(5) 5/29/07 72FR29553

TO: Jenny Tobin, Nuclear Regulatory Commission

FROM: Cheryl K. Rogers, Supervisor
Radioactive Materials Program-WI

DATE: July 11, 2007

SUBJECT: NARM Guidance Comments Requested in FSME-07-051
NUREG 1556, Vol. 21 Draft Guidance

1) This guidance document pertains to possession licenses for Production of Radioactive Material Using an Accelerator. It would be impossible to only use this specific guidance document. The recommendation is:

   Clarify in the text under Discussion in Item 6 what additional guidance should be used for the 3-4 different uses following the production of radioisotopes.

   The table below summarizes the information that should be clearly stated and where the information was found in Draft Vol. 21.

Purpose/Type of Use	**Additional Specific Guidance/Application Required**	**Location in Draft Vol. 21**
Nuclear Pharmacy	NUREG 1556, Vol. 13	Page 8-10 (implied)
Noncommercial Distribution to Consortium Members*	Draft Vol 21, App. P	Page 1-2
Medical Facility	NUREG 1556, Vol. 9, App AA	Note at beginning of App P
Noncommercial Distribution to Consortium Members- not Educational Institutions or Federal Facility	Not addressed	None

*limited to "only educational institutions or federal facilities"

NOTE 1: There are currently licensees who are stand-alone facilities and who are funded via a consortium that are not educational institutions or federal facilities.

NOTE 2: On page 8-10 under Discussion for "Purposes for Which Licensed Material Will Be Used", there is a bullet for "medical use license (e.g. noncommercial radiopharmacy)" that appears to include the consortium type of licensee. If this is an additional term that is being used to cover the same type of activity, then further explanation should be provided.

E-RIDS = ADM-03
All = T. Taylor (TMT)
J. Tobin (JCT1)
D. W Tiktz (DEW2)

SUNSI Review Complete
Template = ADM-013

2) Item 8.5.1, page 8-6
Delete paragraph concerning authorization to possess depleted uranium.

3) Item 8.7.2, page 8-16
Discussion should clearly differentiate between the authorized user who can work on the accelerator and the individual who will prepare the radiopharmaceutical doses. In most facilities the pharmacy prep area will be in the immediate vicinity of and under the same organization and radiation safety program. Qualifications and duties should be clearly identified.

4) Item 8.9, page 8-20
Since the accelerator will produce a radiation field, information regarding shielding sufficient to do an independent assessment of the adequacy of the shielding should be submitted and included as a license condition (contrary to the text)

5) Item 8.10.2, page 8-26
Discussion is lacking concerning type of surveys. Specifically, area monitoring is a term that is not defined.
In addition, under response from applicant, there is no recommendation to add the statement "We reserve the right to upgrade our survey instrumentation" as is found in other guidance documents.

6) Item 8.10.3, page 8-28
Discussion section references Figure 8.6. There is no Figure 8-6

7) Item 8.10.6, page 8-36 thru 8-39
There should be a specific requirement for safety procedures for opening up the accelerator and handling the activation targets. This would typically include "wait times" based on how long the accelerator was in operation and could also specify a radiation level that must be achieved before handling or approaching the targets.

8) Appendices-Missing Information
Where is "Information Needed for Transfer of Control?"

9) Appendices-Missing Information
Where is a Sample/Example Audit Form?