February 12, 2001

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: William F. Kane, Director**/RA/**
Office of Nuclear Material Safety
and Safeguards

SUBJECT: CLOSURE OF NMSS GENERIC ISSUE RELATING TO GAMMA STEREOTACTIC RADIOSURGERY

In accordance with draft Management Directive 6.4, "Generic Issues Program (GIP)," NMSS is informing you of the closure of a candidate generic issue. Each candidate generic issue in the Materials and Waste Arenas is evaluated against standard criteria to determine whether resolution should be tracked within the GIP process or, alternatively, through other planning, budgeting, and performance management mechanisms. Candidate generic issues that are determined to represent credible threats to strategic and performance goal measures, unless current regulatory programs are changed, are tracked within the GIP process. Issues that do not rise to this threshold are dropped from the GIP process, and any follow-up actions are typically tracked within operating plans.

The provisions in draft MD 6.4 afford external stakeholders the opportunity to identify candidate generic issues for evaluation and processing in the GIP. The State of California recently identified such an issue that relates to gamma stereotactic radiosurgery. As a result, the NMSS Generic Issue Review Panel met on January 4, 2001, to determine whether the candidate issue is a generic issue, whether it should be processed and tracked in the GIP, should be dropped, or sent to another NRC program for review. The issue relates to the adequacy of NRC's regulatory program to prevent medical misadministrations that result from human errors associated with the setting of coordinates on the stereotactic frame during gamma stereotactic radiosurgery. The panel decided to drop the issue from further processing through the GIP because the existing regulatory programs were deemed adequate to continue to protect public health and safety. The details of the candidate generic issue and the technical basis for dropping the issue are provided in the attachment.

Attachment: Closure of Candidate Generic Issue on Gamma Stereotactic Radiosurgery

CONTACT: Mark A. Sitek, NMSS/IMNS
(301) 415-5799

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Closure of Candidate Generic Issue on Gamma Knife Treatments

Description and Scope of Issue

NRC was informed in July 2000 of a medical misadministration during gamma stereotactic radiosurgery that occurred in the State of California in September 1998. The misadministration was the result of an erroneous coordinate setting which resulted in an unintended site of the brain receiving 10 gray. The licensee's procedure to independently verify the coordinate setting also failed to identify the error prior to treatment. The State requested that the licensee, as part of their corrective action plan, investigate the manner with which coordinate settings are verified at other facilities that perform gamma stereotactic radiosurgery. The licensee discovered that there is a great deal of variability in this verification process, and as a result, a wide range of probabilities of having a coordinate setting error that could lead to a medical misadministration.

As a result of the findings of the California licensee, the State plans to require all of its licensees that perform gamma stereotactic radiosurgery to change their procedures to improve the process by which coordinate settings are verified. Specifically, these licensees will be required to have a "double check" verification procedure. In this procedure, the coordinates are called out by one individual while person A sets them and persons B and C independently verify the setting. This method of setting coordinates is based on a University of Pittsburgh study which indicated that the probability of coordinate setting errors was reduced from 1 in 400 to 1 in 155,000 when a "double check" procedure is used as opposed to a "single check."

The State of California shared these findings with other Agreements States and NRC because it believes that there are generic implications associated with safely performing gamma stereotactic radiosurgery, particularly with respect to the verification of coordinate settings. As a result, the staff in NMSS evaluated whether current NRC regulatory programs are adequate to prevent medical misadministrations that result from human errors associated with the setting of coordinates on the stereotactic frame during gamma stereotactic radiosurgery.

Basis for Dropping

In order to assess the generic implications of the issue, the panel was presented the various regulations, license conditions, and guidance that govern the setting of coordinates for gamma stereotactic radiosurgery. In addition, the safety significance of human errors associated with coordinate settings was also discussed.

The current and pending regulations in 10 CFR Part 35 require licensees to prepare a written directive prior to gamma stereotactic radiosurgery. Prescribed target coordinate settings for each treatment for each distinct treatment site are required elements of the written directive. In addition, licensees are required to have written procedures which provide high confidence that the written directive will be followed as prepared. Finally, the current guidance on this topic suggests that at least one qualified person independently verify the coordinate settings. The combination of the current regulations and guidance are adequate to the extent that licensees are required to have procedures to ensure that coordinates are set in accordance with the physicians treatment plan and written directive. In those cases where coordinates are not set in accordance with the written directive and the treatment subsequently executed, the current regulatory process will identify and address the issue through the appropriate mechanisms such as enforcement and licensee corrective actions.

ATTACHMENT

The safety significance of erroneous coordinate settings was also evaluated. Examination of current operating data related to gamma stereotactic radiosurgery revealed that the probability of coordinate setting errors is very low. Of the tens of thousands of gamma stereotactic radiosurgery procedures that have been performed over the last ten years, only sixteen misadministrations have been reported with six of these cases involving coordinate setting errors. The misadministrations in these cases did not result in negative health consequences. In fact, the probability that a critical nerve or other sensitive structure will be impacted as a result of a misadministration is small since these structures represent a small portion of the total volume of the brain. The combination of the low probability of misadministration occurrence and the low probability of severe consequences if a misadministration occurs results in the risks associated with coordinate setting errors being very low.

The panel determined that the low risk associated with coordinate setting errors combined with the current and emerging performance-based regulations to require some form of verification do not justify more prescriptive oversight. The panel concluded that this issue does not warrant further processing in the GIP because it is extremely unlikely that strategic and/or performance plan measures would be exceeded as a result of not changing the current regulatory programs that address this issue.

Closure and Tracking

In addition to the evaluation that was conducted as part of the GIP, an Information Notice (IN 2000-22) was issued on December 18, 2000, to applicable licensees to remind them of their responsibilities with respect to written directives and to ensuring that the written directives are followed as planned. Furthermore, a series of best practices on how other licensees ensure correct coordinate settings were identified in IN 2000-22. There are not any additional actions planned nor being tracked which address this issue.