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General Comment

Question A.7.1
Alpha, beta and photon (gamma and x-ray) radiations should be covered by the definition of microsource, as all three of those radiation types could be exploited for microsource therapy (low energy in the case of gammas and x-rays). Microsources should not be limited to microsources should neither be limited to sealed sources with a SS&D registry nor should be required to have a SS&D registry, since most, if not all, such microsources consist of millions of individual microparticles that are infused in an unsealed fashion.

Question A.7.3
A successful team-approach microsource program consists of 1) a properly trained AU who takes ultimate and personal responsibility for the program's success and regulatory compliance, executes proper oversight and delegation of authority of all personnel involved in the microsource procedures; 2) a qualified and properly trained authorized medical physicist and health physicist/RSO, technologists and other personnel; and 3) properly documented procedures for treatment planning (including correct pre- and post-treatment written directives), accurate pre- and post-treatment activity measurement, pre- and post-treatment imaging, proper post-procedure radiation surveys, and appropriate and safe handling of all sources of radioactivity resulting from the procedure. In addition, if dosimetric treatment planning is employed, all software involved should be validated and commissioned by a qualified and properly trained medical physicist.

Question A.7.6
For determining whether a medical event has occurred (as defined in Section 35.3045), 1) if the prescription/treatment plan is total administered activity-based, then the net activity administered needs to be either calculated or measured in order to be able to compare it to the prescription and determine whether or not the difference is above the regulatory lower limit for reporting; and 2) if the prescription/treatment plan is treatment site (plus possibly one or more normal tissue site) activity- or dose-specific, then calculating and documenting the net activity or dose specifically delivered to the

treatment site is required in order to be able to compare it (them) to prescribed activity(ies) or dose(s). In my opinion, determination as to whether or not a medical event has occurred should be made within forty-eight hours, since there should not be more than a one day delay after treatment when the post-treatment written directive is finalized; and it should be practical to determine whether or not a reportable medical event has occurred within one day after the written directive has been finalized.

Question A.7.7
In my opinion, some form of post-treatment imaging should be required, to at least visually confirm that the treatment was delivered in accordance with the written directive. (Depending upon the the amount of and types of radiation that are associated with the treatment, determining quantitatively by imaging what was actually delivered to specific sites may be difficult or impossible.)

Question A.7.8 Microsource therapy-related asks that should require the involvement of an AMP are 1) development, validation and commissioning of, and template creation based on, software used for dosimetry-based treatment planning; 2) development of gamma camera and/or PET imaging protocols and quantification for dosimetric purposes; and 3) radioactivity measurement instrument (e.g., dose calibrator) calibration, and development of pre- and post-treatment measurement methods. I am of the opinion, that AMP should not be restricted to therapeutic medical physicists. Much of microsource therapy, due to its consisting of unsealed radioactivity, involves nuclear medicine, namely, unsealed radionuclide internal dosimetry methods, gamma camera and/or PET imaging and quantification, and calibration of instrumentation for, and measurement of, unsealed sources of radioactivity. Therefore, in my opinion, a nuclear medical physicist with appropriate education, certification and training should also be allowed to be an AMP for microsource therapy.

Question A.7.9
Intra-arterial and direct tumoral infusion should be permitted for microsource manual brachytherapy, and its use should not be limited to that approved in the sealed source and device registry. A number of microsource products are and will be unsealed and consist of millions of individual sources, using a number of different radionuclides. In that case, microsource therapy is actually a form of unsealed radionuclide therapy that has been historically associated with nuclear medicine, and has some commonality with radiopharmaceutical therapy, for which a sealed source and device registry would not apply. Unsealed microsources without a unique delivery system should be allowed, as there are and will be microsource products which use conventional syringes, tubing and needles for delivery. OncoSil is one such product.