record in light of AMS's arguments that the staff could not satisfy the requirements for summary disposition under 10 C.F.R. § 2.749. In so doing, we have focused our review on whether a genuine issue remains in dispute regarding whether the staff had sufficient evidence on which to base an immediately effective order. From our review, we conclude that the staff had demonstrated that no genuine issue of material fact remains in dispute and that the staff is entitled to a decision in its favor as a matter of law.

D. *The Violations Alleged in the Order.*

The staff ordered the license suspension primarily on the basis of its preliminary investigative findings that certain AMS employees had conducted service and maintenance operations on teletherapy equipment which they were not authorized to perform and without adhering to required safety precautions. The order summarized the charges as follows:

The NRC recently has confirmed additional allegations that since the Spring of 1985 and as recently as September 1986, employees of the licensee were directed to perform certain service and maintenance on teletherapy equipment at medical facilities notwithstanding their lack of NRC authorization, their lack of required training to perform the directed maintenance, their lack of appropriate radiation detection and monitoring equipment or required service manuals, and their express objections to performing such maintenance without proper training. In addition, one hospital at which such service and maintenance was performed has indicated its belief that a licensee

employee was unqualified to perform the maintenance of its teletherapy equipment.²³

For the most part, AMS does not deny that its employees undertook maintenance and service activities as the staff alleged.

However, AMS insists that its employees did not engage in any activities for which they were not authorized and denies that management knowingly instructed its employees to violate license requirements. As AMS states in its brief,

AMS has never claimed the work was not done, but has always claimed that its employees did no unlicensed work and has denied that certain of the work was performed in the manner alleged by AMS employees.

AMS Appeal Brief at 12. To assess the merits of AMS's arguments, we first review the relevant requirements of AMS's license and then turn to the evidence that the Licensing Board found sufficient to warrant an immediately effective suspension order.

²³ 51 Fed. Reg. 37,674 (Oct. 23, 1986). The order also references certain alleged violations of radiation safety requirements during operations in February 1985 in a hot cell at AMS's facility. The alleged hot cell violations were the subject of a separate civil penalty proceeding. See LBP-91-09, 33 NRC 212 (1991), rev'd and remanded in part, CLI-93-22, 38 NRC 98 (1993), settlement approved, LBP-94-10, 39 NRC ____ (Mar. 31, 1994). Other than the Licensing Board's brief reference to them in its decision in the instant case, see 31 NRC at 545, these violations involving other aspects of AMS's licensed activity do not figure in the Board's consideration of the issues before it. Earlier in the proceeding the staff had eschewed reliance on those violations to support its position. See Letter to William F. Kolis, Jr., AMS counsel, from Stephen H. Lewis & Colleen Woodhead, NRC staff counsel (Feb. 19, 1987). The staff did not reference the violations in its Motion for Summary Disposition or its brief opposing AMS's appeal, nor did AMS refer to the violations in its Brief in Opposition or in its appeal to us. Consequently, we do not further consider those alleged violations here, and they have no bearing on our decision.

1. "Licensed Operations" Under AMS's License

The staff's order suspended AMS's authorization under NRC Materials License No. 34-19089-01 to install, maintain, service, and dismantle radiography or teletherapy units. At the time that the order was issued, this license and certain documents incorporated by reference defined the basic requirements and limitations on AMS's activities.²⁴ Prior to June 25, 1986, AMS's licensed maintenance and service operations were governed by License No. 34-19089-02 (the "-02" license). As the Licensing Board noted, the two licenses were combined in June 1986.²⁵ Most of the incidents of unauthorized maintenance on which the Licensing Board relied occurred while the "-02" license was in effect. Relevant excerpts from the documents or procedures incorporated by reference in that license are quoted in the Licensing Board's decision and are attached to the staff's summary disposition motion. See 31 NRC at 551-53; MSD Attachments 1-4. Although the license in effect at the time of the suspension order contained updated and revised procedural

²⁴ A copy of the license as it appeared at the time the order was issued is appended to the staff's motion for summary disposition as Attachment 1.

²⁵ 31 NRC at 551; see also Attachment A to Affidavit of George M. McCann, et al. (hereinafter McCann Affidavit), submitted with NRC Staff's Motion for Summary Disposition (hereinafter "MSD"). To ensure that we had a proper understanding of the license requirements and procedures in effect at the relevant times in question, we directed the staff by order dated November 23, 1993, to file on the docket of this proceeding a complete copy of License No. 34-19089-02 and the documents incorporated by reference therein and a copy of the licensee's November 12, 1984 letter which was incorporated by reference in License No. 34-19089-01.

documents and requirements, the changes did not alter materially the essential limitations on AMS's service operations, and none of AMS's arguments against the Licensing Board's interpretation of the license depend on differences between the two licenses.

At times relevant here, Condition 12 of the "-02" license required that activities involving licensed material be performed or supervised by persons designated by AMS's Isotope Committee.²⁶ AMS was also required under condition 14 of the "-02" license to adhere to the statements, representations, and procedures contained in its November 1979 license application and other supporting documents, such as AMS's Factory Training Course and the Cobalt Service Procedures Manual.²⁷ By virtue of their incorporation by reference into the license, the procedures and limitations on activities prescribed in the specified manuals and documents became binding license requirements which AMS was not free to ignore.

Schedule B of the 1979 license application states that --
all work requiring [sic] a specific license which does not involve removal of the source from it's [sic] shielded container, but does include operation of an exposure device, will be performed by persons formally approved to do so by the Advanced Medical Systems, Inc., Isotope Committee.

²⁶ Under Conditions 11.A. and 11.B. of the "-01" license in effect after June 26, 1986, servicing and maintenance of teletherapy and radiography units could be conducted by or under the supervision and in the physical presence of certain named individuals. See MSD Attachment 1.

²⁷ Compare License No. 34-19089-01, Amendment No. 8, Condition 19 (MSD Attachment 1). See AMS's Factory Training Course (MSD Attachment 2); Cobalt Service Procedures Manual (MSD Attachment 3).

MSD Attachment 2 at 3. Under AMS's procedures, service technicians were required to complete specified training before they could be certified by the AMS Isotope Committee to work independently on teletherapy systems as authorized users.²⁸ As defined by AMS's procedures, licensed operations --

include work involving the [radioactive] source or parts of the unit which could result in increased exposure to the source. This includes work on the source shutter or other mechanisms which could expose the source, reduce shielding around the source, or compromise the safety of the unit and result in increased exposure levels.

31 NRC at 552 (quoting AMS's Factory Training Course at 9). As prescribed by the licensee's Cobalt Service Procedures Manual, certain operations could be performed only by a certified person: contamination checks, waste disposal, emergency closing of a stuck shutter, surveys, collimator removal and installation, head installation and removal, shutter service and cleaning, shutter bearing lubrication, and unit tests and demonstration. See MSD Attachment 3 at 9.

The Cobalt Service Procedures Manual also required that --

[p]rior to commencement of the operations outlined in this manual, the licensee for whom the service is being performed will relinquish control over the use of, and the keys for, the equipment and it's [sic] controlled areas to the licensed person in charge until such time as it has been determined by the licensed person that the equipment is in safe operating condition. The licensed person will then return control of the equipment and controlled areas to the licensee.

²⁸ 1979 License Application, Schedule B, at 3 (MSD Attachment 2); Factory Training Course at 9 (MSD Attachment 2); AMS March 10, 1980 letter at 1 (MSD Attachment 3).

Id. at 2. During such operations, AMS employees were required to carry film badges, pocket dosimeters, and audible gamma radiation detectors. Id. at 5. The manual further specifies procedures for unit check-out after completion of service, including steps involving operation of the unit before returning the key to and jurisdiction over the unit to the client. Id. at 17-18. Thus, any maintenance or service that would require testing (including opening the source shutter) to verify the safe and proper operation of the serviced, repaired, or replaced components or subsystems would be a "licensed operation."

2. *Alleged Incidents of Unauthorized Maintenance*

In reviewing the evidence available to the staff at the time the suspension order was issued, the Licensing Board relied primarily on the statements of AMS employees that were prepared during the course of the staff's preliminary investigation. See 31 NRC at 548-51, 554, 556-57. At the time the order was issued, the staff had available information provided to NRC investigators by several current or former AMS employees: service technicians James M. Leslie, Russell P. Fortier, Garnett C. Light, and Richard G. Speer and AMS Field Service Manager Paul Carani. See 31 NRC at 548-51. The statements or interview reports of the service technicians contain allegations of a number of incidents of unauthorized maintenance or service of teletherapy units by unlicensed technicians.

AMS attacks the Licensing Board's reliance on the statements of the service technicians, suggesting that the technicians are

"merely" disgruntled employees. AMS also contends that the statements are not reliable because the statement in one instance is unsigned and thus hearsay and because staff has not provided an affidavit that the statements were "true, accurate, and actually the words of those individuals". AMS Brief at 15.

With the exception of Mr. Light, the statements are signed and sworn by the service technicians.²⁹ Moreover, George M. McCann of NRC Region III signed the statements as a witness to their making and attests to the statements' authenticity in his affidavit accompanying the staff's motion for summary disposition.³⁰ Although the statement reflecting the interview with Mr. Light is signed only by Mr. McCann and the NRC investigator who also conducted the interview, the hearsay nature of the affidavit does not in itself bar its consideration,³¹ nor does the record contain any other evidence suggesting its inherent unreliability.³² As described in the ensuing

²⁹ See MSD Attachments 5, 11, 17, 23 & 38. The witness statements were also provided to AMS with NRC Inspection Report No. 030-16055/86-001(DRSS), issued Nov. 25, 1986 (Exhibit 11 to Application of Advanced Medical Systems, Inc. for Stay of the Effectiveness of Decision (Jan. 16, 1987)).

³⁰ McCann Affidavit ¶¶ 19d & 19e.

³¹ See Duke Power Co. (Catawba Nuclear Station, Units 1 & 2), ALAB-355, 4 NRC 397, 412 (1976).

³² Indeed, a transcribed interview with Mr. Light conducted after the order was issued confirms the basic facts contained in the staff's original interview report regarding Mr. Light's actions at a Veterans Administration hospital in New Jersey and at Eastside Radiology Imaging and Therapy Center in Ohio. See Investigative Interview of Garnett C. Light at 14-18 (Oct. 28, 1986) (MSD Attachment 18).

discussion of the particular violations, AMS does not contest the occurrence of the essential facts that are described in the staff's interview report for Mr. Light or the statements of any of the other service technicians. AMS's general objections to the reliance on the technicians' statements and its bald assertions that the technicians were "disgruntled" employees are insufficient to show a concrete, material dispute of fact.³³

AMS also argues that the Licensing Board erred in finding no dispute of fact because the Regional Administrator had the same "conflicting" evidence available when he revoked the suspension order in its entirety in December 1987. In AMS's view the Regional Administrator's action was tantamount to an admission that "the NRC's actions were neither substantially justified nor that special circumstances existed so as to have made their actions reasonable."³⁴ The Regional Administrator's letter contains no such admission or basis for believing that the staff had confessed error in issuing the original order. Indeed, had staff's letter contained such an admission, we would proceed no further with AMS's appeal, for AMS would have obtained the victory it desires and its appeal would be moot. The letter, however, suggests only that subsequent amendments to AMS's license had superseded the terms of the order and potentially conflicted with them. There is no suggestion in the letter that

³³ See Matsushita Elec. Ind. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).

³⁴ AMS Appeal Brief at 5, 15; see Letter from A. Bert Davis to S. S. Stein, AMS President (Dec. 3, 1987).

the staff admitted that the evidence supporting its order was insufficient to sustain it. We, therefore, proceed to an analysis of the evidence of the violations charged in the order.

The Board identified the following incidents as particularly material to the Board's review:

11. James M. Leslie replaced the timer on the teletherapy unit at Munson Medical Center, Traverse City, Michigan on April 28-29, 1986....

17. AMS employee Russell P. Fortier performed service on the main cable of the teletherapy unit at the Hospital for Joint Diseases, Harlem, N.Y. on May 30, 1985 without survey meter, dosimeter, audible radiation monitor or service manual for the unit....

22. AMS employee Russell P. Fortier replaced the timer in the teletherapy unit and exposed the radioactive source at Ball Memorial Hospital, Muncie, Indiana on October 23-24, 1985....

24. On June 10 and 11, 1986 Garnett Light serviced the wiring between the teletherapy stand and the control console, exchanged the treatment timer in the unit, performed safety tests, performed emergency and interlock checks, and activated the unit at the VA [Veterans Administration] Hospital, East Orange, N.J....

27. Garnett Light installed a head containing the source in the teletherapy unit at Eastside Radiology, Willoughby Hills, Ohio in July 1986 without supervision of an LSE [licensed service engineer]....

34. AMS employee Richard Speer repaired a timer in the teletherapy unit at St. Joseph's Hospital, St. Paul, Minnesota in December 1985....³⁵

AMS does not dispute that Messrs. Leslie, Fortier, Light, and Speer were neither listed on AMS's license nor certified by AMS's Isotope Committee. Rather, AMS maintains that these

³⁵ NRC Staff's "Statement of Material Facts as to Which No Genuine Issue Exists" (appended to MSD); see 31 NRC at 543 n.5.

employees' actions did not constitute "licensed" operations. None of AMS's disputes with the service technicians' statements reveals any real controversy over the employees' actions, even under the most generous reading of AMS's position. As the Licensing Board stated, AMS has provided little more than "bare denials" in the way of evidence that neither contradicts the basic events described in the staff's motion and its supporting materials nor otherwise shows that material issues of fact remain for determination in this proceeding. 31 NRC at 542 n.5. Absent any probative evidence supporting AMS's claims, mere assertions of a dispute do not invalidate the Licensing Board's grant of summary disposition. See First National Bank of Arizona v. Cities Service Co., 391 U.S. 253, 290 (1968); Advanced Medical Systems, Inc., CLI-93-22, 38 NRC 98, 102 (1993).

Mr. Light's removal and reinstallation of a teletherapy head at Eastside Radiology in Willoughby Hills, Ohio, quite clearly violated the limits spelled out in AMS's license.³⁶ Head installation and removal is specifically listed as a "licensed operation" in AMS's procedures manual.³⁷ The teletherapy head contained a radioactive source of some 9,000 curies of the cobalt-60 isotope and could create a significant hazard to

³⁶ See Interview of Garnett C. Light (MSD Attachment 17).

³⁷ Cobalt Service Procedures Manual at 9 (MSD Attachment 3). The head contains the radioactive source within a movable source carrier that moves the source from the shielded to exposed position. McCann Affidavit ¶ 8 and Fig. 3.

patients, clinical staff, and the service technician if not properly handled or installed.³⁸

AMS does not deny that Mr. Light conducted this operation; at most, AMS challenges, on the basis of a 1990 affidavit from Mr. Carani, that Mr. Light was instructed to perform the work over Mr. Light's objection without the presence of an authorized AMS representative. See AMS Appeal Brief at 8-9. Although these assertions might be material to a determination of AMS management's culpability, they do not raise any question regarding the work performed by Mr. Light or otherwise indicate that the staff's reliance on its interview with Mr. Light was unreasonable.

Other alleged instances of unauthorized maintenance or repairs by service technicians involved the wiring of teletherapy units. The NRC investigators' report of their interview with Mr. Light indicates that he completed wiring work on the unit stand and the control console at a Veterans Administration Hospital in East Orange, New Jersey, in June 1986 after the licensed service engineer had departed.³⁹ Mr. Light further indicated that he performed safety tests as well as emergency and interlock checks that required activation of the teletherapy unit and exposure of the radioactive source.⁴⁰ Mr. Fortier's statement describes his

³⁸ See McCann Affidavit ¶ 60; Staff Statements of Material Fact Nos. 29 & 51 (appended to MSD).

³⁹ Report of Interview of Garnett C. Light (MSD Attachment 17).

⁴⁰ Id.

work in May 1985 on the wiring of the main cable for the teletherapy unit at the Joint Disease Tumor Hospital in Harlem, New York.⁴¹ AMS does not dispute that the work was performed, but denies that the work constituted "licensable activities" which could be performed only by persons named in the license or approved by the Isotope Committee.

In determining whether the technicians' activities were "licensable," the staff examined the safety significance of their operations and concluded that, because the work could affect the performance of a number of important radiation and patient safety features of the teletherapy unit, the work was required to be performed or directly supervised by a licensed service engineer. Wiring the main cable, for example, can affect the safe operation of the unit, because the main cable of a teletherapy unit connects the unit to the remote control panel, and the cable contains electrical wiring that affects source exposure equipment and the unit's safety systems. See McCann Affidavit ¶¶ 38-39. Wiring from the control panel links the controls to safety mechanisms in the unit. Id. at ¶ 55. AMS does not dispute these basic facts. Given the importance of proper repair and installation of the main cable and other wiring, the staff

⁴¹ Interview of Russell P. Fortier (MSD Attachment 11). Mr. Fortier also says he did not have radiation monitoring devices with him, which staff alleged violated AMS's Cobalt Services Procedures Manual (MSD Attachment 3 at 5). AMS does not deny that he lacked such equipment, but blames Mr. Fortier for the violation. AMS Appeal Brief at 8. The Licensing Board also noted at least two other instances during which the service technician did not have required radiation monitoring equipment. See 31 NRC at 550.

reasonably concluded that such actions could "compromise the safety of the unit and result in increased exposure levels"⁴² and thus were required to be performed or supervised by a "licensed" engineer approved by the NRC or the Isotope Committee.

In the absence of any supporting affidavit, document, or other proffered evidence, AMS's simple denial that certain work performed by service technicians Light and Fortier was "licensable" is not compelling. See Cleveland Electric Illuminating Co. (Perry Nuclear Power Plant, Units 1 & 2), ALAB-443, 6 NRC 741, 754 (1977). AMS has not rebutted the conclusion that these activities, as supported by staff's affidavit, affected the teletherapy units in such a way that brought them within the scope of licensed service operations under AMS's license and procedures. See, e.g., McCann Affidavit ¶¶ 38, 48, 55, 59, & 69. Indeed, we are unable to find in AMS's appeal brief any challenge to the Board's acceptance of the staff's statements of material fact regarding the significance of various portions of the teletherapy unit to the safe operation of the unit. Even in AMS's answer to the staff's motion for summary disposition, AMS responds for the most part by merely disputing any "alleged improprieties" suggested in the staff's statements. Compare, e.g., Staff's Statements of Fact Nos. 24-26 & 29 with AMS Brief in Opposition to NRC Staff's Motion for Summary Disposition at 32, ¶

⁴² Factory Training Course at 9 (MSD Attachment 2).

The remaining instances of allegedly unauthorized maintenance that the Licensing Board deemed material involved replacement of the teletherapy unit's timer mechanism which controls the amount of time that the patient is exposed to the radioactive source. Mr. Leslie was sent to Munson Medical Center in Traverse City, Michigan, in April 1986 to replace a timer in the teletherapy unit's control console.⁴³ Although AMS quibbles with some of the words used in Mr. Leslie's statement to characterize his actions, AMS denies neither that Mr. Leslie was acting on AMS's behalf nor that Mr. Leslie worked on the timer device in the teletherapy unit. AMS Brief at 5. Moreover, AMS does not dispute that Mr. Fortier replaced the timers at Ball Memorial Hospital in Muncie, Indiana, in October 1985⁴⁴ and that Mr. Speer replaced a timer at St. Joseph's Hospital, St. Paul, Minnesota, in 1985.⁴⁵ Mr. Fortier operated the unit at Ball

⁴³ Interview of James M. Leslie (MSD Attachment 5).

⁴⁴ AMS Appeal Brief at 8; see Interview of Russell P. Fortier (MSD Attachment 11). Mr. Fortier states that he activated the teletherapy unit in connection with the timer replacement at Ball Memorial Hospital; AMS does not deny that he did so or that he was sent to the hospital on AMS's behalf, but contends either that he acted contrary to AMS policy or that a hospital employee with Mr. Fortier may have been authorized to operate the unit. Even if Mr. Fortier acted "contrary to AMS policy", the Commission may act to ensure that activities under the color of AMS's license comply with Commission requirements and do not endanger public health and safety. Not only is AMS's suggestion regarding the hospital employee's activities pure speculation, it also flies in the face of the restrictions of AMS's license procedures that require AMS employees to take control of the teletherapy unit during maintenance. Cobalt Service Procedures Manual at 2 (MSD Attachment 3).

⁴⁵ Interview of Richard G. Speer (MSD Attachment 23).

Memorial Hospital after timer replacement, a clear violation of license conditions and procedures that limit operation of the device to "licensed" service engineers.⁴⁶

AMS argues that timer replacement is not a "licensed operation" because replacement is a relatively simple operation and is performed outside the room wherein the radioactive source is located. AMS Appeal Brief at 5, 8. Although this may be true, AMS's argument misses the mark. The Licensing Board found that work on the timer mechanism, because it controls the amount of time that a patient is exposed to radiation, is work that could result in increased exposure to the source or compromise the safety of the unit and result in increased exposure levels. Therefore, the Board concluded that replacement of a timer was work that must be performed by "licensed" personnel -- which Messrs. Leslie, Fortier, and Speer were not.⁴⁷ The potential

⁴⁶ License No. 34-19089-01, Condition 11.B., and Cobalt Service Procedures Manual at 9 (MSD Attachments 1 & 3). AMS suggests that a hospital employee, identified only as "Fred" in Mr. Fortier's statement, who was present during Mr. Fortier's operation, could have operated the unit if he were a licensed individual under the hospital license. No basis for AMS's fanciful speculation is provided or even suggested in the record that could lead one to conclude a genuine dispute existed as to such facts. In any event, AMS's theory flies in the face of its license requirement that AMS take control of maintenance operations.

⁴⁷ See 31 NRC at 553. In further support of this conclusion, we take official notice of AMS's November 1984 revision of the Cobalt Service Procedures Manual, ISP-25, which was submitted to the NRC with AMS's November 12, 1984 license renewal application. The revised ISP-25 includes the Picker C-9 Maintenance Manual, H57:M, Revision A (March 1, 1979). Section 1, Page 1.0 of the C-9 Maintenance Manual contains a maintenance schedule for C-9 cobalt-60 teletherapy systems. The schedule
(continued...)

effect on the safety of the unit's operation is determinative of whether the maintenance is a "licensed operation" -- not the relative simplicity of a maintenance operation and not the locus of the technician's activity. Nowhere does AMS dispute that, as described in the staff's affidavit, the timer affects the amount of radiation exposure provided during operation of the teletherapy unit.⁴⁸

AMS overlooks the safety of patients who are treated with the unit or hospital employees who assist patients and operate the unit, all of whom could be affected by potentially improper maintenance by AMS employees not qualified or approved for such activities. We see nothing in AMS's license or procedures or in AMS's filings before the Board or us that support such a crabbed view of safety. We therefore affirm the Licensing Board's interpretation of the license and the related procedures.⁴⁹

⁴⁷(...continued)

lists various components and subsystems of the C-9 that require inspection, and states the frequency at which those inspections should be made. Several components listed on the schedule, including the treatment timer, are footnoted with an asterisk. The footnote reads:

* CAUTION: Service and/or adjustment may be performed only by personnel licensed by the NRC or an Agreement State to service Cobalt Units.

The reference indicates that AMS considered treatment timer service a licensable activity and belies AMS's persistent denial of the same throughout this proceeding.

⁴⁸ See McCann Affidavit ¶¶ 8, 30, 32, & 43.

⁴⁹ We note that this interpretation is consistent with contemporaneous generic licensing guidance on teletherapy units, which suggests a standard license condition limiting maintenance
(continued...)

AMS asserts that its management did not instruct the service technicians to undertake any activities that would violate AMS's license. AMS Appeal Brief at 8-9. AMS management's involvement in the violations has no bearing on whether violations may have occurred. It is clear that the service technicians were AMS employees acting on AMS's behalf. If their actions violated AMS's license or Commission regulations, AMS is accountable for the violations and appropriate enforcement action may be taken. Atlantic Research Corp., CLI-80-7, 11 NRC 413, 422 (1980).

In sum, AMS has failed to identify any error in the Licensing Board's determination that the work performed by the unlicensed service technicians fell within the scope of "licensable" activities. Therefore, we affirm the Licensing Board's conclusion that no genuine issue remained regarding the question of whether the staff had sufficient evidence to conclude that licensable activities were being conducted by unauthorized

⁴⁹(...continued)

or repair of any mechanism on the unit that could "expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels." Draft Regulatory Guide and Value/Impact Statement, "Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs", Task FC-414-4, Appendix H, at H-5 (Dec. 1985). The draft regulatory guide specifically defines "safety devices" as "timers, mechanical and electrical interlocks, warning lights and alarms, safety switches, door interlocks, beam collimators, and other devices that actively warn of, limit, or prevent radiation exposure to either patients or personnel." Id. at H-2. AMS referenced this description in its Brief in Opposition (at 13) to the staff's motion.

AMS personnel.⁵⁰ Having found that the staff possessed reliable, probative evidence indicating that violations of AMS's license had occurred, we next consider whether the evidence was sufficient to warrant an immediately effective suspension.

E. Suspension as a Sanction for the Violations

The Licensing Board determined that, based on the evidence of violations of license conditions that agency inspectors and investigators had gathered, the staff was well within its discretion to suspend AMS's license. AMS argues on appeal that the staff had no discretion to impose an immediately effective suspension. At most, AMS maintains, the staff could have issued a show-cause order. AMS's arguments against the Board's determination are unconvincing. The Licensing Board properly found that suspension of AMS's license was a reasonable remedy under the circumstances and was authorized by law.

Without question, the Commission is empowered to impose sanctions for violations of NRC regulations and licenses and to take remedial action to protect public health and safety from the potential effects of such violations or other unsafe practices. The Congress has authorized the Commission to issue such orders

⁵⁰ Although our review has focused on the threshold sufficiency of the staff's evidence as a basis for ordering an immediately effective suspension, the absence of any material dispute over the technicians' activities, coupled with our interpretation of the applicable regulatory requirements, indicates that summary disposition would be appropriate even as to the ultimate merits of the alleged violations. In other words, we see no material dispute with respect to the occurrence of the violations themselves that would have required a hearing under any circumstance in this case.

as "the Commission may deem necessary or desirable ... to protect health or minimize danger to life or property." AEA § 161b, 42 U.S.C. § 2201(b). As we stated in an earlier enforcement proceeding, "[t]he Commission's safety regulations and license conditions reflect the Commission's considered judgment as to what is required to protect the public as well as licensees' employees from the hazards inherent in the industrial use of radioactive byproduct material." Atlantic Research Corp., 11 NRC at 425 (1980). A violation of requirements subjects the violator to the full range of sanctions authorized under the Atomic Energy Act, including revocation of a license. See AEA § 186a and § 234, 42 U.S.C. § 2236(a) and § 2282. Within the limits of the agency's statutory authority, the choice of sanction is quintessentially a matter of the agency's sound discretion.⁵¹

1. *Staff's Basis for the Order's Immediate Effectiveness*

Based on the matters set forth in the order, the Director asserted the following rationale for making the order immediately effective under the provisions of 10 C.F.R. §§ 2.201(c) and 2.202(f):

⁵¹ See Butz v. Glover Livestock Comm'n Co., 411 U.S. 182, 185-87 (1973) (Congress intended to give agency administrators a broad grant of discretion to select the sanction that best serves to deter violations); Go Leasing, Inc. v. National Transp. Safety Bd., 800 F.2d 1514, 1518-19 (9th Cir. 1986) (agency administrator has discretion in selecting from among available sanctions); Robinson v. United States, 718 F.2d 336, 339 (10th Cir. 1983) ("once the agency determines that a violation has been committed, the sanctions to be imposed are a matter of agency policy and discretion").

[I]t appears that the licensee has demonstrated careless disregard for license requirements and, consequently, I lack the requisite reasonable assurance that the licensee will comply with Commission requirements in the future. Continued conduct of certain licensed activities could pose a threat to the health and safety of the public. Specifically, the performance of installation, service, maintenance, or dismantling of radiography or teletherapy units by unauthorized and unqualified individuals could result in the overexposure of individuals receiving or administering teletherapy treatment or performing maintenance or service on radiography or teletherapy units. Therefore, I have determined that the public health, safety and interest require that License No. 34-19089-01 be suspended....

51 Fed. Reg. 37,674.

AMS asserts that the Board erroneously concluded that the staff had a reasonable basis to find willful misconduct by AMS. AMS argues that the Board erred in concluding that there was no litigable issue with respect to AMS management's involvement in the violations. AMS Appeal Brief at 11.

We acknowledge that the staff seemingly invokes both the willfulness⁵² and the public health and safety grounds for making an order immediately effective. It does not appear to us, however, that the Licensing Board in sustaining the order made any particular findings with respect to willful behavior by AMS management. In its decision the Licensing Board found that the staff could readily conclude that "such maintenance, if carried out haphazardly or negligently, posed a great and immediate safety risk to both the person performing the maintenance and

⁵² Under our enforcement policy, conduct may be "willful" if it manifests, at a minimum, a careless disregard for requirements. See 10 C.F.R. Part 2, Appendix C, § IV.C (1994).

patients being treated by the teletherapy units." 31 NRC at 557. As indicated in this passage, the Board sustained the immediate effectiveness on the basis of the potential safety impact of the alleged violations underlying the order. Although the Board indicated that the technicians' failure to use radiation monitoring devices during certain maintenance could indicate "either a lack of respect for or a conscious disregard of radiation safety on the part of the AMS employees or its management," the Board emphasizes the adverse safety impact of such practices through the risk of undetected radiation exposure to AMS workers. 31 NRC at 557.

Because the Licensing Board rested on the public health and safety ground for immediate effectiveness and that ground is sufficient here to sustain the order's immediate effectiveness, we need not consider further whether the order could have been sustained on the basis of alleged willfulness. For the reasons that follow, we agree with the Board that the staff's judgment reflected a reasonable assessment of the significance and safety impact of the violations on which the suspension was based.

As the Licensing Board put it, "[t]he fundamental principle guiding all Commission licensing actions is the paramount consideration of public safety." 31 NRC at 554. The activities in question hardly concerned trivial matters, nor were they isolated occurrences. The alleged violations involved significant license conditions and procedures that were intended to provide assurance of the safe handling and maintenance of

devices containing radioactive material. In the order the staff emphasized the potential for radiation overexposure as a result of maintenance or service of equipment by unauthorized and unqualified persons in violation of the terms of the license. A teletherapy unit contains a high intensity radioactive source that can deliver a substantial -- even lethal -- radiation dose. See McCann Affidavit ¶¶ 7 & 10. As noted in the analysis of the alleged violations, the staff's affidavit further details the potential adverse effects from improper maintenance of a teletherapy unit. Id. at ¶¶ 32, 38, 43-44, 48, 51, 55-56, 60, and 69. AMS never controverted these basic facts. With information that the service technicians were undertaking activities for which they had neither completed the specified training nor obtained NRC or AMS's own committee approval, the staff could reasonably conclude that a suspension of the license was required to remove the potential for significant adverse safety consequences to patients, hospital workers, and AMS employees themselves. Additional information in the technicians' statements that they at times lacked the required radiation monitoring equipment or service manuals during their operations only magnifies the safety concern underlying the staff's order.

In its appeal, AMS maintains that the staff established no risk to public safety and that the staff's invocation of the "public health and safety" ground for immediate effectiveness exceeded its discretion and was inconsistent with NRC precedent. In arguing that no safety risk was posed by the technicians'

activities, AMS points to an affidavit that was prepared in February 1990 by a physicist at two client facilities served by AMS and submitted with AMS's answer to the staff's summary disposition motion.⁵³ All the affidavit says, however, is that during the shutdown of AMS's services, the affiant "discovered no health or safety risks with our teletherapy units." While it is indeed fortunate that no safety problems were discovered in the units, the affidavit has no real bearing on whether the staff acted reasonably in ordering the suspension. The affidavit does not controvert any of the basic facts concerning the technicians' maintenance activities (indeed, the facilities were not ones identified by the technicians as places where they had worked) or the potential hazards associated with an ill-maintained or improperly serviced unit. The affidavit does little more than view events from the easy vantage of hindsight.

The staff was called upon to make a prudent, prospective judgment at the time that the order was issued about the potential consequences of service operations undertaken in apparent violation of the license by unauthorized persons. A reasonable threat of harm requiring prompt remedial action, not the occurrence of the threatened harm itself, is all that is needed to justify immediate action to protect public health and safety. See Consumers Power Co. (Midland Plant, Units 1 & 2), CLI-74-3, 7 AEC 7, 10-12 (1974) (immediate suspension of

⁵³ AMS Appeal Brief at 16 (citing Affidavit of Dr. Arun Kaluskar, Attachment 15 to brief).

construction permit where latent conditions might not be subject to correction in future).

In arguing that the staff had no discretion to issue an immediately effective order, AMS maintains that the NRC lacked the discretion to choose among enforcement options, and that, if any sanction was called for, the agency could only have issued AMS a non-immediately effective order to show cause. AMS Appeal Brief at 26-27, 34. AMS's claims have no credible basis. AMS cites no statutory provision to support its claim that the Director's choice of a sanction violated a "statutory command" that the agency issue a show cause order. See id. at 28. Nor does AMS ever identify any NRC regulation which allegedly has been transgressed. Id. at 27, 34.

AMS relies on a wholly irrelevant analysis of the discretionary function exception under the Federal Tort Claims Act (FTCA). AMS submits that the NRC lacked decision-making discretion because its actions were "operational" in nature. AMS Appeal Brief at 35. To support this claim, AMS draws an analogy to cases brought under the FTCA, in which government agencies were found to have had a duty to take a particular action because they had become operators and not merely regulators. Id. at 35-36. The NRC's enforcement actions in this case bear no resemblance to the assumption of operational control and the performance of day-to-day management activities which occurred in these FTCA cases. As we noted earlier in our opinion, an agency's decision on how to proceed to enforce its regulations

and meet its statutory responsibilities involves at its core an exercise of discretion. The regulatory scheme under the Atomic Energy Act itself "is virtually unique in the degree to which broad responsibility is reposed in the administering agency, free of close prescription in its charter as to how it shall proceed in achieving the statutory objectives." Siegel v. AEC, 400 F.2d 778, 783 (D.C. Cir. 1968).

AMS suggests that the staff's action was inconsistent with Nuclear Engineering Co., supra, 9 NRC 673. AMS's argument is footed on the erroneous premise that the staff had issued a show cause order to the licensee before requiring immediate action from the licensee in Nuclear Engineering Co. See AMS Appeal Brief at 18, 26-27. However, the order in that proceeding, just like the one at issue here, contained both a "show-cause" provision as well as an immediately effective provision requiring specified action pending the outcome of further proceedings. Just as AMS was compelled to suspend certain operations upon issuance of the order, Nuclear Engineering Company was required to resume immediately the responsibilities that it was attempting to abandon under its license. See 9 NRC at 675.

AMS also notes that the staff deferred issuance of an order in Nuclear Engineering Co. until it had inspected the licensee's facility twice. AMS Brief on Appeal at 26; see 9 NRC at 678. The Commission relied on the inspections in Nuclear Engineering Co. to ensure that there was an adequate factual basis, and not mere speculation, to support the staff's order. We see no weaker

basis for immediate action in the instant case. The staff based its order on interviews of persons who had direct knowledge of the service operations at issue. The staff made a reasonable judgment that violations had occurred which could have potentially significant safety consequences. This was an "inquiry appropriate to the facts asserted" and sufficient to warrant an immediately effective order. Nuclear Engineering Co., 9 NRC at 678.

F. *Other Asserted Flaws in the Licensing Board's Decision*

In addition to its disagreement with the Licensing Board's resolution of the factual and legal issues underlying the staff's order, AMS argues that the Licensing Board erred by failing to consider certain other evidence in the record or by failing to resolve other issues. On both counts, AMS's arguments fail.

1. *The Licensing Board's Focus on Evidence Known Prior to Issuance of the Order.*

AMS contends that the Licensing Board erred in focusing on the evidence that was available to the staff on the day that the order was signed.⁵⁴ AMS claims that the Board's decision departs from our earlier decision in Nuclear Regulatory Comm'n (Licensees Authorized to Possess or Transport Strategic

⁵⁴ AMS Appeal Brief at 23. AMS's position on appeal is at odds with the position it took before the Regional Administrator in late 1986 when AMS sought withdrawal of the suspension order and before the Licensing Board when it sought a stay of the order. See AMS Brief in Rescindment of Suspension Order, at 43 (MSD Attachment 36); Memorandum in Support of Application of Advanced Medical Systems, Inc. for Stay of the Effectiveness of Decision, at 5 (Jan. 16, 1987).

Quantities of Special Nuclear Material), CLI-77-3, 5 NRC 16, 19-20 (1977) (citing Consolidated Edison Co., supra, 2 NRC 173).

In its decision, the Board noted that the parties had sought factual findings on events that occurred or were documented after issuance of the order on October 10, 1986. Because the Board viewed AMS's issues as raising the question of whether the staff had acted lawfully or abused its discretion when the summary suspension order was issued, the Board focused its inquiry "only on the information available to the Director at the time he issued the order." 5 NRC at 542 n.5. Given that the only remaining issues for decision in this case concerned the rationale for the staff's initiation of the suspension, we think the Board properly focused on the adequacy of the evidence that the staff had amassed before issuing the order. As we have already noted, we expect the staff to take summary enforcement action if such action is necessary or prudent to protect public health and safety from imminent threat, but such action must be based on more than mere speculation or unfounded allegation. Thus, we would expect the Licensing Board in reviewing the staff's determination to concentrate, as it did in this case, on the probative value of the information within the staff's knowledge when the staff acted summarily to suspend the license.⁵⁵

⁵⁵ This is not to say that the staff would be barred from relying on additional evidence gathered after an immediately effective order is issued to defend the continued effectiveness of the order under the preliminary "adequate evidence" procedure (continued...)

Our earlier decisions in Nuclear Regulatory Comm'n and Consolidated Edison Co. do not mandate a different result. To begin with, both of those decisions concerned Commission review of a staff decision not to take enforcement action. The Commission was faced, therefore, in both instances with the question of whether the circumstances on which the staff relied to decline enforcement action still controlled and should guide the agency's future action toward the licensees. Even in Nuclear Engineering Co., a case closer to the one at hand, the question before the Commission centered on the continuation, pending hearing, of the immediate effectiveness of the order over the licensee's objection.

Unlike those cases, we are not faced with deciding whether the order should have some continuing or future effect or whether some other sanction should be imposed on AMS. The suspension of the license was lifted long ago, and even the conditions for the suspension's rescission ceased to have any operative effect when the Regional Administrator revoked the order in its entirety in late 1987. Thus, consistent with the issues AMS itself put in controversy, we are called to determine only whether the staff acted reasonably within the governing statutory and regulatory

⁵⁵ (...continued)
now codified in 10 C.F.R. § 2.202(c)(2)(i) (1994) or at a full hearing on the merits of the order. In many circumstances the staff may take summary action while continuing related investigations or inspections that may have a bearing on the ultimate outcome of the proceeding. The staff, however, may not issue an immediately effective order based merely on the hope that the staff will thereafter find the necessary quantum of evidence to sustain its immediate effectiveness.

parameters in initiating the license suspension. Our focus is necessarily on the evidence available at the time the order was issued.

Even if we were to agree with AMS that the Licensing Board should have expanded the scope of its review, AMS has not shown that a more expanded review would have led to a materially different result. For all its complaints about the Board's limited review of the evidence, AMS fails to identify any evidence in its appeal brief that the Board ignored which would suggest that the factual events underlying the order had not occurred or that the potential safety hazards of improperly maintained equipment were not significant.

From our own review of the record, we are unable to identify any evidence that would suggest a different result. The only additional evidence provided by AMS in its answer to the staff's summary disposition motion consisted of affidavits prepared in 1990 by a user of teletherapy devices serviced by AMS and by several former or current AMS employees who generally deny that they were directed to intentionally violate NRC requirements.⁵⁶ These affidavits, however, are immaterial, because they lack a tie to the events contemporaneous with the issuance of the order

⁵⁶ Affidavits of Edward Svirgel, Paul A. Carani, Michael Baruffa, Donna Ely, and Dr. Arun Kaluskar, attached to AMS Answer to Staff Motion for Summary Disposition. Mr. Svirgel also disputes that the control console key switch can cause the source to fail to close, but he indicates that it does turn on the source (thereby conceding the device falls within the definition of "licensable" activity in dispute); Mr. Baruffa avers that timers on the units are easy to replace, a point we have already found immaterial to the interpretation of the license condition.

and do not otherwise cast any doubt on the occurrence of the events relied upon by the staff or the alleged safety potential of the service technicians' actions.⁵⁷ Even if we look back to AMS's late 1986 submittal to the Regional Administrator seeking rescission of the suspension or AMS's subsequent application for stay, we do not find any evidence that would suggest the staff's suspension was ill-founded. The thrust of both of those documents is that the staff's interpretation of "licensed" activities was erroneous, not that the events had not occurred. Indeed, if we look, as AMS seems to suggest (AMS Appeal Brief at 23) at the other evidence gleaned up until the time the order was rescinded, we find the staff's position only strengthened by additional examples of unauthorized maintenance.⁵⁸ AMS did not deny the occurrence of the events described in the staff's documentation. Therefore, we see nothing in the record to suggest that the staff lacked a basis to take summary action.

2. No Other Issues Need Be Decided.

In its appeal, AMS also contends that it should be afforded a further opportunity to address the accusation of willfulness

⁵⁷ Were we determining whether the suspension should be reinstated or other sanction imposed or were it necessary to determine the relative culpability of AMS management for the practices at issue, we acknowledge that these later affidavits might have some relevance. However, no such issues remain for our determination.

⁵⁸ See, e.g., MSD at 16-17; Staff Statements of Material Facts As to Which No Genuine Issue Exists Nos. 31, 33, 36, 40-41, 43, 45-49, 58; NRC Inspection Rep't No. 030-16055/86-001(DRSS), at 27-30 (Attachment 11 to AMS's Jan. 16, 1987 Application for Stay).

against AMS and the alleged disparate treatment of AMS in the staff's issuance of a suspension order. AMS Appeal Brief at 11-12, 19. Neither issue merits further consideration.

As we noted earlier, the Licensing Board did not rest on a finding of willfulness to sustain the immediate effectiveness of the suspension, and neither do we rely on such grounds. Although the staff's order asserted AMS's apparent "careless disregard" for regulatory requirements, that assertion, even assuming that it was sufficient to support the order's immediate effectiveness, is not conclusive of AMS management's intent with respect to the circumstances set forth in the order.

We see no reason why the matter should be considered further. The staff "revoked the order in its entirety" in late 1987, and we are aware of no subsequent action that relies on AMS management's relative culpability or intent with respect to the violations connected with the 1986 order. The staff granted AMS's license renewal application in 1989. The period under the enforcement policy within which the violation would be considered as a basis for escalation of subsequent enforcement sanctions has long passed. See 10 C.F.R. Part 2, Appendix C, § VI.B.2(c) & Table 2 (1994). AMS has provided no basis to suggest it is subject to ongoing adverse consequences as a result of the order. In the absence of any such collateral effects of the order, no further hearing need be offered to explore AMS's "willfulness." See Advanced Medical Systems, Inc., CLI-93-8, 37 NRC 181, 186

(1993) (citing cases), appeal docketed, No. 93-3602 (6th Cir., June 3, 1993).

AMS also argues that the Licensing Board "erred in failing to find that AMS was treated differently from other similarly situat[ed] Licensees." AMS Brief at 18. AMS claims that, at the time it received the NRC order, unlicensed individuals employed by other byproduct material licensees were performing licensed work, yet the other licensees received only NRC Information Notice 87-18. Thus, AMS argues, the staff abused its discretion in issuing the suspension order by treating AMS in a disparate fashion.

This allegation of discriminatory enforcement is without merit. AMS must show both that other similarly situated licensees were treated differently and that no rational reason existed for the differential treatment. See Encyclopaedia Britannica v. FTC, 605 F.2d 964, 974 (7th Cir. 1979), cert. denied, 445 U.S. 934 (1980). AMS has never shown that there were other unit manufacturers or service licensees like AMS which had committed comparable violations.⁵⁹ The staff's issuance of Information Notice 87-18 does not demonstrate that the NRC had

⁵⁹ Indeed, the staff acted consistently with its suspension order to AMS by concurrently ordering safety checks at AMS's client hospitals and clinics as a remedial measure to ensure the safety of the teletherapy units. See 51 Fed. Reg. 37,676, 37,678, 37,682-83, 37,685-87 (Oct. 23, 1986) (orders to Ball Memorial Hospital, Eastside Radiology Imaging and Therapy Center, Munson Medical Center, V.A. Hospital, East Orange, N.J., V.A. Hospital Bronx, V.A. Medical Center, Allen Park, MI).

knowledge of particular licensees in violation of similar regulations or license conditions.

Even if AMS successfully had shown that other licensees in its class had engaged in identical unlawful activities, the NRC would not have been obliged to withhold issuance of the suspension order unless others were similarly sanctioned. The Commission may act against one firm practicing an industry-wide violation.⁶⁰ As the Supreme Court has observed,

[I]n the shaping of its remedies within the framework of regulatory legislation, an agency is called upon to exercise its specialized, experienced judgment.... [A]lthough an allegedly illegal practice may appear to be operative throughout an industry, whether such appearances reflect fact and whether all firms in the industry should be dealt with in a single proceeding or should receive individualized treatment are questions that call for discretionary determination by the administrative agency.

Moog Industries, Inc. v. FTC, 355 U.S. 411, 413 (1958). Indeed, it would be unfeasible for an agency to act against every violation. Heckler v. Chaney, 470 U.S. 821, 831 (1985); Baltimore Gas & Elec. Co. v. Heintz, 760 F.2d 1408, 1419 (4th Cir.), cert. denied, 474 U.S. 847 (1985).

Moreover, a sanction within the authority of an administrative agency is not rendered invalid because it is more severe than that issued in other cases. FCC v. WOKO, 329 U.S.

⁶⁰ See FTC v. Universal-Rundle Corp., 387 U.S. 244, 249-52 (1967) (FTC's refusal to withhold enforcement of a cease-and-desist order pending investigation of alleged industry-wide practices did not constitute a patent abuse of discretion); L.G. Balfour Co. v. FTC, 442 F.2d 1, 24 (7th Cir. 1971) (an order should not be set aside "simply because it was directed against a single violator" among many); Rabiner & Jontow v. FTC, 386 F.2d 667, 669 (2d Cir. 1967), cert. denied, 390 U.S. 1004 (1968).

223, 227-28 (1946). A rigid "uniformity of sanctions (which the licensee appears to think necessary) is neither possible nor required." Radiation Technology, Inc., ALAB-567, 10 NRC 533, 541 (1979). Differences in sanctions imposed may be due to any number of factors. Enforcement decisions inherently involve "the exercise of informed judgment on a case-by-case basis." Id. In sum, the ordering of enforcement priorities is left to the agency's discretion. See Heckler, 470 U.S. at 831-32; Heintz, 760 F.2d at 1419.

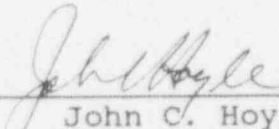
IV. Conclusion

In sum, the staff acted reasonably and had a substantial basis for issuing an immediately effective suspension order. The order was well within the agency's statutory and regulatory authority. Accordingly, AMS's appeal is denied, and LBP-90-17 is affirmed. The proceeding is hereby terminated.

It is so ORDERED.



For the Commission



John C. Hoyle
Acting Secretary of the Commission

Dated at Rockville, Maryland,
this 7th day of June 1994.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of
ADVANCED MEDICAL SYSTEMS, INC.

Docket No.(s) 30-16055-SP

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing COMM DECISION (CLI-94-6)-- 6/9 have been served upon the following persons by U.S. mail, first class, except as otherwise noted and in accordance with the requirements of 10 CFR Sec. 2.712.

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Docket No.(s)30-16055-SP
COMM DECISION (CLI-94-6)-- 6/9

Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
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Dated at Rockville, Md. this
9 day of June 1994


Office of the Secretary of the Commission