

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of)
)
ADVANCED MEDICAL SYSTEMS, INC.) Docket No. 30-16055-CP
One Factory Row)
Geneva, Ohio 44041) (Civil Penalty)

STIPULATION FOR SETTLEMENT OF THE PROCEEDING

I.

On May 30, 1989, the NRC staff (Staff) issued to Advanced Medical Systems, Inc. (AMS) an "Order Imposing Civil Monetary Penalties" (Order) in the amount of \$6,250.00, for four violations of NRC regulations, set out in a "Notice of Violation and Proposed Imposition of Civil Penalties" dated June 28, 1985. AMS requested a hearing on the Staff's Order on June 20, 1989. By Memorandum and Order dated March 19, 1991, the Atomic Safety and Licensing Board (Licensing Board) granted the Staff's motion for summary disposition of the proceeding and sustained the Staff's Order. *Advanced Medical Systems, Inc. (One Factory Row, Geneva, OH)*, LBP-91-9, 33 NRC 212 (1991). AMS appealed the Board's decision on April 26, 1991. By Memorandum and Order dated September 30, 1993, the Commission affirmed in part, and reversed and remanded in part, the Board's decision. *Id.*, CLI-93-22, 38 NRC 98 (1993). In its decision, the Commission directed the Board to give further consideration to the evidence concerning Violation 2 (inadequate survey) and to reconsider the severity level and civil

penalty imposed by the May 30, 1989 Order. Following the Commission's denial of motions for reconsideration filed by the Staff and AMS, the Licensing Board issued an order dated December 14, 1993, in accordance with the Commission's direction, requiring the Staff to file a "motion regarding the adequacy of the AMS survey and the possible termination of this proceeding." *Id.* at 3.

In December 1993 and January 1994, the Staff and representatives for AMS discussed the possibility of reaching an agreement concerning the civil penalty order and settlement of the proceeding. These discussions resulted in a verbal agreement between the parties that AMS would pay \$1800.00 in full settlement of the May 30, 1989 Order; and AMS does not admit or deny Violations 1-3 or the Severity Level classification in the Order and the "Notice of Violation and Proposed Imposition of Civil Penalties" dated June 28, 1985.

The parties have entered into this Stipulation for settlement of this proceeding, subject to the approval of the Atomic Safety and Licensing Board, in lieu of presenting testimony at trial and further adjudication of any issue of fact or law regarding Violation 2, the amount of civil penalty, or the Severity Level classification contained in the Staff's May 30, 1989 Order. The parties acknowledge that the terms and provisions of this Stipulation, once approved by the Atomic Safety and Licensing Board, shall be incorporated by reference into an order, as that term is used in subsections (b) and (o) of section 161 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. § 2201, and shall be subject to enforcement pursuant to the Commission's regulations.

II.

NOW THEREFORE, IT IS STIPULATED AND AGREED by and between the NRC Staff and Advanced Medical Systems, Inc. as follows:

1. Payment by Advanced Medical Systems, Inc. of a civil penalty of \$1800.00, in accordance with paragraph 2 below, shall constitute full satisfaction of the "Order Imposing Civil Monetary Penalty" issued to AMS on May 30, 1989.

2. Within 30 days of the date of approval of this Stipulation by the Atomic Safety and Licensing Board, Advanced Medical Systems, Inc. shall pay a civil penalty in the amount of \$1800.00, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States. Payment by mail shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

3. Advanced Medical Systems, Inc. does not admit or deny Violations 1-3 or the Severity Level classification in the "Order Imposing Civil Monetary Penalties" dated May 30, 1989, and "Notice of Violation and Proposed Imposition of Civil Penalties" dated June 28, 1985.

4. The NRC Staff and Advanced Medical Systems, Inc. waive their rights to further hearings concerning Violation 2, the civil penalty, and the Severity Level classification described in the Staff's May 30, 1989 "Order Imposing Civil Monetary Penalties", and waive any right to contest or otherwise appeal this Stipulation in any

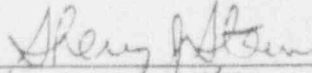
administrative or judicial forum, once approved by the Atomic Safety and Licensing Board.

FOR THE NRC STAFF:

FOR ADVANCED MEDICAL SYSTEMS, INC.:



Colleen P. Woodhead 2/2/94
Counsel for NRC Staff



Sherry J. Stein 2/4/94
Counsel for AMS

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.)	Docket No. 30-16055-CivP-R
One Factory Row)	ASLBP NO. 93-682-01-CivP-R
Geneva, Ohio 44041)	(Civil Penalty)

ORDER APPROVING AND INCORPORATING
STIPULATION FOR SETTLEMENT OF PROCEEDING
AND SETTLING AND TERMINATING THE PROCEEDING

Upon consideration of the Joint Motion for Order Approving and Incorporating Stipulation for Settlement of Proceeding and Settling and Terminating the Proceeding, and upon consideration of the Stipulation for Settlement of the Proceeding executed by the NRC Staff and Advanced Medical Systems, Inc., we find that settlement of this matter as proposed by the parties is in the public interest and should be approved. Accordingly, before the presentation of any testimony at trial or further adjudication of any issue of fact or law regarding Violation 2, or the amount of civil penalty, or the classification of the Severity Level contained in the NRC Staff's May 30, 1989 Order Imposing Civil Monetary Penalty issued to AMS, and upon the consent of the parties, the Stipulation for Settlement of Proceeding is hereby approved and incorporated into this Order, pursuant to Section 81 and Subsections (b) and (o) of Section 161 of the Atomic Energy Act, as

amended, 42 U.S.C. §§ 2111, 2201(b), and 2201(o), and is subject to the enforcement provisions of the Commission's regulations and Chapter 18 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2271, et seq. This proceeding is hereby terminated.

IT IS SO ORDERED,

ATOMIC SAFETY AND LICENSING BOARD

Harry Foreman
ADMINISTRATIVE JUDGE

Ernest Hill
ADMINISTRATIVE JUDGE

Robert M. Lazo, Chairman
ADMINISTRATIVE JUDGE

Bethesda, Maryland

_____, 1994

ATTACHMENT A

_____/94 Stipulation for Settlement of Proceeding

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

RECEIVED
NRC

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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In the Matter of)

ADVANCED MEDICAL SYSTEMS, INC.)

One Factory Row)

Geneva, Ohio 44041)

Docket No. 30-16055-CP

(Civil Penalty)

OFFICE OF SECRETARY
PLANNING & SERVICE
BRANCH

CERTIFICATE OF SERVICE

I hereby certify that copies of "JOINT MOTION OF THE PARTIES FOR ORDER APPROVING AND INCORPORATING STIPULATION FOR SETTLEMENT OF PROCEEDING AND FOR TERMINATION OF THE PROCEEDING", "STIPULATION FOR SETTLEMENT OF THE PROCEEDING" and "ORDER APPROVING AND INCORPORATING STIPULATION FOR SETTLEMENT OF PROCEEDING AND SETTLING AND TERMINATING THE PROCEEDING" in the above-captioned proceeding have been served on the following by deposit in the United States mail, first class, or as indicated by an asterisk, through deposit in the Nuclear Regulatory Commission's internal mail system this 10th day of February, 1994:

Dr. Robert M. Lazo, Chairman*
Administrative Judge
Atomic Safety and Licensing Board
Mail Stop: EW-439
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Harry Foreman
Administrative Judge
Atomic Safety and Licensing Board
1564 Burton Avenue
St. Paul, MN 55108

Ernest E. Hill
Administrative Judge
Atomic Safety and Licensing Board
Hill Associates
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Danville, CA 94526

J.B. Martin*
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U.S. NRC, Region III
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131 North Eagle Street
Geneva, OH 44041

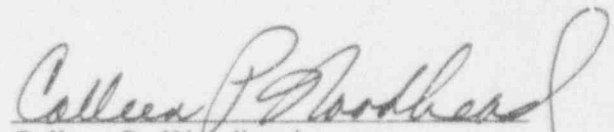
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9309 Colesville Road
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Atomic Safety and Licensing Board
Panel(1)*
Mail Stop: EW-439
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Office of Commission Appellate
Adjudication*
Mail Stop: 16-G-15 OWFN
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Adjudicatory File* (2)
Atomic Safety and Licensing Board
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U.S. Nuclear Regulatory Commission
Washington, DC 20555

Office of the Secretary*
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Colleen P. Woodhead
Counsel for NRC Staff