

May 13, 1996

MEMORANDUM TO: Cynthia D. Pederson, Director
Division of Nuclear Material Safety, Region III

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: SAMPLING AND COUNTING PROCEDURES USED BY
ADVANCED MEDICAL SYSTEMS (AMS)

I am responding to your TAR dated February 22, 1996, regarding the methods used by AMS to sample water from its ground water storage tanks. Our understanding of the TAR identified two broad issues to be addressed:

1. The detection sensitivity that would be considered acceptable in showing compliance with regulations applicable to discharges to sanitary sewer systems.
2. The appropriate methods of sampling the storage tanks to show compliance with sewer discharge regulations.

Although these two issues are connected, they will be addressed separately for convenience and clarity.

1. Showing compliance with the sewer discharge regulations in 10 CFR § 20.2003 usually requires that licensees perform measurements to quantify the concentrations of radioactive materials in the discharge water. Frequently it also requires showing the absence of insoluble materials in that water. Due to technical factors, it is not possible to show the complete absence of insoluble materials in the discharge, and it is therefore necessary to establish a level of measurement sensitivity that would be deemed adequate to satisfy the regulatory requirements. This sensitivity is expressed in terms of the lower limit of detection (LLD) or, as it is frequently called in the industry, the minimum detectable activity (MDA).

NRC has traditionally adopted the industry practice of considering as adequate an MDA that is readily achievable using standard measurement practices and equipment, together with ordinary precautions in performing the measurements. The above practice is subject to the additional industry accepted constraint that the acceptable MDA not be higher than 10% of the applicable limit, unless that value is not readily achievable.

In the case of sewer discharges of water containing ⁶⁰Co, this practice implies that an MDA of no higher than 300 picocuries/liter (pCi/L) would be considered acceptable. However, for ⁶⁰Co, MDA values far lower than 300 pCi/L

Contact: Sami Sherbini
(301) 415-7902

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are easily achievable with even the simplest of detection equipment, and we expect licensees to operate at these lower values. The MDA value that is readily achievable varies depending on many factors, such as local background levels, and should be established on a case-by-case basis and justified by the licensee. In the case of AMS, we suggest that the licensee be requested to propose a reasonable measurement protocol, establish the MDA for that protocol, and submit the details to NRC for approval.

For purposes of showing compliance with the prohibition on discharges of insoluble, non-biological material, we believe the MDA used in reactor environmental technical specifications for ⁶⁰Co may be an appropriate value to use as a reference in this case. This value is 15 pCi/L, and should be readily achievable by AMS. However, we caution that this is not a generic position, and each case that may arise in the future will be evaluated separately. In the case of AMS, the final acceptable MDA may be somewhat higher or lower than 15 pCi/L, depending on the details of the licensee's proposed sampling and counting protocol and what, in our evaluation, constitutes a reasonable attempt for achieving an appropriate sensitivity. The MDA of 15 pCi/L would be applicable both to measurements of total activity in the water sample, as well as any measurements to determine the content of insoluble activity in that sample.

In addition, you should be aware that NRC, in cooperation with EPA, will be conducting a comprehensive survey to include sampling of effluents (ash, sludge, etc.) at sewage treatment plants across the country to determine the effects of reconcentration. Information obtained from this survey will be used to determine if rulemaking is required. However, in the interim, we are considering alternatives to address the current rule language regarding release of insoluble radioactive material. Alternatives include issuing guidance in the form of an Information Notice or requesting the Office of Nuclear Regulatory Research to initiate rulemaking in this limited area.

2. Sampling the water storage tanks at AMS should be performed in such a manner that the results of the water sample analysis can be used to provide a reliable estimate of the radioactive contents of the tank. This is normally achieved by thoroughly mixing the contents before obtaining the sample, but other sampling techniques may be justified in special circumstances. For example, stratified sampling is often performed in waste storage tanks, without first mixing the contents of the tank. Although the results in this case are more difficult to interpret, and the sampling is much more difficult to perform, it is an acceptable sampling method if conducted properly.

If AMS is able to thoroughly mix the contents of the tank prior to sampling, then we suggest that they be encouraged to do so, thereby ensuring easy interpretation of the results. However, if the licensee wishes to adopt an alternative method, they should be permitted to do so, provided the method, together with the calculations necessary to identify and quantify the contents

of the tank, are technically justified and approved by the NRC. AMS may also be permitted to show compliance with the discharge concentration requirements, as well as the prohibition on discharge of insoluble materials, by measuring the total (soluble and insoluble) concentration of ⁶⁰Co in the water. Samples that show no detectable activity above background using this method, together with procedures that achieve an acceptable MDA, as discussed above, need not be separately checked for insoluble material content.

We reviewed the AMS procedure you provided with your TAR, Procedure RSP-019, "Assessment of radioactivity in water samples", and found that it was incomplete and contained several apparent technical errors. We suggest that AMS be requested to develop detailed procedures describing the methods they will use to obtain water samples, the methods they will use to analyze those samples, and the decision logic that they will use to determine if the water in the tank may be discharged. The revised procedures should be reviewed by NMSS before approving routine tank discharges from AMS to ensure their adequacy and also to ensure that the methods selected are technically correct.

Attached, please find a proposed letter to send from RIII to AMS specifically requesting the above identified information necessary for us to make an evaluation on future planned discharges.

We believe that this addresses the questions you raised in your TAR with respect to the issues at AMS. Please call the technical contact indicated above if you need further clarifications or assistance.

Attachment: As stated.

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Memorandum to: Cynthia D. Pederson, RIII

Dated: May 13, 1996

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ATTACHMENT

Robert Meschter, R.S.O.
Advanced Medical Systems, Inc.
1020 London Road,
Cleveland, Ohio 44110

Dear Mr. Meschter,

We have reviewed your practices and procedures for sampling and discharging the waste storage tanks that you use to collect water from the footer drain system on your site, and we have concluded that we need additional information for us to complete our review. Detailed written procedures should be prepared describing the manner in which samples are to be obtained, the methods of sample analysis, the methods to be used to determine insoluble material content, and the logic to be used to determine if the water meets the requirements for discharge from the tank. AMS Procedure RSP-019, "Assessment of Radioactivity in Water Samples" was incomplete and contained several technical errors. A complete, revised procedure needs to be submitted to the NRC for review and approval.

You should also provide written details of the sampling and measurement protocol that are not appropriately included in your procedures. This document should provide the justifications for the value of the Minimum Detectable Activity (MDA) you select for your measurements, including sufficient detail to permit a determination that the selected methods of measurement, including detector type, shielding, background levels, counting times, and other factors represent reasonably achievable performance. These procedures and technical document should be submitted to the NRC for review and approval prior to implementation on a routine basis.

When preparing the above documents, you should address in sufficient detail at least the following issues:

- All tanks must be sampled before discharge of the water to the North East Ohio Regional Sewer District (NEORS), or to any location that would ultimately discharge to that sewer district. You may choose any sampling protocol that is suitable to your specific conditions, but we encourage you to consider thorough mixing of the tank before sampling to facilitate interpretation of the analysis results. In any case, sampling should be performed in such a manner that the sample would enable you to reliably identify and quantify the contents of the tank with a reasonable degree of accuracy. The details of the sampling protocol, such as mixing methods and time, sample size and shape (e.g. cylindrical bottle, Marinelli beaker, etc.), points of sample withdrawal from the tanks, and so on should be included in your sampling procedures.
- Water samples must be analyzed for their content of licensed material, which in your case is limited to ⁶⁰Co. The analysis should be conducted in such a manner as to consistently achieve a sensitivity, expressed in terms of the MDA, that is similar to that achievable using standard measurement techniques for this type of sample throughout the industry.

The chosen analysis methods should include taking appropriate precautions during the measurements, such as providing adequate shielding, ensuring a low background counting location, counting for an appropriately long period of time, using good counting geometries, taking sufficiently large water samples, and so on. Your procedures or technical document should include detailed descriptions of the detectors to be used, the background that would be considered compatible with counting this type of sample, counting geometry, counting time, methods of MDA determination, level of activity that is to be considered indistinguishable from background, logic to be used in deciding if the tank may or may not be discharged, and so on.

- Samples that show no detectable activity above background using procedures that achieve the above-noted MDA need not be checked for insoluble material content. Samples that do show activity above background should be tested further for their content of insoluble licensed material, in your case ⁶⁰Co. This procedure would be considered acceptable provided the MDA used to measure the total activity in the sample is also adequate for purposes of determining the content of insoluble material in that sample. The details of subsequent treatment and testing, and the final disposition of the water, should be detailed in the technical or procedures.
- Acceptable methods for determining insoluble material content are described in NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20." Procedures to determine whether the detected activity differs from background should be based on a previously-established decision level. Use of the MDA as a decision level is not acceptable. NRC considers use of 5 percent probabilities for both Type I and Type II errors acceptable. Use of other error probabilities must be justified. Details of these methods should be included in the technical document, and their implementation should be included in the procedures.

Please call me at (708) 829-9800 if you have any further questions, or need clarifications on any of the above items.

Sincerely,

Cynthia Pederson, Director
Division of Nuclear Material Safety,
Region III