NMSS-0022. Gamma Stereotactic Radiosurgery

DESCRIPTION

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 was 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 plannned 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 was 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 believed that there were generic implications associated with safely performing gamma stereotactic radiosurgery, particularly with respect to the verification of coordinate settings. As a result, the NMSS staff evaluated whether existing NRC regulatory programs were adequate to prevent medical misadministrations that result from human errors associated with the setting of coordinates on the stereotactic frame during gamma stereotactic radiosurgery.

The existing 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

existing guidance on this topic suggested that at least one qualified person independently verify the coordinate settings. The combination of the existing 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 existing regulatory process will identify and address the issue[1] through the appropriate mechanisms such as enforcement and licensee corrective actions.

CONCLUSION

Examination of existing 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 had 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

[1] Memorandum for W. Travers from W. Kane, "Closure of NMSS Generic Issue Relating to Gamma Stereotactic Radiosurgery," February 12, 2001. [ML010390357]

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.

In addition to the staff's evaluation, Information Notice 2000-22[2] was issued to applicable licensees to remind them of their responsibilities with respect to written directives and to ensuring that the written directives were followed as planned. Furthermore, a series of best practices on how other licensees ensure correct coordinate

settings were identified in IN 2000-22.[3] The staff 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. Thus, the issue was dropped from further pursuit.[4]

[2] Information Notice 2000-22, "Medical Misadministrations Caused by Human Errors Involving Gamma Stereotactic Radiosurgery (Gamma Knife)," U.S. Nuclear Regulatory Commission, December 18, 2000. [ML003761619]

[3] Information Notice 2000-22, "Medical Misadministrations Caused by Human Errors Involving Gamma Stereotactic Radiosurgery (Gamma Knife)," U.S. Nuclear Regulatory Commission, December 18, 2000. [ML003761619]

[4] Memorandum for W. Travers from W. Kane, "Closure of NMSS Generic Issue Relating to Gamma Stereotactic Radiosurgery," February 12, 2001. [ML010390357]