Advanced Medical Systems, Inc.

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September 26, 1996

Mr. John R. Madera, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, Illinois 60523-4351

Re: USNRC License No. 34-19089-01

Dear Mr. Madera:

Advanced Medical Systems, Inc. (AMS) is in receipt of your September 3, 1996 letter wherein comments on Radiation Safety Procedure RSP-018, "Operation of the Gamma Spectrometer" and RSP-0189, "Assessment of Radioactivity in Water Samples" were provided. Enclosed are our responses to your comments, along with a description of our proposed follow-up actions.

On March 1, 1995 and March 20, 1995, AMS submitted applications to amend the referenced license to permit release of ground/surface water that collects in the *remediated* foundation drainage system of the London Road facility. As of the date of this letter, USNRC authorization to proceed on this request has not yet been received. However, when that authorization is given, AMS intends to collect and analyze confirmatory samples by the methodology described in RSP-018 and RSP-019. Therefore, your timely concurrence with enclosed is necessary.

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 the attached information.

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 RSP-018 AND RSP-019

USNRC Comment No. 1: The bases for the proposed minimum detectable activity (MDA) of 70 pCi/l for water samples and 15 pCi/l for filters are not well developed or justified in the technical basis section of Procedure RSP-019. AMS should provide a more defensible basis for its choice of MDA. In our letter dated May 31, 1996, we indicated that the MDA should be based on the capability of a detection system that is state of the art for the application but not necessarily extraordinarily specialized or sophisticated. Thus, AMS should expand its technical basis section to include a detailed description of its measurement systems and testing of these systems to evaluate its measurement capabilities.

AMS Response: Partially concur. RSP-019 does not state that the MDA for the counting system is 70 pCi/l for water samples and 15 pCi/l for filters. It does, however, state that the MDA calculated for each sample cannot exceed those values. By meeting this criterion, AMS can demonstrate compliance with mandated release limits. In reality, achievable detection limits for the AMS system have always been less than the maximum permissible values. The technical basis document merely serves to show what the maximum acceptable MDA for both analyses should be.

Action Taken: Step 5.4.3 of RSP-019 will be modified to read: "If the MDA for the sample exceeds 70 pCi per liter, the sample shall be forwarded to a commercial analytical laboratory for confirmatory analysis. Step 5.5.4 will be added to RSP-019 to read: "If the MDA for the sample exceeds 15 pCi per liter, the sample shall be forwarded to a commercial analytical laboratory for confirmatory analysis." Attachment 1, "Technical Basis for Water Discharge Criteria" will be revised to include a description of the AMS gamma spectrometer and its measurement capabilities. A revised copy of RSP-019 will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003, "Control of Radiation Safety Procedures"

USNRC Comment No. 2: The procedures make only brief mention of the quality assurance program to be used for AMS's measuring systems. AMS should develop a more detailed quality assurance program, and provide a detailed description of that program in the technical basis section. The quality assurance program should extend to any outside analytical laboratories that AMS may use to confirm its results.

AMS Response: Concur.

Action Taken: A new Radiation Safety Procedure will be developed to address quality assurance provisions for in-house analyses as well as for samples sent to a commercial analytical laboratory. That procedure will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003.

USNRC Comment No. 3: The procedures do not fully develop the bases for determining whether a sample does or does not show activity. AMS is still using the MDA as a criterion for this purpose, which is incorrect. Thus, AMS needs to develop decision levels which are independent of the MDA, to allow this determination to be made. The development of this decision level should be described in detail in the technical basis section.

AMS Response: Partially concur. The methodology for determining the decision level for the net count rate in a sample will follow an industry-standard or peer-reviewed recommendation. Therefore, it will not be necessary to include the development of the methodology in the technical basis section.

Action Taken: In addition to determination of MDA in Step 5.8.14 of RSP-018, the procedure will be revised to include calculation of a decision level (DL) as an indicator of whether a measurement (e.g., count rate) exceeds "background" by the following methodology:

$$DL(R_s) = 1.645 \times \sqrt{\frac{R_b}{t_b + t_s}}$$

where $DL(R_s)$ = the net count rate (counts per second) below which a sample is considered to have no radioactivity present, R_b = the background count rate (counts per second), t_s = the sample count time, and t_b = the background count time. The reference for this method (Strom, D. J. and P. S. Stansbury, "Minimum Detectable Activity when Background is Counted Longer than the Sample", *Health Physics* 63(3):360-361, 1992) will be listed in Section 3 of RSP-018. This method, in conjunction with a demonstration that the sample's MDA is below release limits, will provide assurance that water discharged is compliant with license limits. A revised copy of RSP-018 will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003, "Control of Radiation Safety Procedures"

USNRC Comment No. 4: The procedures contain several errors concerning the manipulation of the data, most notably the error of using the MDA for making field decisions, and the incorrect equations provided in the procedures for calculating the MDA.

AMS Response: In regard to the use of MDA for making field decisions, this issue was addressed in our response to USNRC Comment 3.

In regard to the use of an incorrect equation for calculation of MDA, we concur if the reviewer is only taking exception to rounding-off of the 2.71 term to three (3) and to the use of the 4.65 term instead of 3.29 for unpaired data (e.g., when the sample count time and the background count time differ). In general, as long as the background count used in the analysis is from a well-known, stable blank, and as long as it is well above zero, the generic use of the 4.65 term will ensure that the chance of detecting an MDA quantity or more would be at least 95%, and that the probability of a Type II error would be less than 0.05. This position, which is supported in Brodsky, A., "Accuracy and Detection Limits for Bioassay Measurements in Radiation Protection - Statistical Considerations" (NUREG-1156, U. S. Nuclear Regulatory Commission, 1986), is applicable to AMS because RSP-018 and RSP-019 dictate the use of *paired blank counts* for the analyses. In other words, the counts are adjusted from a well-known blank (e.g., acquired from a long background count time) so that they reflect a count duration equivalent to that of the sample count (e.g., acquired from a short sample count time). As long as counting conditions remain constant during acquisition of sample count data, a 0.05 probability of a Type II error will be associated with each MDA calculated by either of the following:

$$MDA = \frac{2.71}{t_s} + 4.65\,\sigma_b = \frac{2.71 + 4.65\sqrt{B_R\, t_s}}{t_s\, E_i\, k}$$

or

$$MDA = \frac{2.71}{t_s} + 3.29\,\sigma_b = \frac{2.71 + 3.29\sqrt{B_R\, t_s \left(1 + \frac{t_s}{t_b}\right)}}{t_s\, E_i\, k}$$

Action Taken: The equations for MDA listed in Step 5.8.14 of RSP-018 and Steps 5.4.2 and 5.5.3 will be modified to the following:

$$MDA = \frac{2.71 + 3.29\sqrt{B_R\, t_s \left(1 + \frac{t_s}{t_b}\right)}}{t_s\, E_i\, k}$$

where MDA = the minimum detectable activity (pCi/l), B_R = the background count rate (counts per second), t_s = sample count time (seconds), t_b = the background count time (seconds), E_i = the detector efficiency for ^{60}Co for counting geometry "i" (e.g., either a one-liter Marinelli beaker geometry or a filter geometry), and k = a conversion factor used to convert the results of the calculation into units of "pCi per liter". The reference for this method (Currie, L.A., "Limits for Qualitative Detection and Quantitative Determination", *Analytical Chemistry*, Vol. 40, No. 3, 1968, pp. 586-593) will be listed in Section 3 of RSP-018 and RSP-019. A revised copy of RSP-018 and RSP-019 will be forwarded to the USNRC immediately after it has been reviewed and approved as described in RSP-003, "Control of Radiation Safety Procedures"