Draft Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®

Licensing Guidance

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10 CFR 35.1000 Use

Although yttrium-90 (Y-90) microspheres are manual brachytherapy sources used for permanent implantation therapy, Y-90 microspheres have many unique properties that merit radiation safety considerations other than those required by Title 10 of the *Code of Federal Regulations* (CFR) Part 35, Subpart F, "Manual Brachytherapy." These unique properties include the microspheres' small size, the large number of microspheres used in a treatment, and the route of administration. As a result, Y-90 microspheres are regulated under 10 CFR 35.1000[1], "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

Licensing Guidance

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of TheraSphere® and SIR-Spheres® and is not intended to be the only means of satisfying the requirements for a license. The applicant must submit the information required to meet 10 CFR 30.33 and 35.12, as described below. The applicant should submit additional information and commitments requested below or may, unless the information is specifically required by regulation, submit alternative information and commitments for review by the U.S. Nuclear Regulatory Commission (NRC) staff to make a licensing determination. Any alternative responses must include sufficient detail to meet the requirements in 10 CFR 30.33 and 35.12. The commitments incorporated into the applicant's license by license condition will be reviewed during routine inspections. Applicants are reminded that licenses issued pursuant to 10 CFR 35.1000 must still meet the general requirements in 10 CFR Part 35, Subparts A, B, C, L, and M, except as specified in this guidance. Additionally, applicants must meet applicable requirements of 10 CFR Parts 19, 20, and 30.

[1] Medical Uses of Byproduct Material Licensed under 10 CFR 35.1000 are designated as Compatibility Category D. Agreement States are not required to adopt these regulations for purposes of compatibility, but are not prohibited from adopting Compatibility Category D regulations if they so choose.

General

Radionuclides, Form, Possession Limits, and Purpose of Use

The applicant shall identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use. This information may be submitted under signed and dated letter or NRC Form 313. For example, the following provides the format for an acceptable request.

	TheraSphere®	SIR-Spheres®
Radionuclides (Authorization 6)	Yttrium-90	Yttrium-90
Chemical/Physical Form (Authorization 7)	Glass microsphere (current manufacturer as listed in Sealed Source and Device Registry [e.g., Nordion (Canada), Inc. Model TheraSphere®])	Resin microsphere (current manufacturer as listed in Sealed Source and Device Registry [e.g., Sirtex Model SIR-Spheres®])
Maximum Possession Limit (Authorization 8)	3 Ci total	3 Ci total
Authorized Use (Authorization 9)	TheraSphere® for permanent brachytherapy using Glass Microsphere System as listed in Sealed Source and Device Registry.	SIR-Spheres® for permanent brachytherapy using delivery system as listed in Sealed Source and Device Registry.

Leak Tests

Leak tests are not required for Y-90 microspheres. The small size and large number of Y-90 microspheres make leak testing, as required by 10 CFR 35.67(b), impractical. Further, if leak testing were practical, licensees would not be required to leak test individual microspheres because the activity of each microsphere is below the threshold in 10 CFR 35.67(f)(3).

Authorized Users

NRC has determined that individuals meeting the guidance provided in both A and B below will be considered qualified and can be authorized for the use of Y-90 microspheres. Applicants may also submit alternative training and experience (T&E) commitments to be reviewed on a case-by-case basis by NRC staff. The alternative T&E commitments should include an explanation of why the applicant believes the alternative T&E commitments demonstrates that the individuals are qualified to be authorized users.

Training and Experience

The authorized user (AU) for Y-90 microspheres:

A.

1. Is identified as an AU for medical uses in 10 CFR 35.1000, "Other medical uses of byproduct material" for Y-90 microspheres, 10 CFR 35.400, "Use of sources for manual brachytherapy," or for medical uses in 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required," on one of the following licenses or permits that authorizes the medical use of byproduct material: A Commission or Agreement State license, a permit issued by a Commission master materials licensee, a permit issued by a Commission or Agreement State licensee of broad scope, or a permit issued by a Commission master materials license broad scope permittee; or
2. Meets the training and experience requirements of 10 CFR 35.390 or 10 CFR 35.490; or
3. Meets the training and experience guidelines as follows:

   i.

   a. Board certification in diagnostic radiology by either the American Board of Radiology (ABR) or the American Osteopathic Board of Radiology (AOBR),[2] or 3 years supervised clinical experience in diagnostic radiology, and

[2] As noted on the NRC's Medical Uses Licensee Toolkit Web site, the NRC-approved ABR and the AOBR certificates contain the words "AU eligible" above the ABR or AOBR seal. For the purposes of this guidance, the NRC deems the certificates issued without "AU Eligible" to be adequate to meet T&E in sections A.3.i.a and A.3.i.b. .

b. subspecialty certification in interventional radiology by either the ABR or the AOBR[2], or one additional year of supervised clinical experience in interventional radiology; and

ii. has 80 hours of classroom and laboratory training[3] for byproduct material requiring a written directive, including Y-90 microspheres, which may be concurrent with training received in accordance with Item A.3.i. in:
   a. Radiation physics and instrumentation; and
   b. Radiation protection; and
   c. Mathematics pertaining to the use and measurement of radioactivity; and
   d. Radiation biology; and

iii. has work experience under the supervision of an AU for Y-90 microsphere brachytherapy or training provided by a Y-90 microsphere manufacturer representative involving:
   a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; and
   b. Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters; and
   c. Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject; and
   d. Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures (Appendix N, "Model Emergency Procedures," NUREG-1556, Volume 9 provides additional guidance on this subject. The procedures should address any special circumstances that may be encountered, such as electrostatic charge of

[3] For Board Certified physicians, if the Board Certification is recognized by the NRC on the NRC's Medical Uses Licensee Toolkit Web site for 10 CFR 35.390, 35.392, and 35.394, the applicant or licensee need not submit detailed documentation of those AUs' classroom and laboratory training to satisfy section A.3.ii. The applicant or licensee need only confirm that the individual has completed training in the use of Y-90 microspheres.

microspheres and proper survey instrument and survey technique for beta emitters); and

iv. has work experience under the supervision of an AU for Y-90 microsphere brachytherapy for Y-90 microsphere brachytherapy including:
    a. Evaluation of patient or research subject's treatments to determine whether the administered dosage was in accordance with the written directive. Evaluation must be done after each supervised hands-on case described in section B; and
    b. Using administrative controls to prevent a medical event involving the use of byproduct material (Appendix S, "Model Procedures for Developing, Maintaining, and Implementing Written Directives," NUREG-1556, Volume 9 provides additional guidance on this subject); and

B. has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microsphere for which authorization is sought. This requirement may be satisfied by completing a training program provided by an AU who is authorized for the type of Y-90 microsphere for which the individual is seeking authorization. This clinical use experience should include at least three supervised hands-on cases for each type of Y-90 microsphere for which the individual is seeking AU status. Training may be completed under more than one qualified AU.

In accordance with 10 CFR 35.59, the training and experience specified above must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed. Recent training provided under Section B may be sufficient to show a recentness of training. This recentness of training requirement applies to all individuals, including those who are board certified or listed as an AU on an NRC or Agreement State license.

Note: In the August 2008 revision to this licensing guidance, the NRC formalized an alternate, manufacturer provided clinical training pathway to complete the training and experience criteria in Section B. This alternate pathway remained in this licensing guidance for several years because there were a limited number of AUs who were authorized for each type of Y-90 microsphere, which made it difficult for physicians who were seeking authorization to complete the clinical experience described in Section B under the supervision of another AU already

authorized for the use of Y-90 microspheres. However, after more than 10 years of licensing Y-90 microsphere brachytherapy, the NRC has determined that there is a sufficient number of AUs available to supervise physicians who wish to gain AU status for Y-90 microsphere brachytherapy. Accordingly, the NRC has determined that this alternate pathway, which is specific to only Y-90 microsphere brachytherapy, is no longer necessary in most cases and therefore has removed the alternate pathway from this licensing guidance.

Nonetheless, the NRC recognizes that some physicians may be in the process of using the alternate pathway to become authorized for Y-90 microsphere use. To avoid undue burden, applicants may continue to follow the alternate pathway, described below, in place of section B to demonstrate experience described in section B until 2 years after the date of issuance of the final revision 10 of this licensing guidance.

The requirements of the alternate pathway are that the individual has successfully completed training in the operation of the delivery system, safety procedures, and clinical use for each type of Y-90 microsphere for which authorization is sought. This requirement may be satisfied by completing a training program provided by a Y-90 microsphere manufacturer. This clinical use experience should include at least three supervised hands-on *in-vitro* simulated cases, conducted under the manufacturer's supervision, for each type of Y-90 microsphere for which the individual is seeking AU status. *In-vitro* simulated cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures. Following the license amendment that names the individual as an AU for Y-90 microsphere use, the first three patient cases completed by the individual should be hands-on and supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which the individual is authorized. The individual should complete these three cases within 6 months following the license issuance or amendment that names the individual as an AU for Y-90 microsphere use. If circumstances (i.e. lack of patient requiring treatment) do not allow the AU to complete these three cases within 6 months, the licensee may submit documentation to the NRC requesting an extension of this timeframe. The supporting documentation should include a commitment to perform continuing training and experience (e.g. 1 additional in-vitro case prior to performing patient cases) in the use of the type of Y-90 microsphere requested until the first three patient cases are completed.

The following provides a standard license condition that may be used to grant AU status to a physician for Y-90 microsphere use under this alternate pathway until the pathway is removed.

> Physicians [insert names of authorized users] are permitted to work as authorized users for [TheraSphere® and/or SIR-Spheres®] yttrium-90 microsphere use in accordance with the letter(s) dated (enter dates of letters). Within 6 months of being authorized for medical use of each manufacturers' yttrium-90 microspheres, each authorized user must complete at least three clinical patient cases, in the physical presence and under the supervision of a manufacturer representative. The licensee shall submit documentation from the manufacturer of each physician's clinical experience within 7 months of the date of the amendment adding the authorized user. Absent such documentation, the license may be amended to remove authorized users from the license.

Training and Experience Documentation

The applicant must submit documentation of the above training and experience. This documentation shall include the clinical use cases. For individuals obtaining clinical use experience under the alternate pathway, this documentation shall include documentation from the manufacturer of the three *in-vitro* simulated cases and a commitment that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative for each type of Y-90 microsphere for which authorization is sought. Additionally, for applicants using the alternate pathway, the licensee's commitment will include submitting documentation from the manufacturer to the appropriate NRC Regional Office within 30 days of when these three patient cases have been satisfactorily completed.

Team Approach

Microsphere brachytherapy treatment is usually conducted using a multi-disciplinary team approach. The AU should consult, as necessary, with individuals with expertise in:

- cancer management (e.g., radiation or medical oncology),
- catheter placement,
- radiation dosimetry, and
- safe handling of unsealed byproduct material.

One individual may satisfy more than one of the listed areas of expertise.

Notification

NRC recognizes that if an AU satisfies the training and experience listed in NRC's licensing guidance for Y-90 microspheres and is currently listed on a Commission or Agreement State medical use license or permit for a specific type of microsphere, the AU should be allowed to work under a different license for the medical use of the same type of microsphere. A limited specific medical use applicant initially applying for authorization for the medical use of Y-90 microspheres or an existing licensee applying for an amendment may request authorization to notify the NRC in the future that it has permitted an AU to work at its facility without requesting an additional license amendment, provided the following conditions are met:

1. the AU satisfies the training and experience listed in NRC's licensing guidance for Y-90 microspheres; and
2. the AU is currently listed for the same type of Y-90 microsphere use on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master material license broad scope permittee; and
3. the licensee provides the NRC a copy of the license or permit on which the AU is listed for the specific microsphere use;
4. the licensee provides the NRC documentation of the completion of three patient cases for AUs approved under the alternate pathway; and
5. the licensee provides documentation of the above listed conditions to NRC for each AU no later than 30 days after the date that the licensee allows the AU to work as an AU for the specific type of microsphere.

If this authorization is approved, these notification conditions will be incorporated as license conditions in the licensee's license.

Grandfathering

If a licensee adopts this revision of Y-90 microsphere training and experience criteria, physicians who are currently authorized for the medical use of a specific type of Y-90 microsphere under previous criteria do not have to meet the revised criteria for that type of microsphere.

License Commitments

The applicant shall commit to follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where replaced by the following licensing commitments:

Training

The applicant shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

Procedures for Administration

The licensee shall commit to following the manufacturer's procedures for calculating and documenting the dose or activity to the treatment site; preparing the dose for administration; determining shunting to non-treatment sites; and performing pre- and post-vial dose measurements; or submit alternative methods.

Administration of Y-90 microspheres must be performed in accordance with the written directive. The licensee shall record the dose or activity delivered to the treatment site. 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 determined the administered dose or activity and the date.

Written Directives

For the purpose of written directive and medical event reporting requirements in the Y-90 microsphere guidance, “prescribed dose” means the total dose (rad or Gy). Alternatively, prescribed activity (mCi or GBq) may be used in lieu of prescribed dose. If prescribed activity is used in lieu of prescribed dose, activity should be used for all documentation and evaluations.

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 model of spheres (e.g. TheraSphere® or SIR-spheres®) or manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement “or dose or activity delivered at stasis.”

Termination of Treatment Due to Stasis

If the administration was terminated because of stasis, then the total dose or activity to the treatment site is the value of the total dose or 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 determined the administered dose or activity, the date, and the signature of an AU for Y-90 microspheres.

Emergent Patient Conditions

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 or activity, the date, and the signature of an AU for Y-90 microspheres.

Medical Event Reporting

The licensee shall commit to report any event, except for an event that results from intervention of a patient or human research subject, in which:

- 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
- the administration of byproduct material: to the wrong individual or human research subject; via the wrong route; or by the wrong mode of treatment; or
- the total dose or activity delivered differs from the prescribed dose or activity, as documented in the written directive, by 20 percent or more, except when stasis or emergent patient conditions are documented and resulted in a total dose or activity administered that was less than that prescribed; or
- the administration of byproduct material results in dose or activity to an organ or tissue other than the treatment site, as documented in the written directive, except for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures. For the purpose of this document, shunting is defined as an unexpected blood flow (i.e. due to patient vasculature) causing the Y-90 microspheres to flow to an unwanted location. Unexpected dose or activity to an organ or tissue other than the treatment site that is caused by catheter placement during delivery of the Y-90 microspheres is not considered shunting.

Additionally, the licensee shall comply with the medical event reporting and notification requirements as described in 10 CFR 35.3045(b)-(g).

Sealed Source and Device Use

The licensee should commit to use only yttrium-90 microspheres for therapeutic medical uses as approved in the Sealed Source and Device Registries for TheraSphere® and SIR-spheres®, including maximum activity per vial limit.

Inventory

Due to the short half-life of Y-90 (64 hours) and the fact that microspheres are not managed as individual discrete sources, the requirements in 10 CFR 35.67 for semi-annual physical inventory of brachytherapy sources and recordkeeping in 10 CFR 35.2406 are not applicable to microspheres. Rather, the requirements for brachytherapy source accountability (10 CFR 35.406), receipt (10 CFR 20.1906), labeling (10 CFR 20.1904 and 10 CFR 35.69), storage (10 CFR 20.1801 and 10 CFR 35.92), and disposal (see the "Waste Disposal Issues" section of this guidance document) are sufficient to ensure accountability of Y-90 in the form of microspheres possessed by a licensee.

Labeling

The licensee should commit to the following when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

- Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
- Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

Patient Release

The licensee should commit to develop procedures that describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his or her release in accordance with 10 CFR 35.75. Guidance for release of patients or human research subjects following administration of radioactive materials may be found in Regulatory Guide, 8.39, "Release of Patients Administered Radioactive Materials."

Radiation Protection Program Changes

This guidance may be revised as additional experience is gained regarding the medical use of TheraSphere® and SIR-Spheres® Y-90 microspheres. A licensee currently authorized to use these products that is committed by license condition to following provisions in a previous

revision of this guidance may request a license amendment to commit to following this revision of the guidance instead. The licensee must apply for and receive this license amendment in order to make program changes to conform to this revision of the guidance.

An applicant initially applying for authorization for the medical use of TheraSphere® and SIR-Sphere® Y-90 microspheres, or a licensee applying for an amendment to conform with this revision of the guidance may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

1. the revision is in compliance with the regulations; and
2. the revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC's Medical Uses Licensee Toolkit Web site;
3. the revision has been reviewed and approved by the licensee's Radiation Safety Officer and licensee's management; and
4. the affected individuals are instructed on the revised program before the change is implemented; and
5. the licensee will retain a record of each change for 5 years; and
6. the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

Notes to Licensees

Change in Physical Conditions of Use

If the physical conditions of use exceed those reported in the Sealed Source and Device (SSD) certificate, the limited specific medical use licensee should request an amendment for the new

conditions, and a broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Use of Other Y-90 Microspheres

The SSD safety evaluation for a specific manufacturer's Y-90 microsphere does not cover the use of any other Y-90 microspheres, including those prepared by an authorized nuclear pharmacist or an authorized user qualified to prepare radioactive drugs. The medical use of such a source will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new Y-90 microspheres, and compatibility of the new microspheres with microsphere delivery system(s).

The SSD safety evaluation for a given manufacturer's Y-90 microsphere delivery system does not cover the use of that manufacturer's Y-90 microspheres with another manufacturer's delivery system or the use of another manufacturer's Y-90 microspheres with the given manufacturer's delivery system. Before authorization, the medical use of such a delivery system will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the microsphere delivery system, and compatibility of the new delivery system with the Y-90 microspheres.

TheraSphere® Use Outside Humanitarian Device Exemption (HDE) Restrictions

The Nordion (Canada) TheraSphere® Y-90 glass microspheres are approved by the U.S. Food and Drug Administration (FDA) under the provisions of a "Humanitarian Device Exemption" (HDE No. H9800006), which includes unique restrictions on the medical use of the device. Nothing in the NRC license relieves the licensee from complying with those FDA requirements.

If the Institutional Review Board, as defined in 45 CFR 46, that is required to approve and monitor the use of the Nordion (Canada) TheraSphere® Y-90 microspheres determines that the particular use of TheraSphere® Y-90 microspheres is for research purposes, the licensee must meet the requirements in 10 CFR 35.6, "Provisions for research involving human subjects." (Note: One of the conditions of approval for an HDE is that there be an Institutional Review

Board initial review and approval before a humanitarian use device is used at a facility, as well as continuing review of its use.)

Waste Disposal Issues

Y-90 microspheres are known to potentially contain radioactive impurities, some of which are long lived (i.e., half-lives of greater than 120 days) (Refer to Information Notice (IN) 2007-10, "Yttrium-90 Therasphere® and SIR-Spheres® Impurities"). Due to different manufacturing processes, the activity and radionuclides of the impurities vary for different Y-90 microsphere products. Impurities that have been recently found in reactor activated microspheres include small amounts of long lived radionuclides such as europium-152, europium-154, and cobalt-60, and short lived radionuclides (i.e., half-life less than 120 days) such as yttrium-88 and yttrium-91.[4] Impurities that have been recently found from microspheres with generator produced Y-90 include trace amounts of strontium-90.[5] Additionally, the NRC has been notified that short lived yttrium-88 has also been found in microspheres with generator produced Y-90.

Licensees should be aware that the activity and type of impurities can change. The NRC does not limit manufacturers to specific manufacturing processes, and it is therefore possible for the activity and types of radionuclide impurities to change for both products. Additionally, unused or partially used vials are likely to contain higher activities of impurities.

Although impurities need not be listed on an NRC license; licensees are responsible to ensure the microspheres are handled and disposed of in accordance with 10 CFR Part 20 and Part 35 requirements. Specifically, 10 CFR 35.92 requires that licensees monitor byproduct material with a physical half-life of less than or equal to 120 days at the surface before disposal and determine that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter before disposal. Therefore, regardless of the length of time they have been allowed to decay, licensees are not permitted to dispose of Y-90

[4] J. Metyko, J. Williford, W. Erwin, J. Poston, S. Jiminez, Long-lived Impurities of ^{90}Y-labeled microspheres, TheraSphere and SIR-Spheres, and the impact on patient dose and waste management. Health Phys. **103**(3), S204-S208 (2012).
[5] J. Metyko, W. Erwin, J. Poston, and S. Jimenez, ^{90}Sr Content in ^{90}Y-labeled SIR-Spheres and Zevalin. Health Phys. **107**(5), S177-S180 (2014).

microspheres if radioactivity can be distinguished from the background radiation level with an appropriate radiation detection survey meter.

If waste is determined to contain impurities with a physical half-life of greater than 120 days that can be distinguished from the background radiation level with an appropriate radiation detection survey meter, the licensee may need to use one or more of the following means to dispose of waste associated with Y-90 microspheres:

- return the microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or
- transfer the microspheres to an authorized recipient pursuant to requirements in 10 CFR Part 20 and Part 30.

See Regulatory Information Summary 2004-17, Revision 1, "Revised Decay-in-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material," for more information regarding requirements for holding waste for decay-in-storage.

Autopsy and Cremation

Y-90 microspheres are permanent implants that are not removed from the body by biological methods. Because Y-90 has a 64-hour half-life, in most cases Y-90 will have significantly decayed before a patient's death. Patients treated with Y-90 microspheres will not usually represent an external radiation hazard to persons handling the body. However, in the case of autopsy or cremation, the radiation hazard increases due to the need for individuals to handle tissues that may contain radioactive material, especially if the death occurs soon after treatment with Y-90 microspheres. For autopsy or cremation of patients with permanent implants, the National Council on Radiation Protection and Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients," December 2006, may contain helpful information. Additionally, NUREG-1556, Volume 9, Appendix N, "Model Procedures for Developing, Maintaining, and Implementing Written Directives," contains additional guidance regarding autopsy and cremation of patients who have received therapeutic amounts of radionuclides.

Paperwork Reduction Act Statement

The information collections contained in this draft guidance are covered by the requirements of 10 CFR Parts 30 and 35, which were approved by the Office of Management and Budget, approval numbers 3150-0017 and 3150-0010.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

SUBJECT: DRAFT YTTRIUM-90 MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES THERASPHERE® AND SIR-SPHERES® LICENSING GUIDANCE, REVISION 10

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