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OCT 16 1989

Advanced Medical Systems, Inc.
ATTN: Ms. Sherry J. Stein, Director
Regulatory Affairs
1020 London Road
Cleveland, OH 44110

License No. 34-190E9-01

Dear Ms. Stein:

This is in response to your July 13, 1989 letter regarding our Oak Ridge Associated Universities (ORAU) Report; and your July 20, 1989, September 25, 1989 letters regarding comments made by Mr. Davis at the June 1, 1989 Commission meeting.

With regard to your July 13, 1989 letter, you state that the ORAU Report inaccurately portrays restricted and unrestricted areas at the AMS London Road facility. We agree that some unrestricted areas identified in the report are not consistent with AMS area designations. Upon completion of our evaluation of your decontamination activities, we will issue a report which will clarify the restricted and unrestricted area designations used in the ORAU Report.

With regard to your July 20, 1989 and September 25, 1989 letters, you asked five questions concerning Mr. Davis' remarks at the June 1, 1989 Commission meeting. For clarity, your questions have been repeated below along with our response.

1. Question

On page sixty-three (63) of the transcript you state: "We concluded during the senior management meeting that Advanced Medical Systems will continue to require close NRC attention." In light of the fact that AMS has made every attempt to both comply with each NRC request and to maintain an amiable relationship with the NRC, please state the basis for this statement.

Response:

This remark was based on the collective judgement of NRC management which considered, among other things, the ongoing decontamination effort and facility modifications at the AMS London Road facility and changes in management positions requiring approval by the NRC on the AMS license. These issues were discussed in our June 23, 1989 letter to AMS.

2. Question:

On page sixty-four (64) of the transcript you state: "There was also a problem with the servicing of [AMS'] teletherapy units at medical facilities, but this has been resolved from a technical standpoint." AMS

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is unaware of any alleged servicing problems in the past few years; neither have we been notified by the NRC of any such problems. Since no alleged service problems have been brought before the Commissioners in recent past by Region III, please identify specifically the basis for this extremely negative and defamatory remark.

Response

This was a reference to the October 10, 1986 Order to AMS and an NRC November 25, 1986 inspection report in which the staff concluded unlicensed AMS service technicians were performing licensed activities at medical facilities.

3. Question:

On page sixty-four (64) of the transcript you state that: "The licensee has made significant progress in decontaminating its facility, expect [sic] we still have some concern about the levels which remain in the hot cell and will be pursuing this with the licensee further in the near future." Despite this, on page sixty-five (65) of the transcript you admit that AMS is now in a "decontaminated state." Since you seem to agree on page sixty-five (65) of the transcript that AMS is in a decontaminated state, please set forth the basis for your negative remarks concerning hot cell radiation levels.

Response:

The phrase "decontaminated state" refers to the general status of your facilities and was a reference to areas other than the hot cell and the Waste Holdup Tank Room. The concern for hot cell radiation levels was expressed to AMS in our June 23, 1989 letter.

4. Question:

On page sixty-four (64) you allege that "[the NRC need[s] to tie down a schedule for completion of those [facility] modifications and also we need to look at design details. The information we have looked at so far has been not as detailed as we feel we need to see." Given the fact that Region III officials specifically informed AMS that the NRC only wished to be provided with general details about facility modifications and AMS has been long awaiting a timely reply from your office concerning these modifications, please identify the basis for these comments.

Response:

The necessity for details and a schedule were conveyed to the AMS staff in a February 10, 1989 meeting at the London Road facility and in our June 23, 1989 letter.

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5. Question:

Finally, on page sixty-four (64) of the transcript you state: "We have a couple organizational concerns in that they have recently lost their radiation safety officer and service manager." We do not understand who you are referring to as service manager, and therefore request that you state your basis for this remark.

Response:

This was a reference to the departure of Mr. Theodore Hebert from the employ of AMS.

We believe this satisfactorily responds to your concerns.

Sincerely,

ORIGINAL SIGNED BY C. E. NORELIUS

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

cc: S. S. Stein, Ph.D., P.E.

cc w/ltrs dtd 07/13/89,
07/20/89, and 09/25/89:
DCD/DCB (RIDS)

RIII
See Attached
Slawinski/rr
10/ /89

^{yes}
RIII
BSM
Mallett
10/13/89

RIII
See Attached
Berson

RIII
See Attached
Grobe

OGC
See Attached
Woodhead

^{yes}
NMSS
via
to Glenn via
Glenn
10/13/89

RIII
See Attached
Norelius

5. Question:

Finally, on page sixty-four (64) of the transcript you state: "We have a couple organizational concerns in that they have recently lost their radiation safety officer and service manager." We do not understand who you are referring to as service manager, and therefore request that you state your basis for this remark.

Response:

This was a reference to the departure of Mr. Theodore Hebert from the employ of AMS.

If the above clarifications are not adequate, we suggest that we meet to resolve them.

Sincerely,

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

cc: S. S. Stein, Ph.D., P.E.

cc w/ltrs dtd 07/31/89 and
09/25/89:
DCD/DCB (RIDS)

R111
WHL
Slawinski
10/01/89

R111
Mallett/jl
10/11/89

R111
R111
Berson Grobe
10/12
revision industry

yes
OGC
VIA telephone
call on 10/12/89
Woodhead
Bm for

NMSS
Glenn

R111
Norelius