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UNITED STATES
NUCLEAR REGULATORY COMMISSION
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APR 09 1991

James Moss, President
Tulsa Gamma Ray, Inc.
1127 South Lewis Avenue
Tulsa, Oklahoma 74104

RE: TULSA GAMMA RAY, INC.
Docket No. 30-12319 - CIVP
License No. 35-17178-01

Dear Mr. Moss:

Enclosed please find a copy of the Atomic Safety and Licensing Board's opinion in *Advanced Medical Systems, Inc.*, LBP-91-09, dated March 19, 1991.

In my opinion this decision impacts directly upon your case on the issues of aggregation to severity level III and the amount of the penalty. I refer you specifically to pages 26-32 of the enclosed opinion. This is to advise you that I will be asking the Board in this case to follow the decision in *Advanced Medical Systems, Inc.*, on those two issues.

If you have any questions regarding this matter, please do not hesitate to contact me.

Thank you for your courtesies in this matter.

Sincerely,

Susan L. Uttal
Attorney, Office of the
General Counsel

Enclosure: As stated

cc: Service List

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LBP-91-09

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD

Before Administrative Judges:

Robert M. Lazo, Chairman
Harry Foreman
Ernest E. Hill

In the Matter of ADVANCED MEDICAL SYSTEMS, INC. One Factory Row Geneva, Ohio 44041	Docket No. 30-16055-CivP ASLBP No. 89-592-02-CivP (Civil Penalty) March 19, 1991

MEMORANDUM AND ORDER
(Granting NRC Staff Motion for Summary Disposition and Terminating Proceeding)

I.

In this enforcement action proceeding, the NRC Staff comes before the Atomic Safety and Licensing Board seeking a summary end to litigation concerning a civil penalty imposed on Advanced Medical Systems, Inc. ("AMS") of Geneva, Ohio, for alleged license violations occurring in late 1984. As a result of investigations conducted by the staff of the Nuclear Regulatory Commission, the Director of the Office of

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Inspection and Enforcement issued a Notice[1] in June of 1985 which concluded that four regulatory and license condition violations had occurred, together constituting a single Severity Level III violation under Commission policy considerations.[2] As a result of further investigations, the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operational Support issued an Order Imposing Civil Penalties in the amount of $6,250 against AMS in May of 1989.[3]

The Staff now comes before us seeking three independent determinations: 1) that there are no factual disputes remaining for hearing; 2) that there were violations of either Commission regulations or AMS license conditions; and 3) that the Director correctly interpreted Commission policy in his decision to impose the Severity Level III fine.

The four alleged violations are as follows:

1) An AMS employee received a whole body dose of 2.9 rems in the fourth calendar quarter of 1984. This dose exceeded the 10 C.F.R. § 20.101(a) limit of one and one

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[1]Advanced Medical Systems, Inc., Notice of Violation and Proposed Imposition of Civil Penalties, June 28, 1985.

[2]General Statement of Policy and Procedure for NRC Enforcement Actions, 10 C.F.R. Part 2, Appendix C.

[3]Advanced Medical Systems, Inc., Order Imposing Civil Monetary Penalties, May 30, 1989 (54 Fed. Reg. 24433, June 7, 1989).

quarter rem per calendar quarter because conditions provided in 10 C.F.R. § 20.101(b) which would permit a greater occupational dose were not applicable;

2) On November 6 and 21, 1984, inadequate radiation surveys of the Licensee's hot cell were conducted prior to entry of the cell by AMS employees. The Licensee's method of surveying the hot cell violated 10 C.F.R. § 20.201(b);

3) On the afternoon of November 21, 1984, two AMS employees failed to read their dosimeters at intervals consistent with the anticipated dose rate they would receive while working in the hot cell. This failure violates Condition 16 of the AMS license which references the AMS "Radiation Safety Procedures Manual, ISP-1," dated July 1983, Section 7.2.c.; and

4) The dosimeters used by the two individuals who worked in the hot cell on November 6 and 21, 1984, had not been calibrated for more than 180 days. The failure to calibrate dosimeters violates the AMS License Condition 16 which references Section E of the AMS application, which requires dosimeters to be calibrated at intervals of 180 days or less or before first use, if longer than 180 days since last calibration.

II.

In order for the Staff to prevail, it must first demonstrate that there are no material factual issues remaining in the case. The Commission's Rules of Practice

provide for summary disposition of a case where the statements of the parties in affidavits and other filings show there is no genuine issues of material fact.[4] If there are no material facts in dispute, the Board may rule for the moving party as a matter of law.

The party moving for summary disposition is required by Commission regulations to annex to the motion a separate, short and concise statement of the material facts as to which the moving party contends that there is no genuine issue to be heard.[5] The party opposing the motion is required by the same regulations to annex to any answer a separate, short, and concise statement of the material facts as to which it is contended there exists a genuine issue to be heard.[6] All material facts set forth in the statement required to be served by the moving party will be deemed to be admitted unless controverted by the statement required to be served by the opposing party.[7] A party opposing the motion may not rest upon the mere allegations or denials of its answer; its answer by affidavits or as otherwise

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[4] 10 C.F.R. § 2.749(d).

[5] 10 C.F.R. § 2.749(a); Dairyland Power Cooperative (LaCrosse Boiling Water Reactor), LBP-82-58, 16 NRC 512, 520 (1982).

[6] Id.

[7] Id.

provided by regulation must set forth specific facts showing that there is a genuine issue of fact.[8]

The burden of proof with respect of summary disposition is upon the movant who must demonstrate the absence of any genuine issue of material fact.[9] The record and affidavits supporting and opposing the motion must be viewed in the light most favorable to the party opposing the motion.[10] The opposing party need not show that it would prevail on the issues but only that there are genuine issues to be tried.[11] When a proper showing for summary disposition has been made by the movant, the party opposing the motion must aver specific facts in rebuttal. Where the movant has satisfied its initial burden and has supported its motion by affidavit, the opposing party must proffer countering evidential material or an affidavit explaining why it is impractical to do so.[12]

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[8] Id.; Texas Utilities Generating Company (Comanche Peak Steam Electric Station), LBP-82-17, 15 NRC 593, 595-96 (1982).

[9] Alabama Power Company (Joseph M. Farley Nuclear Plant, Units 1 and 2), ALAB-182, 7 AEC 210, 217 (1974).

[10] See Public Service Company of New Hampshire (Seabrook Station, Units 1 and 2), LBP-74-36, 7 AEC 877 (1974) and cases cited therein.

[11] Commonwealth Edison Company (Braidwood Nuclear Power Station, Units 1 and 2), LBP-86-12, 23 NRC 414, 418 (1986).

[12] Public Service Company of New Hampshire (Seabrook Station, Units 1 and 2), LBP-83-32A, 17 NRC 1170, 1174 n.4 (1983). We note at this juncture that AMS has neither

(continued...)

A.

The Staff's Motion sets forth five statements of material fact about which, the Staff claims, no genuine issue exists:

1) An AMS employee received a whole body dose of 2.9 rems in the fourth quarter of 1984;

2) On November 6 and 21, 1984 surveys of radiation levels at the door of the hot cell at the AMS facility were the only surveys made to assess the possible exposure of AMS employees who worked in the hot cell;

3) The surveys made at the door of the AMS hot cell on November 6 and 24, 1984 were not adequate to detect the radiation level within the hot cell;

4) On November 21, 1984 two AMS employees failed to read their dosimeters between entries to the hot cell;

5) Dosimeters used by two AMS employees on November 6 and 21, 1984 had not been calibrated for more than 180 days.

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[12](...continued)
attached affidavits to its Answer nor offered explanation as to why it chose not to do so. Instead, AMS has mounted its defense by relying on statements made in the transcribed interviews the Staff has attached to its Motion. Counsel for AMS is not unfamiliar with summary disposition procedures and the use of affidavits. See Advanced Medical Systems, Inc. (One Factory Row, Geneva, Ohio 44041), LBP-90-17, 31 NRC 540 (1990). While this tactic is not in itself fatal to the AMS cause (see Cleveland Electric Illuminating Company (Perry Nuclear Power Plant, Units 1 and 2), ALAB-443, 6 NRC 741, 752-7544 (1977)), it provided AMS with little in the way of direct, contradictory evidence to aid its effort to establish the existence of genuine issues of material fact.

We will address these factual contentions first, seriatim, then we will turn to the other issues in this proceeding.

B.

Contention 1. An AMS employee received a whole body dose of 2.9 rems in the fourth calendar quarter of 1984.

The Staff meets its initial burden by offering in support of its contention a signed letter from Harold Irwin of Advanced Medical Systems, Inc., dated March 8, 1985, sent to the U.S. Nuclear Regulatory Commission in which he states that an AMS employee received a 2,900 millirem exposure during the month of November, 1984.[13] This fact is further supported by a Radiation Detection Company (Sunnyvale, California) Dosimetry Report for the month of November, 1984 which shows the AMS employee named in the Irwin letter to have received 2,900 millirems of radiation during that time period.[14]

AMS does not dispute this statement of material fact in its Answer. The statement is deemed admitted.[15]

Contention 2. On November 6 and 21, 1984 surveys of radiation levels at the door of the hot cell at the AMS

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[13]Staff Motion, Attachment 1, Attachment D at 1.

[14]Id. at 5.

[15]All material facts set forth in the statement required to be served by the moving party will be deemed to be admitted unless controverted by the statement required to be served by the opposing party. 10 C.F.R. §2.749(a).

facility were the only surveys made to assess the possible exposure of AMS employees who worked in the hot cell.

The Staff offers the sworn and transcribed statements of two individuals present on the cell entries on November 6 and 21, "Individual A" and Glenn Sibert, respectively one of the AMS employees who entered the hot cell and his supervisor, and a third individual, Howard Irwin, who is a self-described "manager" in the AMS corporate hierarchy. The three individuals describe the pre-entry procedures conducted on the two dates in question. As described, one air sample reading was taken by remote sensor on each day to detect airborne contamination in the cell.[16] Also, one radiation survey was taken at the cell door each day using a hand held radiation monitor to detect non-airborne radiation levels within the cell.[17] AMS documents referred to as "ISP-18" also show that "stay time" estimates for individuals entering the cell were based on radiation levels detected at the cell door.[18]

The AMS Answer counters by stating that preparation for the cell entries "began several days in advance."[19] AMS

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[16]Staff Motion, Attachment 7 at 13-14; Attachment 8 at 26-28; and Attachment 6 at 24.

[17]Staff Motion, Attachment 6 at 14; Attachment 8 at 27-28, 47-48; and Attachment 7 at 24-27.

[18]Staff Motion, Attachment 1 at Attachment B.

[19]AMS Answer at 6.

offers statements by Glenn Sibert to support this assertion:[20]

> Prior to going into the cell we always picked and checked the cell for stray pellets, because the way they were buying the cobalt it comes in a canister and when you cut it open it flies in every direction. We had to spend at least two or three days scanning for pellets every time we went in. . . . With the probe, a Victoreen 500 meter . . . [we would scan [the cell] using manipulators. . . . We get it as low as we could get it with that meter. Then the next procedure was to get ready to go in."

Howard Irwin also agrees that remote probe radiation detection is performed prior to cell entry as part of the cell decontamination procedures.[21]

The AMS Answer misses the mark. Neither Mr. Sibert nor Mr. Irwin state that the remote sensor was used to assess possible exposure of AMS employees who worked in the hot cell on November 6 and 21. They say only that the remote sensor was used as part of the pre-entry decontamination procedures.[22] Although decontamination would have lowered

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[20]Staff Motion, Attachment 8 at 24-25.

[21]Staff Motion, Attachment 7 at 25-27.

[22]Two other points are tangentially significant. First, Glenn Sibert admitted that the remote probe "could only survey to a certain point, and then it got to the point where you had to open up the cell door and stick a meter in." Staff Motion, Attachment 8 at 59. Second, Howard Irwin admitted that the remote probe was not calibrated. Staff Motion, Attachment 7 at 26. It appears the remote probe would have been incapable of providing accurate

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the potential radiation risks in the hot cell, it is, in itself, immaterial to the Staff's assertion that the cell door surveys were the only surveys made to assess potential radiation exposure levels.

By not disputing the Staff's factual statement in its Answer the Licensee has failed to carry its burden. The statement is deemed to be admitted.

Contention 3. The surveys made at the door of the AMS hot cell on November 6 and 21, 1984 were not adequate to detect the radiation level within the hot cell.

As the foundation for this assertion, the Staff provides the results of the actual dosimeter readings taken from the hot cell entries conducted on November 6 and 21. The results demonstrate that the actual exposure readings were nearly 50% higher on both dates than the anticipated exposures calculated on the basis of the door surveys taken on those dates.[23]

There is little, if any, merit to the AMS rebuttal. The AMS Answer makes a series of assertions that skirt but do not confront the issue presented by the Staff. AMS points to Mr. Sibert's unsupported opinion that the cell

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[22](...continued)
measurements of potential radiation exposure even if it had been used. Therefore, whether or not the remote probe was used becomes immaterial to whether or not a regulatory violation occurred, as will be discussed, infra.

[23]Staff Motion, Attachment 1 at 4 and 6.

door would always have the greatest potential for radiation exposure; to Mr. Sibert's opinion that adequate surveys were performed; and the assertion that most of the required work leading to exposure would be conducted at the door to the cell.[24] In addition, AMS argues that "no evidence was ever presented to demonstrate that Mr. Sibert's results would have been different had he done his surveys any differently."[25]

These statements do little to either rebut the Staff's claim or to establish the existence of a material fact in dispute. As AMS admits, on both days the hot cell entries were made, the only calibrated radiation readings were ones conducted at the door of the hot cell by slightly opening the door and extending a hand held radiation detector into the cell. The Staff has presented direct evidence, in the form of signed AMS reports, that the cell door survey technique underestimated actual radiation exposure by 50% on both dates in question. AMS has neither challenged those readings nor offered an explanation for the underestimation.

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[24]AMS argues that since the cask containing the cobalt shipment is of such a substantial size, the employees do not actually enter the room when they wheel the cask in the hot cell. Therefore AMS asserts that the door survey is adequate. However, the November 6 entry entailed replacing light bulbs and a wall bracket, and the November 21 entry entailed replacing the frame, table top and trashbag, and the installation of the sink after the cask had been removed. Staff Motion, Attachment 1 at 5 and Attachment 9 at 25.

[25]AMS Answer at 7 and cites therein.

The Staff has presented unrefuted evidence that the radiation surveys conducted on November 6 and 21, 1984 were inadequate for the purposes of assessing radiation levels in the hot cell and AMS is remiss by not countering that factual assertion in its Answer. The fact is deemed to be admitted.

Contention 4. On November 21, 1984 two AMS employees failed to read their dosimeters between entries to the hot cell.

On November 21, the hot cell door was opened twice -- once in the morning and once in the afternoon. In the morning, Individuals A and B pushed cask containing cobalt-60 into the cell. There is no dispute that there occurred only one cell entry by each individual during the morning. After the cell door was closed that morning, Individual A checked his dosimeter but did not record the results.[26] Individual B believes he read his dosimeter after leaving the decontamination room and says he "probably" told someone the reading "out of habit."[27] There is no evidence that either of the dosimeter readings taken in the morning were ever recorded.[28]

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[26]Staff Motion, Attachment 6 at 35-36.

[27]Staff Motion at 26-27.

[28]While the morning entry plays no part in the dispute at hand, it is instructive in defining the AMS rebuttal argument.

In the afternoon, the cell door was again opened. After Individuals A and B entered the cell to move the cask out, they had trouble with the device that aids the movement of the cask. They stepped out of the cell into the decontamination room and moved behind the cell door to receive further instructions from Glen Sibert. After learning how to correct the problem, Individuals A and B again entered the cell, made the necessary adjustments, and moved the cask out of the cell. Next, Individual B reentered the cell to replace the frame and table top. Individual A then reentered the cell to install the sink and to replace the trash bag on the cell wall. Both Individual A and B state that at least three cell entries were made in the afternoon.[29] Both Individual A and B state that each read his dosimeter only after they exited the decontamination room when the work was completed.[30]

AMS counters with three arguments -- that only one cell entry was made in the afternoon; that Josephine Powell, whose job it was to monitor how long each individual remained in the cell, requested Individuals A and B to read their dosimeters through the P.A. system; and that

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[29]Staff Motion, Attachment 6 at 20; Attachment 8 at 25.

[30]Staff Motion, Attachment 6 at 20-21, 36; Attachment 8 at 26.

Mr. Sibert remembered Individual A and B checking their dosimeters and calling out an interim reading.[31]

The first argument would directly counter the Staff's assertion if in fact only two cell entries had taken place. Since both Individuals read their dosimeters after they left the decontamination room in the morning, and if there was only one cell entry in the afternoon, technically, an interim reading would have been taken prior to cell entry. However, the evidence upon which AMS relies to support this semantic argument is less than solid.

AMS points to statements made by Glen Sibert to argue that only two cell entries were made on November 21. In Mr. Sibert's opinion, a "typical cell procedure" amounted to "[p]ush[ing] the container in, unload[ing] it and pull[ing] it out of the cell. Just really two [entries]."[32] He repeatedly states that only two entries were made on November 21. However, this assertion becomes clearer when he admits that in his opinion, when the hot cell door is open, the hot cell and the decontamination room became one in the same for the purposes of a "cell entry," i.e., if the door is open, stepping out of the hot cell into the

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[31]AMS Answer at corrected page 8.

[32]Staff Motion, Attachment 8 at 52-53 and 70.

decontamination room does not mean that you had to "reenter" the hot cell.[33]

On the other hand, Mr. Sibert admits that the two AMS employees working in the hot cell had to come out and stand behind the cell door in the decontamination room to receive instructions when they started to have trouble removing the container.[34] He also admitted that if a person is in the decontamination room, that person cannot be in the hot cell.[35] More on point, earlier in his interview he directly contradicts his later statements concerning hot cell entries:[36]

> Q. I would like to have your definition of what constitutes an entry into the cell as far as time in the cell. While you're in the decontamination room, is it after you go into the cell itself?
>
> A. Into the cell itself. Decontamination room is one thing and the cell is different. Between the decon room and the cell you got 5-1/2 feet high density concrete and in the lab you got regular double doors with vents.

Mr. Sibert's inconsistent statements simply lack credibility.

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[33] Id. at 54.

[34] Id. at 53-54.

[35] Id. at 55.

[36] Id. at 38.

The AMS arguments alleging that "one minute dosimeter checks were requested by Josephine Powell through the P.A. system" and that "she let them know when to check their dosimeters"[37] do little to establish whether or not the dosimeters were actually read prior to cell entry or at appropriate intervals during the procedure. AMS has not offered any affidavit by Ms. Powell stating either that she made the requests or that she saw the dosimeters being read.

The closest AMS comes to directly challenging the Staff's statement is an assertion that Mr. Sibert recalled one of the individuals calling out an interim dosimeter reading of 160 millirems during the procedures.[38] However, this statement by Mr. Sibert also proves different than it appears on first blush:[39]

> Q. Do you know if on either event, the 6th or the 21st, they checked their dosimeters at the one-minute interval?
>
> A. I recall asking them what they picked up, and --
>
> Q. That would be --
>
> A. I asked [Individual A] and [Individual B] and it seems to me, like they told me, that they picked up 160MR.
>
> Q. Okay, that doesn't jive with the -- doesn't coincide with the information

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[37]AMS Answer at 8 (corrected page).

[38]AMS Answer at corrected page 8.

[39]Staff Motion, Attachment 8 at 51-52 and 70-71.

that they recorded. They got about 845MR dosimeter reading.

A. Yes. Is that for the 21st?

Q. Yes, we're on the 21st. That's the date.

A. Well, 845 is their final dosimeter reading.

Q. Okay, that was at the -- at the end of how many entries was that?

A. That would be -- their final dosimeter reading would be at the end of that work time. Now see, what had to be done that day, the container had to be put into the cell. I have to go out of the cell, or out of the lab, take a shower, get dressed, come back out to the cell window to get ready to unload this container.

While I'm getting it unloaded, these two are in the lab out of the high radiation area. They are out of the -- over by the view window where you can look into the lab, and they have to wait until I get that container unloaded before we make preparations to take the container out of the cell.

Q. Okay, so you remember them making how many dosimeter checks during those intervals?

A. I know one, 160, is what they told me they picked up, and that's about all I can remember.

. . . .

Q. Did these individuals that were working there read their dosimeters at the times indicated prior to entry and at times within the work period?

A. The dosimeters were read.

Q. Earlier you indicated that you don't recall seeing them read these

> dosimeters during the work period. Are you assuming they did?
>
> A. They did read them. You got to read them through a plastic bag.
>
> Q. Earlier in the interview you indicated that you don't recall having seen them do this. You just --
>
> A. No, I didn't see them. Like I said, I am not aware -- I can't be a mother hen to them. Otherwise -- I can't watch every move they make, because during the course of cobalt being put away I'm in and out, in and out.

On the basis of the statements made during the investigatory interviews, the 160 millirem reading was one taken after the two AMS employees left the decontamination room in the morning, prior to suiting up again for the afternoon entries. Both individuals remember reading their dosimeters at that time. Individual B stated that he probably called out his dosimeter reading. Both individuals have stated that they did not read their dosimeters during the afternoon procedures until they left the decontamination room for the final time.[40] AMS has offered no credible

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[40]The only other potential eye-witnesses to the hot cell entries would have been Josephine Powell and who ever was stationed at the monitoring window timing the entries. Mr. Sibert never saw the dosimeters being read and AMS failed to offer any affidavits by those persons who would have been at the monitoring window instructing that the dosimeters be read. Indeed, we find it peculiar that Counsel for AMS did not attach an affidavit from Ms. Powell.

evidence to raise a doubt as to the veracity of those statements.

Contention 5. Dosimeters used by two AMS employees on November 6 and 21, 1984 had not been calibrated for more than 180 days.

The AMS Answer states:[41]

> [T]he standard practice for calibration of dosimeters was to compare the dosimeter readings with film badge readings. . . . This practice modified a 1979 procedure which was found to be unworkable because it yielded a 25% discrepancy. . . . The NRC has never been able to produce any evidence that the dosimeters were not in calibration or that the method of calibration used in November, 1984 was not adequate.
>
> . . . .
>
> Once again, while the NRC Staff may dispute whether the calibrations were acceptable, there is testimony that calibrations were performed.

Unfortunately, both the Staff and AMS have either misstated or misinterpreted the material fact to be argued. The question is not whether the dosimeters were calibrated, because that is immaterial to the issue of whether the dosimeters were calibrated in the manner set forth in the AMS license agreement.[42] It is that fact that is germane to

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[41]AMS Answer at 8-9.

[42]The statement of material fact argued by the Staff should have more appropriately read: Dosimeters used by two AMS employees on November 6 and 21, 1984 had not been calibrated for more than 180 days <u>according to the</u>

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the issue of a license violation. Regardless, the pleadings and accompanying documents demonstrate that AMS has admitted deviating from license conditions with regard to the calibration of the dosimeters used in November 1984.[43] The issue is moot.

C.

We next address whether or not AMS has violated Commission regulations or conditions which are part of its own license agreement in order to determine the larger issue of whether the Director's actions were correct with respect to the imposition of the monetary penalty against AMS. To do so, we once again revisit the four violations as they are set forth in the Notice of Violation of June 28, 1985 and the Staff Summary Disposition Motion.

Violation 1. An AMS employee received a whole body dose of 2.9 rems in the fourth calendar quarter of 1984. This dose exceeds the 10 C.F.R. § 20.101(a) limit of one and one quarter rem per calendar quarter. Conditions provided in 10 C.F.R. § 20.101(b) which permit a greater occupational dose are not applicable in this situation.

On May 24, 1988, Dr. Seymor Stein, President of AMS, wrote to the Director, Office of Inspection stating, without

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[42](...continued)
calibration techniques set forth in the AMS license agreement.

[43]Staff Motion, Attachment 3 at 3-4, and Attachment 7 at 35-37.

qualification, that "AMS wishes to concede that technically a violation of 10 CFR 20.101(a) did occur."[44] The Board finds no reason to disagree.

Violation 2. On November 6 and 21, 1984, inadequate surveys at the door of the hot cell at the AMS facility were made. This failure to adequately survey a high radiation area, prior to potential exposure to humans, violates 10 C.F.R. 20.201(b).

10 C.F.R. 20.201(a) requires that each licensee make such surveys as may be necessary to comply with all sections of 10 C.F.R. Part 20. As defined in 10 C.F.R. § 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. Mr. Sibert stated that the only survey of the radiation level in the hot cell was the one taken at the door to the cell and the

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[44]Staff Motion, Attachment 4. 10 C.F.R. § 20.101(a) limits the whole body dose of an individual in a restricted area to one and one quarter rems per calendar quarter, except as provided by 10 C.F.R. § 20.101(b). The technical violation involved AMS's failure to document Individual B's past exposure levels under § 20.101(b)(1) prior to his entry into the hot cell in November. The only written record of Individual B's exposure history extant was signed in January 1985 -- after Individual B had received a 2.9 rem dose of radioactivity -- and post-dated to September 1984 to make it appear that regulations had been complied with. See AMS Answer at 4.

air sample to determine airborne contamination.[65] Howard Irwin also stated that the in-cell monitor was only used for decontamination and not to assess the amount of time workers could stay in the hot cell.[66] Moreover, the in-cell monitor was not calibrated during the November entries.[67] When a comparison is made between the exposure estimate based on the cell door survey and the actual dose received by the two employees, the calculation from the cell door survey underestimates the actual exposure by 50%.[68] As we have already noted, a radiation survey with a margin of error of 50% is not a reliable survey capable of protecting health or promoting safety in any stretch of the imagination. We can find no fault with the Director's decision pertaining to this violation of 10 C.F.R. §§ 20.201(a) and (b).

Violation 3. On November 21, 1984, two AMS employees failed to read their dosimeters at intervals consistent with the anticipated dose rate. This failure violates Condition 16 of the AMS license which references the AMS "Radiation

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[65]Staff Motion, Attachment 8 at 25 and Attachment 6 at 13-15, 19.

[66]Staff Motion, Attachment 7 at 25-27.

[67]Staff Motion, Attachment 7 at 26.

[68]Staff Motion, Attachment 1 at 4-6. AMS personnel should have become aware of the discrepancy between the estimated and actual exposure after the November 6 entry. However, no corrections were made, based on the information gathered on November 6, prior to the November 21 entry.

Safety Procedures Manual, ISP-1," dated July 1983, Section 7.2.c.

License Condition No. 16 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in "Radiation Safety Procedures Manual, ISP-1" dated July 1983. Section 7.2.c. "Personnel Monitoring" of ISP-1 states, "Work in high dose areas will be preceded by a survey with appropriate monitoring equipment and an estimated total accumulated exposure determined. . . . The pencil type dosimeters will be read at intervals consistent with the anticipated dose rate to determine that the actual exposure is not greater than the anticipated exposure."[49]

There is no dispute that on November 21, 1984, two individuals worked in the licensee's hot cell, an area where high radiation levels exist.[50] The licensee estimated a

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[49]The Staff's reliance upon supporting documents as the basis for license requirements is consistent with the Atomic Energy Act, Commission regulations and past Commission practice. See Atomic Energy Act of 1954, Section 182(a), 42 U.S.C. § 2232 (Commission authority to require supplemental information from license applicant and to incorporate such into license); 10 C.F.R. § 30.34; 10 C.F.R. § 35.26(b); Preamble to NRC Form 374 (5-84). Also, in late 1986, the Commission published notice in the Federal Register of its revision to 10 C.F.R. Parts 30-35. Final Rule, 51 Fed. Reg. 36,932 (1986). In that notice, the Commission gives a clear account of its regulatory program and licensing practices regarding byproduct material licenses of the type issued to AMS. See id. at 36,933.

[50]On April 25, 1985, the licensee made a survey of the interior of the hot cell utilizing a Victoreen 500

(continued...)

work exposure for the day to be approximately 750 millirems and established one minute as the "maximum allowable exposure time before checking dosimeters."[51] When the two individuals who entered the hot cell read their dosimeters for the first time that afternoon (upon exiting the decontamination room), both 1 rem dosimeters were off-scale. Individual A had received a 1625 millirem dose and Individual B had received a 1600 millirem dose for that day, more than twice the estimated dose for each person. Had the dosimeters been read consistent with anticipated dose rates, at approximately one minute, the overexposures should not have occurred.

AMS has produced no evidence to support a claim that dosimeters were read consistent with anticipated dose rates. The two individuals who entered the cell have both stated that they did not read their dosimeters until the end of the procedure. There is sufficient, unrebutted evidence to find a violation of License Condition 16.

Violation 4. On November 6 and 21, 1984, the licensee allowed two individuals to enter a high radiation area

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[50](...continued)
Electrometer with a model 550-6A high energy probe. The survey showed radiation levels inside the cell as high as 81 rems per hour. This amount was approximately four times higher than the radiation level used by the licensee when calculating cell stay times during November.

[51]Staff Motion, Attachment 1, Attachment C at page 1 of 2.

equipped with dosimeters that had not been calibrated within a 180 day time period prior to their use.

License Condition No. 16 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application received July 16, 1979, and in certain referenced documents. Schedule E of the application states that dosimeters will be calibrated at intervals of 180 days or less or before first use if longer than 180 days since last calibration. The licensee is required, in accordance with the provisions of License Condition No. 16, to calibrate dosimeters by using a calibrated (cobalt) radiation source.[52] Both Dr. Stein and Howard Irwin acknowledged that dosimeter calibration procedures at AMS involved calibrating dosimeters by comparison with film badge readings instead of the procedure found in the AMS license agreement.[53]

AMS is bound by its license agreement to follow the conditions of that agreement which clearly called for calibration by radiation source. Calibration by radiation source is the method used throughout the nuclear industry and is the only calibration method currently approved by the

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[52]Staff Motion, Attachment 5, Appendix at 4.

[53]Staff Motion, Attachment 3 at 3-4, and Attachment 7 at 35-37.

Commission.[54] By its own admission, AMS failed to follow license conditions in the calibration of its dosimeters. We therefore have no alternative than to find AMS in violation of License Condition No. 16.

III.

The Staff Motion requests the Board's concurrence that the imposition of a civil penalty of six thousand two hundred fifty dollars is "consistent with Commission policy."[55] The Staff has attached to its Motion an affidavit of James Lieberman, Director of the Office of Enforcement which explains that the Staff's calculation of the amount of the civil penalty is in accordance with the Commission's "General Statement of Policy and Procedure for NRC Enforcement Actions."[56] In his affidavit, Mr. Lieberman states that the four violations are considered collectively as a Severity Level III violation as defined in the Policy Statement at Section C.4. of Supplement IV and Section C.1. of Supplement VI. Under Table 1B (Base Civil Penalties for Severity Levels) the base civil penalty amount for a Severity Level III violation is 50 percent of the amount

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[54]Staff Motion, Attachment 5 at 4.

[55]Staff Motion at 11.

[56]10 C.F.R. Part 2, Appendix C.

listed in Table 1A, or in this case, $5,000. Mr. Lieberman goes on to state:[57]

> As provided in the Policy [Statement] under Section IV.B.3., the base civil penalty was increased by 25% in the June 28, 1985 Proposed Civil Penalties Notice because of the failure of AMS to implement previous corrective action for prior similar problems. Specifically, a March 1983 inspection resulted in a July 13, 1983 order Imposing Civil Monetary Penalties of $4,000 because of circumstances surrounding an overexposure . . . . in or near the licensee's hot cell. . . . Those circumstances were similar to circumstances described in the June 28, 1985 Notice . . . . and included failure to follow procedures for checking dosimeters while working in a high dose rate area.

The AMS answer does not follow the usual procedural pleading the Board has seen most often in enforcement proceedings involving the imposition of civil penalties. It is the case, more often than not, that licensee's counsel seeks mitigation of the civil penalty.[58] Instead, AMS argues that the NRC Staff "erred in considering the alleged four violations to be collectively at a Severity Level

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[57]Staff Motion, Affidavit of James Lieberman (attached) at 2.

[58]AMS does cite portions of the Commission's Policy Statement regarding the imposition of civil penalties which have bearing on the mitigation of those penalties. However, no argument is made that these considerations were improperly overlooked in the Director's decision to impose the penalties.

III . . . due to the fact that they do not meet any of the conditions of Severity Level III either collectively or singularly . . . . [and] would be, at most, Level IV, not Level III [violations]."[59]

We have chosen to set out those portions of 10 C.F.R. Part 2, Appendix C -- General Statement of Policy and Procedure for NRC Enforcement Actions -- in this text because the language of that Statement leaves no room for doubt that the Director's decision to levy a Severity Level III violation finds its foundation in those guidelines:

> The following statement of general policy and procedure explains the enforcement policy and procedures of the U.S. Nuclear Regulatory Commission and its staff in initiating enforcement actions, and of presiding officers . . . . in reviewing these actions. . . .
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> . . . .

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[59]AMS Answer at 25. Counsel for AMS mounts this challenge in a portion of the AMS answer entitled V. STATEMENT OF MATERIAL FACTS WHICH ARE IN DISPUTE. AMS Answer at 25. Counsel goes on to state:

> The basis of Mr. Lieberman's judgement certainly raises a question of material fact. . . . [E]ven if the violations were properly Level III violations, James Lieberman's statement that the imposition of the fine as being in accordance with 10 CFR Part 2, Appendix C . . . . is a material fact in dispute."

AMS Answer at 25-26. If the basis for the Director's judgement is to be upheld in accordance with Commission regulations, it is clearly a question of law that will determine the outcome.

The purpose of the NRC enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety . . . . by:

* Ensuring compliance with NRC regulations and license conditions; . . .

* Deterring future violations and occurrences of conditions adverse to quality;

* Encouraging improvement of licensee and vendor performance . . . .

. . . .

. . . . Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

. . . .

. . . . Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern.

. . . .

. . . . While examples are provided in Supplements I through VIII for determining the appropriate severity level for violations in each of the eight activity areas, the examples are neither exhaustive nor controlling. . . . Each of the examples in the supplements is predicated on a violation of a regulatory requirement. . . . In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

. . . .

> . . . . Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations. . . . Civil penalties are proposed absent mitigating circumstances for Severity Level I and II violations, are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar[3] to previous violations for which the licensee did not take effective corrective action.
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> [3]The word "similar," as used in this policy, refers to those violations which could have been reasonably expected to have been prevented by the licensee's corrective action for the previous violation.
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> . . . .
>
> NRC reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. . . .

Under Appendix C, Supplement IV the Director identified an example of a Severity Level III violation with significantly similar, if not identical, circumstances surrounding the AMS violations of 10 C.F.R. §§ 20.101 and 20.102 regarding adequate radiation surveys and worker safety:

> Substantial potential for an exposure or release in excess of 10 C.F.R. 20 whether or not such exposure or release occurs (e.g., entry into high radiation areas, such as under reactor vessels or

> in the vicinity of exposed radiographic sources, without having performed an
>
> adequate survey, operation of a radiation facility with a nonfunctioning interlock system);[60]

Under Appendix C, Supplement VI the Director identified another example of a Severity Level III violation that, while broader in scope than the previous example, is representative of the licensee's obligation to follow the express conditions of its materials license agreement under 10 C.F.R. Part 30 through 35 regarding materials operations:[61]

> Failure to control access to licensed materials for radiation purposes as specified by NRC requirements;[62]

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[60] 10 C.F.R. Part 2, Appendix C, Supplement IV -- Severity Categories, Health Physics 10 C.F.R. Part 20, § C.4.

[61] In this context, 10 C.F.R. 30.34(e) states: The Commission may incorporate, in any license issued pursuant to the regulations in this part and Parts 31 through 35 and 39, at the time of the issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer or byproduct material as it deems appropriate or necessary in order to: . . . . Protect health or to minimize danger to life or property.

[62] 10 C.F.R. Part 2, Appendix C, Supplement VI - Severity Categories, Fuel Cycle and Materials Operations, § C.1.

We see no reason to disturb that portion of the Director's analysis. Moreover, even if we were to consider the AMS violations to be Severity Level IV violations, the policy guidelines clearly allow the Director the discretion to impose fines for Level IV, especially in the case of repeated violations, as is the case here.[63] The AMS argument that its violations amount to "Level IV, not Level III" violations carries no weight. Accordingly, we find the Director's decision to impose the civil penalty in the amount of $6,250 to be fully in accordance with Commission policy and see no reason to overturn the decision or to mitigate the penalty.

IV.

There remains one matter the Board has decided on its own to address. Counsel for AMS has argued that "Summary Disposition is not the appropriate administrative action to take . . . ."[64] Counsel opines that "all interrogatories [sic] were conducted in the absence of AMS's Counsel. As such, AMS has had no opportunity for cross-examination."[65] Counsel borrows language from Poller v. Columbia

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[63]As stated earlier, AMS was fined $4,000 in 1983 for an overexposure with circumstances similar to the circumstances occurring in November, 1985.

[64]AMS Answer at 30.

[65]AMS Answer at 11.

Broadcasting System, Inc., 368 U.S. 464 (1962) to support an argument that can be interpreted no other way than to imply that AMS has been denied due process if summary disposition is granted. A succinct statement from Poller has been used in the AMS Answer to illustrate this point:[66]

> Trial by affidavit is no substitute for trial by jury which so long has been the hallmark of 'even handed justice'.

We do share the same view of summary disposition in the matter before us, for two reasons. First, from the time AMS petitioned for a hearing on this matter (June 20, 1989), or even from the time of the filing of the Staff's Motion (August 29, 1990) to the time the AMS Answer was submitted (October 4, 1990), there was significant passage of time to engage in voluntary discovery and to solicit interrogatories and affidavits from the people who would have been most informed on the circumstances taking place on the dates in question. There are many indications that AMS had direct access to the facts, as it appears that several of the individuals AMS relies on to make its case are either AMS employees or ex-employees located within close proximity to the AMS facilities. Moreover, even if adversarial posturing could have inhibited the effectiveness of voluntary discovery, we find nothing in the Commission's regulations

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[66] Poller, supra 368 U.S. at 473.

that would have prohibited Counsel for AMS from petitioning the Board for formal discovery even prior to a prehearing conference.[67]

Second, our reading of Poller shows that case to be concerned with issues not present in the case before us -- foremost among them, conspiracy. AMS misquotes from Poller the exact language that should have alerted Counsel that the case is inapposite:[68]

> We look at the record on summary judgement in the light most favorable to . . . . the party opposing the motion, and conclude here that it should not have been granted. We believe that summary procedures should be used sparingly in complex antitrust litigation where motive and intent play leading roles, the proof is largely in the hands of the alleged conspirators, and hostile witnesses thicken the plot. [Emphasis supplied] It is only when the witnesses are present and subject to cross-examination that their credibility and the weight to be given their testimony can be appraised.

There is no motive or intent at issue here, just facts. If there is no material factual dispute and the case can be decided as a matter of law, no due process has been denied.

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[67]The regulatory prohibition against discovery prior to a prehearing conference found in 10 C.F.R. § 2.740(b)(1) is limited to "an application for a construction permit or an operating license for a production or utilization facility."

[68]AMS Answer at 11, quoting Poller, supra, 368 U.S. at 473. We note with disapproval that Counsel for AMS omitted the Justices' reference to "antitrust" litigation in the cited paragraph in its Answer.

V.

For all the foregoing reasons and upon consideration of the entire record in this matter, it is this 19th day of March, 1991.

ORDERED

(1) the NRC Staff Motion for Summary Disposition (August 29, 1990) is granted;

(2) Advanced Medical Systems, Inc. of Geneva, Ohio is found to have violated Commission regulations and license conditions as those violations have been set forth in the Notice of Violation and Proposed Imposition of Civil Penalties (June 28, 1985);

(3) the Order Imposing Civil Monetary Penalties (May 30, 1989) in the amount of $6,250 issued by the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operational Support is sustained; and

(4) there being no additional issues pending in the matter, this Civil Penalty proceeding is terminated.[69]

Pursuant to 10 C.F.R. § 2.762, within ten days after its service, any party may appeal this Memorandum and Order by filing a Notice of Appeal with the Commission. Each appellant shall file a brief supporting its position on appeal within thirty (30) days, (or within forty (40) days

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[69]One companion case remains pending: In the Matter of Advanced Medical Systems, Inc. (Decontamination Order) Docket No. 30-16055-OM, ASLBP No. 87-555-01-OM.

if the Commission Staff is the appellant) after the filing of the Notice of Appeal.[70]

THE ATOMIC SAFETY AND
LICENSING BOARD

Robert M. Lazo

Robert M. Lazo, Chairman
ADMINISTRATIVE JUDGE

Robert M. Lazo for

Harry Foreman
ADMINISTRATIVE JUDGE

Robert M. Lazo for

Ernest E. Hill
ADMINISTRATIVE JUDGE

[Administrative Judges Harry Foreman and Ernest E. Hill concur with this Memorandum and Order but were unavailable to sign this final draft of the decision.]

Bethesda, Maryland
March 19, 1991

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[70] See 10 C.F.R. § 2.785 as amended October 18, 1990 (55 Fed. Reg. 42,944, October 24, 1990).