



February 12, 2009

Customer Service Department  
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### **Customer License Amendment Information**

In general, if a licensee has not purchased Cs-131 brachytherapy seeds in the past they may need to amend their radioactive materials license to add IsoRay CS-1 brachytherapy seeds. The following information is what license reviewers may look for in reviewing an amendment request in reviewing the amendment.

If you have any questions or would like additional clarification, please contact Dale Boyce, RSO at (509) 375-1202 x254 or [dboyce@isoray.com](mailto:dboyce@isoray.com).

### **Sealed source regulatory Information**

IsoRay Cs-131 Model Cs-1  
510(K): K030162  
Regulation 21 CFR 892.5730  
Radionuclide brachytherapy source  
Regulatory Class II  
Product code: 90 KXK  
Approval received: March 28, 2003

Sealed Source and Device Registry Number: WA-1220-S-101-S  
Approved September 17, 2004

### **Activities to request**

Radioactive materials are regulated by the total internal activity (GBq, Ci, or mCi) at the time of shipment by the manufacturer to the authorized users. Brachytherapy seed strength is normally described by the radiation emanating from the source in Air Kerma (U) which has the units of  $\mu\text{Gy m}^2/\text{hr}$  and is shortened to "U". For inventory purposes, the Air Kerma (U) seed strength can be converted to internal activity (mCi) by multiplying by 2.124.

Most, but not all, implant cases are below 500 mCi at the time of implant. To accommodate delay time during shipping, customers should request a radioactive material license with a total inventory of at least 600 mCi (0.6 Ci) for each patient treatment to take place in a given week. This allows the user to receive the entire week's inventory on a single day allowing for preparations in advance of the patient implants. IsoRay recommends asking for a minimum of 2 Ci for the initial request, and 5 to 10 Ci for customers that do many implants.

For states that specify a per seed maximum, the customer should also request at least a 10 mCi per seed maximum. IsoRay's Sealed Source Device Registry currently allows us to manufacture seeds with up to 65 mCi for potential future applications.

### **Exposed Seeds**

Occupational radiation exposure from brachytherapy seeds is dependent on the dose rate from the seeds and the manner in which they are handled and shielded. Short-lived  $^{131}\text{Cs}$  and  $^{103}\text{Pd}$  seeds deliver a therapeutic dose in a much shorter time than  $^{125}\text{I}$ . The shorter half-life has radiobiological advantages that are beneficial to the patient.

The dose rate from exposed seeds is measured in Air Kerma Strength ( $S_k$ ). Air Kerma Strength is measured in terms of rads/hour at 1 cm from the source (U).

The total Air Kerma strength for a given brachytherapy case can be determined from nomograms developed for each isotope<sup>1-4</sup>. These nomograms allow one to estimate the total Air Kerma strength required based on the volume of the prostate. Prostate volumes can vary from less than 20 cc to greater than 70 cc, but typically will be in the range of 40 cc to 50 cc. Taking 40 cc as an example the total case Air Kerma strength at the time of implant for each of the three isotopes would be approximately:

$^{125}\text{I}$	40 U	(145 Gy prescribed dose)
$^{103}\text{Pd}$	205 U	(125 Gy prescribed dose)
$^{131}\text{Cs}$	142 U	(115 Gy prescribed dose)

This indicates that for a given therapy the dose rate from a fully exposed case of seeds will be about 20% less from  $^{131}\text{Cs}$  than from  $^{103}\text{Pd}$ . Both  $^{131}\text{Cs}$  and  $^{103}\text{Pd}$  require the clinician to pay more attention to shielding and time of exposure than does  $^{125}\text{I}$ . However, based on years of clinical experience, both can be handled safely in routine clinical practice.

### **Dose from a patient after $^{131}\text{Cs}$ implant**

Patients implanted with  $^{125}\text{I}$  and  $^{103}\text{Pd}$  seeds will give off lower dose rates than  $^{131}\text{Cs}$  on the day of implant due to the lower Air Kerma strength of  $^{125}\text{I}$ , and the greater absorption in tissue of the radiation from  $^{103}\text{Pd}$ , despite the higher total Air Kerma per case for  $^{103}\text{Pd}$ .

Health care providers can expect to see a dose rate at one meter from a typical  $^{131}\text{Cs}$  patient of approximately 2 mrad/hr. This depends on patient weight and the total Air Kerma strength of the implant. Thin patients with large prostates will deliver higher dose rates.

## **Patient Release Criteria**

The criteria to be considered in determining patient release are delineated in Appendix U of NUREG 1556, Vol. 9<sup>5</sup> and NCRP Report No. 37<sup>6</sup>, chapter 4, "Release from Hospital of Patients Containing Radioactive Material." Since <sup>131</sup>Cs is not explicitly listed in Table U1 of NUREG 1556 or in NCRP Report No. 37, special instructions are required. The specific patient release instructions should be based on the implanting facility's protocol and/or the Doctor's instructions given to his/her patient. IsoRay's policy is not to dictate what should or should not be included in patient release instructions, but to provide information and guidelines regarding <sup>131</sup>Cs that are helpful in counseling patients about radiation safety following a <sup>131</sup>Cs implant.

The NUREG guidance permits an occupancy factor of 0.25 at one meter from the patient to be used in estimating the dose to a maximally exposed individual, usually a spouse. With an allowable exposure of 500 mrad, the allowable dose rate from a <sup>131</sup>Cs patient on day 0 is 6 mrad/hr.

$$333 \text{ hours} \times 6 \text{ mrad/hr} \times 0.25 = 500 \text{ mrad} \quad (\text{see NUREG 1556 Equation U.1})$$

Thus, patients may be released at or below 6 mrad/hr, with instructions. (The highest dose rate at one meter that IsoRay is aware of from a <sup>131</sup>Cs implant patient is 4 mrad/hr.)

Another approach to instructions for patient release is to directly compare the expected dose to a family member from <sup>125</sup>I or <sup>131</sup>Cs. Since <sup>125</sup>I is prescribed at 145 Gy and <sup>131</sup>Cs is prescribed at 115 Gy, and the energy of the radiation from both isotopes is similar, the dose to a family member will be proportional to the prescribed dose. Given similar behaviors of the patient and family, over time, an <sup>125</sup>I implant will result in approximately 25% higher total dose to the family member than a <sup>131</sup>Cs implant.

Note: Attention should be given to the type of survey instrument used to make patient release determinations. Many GM survey instruments over-respond significantly to the radiation from both <sup>125</sup>I and <sup>131</sup>Cs, but respond fairly accurately to <sup>103</sup>Pd. It is best to use a properly calibrated thin window ion chamber or equivalent to measure the dose rate from a <sup>131</sup>Cs implant.

## **General Precautions to be Addressed with the Patient**

Travel and contact with small children or pregnant women can occur, but they should remain 3- 6 feet from the patient and be limited to a maximum of 5 minutes per day. Children should not sit on the patient's lap during the first 15 days following a <sup>131</sup>Cs implant. A patient's spouse may sleep in the same bed if there is no risk of pregnancy. Sexual intercourse may resume within a few weeks post-implant. Very occasionally, a seed can be expelled in the semen on ejaculation. If this does happen, it will usually occur in the first few ejaculations; therefore it is advisable to use a condom for the first two or three occasions of intercourse following implant.

Patients can usually get back to normal activities and work within a few days. Follow up medical examination is recommended after four to six weeks, and then every three months for a year, every six months up to five years, and then annually.

## **References**

1. Anderson LL, "Spacing nomograph for interstitial implant of  $^{125}\text{I}$  seeds," Med Phys 3:1 (1976).
2. Anderson LL, Moni JV, and LB Harison, "A nomograph for permanent implants of Palladium-103 seeds," Int J Radiat Oncol Biol Phys 27:1 (1993).
3. Cohen GN, Amols HI, Zelefsky MJ, and M. Zaider, "The Anderson nomograms for permanent interstitial prostate implants: a briefing for practitioners," Int J Radiat Oncol Biol Phys 53:2 (2002).
4. Private communication, D. Dryden to IsoRay Medical, "Cs-131 Nomogram", October 2005.
5. U.S. NRC, Release of Patients Administered Radioactive Materials, NUREG 1556, Vol. 9, Appendix U.
6. Precautions in the management of Patients Who Have Received Therapeutic Amounts of Radionuclides, NCRP Report 37, Washington DC (1970)