UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 14, 1996

MEMORANDUM TO: John Madera, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety, RIII

FROM: Josephine Piccone, Acting Chief
Operations Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: REVIEW OF THE PROPOSED WATER ANALYSIS PROCEDURES RECENTLY SUBMITTED BY ADVANCED MEDICAL SYSTEMS (AMS)

We have reviewed the water analysis procedures recently developed by AMS and sent to region III on June 11, 1996. These procedures included RSP-018, Operation of the Gamma Spectrometer, and RSP-019, Assessment of Radioactivity in Water Samples. Both procedures were dated June 11, 1996. Our major concerns with the procedures are discussed below. More detailed comments are provided in the attachment to this memorandum.

1. The bases for the proposed maximum detectable activity (MDA) of 70 pCi/l for water samples and 15 pCi/l for filters are not well developed and justified in the technical basis section of Procedure RSP-019. We suggest that AMS provide a more defensible basis for their choice of MDA. In our letter to them dated May 31, 1996, we suggested that the MDA 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. We recommend that AMS expand their technical basis section to include a detailed description of their measurement systems and their testing of these systems to evaluate their measurement capabilities.

2. The procedures make only brief mention of the quality assurance program to be used for their measuring systems. We suggest that AMS develop a better 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 their results.

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3. The procedures do not fully develop the bases for determining whether a sample does or does not show activity. They are still using the MDA as a criterion for this purpose, which is incorrect. They need to develop decision levels, independently 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.

4. AMS has not resolved the discrepancies that appeared several times between their water analyses and those performed by The Northeast Ohio Regional Sewer District (NEORSD). These discrepancies appear to have been due to differences in sampling protocols.

5. The procedures contain several errors in 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.

Attachment: As stated

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ATTACHMENT

COMMENTS ON AMS PROCEDURES

Procedure RSP-018: Operation of the Gamma Spectrometer

Page 2, 5.1.3:

It is not clear what is meant by "so that the two primary peaks fall in channels 155 and 176." Confirm that the maxima of the Co-60 peaks occur at these channel numbers?

Procedure RSP-019: Assessment of Radioactivity in Water

1. Page 3, 5.1.2: It is not clear whether the analysis is to be performed in-house or by a commercial laboratory. It should be clear that the laboratory performing the analyses must participate in a quality assurance/quality control program that is approved by AMS and periodically audited by a recognized group or organization outside the organization that operates the laboratory. Pre-qualification of the laboratory is only part of this ongoing program. A later section (5.4.3) states that samples may be forwarded to a commercial analytical laboratory for confirmatory analysis. Some indication should be provided as to when such an action may be necessary.

2. Page 3, 5.2.1: Sampling these tanks has a history that indicates that different results are obtained from samples taken from various locations within the tank. The differences in the results have not been explained, giving the impression that the mixing used by AMS to date has not been effective, and that there remained stratification of the Co-60 even after prolonged mixing. It is therefore necessary for AMS to do one of two things: either explain the differences in the results obtained in the past, or conduct tests to demonstrate that their proposed method does indeed produce representative samples. Without such data, the results will remain suspect because of unexplained past anomalies.

3. Page 3, 5.2.3: In the note, it is stated that samples may be collected from any location in the tank. In the interest of consistency, we suggest specifying a sampling method at this point.

4. Page 4, 5.4.2: It is not clear where the MDA of 70 pCi/l comes from. In our letter to AMS, we stated that AMS should establish a counting method that is considered typical of current and ordinary state of the art for such an

application. We have not seen any data to show that the licensee has done that. We therefore suggest that the licensee establish their well-shielded counting system, in a low background area, select a reasonably long counting time, and then establish the sensitivities achievable by such a system. We are confident that the MDA will be far lower than the proposed 70 pCi/l. Also, in the equation for MDA, if the time is to be in seconds, the procedure should clearly indicate that the count rate B_R must also be in counts per second.

The Note at the end of this section is not correct. The MDA will not ensure a 0.05 probability of a Type II error when comparing the sample result to the background result. Suggest removing or rewriting to more accurately reflect the technical meaning of the MDA.

The equation for MDA given in this section, and elsewhere in the procedure, is incorrect. The equation, in the form given, contains the implicit assumption that the sample (or gross) counting time and the background counting time are equal. This is not the case, however, because the background is counted for 8 hours, whereas the samples are counted for times less than 8 hours (See procedure RSP-018 for sample counting times). The equation in the form given will underestimate the MDA.

5. Page 4, 5.5.1: This step requires that all samples less than 100 pCi/l be drawn through a filter, even those that show no activity that is statistically different from background. The licensee should confirm that this is the intent.

Finally, information should be added to the section that indicates that proper procedures performed by trained individuals will be used to ensure that the sample will be drawn correctly through the filter.

6. Page 5, 5.5.3: Although the origin of the 15 pCi/l detection concentration level is mentioned in the technical basis section of the document, adequate techincal support for this number is not provided. This information should be provided.

This step, or the remainder of the procedure, does not describe what to do with the results of the analyses on the filter. What criteria are to be used to decide if the filter indicates insoluble activity?

7. Page 6, 5.7.4:

The condition given in 5.7.4.2 is not acceptable. The use of MDA as criterion for deciding if activity significantly different from background was detected is incorrect. The licensee must establish a decision level, independently of the MDA, that will be used to make this determination.

Technical Basis for Water Discharge Criteria

1. Page 7, Second point:

This point contradicts the first point. The first point stresses the regulatory requirement that no insoluble Co-60 may be discharged to the sewer. The second point tries to estimate the amount of insoluble Co-60 that may be discharged to the sewer without causing the ash to exceed 8 pCi/g. The analysis in the second point also neglects to consider the possibility that Co-60 discharged to the sewer as soluble cobalt may still end up in the ash because of a number of reasons, such as precipitation of the "soluble" cobalt during waste treatment, or settling of the "soluble" cobalt that is, in fact, not soluble but very finely dispersed insoluble material. We suggest re-assessment of the second point and possibly deleting.

2. Page 7, Third point:

The drinking water standard is not relevant in this case. It is suggested that it be removed because it does not contribute to the technical basis being developed.

3. Page 8, Second Point from the bottom:

This statement concerning Information Notice (IN) 94-07, that "the standard does not provide guidance on how much gross beta activity indicates an insoluble material," is incorrect. The standard states, on Page 4, that "activity in the suspended solids portion of the effluent greater than that found in similarly processed background water samples would indicate the presence of insoluble radioactive material." In other words, the IN states that any activity that is statistically distinguishable from background indicates the presence of insoluble material. Background in this case is the filter residue from water filtered in the same manner as the sample. The water used to produce the background filter is water obtained locally but that is not contaminated by the licensee's operation.

4. Page 9, First point:

This point is at variance with the data NRC has been getting from both commercial

laboratories that were used by AMS and NEORSD to analyze the water samples from the discharge tanks. The results from these laboratories were routinely reported as having been obtained using equipment capable of measuring 1-2 pCi/l using counting times as low as one to two hours. How can these values be reconciled with the values indicated in this point?

In this connection, AMS has not described the system it intends to use for sample analyses. We suggest including this in the technical basis section. It is necessary to know the system to be used, type and size of detector, counting times, background levels in the counting laboratory, location of laboratory within the AMS facility, shielding for the detector, methods of spectral analysis to be used, type of blank samples, and source of water to serve as the background, and the quality assurance program for the system.

Date: August 20, 1996

Call made August 20, 1996 to Tom Lenhart (NEORSD) ((216) 881-6600) at 3:22 pm our local time.

I indicated that as far as a status report, there was no new information that I could give him except that the first petition draft decision was moving between OGC and NMSS several times since the last call. The third petition was associated with the license and that the director's decision was hinged on the license renewal hearing. We discussed the facts that AMS was attempting to dispose of the large quantity of bulk and sealed source cobalt-60, and that that item had a high profile here a the agency. I indicated that is there are three Commissioners at the moment, and that there had been two nominations that needed Congressional approval. No other information was discussed.

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