ARIZONA RADIATION REGULATORY AGENCY

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ARRA INFORMATION NOTICE 2014-IN-04: TO INFORM ALL MEDICAL LICENSEES ABOUT THE INCREASED NUMBER OF MEDICAL EVENTS INVOLVING YTTRIUM-90.

ADDRESSEES

All medical licensees who are authorized to possess Yttrium-90.

PURPOSE

The Arizona Radiation Regulatory Agency is issuing this information notice (IN) to inform Arizona licensees of the increased number of medical events involving Y-90.

DISCUSSION

The Agency, Nuclear Regulatory Commission, as well as other Agreement States have seen miscalculations, wrong lobe injections, and under doses due to flow problems. The causes of the flow problems have varied with no single cause predominating. The most common problem was microsphere settling due to low flow rates. The reported reasons for the slow flow have been:

* Pause during the procedure resulting in settling
* Clumping
* Leaking of priming line and reduced pressure
* Angled needle insertion
* Defective catheter
* Deformation of tube and limited flow form a hemostat
* Slow flush due to small arteries
* "Dose seemed harder to push"
* Low flow rate
* Impeded flow due to piece of septum in vial
* Clamp not fully opened
* Stasis due to vascular spasm, small/fragile vessels slowed delivery or malfunction of delivery system
* Occlusion of catheter due to microcatheter (catheters < 2.8 French)
* Procedure halted because of patient pain (this should not be listed as a medical event)
* Slow delivery that led to settling
* Microspheres stuck to septum

<u>Specific Y-90 information including written directives, dose calculations, and inventories</u>

• The written directive shall include the patient or human research subject's name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the prescribed dose/activity; the manufacturer; and, if appropriate for the type of microsphere used, the statement "or dose/activity delivered at stasis." The written directive should specify the maximum dose(s)/activity(ies) that would

be acceptable to the specified site(s) outside the primary treatment site due to shunting (e.g. lung and gastrointestinal tract).

- Administration of Y-90 microspheres must be performed in accordance with the written directive. If the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure), the AU should document such changes in the written directive within 24 hours after the completion or termination of the administration. The modification to the written directive should include the reason for not administering the intended dose/activity, the date, and the signature of an AU for Y-90 microspheres.
- The licensee shall record the administered dose/activity delivered to the primary treatment site and to the other specified site(s). If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred and the administration was terminated. The record should be prepared within 24 hours after the completion or termination of the administration and must include the name of the individual who made the assessment, the date, and the signature of an AU for Y-90 microspheres, if terminated due to stasis.
- The licensee shall follow the manufacturer's procedures for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements; or submit alternative methods.
- The semi-annual physical inventory of microsphere aggregates (e.g. vials) should include:
  1) the radionuclide and physical form; and
  2) unique identification of each vial in which the microspheres are contained; and
  3) the total activity contained in each of the vial(s); and
  4) the location(s) of the vial(s).

Medical Event Reporting Criteria

1) The administration of byproduct material results in a dose that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from the use of the wrong radionuclide; or
2) The administration of Y-90 microspheres results in a dose
   a) that differs from the prescribed dose or the dose that would have resulted from the prescribed activity, as documented in the written directive, by more than 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue, and the total dose/activity administered differs from the prescribed dose/activity, as documented in the written directive, by 20 percent or more; or
   b) that exceeds 0.05 Sv (5 rem) effective dose equivalent or 0.5 Sv (50 rem) to an organ or tissue from an administration to the wrong individual or human research subject, via the wrong route, or by the wrong mode of treatment; or
   c) to an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and by 50 percent or more of the prescribed dose/activity expected to that site from the administration of Y-90 microspheres, if carried out as specified in the written directive

Please note that if the authorized user changes the dose to the patient during administration, the written directive needs to be changed within 24 hours of the change. If the written directive is not changed, then the original prescription is valid and the dose needs to be evaluated against the above medical event criteria.

CONCLUSION

The Agency is requesting that each licensee review their Yttrium-90 program and evaluate all of their written directives for the past two(2) years against the medical event reporting requirements. If the licensee discovers a reportable event, please contact the Agency immediately.

If there are any questions or concerns regarding this informational notice, please contact Brian Goretzki at 602-255-4840.