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**Docket:** NRC-2017-0215
Yttrium-90 Microsphere Brachytherapy Sources and Devices Therasphere and SIR-Spheres

**Comment On:** NRC-2017-0215-0024
Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres; Draft Guidance; Extension of Comment Period

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## Submitter Information

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## General Comment

As stated in 67 FR 20250, published on April 24, 2002, the NRC added Subpart K to Part 35 so that there would be codified regulatory requirements and a more clearly defined process to obtain a license, or a license amendment, for a new medical use of byproduct material or radiation from byproduct material, i.e., an emerging technology. The commenter questions whether the use of Yttrium-90 microspheres should continue to be authorized as an emerging technology licensed under 10 CFR 35.1000. As noted in 82 FR 51655, the NRC first developed Licensing Guidance for Y-90 microspheres in 2002, and has almost 15 years of licensing and inspection experience with this technology. Fifteen years of experience should have allowed NRC sufficient time to evaluate this technology and determine if it is truly a technology that does not meet one of the existing Subparts D through H. If it does not meet one of the existing Subparts D through H, the time has come for rulemaking. The NRC can't just keep using Licensing Guidance as a means to avoid the challenges of rulemaking. Truly emerging technologies may be seen as having an unknown risk. Once the risk becomes clear, such as after 15 years of regulation under 10 CFR 35.1000, the degree of regulation that is needed to minimize the risks can be defined and properly put into rulemaking. The commenter does not believe that the intent of 10 CFR 35.1000 was to allow Licensing Guidance to be utilized indefinitely in lieu of rulemaking.

The stated purpose of 10 CFR 35.1000 Licensing Guidance is to offer or describe acceptable approaches to provide the additional information needed by NRC to approve a license or license amendment for a use not specifically addressed in Subparts D through H. As such, the licensing guidance should only address those items required to obtain a license. It should only address that information required by regulation, specifically 10 CFR 35.12(b) through (d). This means that the licensing guidance should focus on the radiation safety aspects of the "emergent" medical use, including radiation safety precautions and instructions; methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

The Y-90 Microspheres Licensing Guidance goes beyond the information needed by NRC to approve a license or license amendment. Specifically, it provides exemptions for regulatory requirements for Written Directives and for Medical Event Reporting. Exemptions are only to be granted by the NRC as authorized by law and are otherwise deemed to be in the public interest. Has that analysis been performed for these exemptions? The commenter questions whether Licensing Guidance, even if tied to a license as a commitment, should be authorizing exemptions to NRC regulatory requirements. It has been established that the NRC regulations shall govern unless the statements, representations, and procedures in the license application and correspondence are more restrictive than the regulations. The Written Directive criteria and Medical Event Reporting criteria in the Y-90 Microspheres Licensing Guidance can be seen as less restrictive, so the regulations would govern, making their inclusion in the Licensing Guidance confusing.

The way that the Written Directive criteria are described in the Y-90 Microspheres Licensing Guidance is flawed in that it does not clearly specify that the written directive is required to be dated and signed by an Authorized User prior to the administration. There should always be a written directive prior to administration that specifies the prescribed dose or activity, and that is dated and signed by an Authorized User prior to administration. The Licensing Guidance does not clearly specify this, which can lead to poor practices of preparing Written Directives after the fact.

The criteria for Medical Event reporting in the Licensing Guidance are inconsistent with the Medical Event reporting criteria in 10 CFR 35.3045. It is unclear as to the justification of having different reporting criteria for Medical Events involving microspheres. As noted, the regulations govern when they are more restrictive than license conditions, making the inclusion of the alternate criteria confusing. Having alternate criteria for Medical Event reporting for Y-90 Microspheres also impacts Congressionally-mandated Abnormal Occurrence reporting.

It is time for NRC to stop using Licensing Guidance in lieu of rulemaking for these technologies, such as Yttrium-90 microspheres, and promptly commence rulemaking. If Licensing Guidance is going to continue to be utilized, it should focus on acceptable approaches to provide the information needed by NRC to approve a license or license amendment, and should not authorize exemptions to NRC regulations that are unenforceable and have not been determined to be in the public interest.