



# **Radium-223 Dichloride Subcommittee Report**

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## **Subcommittee Membership**

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**James Welsh, M.D.**

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## **Subcommittee Charge**

**To provide recommendations on  
licensing of radium-223 ( $^{223}\text{Ra}$ )  
dichloride ( $^{223}\text{RaCl}_2$ )**

## **Background**

- **$^{223}\text{RaCl}_2$ : A first-in-class, alpha particle-emitting therapeutic radiopharmaceutical**
- **Intended indication: Treatment of skeletal metastases in advanced, castrate-resistant prostate cancer**
- **Appears to be safe and effective and, uniquely, to prolong life**
- **Ready to inject: No preparation necessary nor radiochemical decomposition possible**
- **Patient-specific weight-normalized dosing (50 kBq/kg) from a pre-calibrated 1,000-kBq/ml solution**

## 1<sup>st</sup> Issue: Licensure

- **Any special credentialing required to administer  $^{223}\text{RaCl}$ ?**
- **§35.300 applies**
- **Credentialing options**
  - **§35.390, Category (3)**  $\gamma_s, \beta_s$
  - **§35.390, Category (4)** *Not “emissions-specific”*
  - **§35.390, New Category for  $\alpha$ -emitters**
  - **§35.1000, “Other” - specific license amendment**

## **Sub-Committee Recommendation**

**Physicians authorized to use therapeutic radiopharmaceuticals under § 35.390 or § 35.396 already have the requisite education, training, and experience to safely and effectively use  $^{223}\text{RaCl}_2$  ...**

**Licensing of authorized users of  $^{223}\text{RaCl}_2$  under § 35.390 (Category (G)(3) or (G)(4)) or § 35.396(d)(2) is therefore recommended.**

## **2<sup>nd</sup> Issue: Calibration of Administered Activity**

- **End-user calibration**
  - **Is it necessary?**
  - **Can it be done accurately?**
- **Dose calibrators do not have  $^{223}\text{Ra}$  setting**
- **$^{223}\text{Ra}$** 
  - **Secular equilibrium**
  - **Complex decay scheme**
- **NIST-traceable standard**



## **Sub-Committee Recommendation**

**To minimize the probability of a therapeutic misadministration, an appropriate radioassay system for measurement of the  $^{223}\text{Ra}$  activity prior to its administration and the residual activity following its administration is recommended**

## **Abbreviations and Acronyms**

- **ACMUI: Advisory Committee on Medical Uses of Isotopes**
- **NIST: National Institute of Standards and Technology**
- **$^{223}\text{RaCl}_2$ : Radium-223 radium dichloride**