



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

SEP 24 1996

Stephen Haddock, RSO
Advanced Medical Systems, Inc.
1020 London Road
Cleveland, Ohio, 44110

Dear Mr. Haddock:

We have completed our review of your July 8, 1996 request for an amendment to NRC License Number 34-19089-01 and find that we need additional information in the following two areas:

- Exemption provisions to Radiation Safety Procedures (RSP); and
- Technical deficiencies of RSPs pertaining to the Building Recovery Project (BRP).

Exemption Provisions to RSPs

It is clear from the review of your submittal that you would like authorization to make changes to the RSPs as necessary without amending your license. This is also evident in the resubmittal of your application for renewal.

The regulations require that licensees develop and implement procedures that will ensure compliance with the regulations. 10 CFR Part 20, Section 20.1101 states, in part, that "each licensee shall develop and implement a radiation protection program sufficient to ensure compliance with the provisions of Part 20." Section 20.1101 further states that "the licensee shall use procedures and engineering controls to achieve doses ALARA." The NRC and its contractors have developed numerous guidance documents which provide acceptable procedures that can be used in achieving these goals. Alternatively, licensees may submit their own procedures for review. Nevertheless, licenses are issued based upon the adequacy and acceptability of facilities, equipment, training, and procedures that comprise a radiation safety program. In order for the NRC to enforce a license and a licensee's radiation safety program, the facilities, equipment, training and procedures become part of the license.

There may be circumstances, however, in which licensees may not be tied to specific step-by-step procedures. This is commonly found in broad scope licenses for licensees who have an extensive radioactive materials program with a wide variety of radionuclides and uses. Broad scope licenses are only issued to organizations that have, among other things, a good regulatory performance record, a program of a scope that has a need to use a variety of radionuclides, the operational flexibility to support numerous uses and users, and an administrative structure adequate to ensure safe operations. Furthermore, NRC authorization to change and modify procedures is limited to elements that are not considered to have an impact on health and safety. An example would be specific procedures for conducting annual inventory of radioactive material, or the ordering of packages containing licensed material, etc.

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If AMS wishes to pursue its request for authorization to modify Radiation Safety Procedures (RSP's) without amending its license, then it must submit the following:

1. Justification for the request. You must demonstrate the need for the flexibility. It does not appear that AMS has the extensive materials program that would justify the authorization.
2. An expanded radiation safety program from that which is described in RSP-001. The program must fulfill Item 2 of Regulatory Guide 10.5, entitled "Contents of an Application." Please also submit a separate Radiation Safety Manual containing procedures for NRC review.
3. A commitment that changes made without NRC approval will be limited to those in the Radiation Safety Manual, and will not have an impact on health and safety.
4. Criteria and methodology for making procedural changes to RSPs. For example, a system must be in place for Committee review and approval of changes. Minimum criteria, in terms of equipment and radiation safety practices, must be established for RSPs that are not tied down in the license. Examples of topics the criteria should address are use of dosimetry, air sampling equipment, bioassay requirements, use of protective clothing, types and frequencies of surveys. The minimum equipment and radiation safety practices for RSPs should be based on the radiation hazard characterization of the area where work will be performed. For example, work to be done in (1) radiation areas, (2) high radiation areas, and (3) very high radiation areas, should each have its own set of minimum criteria. Any in-house change to an RSP would be acceptable only if the minimum criteria were met, and the Committee reviewed and approved the proposed change. The criteria must be submitted for NRC review and approval, along with a commitment that it will be used by the Committee during review of any proposed change to a RSP that is not tied down in the license. Modification of criteria will require an amendment to the license.
5. Submit examples of types of variances and exceptions you want to make to RSPs. Keep in mind that NRC policy is to only allow licensees to make changes to procedures that have no impact on health and safety.

Technical Deficiencies of RSPs

1. Training - RSP-007
 - a. 5.1.3 should be changed to state that workers be trained "prior to assuming duties," instead of "prior to exposure."

- 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.
- 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.
- d. Attachment 1 to 5.3.2 should be modified to reflect the name of the new RSO.
- 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.
- 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.
- 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.
- h. 5.7 should be modified to include the criteria the RSO will use to evaluate and 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?
- 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.

2. Exposure Control - RSP-010

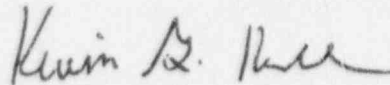
- a. 5.2.1.1 references a TDE. TDE is not defined in Part 20. it appears that you are referencing the sum of the DDE and CDE to any individual organ or tissue. Please clarify.
- b. 5.6.4.1 should include the criteria under which the RSO will provide pocket dosimeters.

- 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.
- 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.
- e. 5.10.2 should be changed to read the $TEDE = CEDE + DDE$.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 01585.

If you have any questions or require clarification on any of the information stated above, you may contact us at (630) 829-9887.

Sincerely,



Kevin G. Null
Licensing Reviewer

License No. 34-19089-01
Docket No. 030-16055

Enclosure: Regulatory Guide 10.5