

# Advanced Medical Systems, Inc.

1020 London Road  
Cleveland, Ohio 44110  
(216) 692-3270  
Fax (216) 692-3269

PUBLIC/PDR

November 1, 1996

030-16055

Mr. Kevin G. Null  
Licensing Reviewer  
United States Nuclear Regulatory Commission  
801 Warrenville Road  
Lisle, Illinois 60523-4351

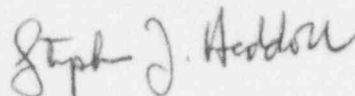
Re: USNRC License No. 34-19089-01 - Control Number 01585

Dear Mr. Null:

Advanced Medical Systems, Inc. (AMS) is in receipt of your September 24, 1996 letter wherein comments on our July 8, 1996 license amendment request were provided. Enclosed are our responses to your comments, along with a description of our proposed follow-up actions. This letter replaces the letter dated October 31, 1996.

Please call me at (216) 692-3270 if you have any questions or if I can assist you in any way in expediting your review of our application and the attached information. AMS is looking forward to timely receipt of our amended license.

Sincerely,



Stephen J. Haddock, R.S.O.

cc: E. L. Svigel  
D. A. Miller, Esq. - Stavole & Miller  
C. D. Berger, C.H.P. - IEM

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**RESPONSE TO USNRC COMMENTS ON  
JULY 8, 1996 LICENSE AMENDMENT REQUEST**

**USNRC Comment Regarding Exemption Provisions :** Additional information is needed in regard to Exemption Provisions to RSPs.

**AMS Response:** Partially concur. In an effort to expedite USNRC action on the July 8, 1996 amendment request, authorization for AMS to make changes to Radiation Safety Procedure RSP-013, "Control of Radioactive Waste", RSP-007, "Training in Radiation Protection", RSP-010, "Exposure Control", and RSP-009, "Contamination Control" will be eliminated. However, this commitment does not apply to AMS's November 9, 1995 application for license renewal. AMS will address that issue at the opportune time.

**Action Taken:** Section 6 of Radiation Safety Procedures RSP-013, "Control of Radioactive Waste", RSP-007, "Training in Radiation Protection", RSP-010, "Exposure Control", and RSP-009, "Contamination Control" will be modified to read as follows: "Variances and exceptions to the requirements of this RSP shall be permitted pursuant to the written authorization of the RSO and the RSC, and after approval by the USNRC."

**USNRC Comment No. 1.a:** 5.1.3 should be changed to state that workers be trained "prior to assuming duties," instead of "prior to exposure."

**AMS Response:** Concur.

**Action Taken:** RSP-007, section 5.1.3 will be changed to state that workers will be trained "prior to assuming duties," instead of "prior to exposure."

**USNRC Comment No. 1.b:** 5.2.2 states that escorted individuals are exempt from training. However, we feel that escorted individuals should, as a minimum, be trained in such things as radiation caution signs, restricted vs. unrestricted areas, radiation dose levels in the facility and the likelihood of receiving dose, use of dosimetry, etc. Please modify this procedure.

**AMS Response:** Concur.

**Action Taken:** RSP-007, section 5.2.2 will be deleted.

**USNRC Comment No. 1.c:** 5.2.3 should be expanded to explain who will determine the level of training an individual will receive and what criteria will be used to evaluate the level of training to be given. Illustrate how you propose to correlate radiological hazard to training given, and describe each level and the corresponding training that will be given.

**AMS Response:** Concur.

**Action Taken:** A "Note" will be added after section 5.2.3 of RSP-007 that states: "For example, individuals at the London Road facility that do not access or do work in restricted areas may receive only Visitor Training. Individuals with the potential to incur between 100 and 500 millirem TEDE shall receive General Employee Training (GET). Individuals with the potential to incur in excess of 500 millirem TEDE shall receive GET and Radiation Worker Training."

**USNRC Comment No. 1.d:** Attachment 1 to 5.3.2 should be modified to reflect the name of the new RSO.

**AMS Response:** Concur.

**Action Taken:** Attachment 1 to RSP-007 will be modified to reflect the name of the new RSO, Mr. Stephen J. Haddock.

**USNRC Comment No. 1.e:** 5.3.3 should be modified to include training in the use of dosimetry (when required to be used), and areas of the building where radioactive material is used/stored. Please include these in Attachment 2 to 5.3.3 as topics for General Employee Training.

**AMS Response:** Concur.

**Action Taken:** Attachment 2 to RSP-007 will be modified to include (1) the use of dosimetry (if required), and (2) the location of restricted areas at AMS.

**USNRC Comment No. 1.f:** Attachment 3 to 5.3.4 does not indicate if radiation workers receive training in the use of dosimetry. Please include this in the training.

**AMS Response:** AMS takes exception to this comment. In item 2.m of Attachment 3 to RSP-007, it states that "Radiation monitoring programs and procedures" are addressed in RWT. This discussion includes the use of dosimetry by radiation workers.

**Action Taken:** None required.

**USNRC Comment No. 1.g:** 5.5.2 should be modified to include the criteria the RSO will use in evaluating and approving individuals who can provide GET or RWT training.

**AMS Response:** Concur.

**Action Taken:** A "Note" will be added after section 5.5.2 of RSP-007 that states: "For example, if the instructor has satisfactorily completed a training program for teaching the subjects they are expected to teach within the last year, or if the instructor has the academic credentials and instructional experience necessary for teaching the subjects (e.g., CHP, NRRPT, five or more years of experience), the instructor may be considered qualified." A second "note" will be added after section 5.5.2 of RSP-007 that states: "If training services are contracted, the vendor should provide a minimum of three (3) references that will attest to the fact that the instructor(s) has(ve)

competent instructional skills and knowledge of the applicable subject matter, and that will attest to the fact that the vendor provides professional services and quality products."

**USNRC Comment No. 1.h:** 5.7 should be modified to include the criteria the RSO will use to evaluate the give "credit for" non-AMS training that may be equivalent to AMS' training. For example, what would be the minimum acceptable subjects and length of training, etc?

**AMS Response:** Concur.

**Action Taken:** A "Note" will be added after section 5.7.2 of RSP-007 that states: "In order for training to be equivalent, it must address those issues contained in Attachments 2 or 3, as applicable." The duration of GET and RWT will be included on Attachment 2 and 3, respectively.

**USNRC Comment 1.i:** 6.0 must include a description of the criteria that will be used to evaluate the proposal for waivers described in 6.1 and 6.2.

**AMS Response:** Concur.

**Action Taken:** A "Note" will be added after section 6.1 of RSP-007 that states: "GET may be waived, at the discretion of the RSO, if the individual has credentials in the field of radiation protection (e.g., CHP, CIH, CSP, NRRPT, two or more years of work experience at a nuclear facility), or if equivalent training as described in 5.7 has been received within the past calendar year." A "Note" will be added after section 6.2 of RSP-007 that states: "RWT may be waived, at the discretion of the RSO, if the individual has credentials in the field of radiation protection (e.g., CHP, NRRPT, five or more years of radiation work experience), or if equivalent training as described in 5.7 has been received within the past calendar year."

**USNRC Comment 2.a:** 5.2.1.1 references a TDE. TDE is not defined in Part 20. It appears that you are referencing the sum of the DDE and CDE to any individual organ or tissue. Please clarify.

**AMS Response:** Total Dose Equivalent (TDE) is defined, in RSP-002, "Definitions" as "the sum of the deep dose equivalent (for external exposures) and the committed dose equivalent (for internal exposures) to that organ or tissue for which non-stochastic effects are limiting." The use of RSP-002 is clearly specified in section 4 of RSP-010. AMS maintains that it is unnecessary to re-define terms in order to demonstrate compliance with applicable regulations.

**Action Taken:** The definition of TDE in RSP-002 will be modified to read: "the sum of the deep dose equivalent (for external exposures) and the committed dose equivalent (for internal exposures) to that organ or tissue for which non-stochastic effects are limiting. Using the terminology in 10 CFR 20, wherein TDE is not defined, the TDE is equivalent to the sum of the DDE and the CDE to any individual organ or tissue."

**USNRC Comment 2.b:** 5.6.4.1 should include the criteria under which the RSO will provide pocket dosimeters.

**AMS Response:** Concur.

**Action Taken:** Section 5.6.4.1 of RSP-010 will be modified to read: "The RSO shall provide each monitored individual who enters a restricted area as part of their work a self-indicating, dose integrating device such as a Pocket Ionization Chamber (PIC), which is considered to be a "secondary" dosimetry device."

**USNRC Comment 2.c:** 5.6.6.1 should be specific as to what conditions will require the use of extremity monitoring. For example, individuals likely to receive 10 percent of Part 20 limits for external exposure should be monitored, as should individuals who enter a high or very high radiation area.

**AMS Response:** Concur.

**Action Taken:** Section 5.6.6.1 of RSP-010 will be modified to read: "For work situations in which extremity exposures are expected to be significantly greater than whole body exposures or if extremity exposures are expected to exceed 5,000 mrem  $H_p$ , the RSO shall specify additional dosimetry devices to be placed on the extremities to measure extremity dose."

**USNRC Comment 2.d:** 5.7.1 establishes a threshold of 500 millirem CEDE from internal sources as the point at which a routine internal exposure monitoring program be started. 20.1502(b)(1) requires the monitoring of occupational intake of radioactive material for those likely to receive in one year, 10 percent of an ALI. Please change 5.7.1 accordingly.

**AMS Response:** AMS takes exception to this comment. For all radionuclides, 500 millirem CEDE from internal sources is equal to 10 percent of the ALI. For ease of use and for procedural consistency, AMS prefers to list dose limits and monitoring limits in the same units (e.g., dose equivalent). It is a simple matter, if the need should arise, to convert a primary dose limit to as secondary dose limit (e.g., intake limit) through the use of Appendix B of 10 CFR 20.

**Action Taken:** None required.

**USNRC Comment 2.e:** 5.10.2 should be changed to read the  $TEDE = CEDE + DDE$ .

**AMS Response:** AMS takes exception to this comment. The deep dose equivalent ( $H_D$ ) is defined in RSP-002, "Definitions" as "the dose equivalent from external whole body exposure at a tissue depth of one (1) centimeter." The use of RSP-002 is clearly specified in section 4 of RSP-010. AMS maintains that it is unnecessary to re-define terms in order to demonstrate compliance will applicable regulations.

**Action Taken:** None required. However, the definition of "deep dose equivalent" in RSP-002 will be modified to read: "The dose equivalent from external whole body exposure at a tissue depth of one (1) centimeter. In 10 CFR 20, the deep dose equivalent is designated as DDE." The

definition of TEDE in RSP-002 will be modified to read: "The sum of the deep dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). Using the terminology in 10 CFR 20, the TEDE is equivalent to the sum of the DDE and the CEDE."