

Georgia Department of Natural Resources

4244 International Parkway, Suite 114, Atlanta, Georgia 30354

Lonice C. Barrett, Commissioner
Environmental Protection Division
Harold F. Reheis, Director
(404) 362-2675

July 17, 2001

To: State Radiation Control Programs
NRC Regional Office Programs

RE: Changes in source certification for Theragenics Corporation's TheraSeed® Model 200

Dear Program Managers:

This correspondence serves as a follow-up to a previous letter dated March 10, 2000, which served to provide information about upcoming changes to Theragenics' sealed source certification to indicate source activity and air kerma strength based on two different calibration methods.

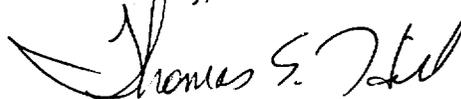
To summarize, the TheraSeed® Model 200 brachytherapy implant seed contains Pd-103. Prior to 1999, since there had not been a NIST-traceable standard for Pd-103, Theragenics had been calibrating the seeds by using a NIST-traceable Cd-109 standard. The calibration provided results in terms of apparent activity, in units of mCi. The air kerma strength, in units of U, was then calculated. This information had been included on the sealed source certification that accompanied each shipment. In 1999, the National Institute of Standards and Technology (NIST), in cooperation with the American Association of Physicists in Medicine (AAPM), developed a new national standard, based on air kerma strength using the Wide Area Free Air Chamber (WAFAC), for calibration of all Pd-103 brachytherapy seeds. Using this method, the calibration provided results in terms of air kerma strength, in units of U. The apparent activity, in units of mCi, was then calculated. These two methods yielded different results for apparent activity and air kerma strength. For an explanation of these results, refer to the article, "Recommendations of the AAPM on Pd-103 Interstitial Source Calibration and Dosimetry: Implications for Dose Specification and Prescription." This article was accepted for publication in January 2000 by Medical Physics. A copy of this article can be found on the American Association of Physicists in Medicine's website at <http://www.aapm.org> as the "Draft of AAPM Report 69."

Effective March 20, 2000, Theragenics began providing its customers a sealed source certification that included apparent activity and air kerma strength as determined by both methods. Theragenics sent a letter to its customers advising of this change in calibration information. Included in the letter was a statement asking the customer to confirm which dose rate constant (i.e., Cd-109 or WAFAC) was programmed into the treatment planning software prior to changing its ordering procedures. The labeling on the vials and the shipping containers would continue to reflect the activity as determined by the current Cd-109 calibration method. On March 5, 2001, Theragenics implemented a correction to the NIST standard as directed by the AAPM and NIST. This transition was addressed in "Evaluation of Effect of Corrected NIST 1999 WAFAC Standard on Previously Recommended Dose Rate Constant of 0.665 and on Recommended Prescribed Doses -- RE: Model 200 TheraSeed® Pd-103 Brachytherapy Source," dated December 15, 2000, by R. Nath, Ph.D and J. Williamson, Ph.D. This report was forwarded by Theragenics to its customers in a letter dated December 27, 2000.

Effective August 20, 2001, Theragenics will only accept orders for the TheraSeed® Model 200 brachytherapy implant seed in units of air kerma strength based on the corrected NIST 1999 WAFAC standard. Effective September 10, 2001, the sealed source certifications provided with all orders of TheraSeed® will only list activity and air kerma strengths in terms of the corrected NIST 1999 WAFAC standard. The only reference on the sealed source certification to the Cadmium-109 standard will be in a footnote, where the "equivalent" mean seed activity and activity range will be listed. Additionally, the labels on the vials and the shipping pigs will list values in terms of the corrected NIST 1999 WAFAC standard.

A copy of the correspondence from Theragenics, requesting this change, is enclosed. Because of the number and size, the attachments to the correspondence will be mailed with a hard-copy. If you have any questions, please feel free to contact Eric Jameson of our program at (404) 362-2675.

Sincerely,



Thomas E. Hill, Manager
Radioactive Materials Program

Enclosure -- as noted

01 JUL 31 AM 9:37
OSP

STP-006 Template
RIDS DIST: SP03

July 6, 2001

**THERASEED® NOTIFICATION OF CHANGE
FOR ALL CLIENTS**

We would like to notify you of two important implementation dates regarding order entry changes for the TheraSeed® Model 200 interstitial implant device and reformatting of the associated seed strength certification form and labels.

- I. Beginning Monday, August 20, 2001, Theragenics will only accept orders in units of air kerma strength based on the corrected NIST 1999 WAFAC standard ($S_{K, N99}$).**
- II. For TheraSeed® orders shipped on or after September 10, 2001, Theragenics will eliminate the section of the TheraSeed® seed strength certification that contains the source strength via Cadmium-109 point source calibration. However, essential information based on Theragenics' internal ^{109}Cd calibration system will be retained as a footnote on the seed strength certification form. Specifically, the new footnote will state the mean seed activity and the activity range in mCi ($A_{\text{app}, T97}$) based on the Theragenics' internal ^{109}Cd calibration system.**
- III. For TheraSeed® orders shipped on or after September 10, 2001, the vial and pig labels will list the total apparent activity in mCi ($A_{\text{app}, N99}$) and the air kerma strength range in U ($S_{K, N99}$) based on corrected NIST 1999 WAFAC standard.**

I. Change in Ordering Process

Beginning August 20, 2001, Theragenics will **only** accept orders in units of $U_{\text{NIST}} (S_{K, N99})$. Orders will **not** be accepted in units of mCi apparent ($A_{\text{app}, N99}$) or mCi apparent ($A_{\text{app}, T97}$). For clients currently using the corrected NIST 1999 WAFAC standard, this revision to the ordering process requires **NO CHANGE**.

The change in ordering practice will enhance uniformity and reduce inadvertent ordering errors. This new procedure conforms to the brachytherapy standard of practice, as recommended by the AAPM. (See Reference 3 identified in Attachment I.)

Converting orders from units of mCi apparent based on the Cd-109 system ($A_{\text{app}, T97}$) to the air kerma strength based on the corrected NIST 1999 WAFAC standard ($S_{K, N99}$) is addressed in Attachment VIII- (B) and Attachment VIII- (C).

If you order through a distributor, they may specify additional ordering practices or options.

II. Change in Seed Strength Certification Format

For TheraSeed® orders shipped on or after **September 10, 2001**, Theragenics will no longer provide the section on the seed strength certification form titled "**SOURCE STRENGTH VIA CADMIUM-109 POINT SOURCE CALIBRATION STANDARD**". However, the apparent activity ($A_{app, T97}$) for TheraSeed®, based on Theragenics' internal ^{109}Cd calibration system for both the mean seed activity and the activity range, will be listed in a footnote on the revised certification form. (A sample copy of the new form is provided in Attachment I.)

The majority of our clients have transitioned from the ^{109}Cd calibration standard to the NIST 1999 WAFAC standard as originally implemented by Theragenics on March 20, 2000, and as adjusted in 2000 for the corrected NIST 1999 WAFAC data beginning March 5, 2001. After discussions with clients and regulators, we believe this reformatting of the seed strength certification form will reduce the possibility of inadvertent errors.

III. Changes in Labels to Information Based on the Corrected NIST WAFAC

For TheraSeed® orders shipped on or after September 10, 2001, the labeling of the seed containers (lead pig, vial, etc.) for the purpose of **total** apparent activity will be expressed in terms of the apparent activity ($A_{app, N99}$), calculated from the corrected NIST 1999 WAFAC air kerma strength standard (i.e., $A_{app, N99} = S_{k, N99} / 1.293$). Please note that this apparent activity ($A_{app, N99}$) is approximately 24% greater than the apparent activity based on the ^{109}Cd calibration standard (i.e., $A_{app, N99} / A_{app, T97} = 1.24$.) Also, the current practice of identifying the activity range in units of mCi ($A_{app, T97}$) on vial labels will be replaced with providing the air kerma strength range in units of $S_{k, N99}$ (corrected). Regarding the label for a seed of known activity, this change will also represent an increase of approximately 24% in the listed mCi units, i.e., higher than the current values for the "SAME" seed strength. (See Section VI.)

Attachment II provides a sample copy of both the pig label and the vial label.

IV. Changes in License Possession Limits

If your possession limit is 500 mCi or less and you perform multiple cases on the same day, you should inform your state regulators that you will need an administrative amendment to your license. This amendment request is needed because of the redefining of the activity unit based on the corrected NIST 1999 WAFAC standard (i.e., approximately 24% higher shipped activity.) Our state regulators, the Georgia Dept. of Natural Resources, are sending an information notice to all state regulators. This letter, as well as a sample amendment request, is available to you. Please contact the Theragenics' Physics staff at 1-877-960-1234. Theragenics will begin to compare your ordered activity level to the corrected NIST 1999 WAFAC standard on **August 20, 2001**. To avoid any disruption in shipments, you should have the required updates for your possession license on file with Theragenics by that date. If your possession limit is 500 mCi or more, please verify that your limit is high enough to accommodate a 24% increase in shipped activity.

Theragenics maintains accurate records to ensure that shipments of TheraSeed® do not exceed your possession limit. If you fall into the category of having a low possession limit, we will work with you on an individual basis to guarantee that your future orders and implants are not impacted by this change in definition of activity.

V. Fax Order Confirmation

Beginning on August 20, 2001, Theragenics will use a modified fax order confirmation and a modified fax order reservation. These forms will indicate that the order was recorded in units of corrected $S_{K, N99}$, and will also reference the $A_{app, N99}$ units for seed strength for the order. Please contact your Distributor or Theragenics' Customer Service (direct customers only) for sample fax confirmations (order and reservation). The fax confirmations will indicate, as a footnote, the ordered seed strength activity in units of $A_{app, T97}$. Theragenics' internal Cd-109 standard units.

VI. Seed of Known Activity / Air Kerma Strength

In Theragenics' letter to customers, dated February 4, 2000, which implemented the original NIST 1999 WAFAC system, Theragenics indicated we would continue to ship seeds of known activity to requesting customers but only in units of $A_{app, T97}$. NIST and the AAPM Task Group No. 64 (*Med. Physics*, Vol. 26, No. 10, Page 2054-2076, October 1999) recommend that client facilities obtain an AAPM ADCL calibrated dose calibrator or well chamber for verification of seed strength measurements after seed shipment receipt, or use seeds individually calibrated at an AAPM ADCL for dose calibrator or well chamber calibration. Some clients order one seed in a vial with associated Theragenics' assay information providing the seed strength, and use this seed to adjust client in-house calibrators / well chambers to assess shipped seed strength in future seed strength monitoring practice.

For "seed of known activity" orders, Theragenics currently provides additional calibration (seed strength) information in a letter format in units of $A_{app, T97}$ and a specification of the time / date when the measurement was made at Theragenics. "Seed of known activity" orders shipped on or after September 10, 2001 will not contain this seed strength information letter. The seed strength results will be in units of air kerma strength ($S_{K, N99}$) based on the corrected NIST 1999 WAFAC standard.

Seed strength results for "seed of known activity" orders will be printed on the standard seed strength certification form. (A sample is provided in Attachment III.) Your use of these "seed of known activity" orders will involve increasing the seed strength shown on the certification, from 12 o'clock noon on the implant date to a value corresponding to the time / date of your in-house measurements associated with dose calibrator or well chamber adjustment. As illustrated in Attachment III, the value shown for the mean seed air kerma strength is the actual strength determined in our Theragenics' measurement decayed to the implant date, 12 o'clock noon (i.e., the mean strength and the actual strength are the same numerically because the order is for one seed.) However, the mean seed air kerma strength will usually not be equal to the mid-point of the air kerma strength range shown on the certification sheet. This result represents a change to our practice in selecting the seed of known strength. The mCi value in terms of the Theragenics' internal historical ^{109}Cd system, $A_{app, T97}$, is shown in the footnote on the certification.

Attachment IV provides the sample vial label associated with the sample certification in Attachment III. The vial label provides the range in air kerma strength. In the sample shown, the mean air kerma strength from the certification is not at the mid-point of this range. Also, the **Total Activity** shown on the label for this vial is in terms of $A_{app, N99}$ in mCi based on the corrected NIST 1999 WAFAC standard and is the same value as shown on the certification sample. This $A_{app, N99}$ is approximately 24% higher than the $A_{app, T97}$ value, and should be noted as a significant change by any clients continuing to use Theragenics' internal Cd-109 standard beginning on or after September 10, 2001.

Your internal procedures using the "seed of known activity" orders may require modification.

VII. Shipping Box Insert And Vial - Pig "Notice / Warning Of Change"

Attachment V provides samples of additional notices or warnings of the above changes for inserts in the shipping box and attachments to vials and pigs. These will be included beginning with order shipments on September 10, 2001 and will continue until October 12, 2001.

VIII. Transition

Beginning August 20, 2001, Theragenics will stop taking orders based on $A_{app, T97}$ and will **only** accept orders in units of air kerma strength ($S_{k, N99}$) based on corrected NIST 1999 WAFAC standard. Orders placed before August 20, 2001 in units of $A_{app, T97}$ will be delivered with seed strength units, as ordered; however, the $A_{app, T97}$ information will only be included on the certification form as a footnote for orders shipped on or after September 10, 2001. Beginning August 20, 2001, fax confirmation forms will be modified to include the $A_{app, T97}$ information as a footnote and Theragenics will compare your order activity in units of $A_{app, N99}$ (i.e., 24% higher than $A_{app, T97}$) to your license possession limit.

Clients currently ordering in units of $A_{app, T97}$ are encouraged to use the period from the date of this letter through August 20, 2001 as a transition period to change their internal practices and procedures from ordering in units of $A_{app, T97}$ to ordering in units of $S_{k, N99}$.

Clients with standing orders or long lead-time orders, who previously anticipated receiving the current seed strength certification form, will receive the new certification form for shipments on or after September 10, 2001. Label changes and certification form changes will be implemented on shipments beginning September 10, 2001. On that same date, the current seed of known activity practice will be replaced with the seed of known air kerma strength certification practice.

Appendix VI provides a table displaying the above transition schedule.

IX. What You Will See Different In The Shipping Box

Attachment VII provides a table displaying a list of new items and a list of modified items in the shipping box.

X. Check List

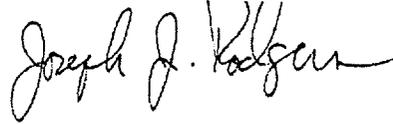
Attachment VIII provides suggested check lists and examples to assist you in making this transition. Part (A) is addressed to all users of TheraSeed®. Part (B) is addressed to current clients using the Cd-109 system of calibration, and includes important information (not published) that is needed to transition to the corrected NIST 1999 WAFAC system. Part (C) includes information for clients choosing to continue to use the Cd-109 system of calibration and Part (D) addresses International Cd-109 users.

Thank you for your continued support of our TheraSeed® product while we implement these improvements. As always, if you have any questions, please contact TheraSeed® Customer Service and ask for the Theragenics' Physics staff.

Sincerely,



T. Tydings Robin, Jr., Ph.D.
Director of Nuclear Standards



Joseph J. Rodgers, M.S.
Radiation Safety Officer
Associate Director of Health Physics

Attachments:

- I. Sample seed strength certification form
- II. Pig and Vial Label Samples
- III. Sample Certification for Seed of known U_{NIST}
- IV. Sample Label for Seed of known U_{NIST}
- V. Sample shipping box warning labels, inserts, etc.
- VI. Transition Schedule Table - Summary
- VII. Physical Items in Shipping box: Changed or New
- VIII. Check Lists (A) NIST users, (B) Cd-109 users transitioning to NIST, (C) Cd-109 users remaining with Cd-109 calibration results and (D) International Cd-109 users

THERAGENICS CORPORATION 5203 Bristol Industrial Way, Buford, GA 30518 USA

TheraSeed® Certification Palladium-103 Sealed Source for Medical Use

Sales Order No. 00000

SAMPLE

The radioactive sources listed below are certified to have the following characteristics on the reference date:

Mercy Hospital
0000 Hospital Road
Any City, Any State 12345

Reference Date- 7/4/2001
1200 Eastern Time USA
1700 Greenwich Mean Time

LICENSE: NM-12345
TIMELY FILED: NO

EXPIRES: 11/20/2004

LIMIT: 5000 mCi ($A_{app,T99}$)*

ALL SEEDS HAVE PASSED A LEAK TEST SHOWING <5 nCi (<185 Bq) OF REMOVABLE Pd-103 ACTIVITY
ALL VALUES ON PIG AND VIAL LABELS ARE BASED ON THE CORRECTED NIST 1999 WAFAC CALIBRATION ($A_{app,N99}$, $S_{K,N99}$)

PATIENT NAME:

Package 1	Pig 1	Lot ID 0115A	Product(s) TS200	No. of Seeds 95
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SOURCE STRENGTH VIA NIST 1999 WAFAC THERASEED® MODEL 200 STANDARD FOR ¹⁰³ Pd (CORRECTED)†††	
†† Total Activity - mCi ($A_{app,N99}$)	164.58
†† Mean seed Activity - mCi ($A_{app,N99}$)	1.73
†† Activity Range - mCi ($A_{app,N99}$)	1.71 - 1.75
†† Total Activity - MBq ($A_{app,N99}$)	6089.45
†† Mean seed Activity - MBq ($A_{app,N99}$)	64.10
†† Activity Range - MBq ($A_{app,N99}$)	63.30 - 64.90
††† Mean Seed Air Kerma Strength - $\mu\text{Gy}\cdot\text{m}^2\cdot\text{h}^{-1}$ ($S_{K,N99}$)	2.24
††† Air Kerma Strength Range - $\mu\text{Gy}\cdot\text{m}^2\cdot\text{h}^{-1}$ ($S_{K,N99}$)	2.21 - 2.27

† Guidance from the AAPM^{1,2} cautions the use of appropriate dose rate constant as recommended by the AAPM in reference 1. See Reference 5.

†† Per convention adopted by AAPM^{1,3}, $A_{app,N99}$ is calculated by dividing $S_{K,N99}$ by 1.293.

††† Based on NIST 1999 WAFAC standard for TheraSeed® Model 200 Palladium-103 air kerma strength. (Based on data from year 2000 or later)

References to Guidance from The American Association of Physicists in Medicine, The American Brachytherapy Society, and Theragenics Consultants:

- Williamson et al, "Recommendations of the American Association of Physicists in Medicine on ¹⁰³Pd Interstitial Source Calibration and Dosimetry: Implications for Dose Specification and Prescription," Med. Phys. 27 (accepted for publication January 2000)
- Nath et al, "Dosimetry of Interstitial Brachytherapy Sources: Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43," Med. Phys. 22 (2), February 1995
- Williamson et al, "On the Use of Apparent Activity (A_{app}) for Treatment Planning of ¹²⁵I and ¹⁰³Pd Interstitial Brachytherapy Sources: Recommendation of the AAPM Therapy Committee Subcommittee on Low-Energy Brachytherapy Source Dosimetry," Med. Phys. 26 (12), December 1999
- Byer, et al., "American Brachytherapy Society Recommendation for Clinical Implementation of NIST-1999 Standards for ¹⁰³Palladium Brachytherapy," Int. J. Radiation Oncology Biol. Phys. Vol 47, No. 2, pp. 273-275, 2000
- TheraSeed® Notification of Change dated December 27, 2000 enclosing report dated December 15, 2000, by R. Nath, Ph.D. and J. Williamson, Ph.D., recommending $\Lambda = 0.68 \text{ cGy h}^{-1}\text{U}^{-1}$ (available from Theragenics' Customer Service 1-877-960-1234)

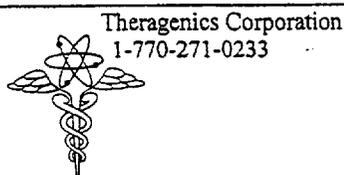
SOURCE STRENGTH VIA CADMIUM-109 POINT SOURCE CALIBRATION STANDARD**:

*** Mean seed Activity - mCi ($A_{app,T97}$)=1.4 mCi ($A_{app,T97}$) and *** Activity Range - mCi ($A_{app,T97}$) = 1.38 - 1.42 mCi ($A_{app,T97}$)

* Nomenclature and symbols adopted from reference ¹

** Guidance from the AAPM^{1,2} cautions the use of appropriate dose rate constant as recommended in TG-43² and reference 1.

*** Source strength values are apparent activity determined as of the above reference date relative to sodium iodide detector measurement calibrated with a Cadmium-109 standard traceable to NIST and using air kerma strength conversion factor of 1.293 per TG-43.



Date

PIG AND VIAL LABEL SAMPLES

TheraSeed		Made in U.S.A. By: Theragenics Corporation Buford, GA 30518
Palladium Seeds-(Pd-103)		
Radionuclide Brachytherapy Source		
Caution: RADIOACTIVE MATERIAL		
Order No. <u>0000</u>	No. of Seeds <u>95</u>	
Sk Range <u>2.21-2.27</u> U (Sk.N99)		
Total Activity <u>164.58</u> mCi (A _{app.N99})		
Assay Date <u>7-04-01</u>	LOT <u>0115A</u>	
<small>Patent No.'s 4,702,228; 4,794,118; 5,405,308. CAUTION: Federal law restricts this device to sale by or on the order of a physician.</small>		
1011031-USA 0601		

(a) Sample Vial Label

 <p>CE 0044 THERAGENICS CORPORATION</p>	<p>TheraSeed Palladium Seeds-(Pd-103) (NON STERILE)</p>	
	<p>Radionuclide Brachytherapy Source</p> <p><small>Description: TheraSeed Palladium-103 consists of a welded titanium shell containing two Palladium-103 pellets and a lead filter. Patent Nos. 4,702,228; 4,794,118; 5,405,308.</small></p> <p><small>WARNING: Licensed by the Georgia Department of Natural Resources for distribution pursuant to license pursuant to (B) and Rule 391-3-40. This Chapter or under equivalent license of the Nuclear Regulatory Commission, an Agency of the Federal Licensing State.</small></p> <p><small>CAUTION: Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety procedures at all times.</small></p>	<p>Order No. <u>0000</u> Pig No. <u>1</u></p> <p>Sk Range <u>2.21-2.27</u> U (Sk.N99)</p> <p>Total Activity</p> <p>This Pig <u>164.58</u> mCi (A_{app.N99})</p> <p>Number of Seeds <u>95</u> REF <u>TS200</u></p> <p>Assay Date <u>7-04-01</u> LOT <u>0115A</u></p> <p>Caution: RADIOACTIVE MATERIAL</p> <p>Ⓢ Single use</p> <p>⚠ See package insert for instructions on handling and storage of TheraSeed®</p> <p style="text-align: right;"><small>Made in U.S.A. By Theragenics Corporation Buford, GA 30518 U.S.A.</small></p> <p style="text-align: right;"><small>1011030-USA 0601</small></p>

(b) Sample Pig Label (for loose seeds, Mick cartridge and Express Seeding Cartridge)

THERAGENICS CORPORATION 5203 Bristol Industrial Way, Buford, GA 30518 USA

TheraSeed® Certification Palladium-103 Sealed Source for Medical Use

Sales Order No. 0000

The radioactive sources listed below are certified to have the following characteristics on the reference date:

Mercy Hospital
0000 Hospital Road
Any City, Any State 12345

SAMPLE FOR SEED OF KNOWN U

Reference Date-7/4/2001
1200 Eastern Time USA
1700 Greenwich Mean Time

LICENSE: NM-12345 EXPIRES: 11/20/2004 LIMIT: 5000 mCi ($A_{app,N99}$)^{*}
TIMELY FILED: NO

ALL SEEDS HAVE PASSED A LEAK TEST SHOWING <5 nCi (<185 Bq) OF REMOVABLE Pd-103 ACTIVITY
ALL VALUES ON PIG AND VIAL LABELS ARE BASED ON CORRECTED NIST 1999 WAFAC CALIBRATION ($A_{app,N99}$, $S_{K,N99}$).

PATIENT NAME:				
Package 1	Pig 1	Lot ID 0115A	Product(s) TS202	No. of Seeds 1

SOURCE STRENGTH VIA NIST 1999 WAFAC THERASEED® MODEL 200 STANDARD FOR ^{103}Pd (CORRECTED) ^{†††}	
^{††} Total Activity – mCi ($A_{app,N99}$)	1.72
^{††} Mean seed Activity – mCi ($A_{app,N99}$)	1.72
^{††} Activity Range – mCi ($A_{app,N99}$)	1.71 – 1.75
^{††} Total Activity – MBq ($A_{app,N99}$)	63.64
^{††} Mean seed Activity – MBq ($A_{app,N99}$)	63.64
^{††} Activity Range – MBq ($A_{app,N99}$)	63.30 – 64.90
^{†††} Mean Seed Air Kerma Strength – $\mu\text{Gy}\cdot\text{m}^2\cdot\text{h}^{-1}$ ($S_{K,N99}$)	2.22
^{†††} Air Kerma Strength Range – $\mu\text{Gy}\cdot\text{m}^2\cdot\text{h}^{-1}$ ($S_{K,N99}$)	2.21 – 2.27

[†]Guidance from the AAPM^{1,2} cautions the use of appropriate dose rate constant as recommended by the AAPM in reference 1. See Reference 5.

^{††}Per convention adopted by AAPM^{1,3}, $A_{app,N99}$ is calculated by dividing $S_{K,N99}$ by 1.293.

^{†††}Based on NIST 1999 WAFAC standard for TheraSeed® Model 200 Palladium-103 air kerma strength. (Based on data from year 2000 or later).

References To Guidance From The American Association Of Physicists In Medicine, The American Brachytherapy Society and Theragenics consultants:

- Williamson et al, "Recommendations of the American Association of Physicists in Medicine on ^{103}Pd Interstitial Source Calibration and Dosimetry: Implications for Dose Specification and Prescription", Med. Phys. 27 (accepted for publication January 2000)
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- Williamson et al, "On the Use of Apparent Activity (A_{app}) for Treatment Planning of ^{125}I and ^{103}Pd Interstitial Brachytherapy Sources: Recommendation of the AAPM Therapy Committee Subcommittee on Low-Energy Brachytherapy Source Dosimetry", Med. Phys. 26 (12), December 1999
- Byer, et al., "American Brachytherapy Society Recommendation for Clinical Implementation of NIST-1999 Standards for ^{103}Pd Palladium Brachytherapy", Int. J. Radiation Oncology Biol. Phys. Vol 47, No. 2, pp. 273-275, 2000
- TheraSeed® Notification of Change dated December 27, 2000 enclosing report dated December 15, 2000 by R. Nath, PhD. and J. Williamson, PhD., recommending $\Lambda = 0.68 \text{ cGy h}^{-1}\text{U}^{-1}$ (available from Theragenics Customer Service 1-877-960-1234)

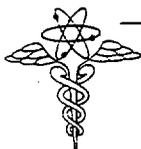
SOURCE STRENGTH VIA CADMIUM-109 POINT SOURCE CALIBRATION STANDARD^{**}:

^{***}Mean seed Activity – mCi ($A_{app,T97}$) = 1.39 mCi ($A_{app,T97}$) and ^{***}Activity Range – mCi ($A_{app,T97}$) = 1.38 – 1.42 mCi ($A_{app,T97}$)

*Nomenclature and symbols adopted from reference 1.

**Guidance from the AAPM^{1,2} cautions the use of appropriate dose rate constant as recommended in TG-43² and reference 1.

***Source strength values are apparent activity determined as of the above reference date relative to sodium iodide detector measurement calibrated with a Cadmium-109 standard traceable to NIST and using air kerma strength conversion factor of 1.293 per TG-43.



Theragenics Corporation
1-770-271-0233

Date _____

LABEL FOR SEED OF KNOWN U_{NIST}

TheraSeed		Made in U.S.A. By: Theragenics Corporation Buford, GA 30518
Palladium Seeds-(Pd-103) Radionuclide Brachytherapy Source		
Caution: RADIOACTIVE MATERIAL		
Order No. <u>0000</u>	Number of Seeds <u>1</u>	
SK Range <u>2.21-2.27</u>	U (S _{K,N99})	
Total Activity <u>1.72</u>	mCi (A _{app,N99})	
Assay Date <u>7-04-01</u>	LOT <u>0115A</u>	
<small>Patent No.'s 4,702,228; 4,784,116; 5,405,309. 1011031-USA 0601</small>		
<small>CAUTION: Federal law restricts this device to sale by or on the order of a physician.</small>		

(a) Sample Vial Label

 <p>CE 0044 THERAGENICS CORPORATION</p>	<p>TheraSeed Palladium Seeds-(Pd-103) (NON STERILE)</p>	
	<p>Radionuclide Brachytherapy Source</p> <p><small>Description: TheraSeed consists of a welded titanium shell containing two Palladium-103 pellets and a stainless steel cap. Patents 4,702,228; 4,784,116; 5,405,309.</small></p> <p><small>WARNING: Licensed by the Georgia Department of Natural Resources for distribution. It is licensed pursuant to (9) and Rule 391-3-10. It is also licensed under equivalent licenses of the Nuclear Regulatory Commission, an Agency of the U.S. Department of Energy, and the State Licensing State.</small></p> <p><small>CAUTION: Federal law restricts this device to sale by or on the order of a physician. Maintain proper radiation safety procedures at all times.</small></p>	<p>Order No. <u>0000</u> Pig No. <u>1</u></p> <p>SK Range <u>2.21-2.27</u> U (S_{K,N99})</p> <p>Total Activity <u>1.72</u> mCi (A_{app,N99})</p> <p>This Pig <u>1</u> REF <u>TJ202</u></p> <p>Number of Seeds <u>1</u></p> <p>Assay Date <u>7-04-01</u> LOT <u>0115A</u></p> <p>Caution: RADIOACTIVE MATERIAL</p> <p>Ⓢ Single use ⚠ See package insert for instructions on handling and storage of TheraSeed®</p> <p style="text-align: right;"><small>Made in U.S.A. By Theragenics Corporation Buford, GA 30518 U.S.A.</small></p> <p style="text-align: right;"><small>1011030-USA 0601</small></p>

(b) Sample Pig Label (for Seed of Known U)

SAMPLE COPIES OF ADDITIONAL SHIPPING BOX INSERTS, WARNING LABELS, ETC.

ATTENTION! The measurements contained on the label of this package are in units of mCi apparent ($A_{app,N99}$) and U ($S_{K,N99}$) based on the corrected NIST 1999 WAFAC standard.
10-11-025 0601 Sample

(A) Sample "Attention" Vial Label

ATTENTION! The measurements contained on the label of this package are in units of mCi apparent ($A_{app,N99}$) and U ($S_{K,N99}$) based on the corrected NIST 1999 WAFAC standard.
10-11-019 0601 Sample

(B) Sample "Attention" Pig Label



ATTENTION!!

FOR ALL CLIENTS IMPORTANT CHANGES IMPLEMENTED

This information Applies to THERASEED® Orders Shipped

On or After September 10, 2001

- 1) The enclosed order for THERASEED® was shipped on or after September 10, 2001.
- 2) If this order was placed on August 20, 2001 or later, the only seed strength units that were accepted by Theragenics were the corrected NIST 1999 WAFAC system units.
- 3) The seed strength certification is different from orders shipped prior to September 10, 2001:
 - Only the corrected NIST 1999 WAFAC system information is printed in the main text.
 - The information related to the historical Cd-109 calibration system is printed as a footnote.
- 4) The labels for vials and pigs are different from orders shipped prior to September 10, 2001:
 - Seed strength range is given in air kerma units based on the corrected NIST 1999 WAFAC system.
 - Total activity is given in mCi apparent based on the corrected NIST 1999 WAFAC system.
- 5) Please be advised of the following facts regarding shipped orders containing only one seed, or a “seed of known strength”:
 - The “Known Activity” form that lists the seed strength at the time the seed is assayed at Theragenics will no longer be provided. The seed strength certification will still be provided that lists the seed strength on the date of implant. To calculate the seed strength on the date you are checking your dose calibrator or well chamber response, you must escalate the value listed on the certification accordingly.
 - The seed strength reported on the certification is the measurement response recorded at Theragenics, but may not be in the center of the range listed for the order.
- 6) Details of the above changes are included in:

THERASEED® NOTIFICATION OF CHANGE FOR ALL CLIENTS
DATED JULY 6, 2001

Available from Theragenics® Customer Service (1-877-960-1234) or your Distributor. Please review the material and adjust your practice as necessary prior to implementing this order.



Sample Front Side of New Ordering Protocol

THERASEED® ORDERING PROTOCOL: CALIBRATION SYSTEM OPTION

August 20, 2001

Theragenics' TheraSeed® product currently can be ordered using only one seed strength measurement unit. The product can be ordered:

-- in units of U_{NIST} , ($S_{K,N99}$), i.e. corrected NIST 1999 WAFAC standard.

- 1) You **MUST** have your TheraSeed® order entered in terms of air kerma strength in units of U_{NIST} , ($S_{K,N99}$). Note that Theragenics' current shipments in U_{NIST} units are based on the NIST 1999 WAFAC calibration system and, since March 5, 2001, all such calibration results are based on the "corrected" approximately 5% NIST shift.
- 2) Review the order confirmation for the TheraSeed® product and confirm that the source strength ordered matches the desired source strength. Confirm that the source strengths compared have the same units. (**Caution:** Apparent activity mCi ($A_{app, T97}$) should not be confused with apparent activity mCi ($A_{app, N99}$) based on the corrected NIST 1999 WAFAC standard. **An order placed in the incorrect units could result in a misadministration event.**)
- 3) Verify the seed strength of delivered seeds with facility quality assurance checks. Compare the seed strength measured with the TheraSeed® product labels and the certification provided with each order. The TheraSeed® product labels state source strength range in terms of U ($S_{K,N99}$), Total apparent activity in terms of mCi ($A_{app, N99}$) only. The TheraSeed® certification provides seed strength values in two (2) primary units:
 - 1) apparent activity, mCi ($A_{app, N99}$), based on the corrected NIST 1999 WAFAC calibration standard
 - 2) air kerma strength, U ($S_{K,N99}$), based on the corrected NIST 1999 WAFAC calibration standard
 In addition, a footnote on the certification form provides the mean seed activity, mCi ($A_{app, T97}$), based on Theragenics' historical internal ^{109}Cd calibration systems and also the activity range in mCi ($A_{app, T97}$), based on Theragenics' historical internal ^{109}Cd calibration system.
- 4) Please note that your treating institution's treatment planning process and seed receipt strength verification process, need to assure consistency in ordering seeds with the appropriate units (i.e., seed strength calibration system desired). Note references on the sample certification form on the back side of this protocol.
- 5) Please discuss any questions with your sales representative.

Illustration based on 1.60 U seed strength in corrected 1999 NIST WAFAC System:

(NOTE: Relation between Theragenics and NIST system indicates approximate current relationship.)

CALIBRATION SYSTEM	THERAGENICS' INTERNAL SYSTEM BASED ON NIST TRACEABLE ^{109}Cd	CORRECTED NIST 1999 WAFAC
UNITS OF SEED STRENGTH		
mCi (apparent activity)	1.0 -- $A_{APP,T97}$ (cannot order in these units)	1.237 -- $A_{APP,N99}$ (cannot order in these units)
U (air kerma strength)	1.293 -- $S_{K,T97}$ (cannot order in these units)	1.60 -- $S_{K,N99}$ (<u>must</u> order in these units)

Note: The above official nomenclature is defined in an article in *Medical Physics*, authored by J. Williamson, Ph.D., et. al. (see AAPM Report 69, *Medical Phys.* 27 (4), page 634, April 2000)



Sample Back Side of New Ordering Protocol

Theragenics Corporation 5203 Bristol Industrial Way, Buford, GA 30518 USA
TheraSeed® Certification Palladium-103 Sealed Source for Medical Use

Sales Order No. 0000

The radioactive sources listed below are certified to have the following characteristics on the reference date:

Mercy Hospital
0000 Hospital Road
Any City, Any State 12345

SAMPLE

Reference Date—7/4/2001
1200 Eastern Time USA
1700 Greenwich Mean Time

LICENSE: NM-12345 EXPIRES: 11/20/2004 LIMIT: 5000 mCi ($A_{app,N99}$)^{*}
TIMELY FILED: NO

ALL SEEDS HAVE PASSED A LEAK TEST SHOWING <5 nCi (<185 Bq) OF REMOVABLE Pd-103 ACTIVITY
ALL VALUES ON PIG AND VIAL LABELS ARE BASED ON CORRECTED NIST 1999 WAFAC CALIBRATION ($A_{app,N99}$, $S_{K,N99}$).

PATIENT NAME:					
Package 1	Pig 1	Lot ID 0115A	Product(s) TS200	No. of Seeds 95	

SOURCE STRENGTH VIA NIST 1999 WAFAC THERASEED® MODEL 200 STANDARD FOR ¹⁰³ Pd† (CORRECTED)†††	
†† Total Activity – mCi ($A_{app,N99}$)	164.58
†† Mean seed Activity – mCi ($A_{app,N99}$)	1.73
†† Activity Range – mCi ($A_{app,N99}$)	1.71 – 1.75
†† Total Activity – MBq ($A_{app,N99}$)	6089.45
†† Mean seed Activity – MBq ($A_{app,N99}$)	64.10
†† Activity Range – MBq ($A_{app,N99}$)	63.30 – 64.90
††† Mean Seed Air Kerma Strength – $\mu\text{Gy}\cdot\text{m}^2\cdot\text{h}^{-1}$ ($S_{K,N99}$)	2.24
††† Air Kerma Strength Range – $\mu\text{Gy}\cdot\text{m}^2\cdot\text{h}^{-1}$ ($S_{K,N99}$)	2.21 – 2.27

†Guidance from the AAPM^{1,2} cautions the use of appropriate dose rate constant as recommended by the AAPM in reference 1. See Reference 5.

††Per convention adopted by AAPM^{1,3}, $A_{app,N99}$ is calculated by dividing $S_{K,N99}$ by 1.293.

†††Based on NIST 1999 WAFAC standard for TheraSeed® Model 200 Palladium-103 air kerma strength. (Based on data from year 2000 or later).

References To Guidance From The American Association Of Physicists In Medicine, The American Brachytherapy Society and Theragenics consultants:

- Williamson et al, "Recommendations of the American Association of Physicists in Medicine on ¹⁰³Pd Interstitial Source Calibration and Dosimetry: Implications for Dose Specification and Prescription", Med. Phys. 27 (accepted for publication January 2000)
- Nath et al, "Dosimetry of Interstitial Brachytherapy Sources: Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43", Med. Phys. 22 (2), February 1995
- Williamson et al, "On the Use of Apparent Activity (A_{app}) for Treatment Planning of ¹²⁵I and ¹⁰³Pd Interstitial Brachytherapy Sources: Recommendation of the AAPM Therapy Committee Subcommittee on Low-Energy Brachytherapy Source Dosimetry", Med. Phys. 26 (12), December 1999
- Byer, et al., "American Brachytherapy Society Recommendation for Clinical Implementation of NIST-1999 Standards for ¹⁰³Palladium Brachytherapy", Int. J. Radiation Oncology Biol. Phys. Vol 47, No. 2, pp. 273-275, 2000
- TheraSeed® Notification of Change dated December 27, 2000 enclosing report dated December 15, 2000 by R. Nath, PhD. and J. Williamson, PhD., recommending $\Lambda = 0.68 \text{ cGy h}^{-1}\text{U}^{-1}$ (available from Theragenics Customer Service 1-877-960-1234)

SOURCE STRENGTH VIA CADMIUM-109 POINT SOURCE CALIBRATION STANDARD**:

***Mean seed Activity – mCi ($A_{app,T97}$) = 1.4 mCi ($A_{app,T97}$) and ***Activity Range – mCi ($A_{app,T97}$) = 1.38 – 1.42 mCi ($A_{app,T97}$)

*Nomenclature and symbols adopted from reference 1.

**Guidance from the AAPM^{1,2} cautions the use of appropriate dose rate constant as recommended in TG-43² and reference 1.

***Source strength values are apparent activity determined as of the above reference date relative to sodium iodide detector measurement calibrated with a Cadmium-109 standard traceable to NIST and using air kerma strength conversion factor of 1.293 per TG-43.



Theragenics Corporation
1-770-271-02

Date

Transition Schedule Table for 2001 - Summary (See Check Lists in Attachment VIII)

July 6 to Sept 10	Theragenics includes a notice in the shipping box which announces the issuing of the "THERAGENICS NOTIFICATION OF CHANGE FOR <u>ALL</u> CLIENTS", dated July 6, 2001
July 16 to 31	Request backup material for client license amendment application, as appropriate (see first entry below for August 20)
July 22 to 25	Opportunity to discuss detail of transition at Theragenics Booth (#1034) at AAPM meeting in Salt Lake City on July 22 -25, 2001
August 6	Theragenics to issue a reminder letter regarding the transition
August 6-20	Cd-109 calibration system users who switch to the NIST system, coordinate treatment planning and ordering in units of mCi Cd-109 system units and order receipt / assay in units of corrected NIST 1999 WAFAC system (adjust transition schedule as needed).
August 20	Complete obtaining approved Radioactive Material License amendment increasing possession limit for Pd-103, Model 200 by a nominal 25%.
August 20	Order TheraSeed [®] in units of corrected NIST 1999 WAFAC system, U _{NIST} , only
August 20	Theragenics confirms orders and reservations in units of corrected NIST 1999 WAFAC system with Cd-109 system units provided in footnote.
August 20	Theragenics implements comparison of order request in units of mCi in units of corrected NIST 1999 WAFAC system to client license possession limit.
September 10	Theragenics' shipments with new certification and labels begins



Physical Items in Shipping Box

List of Items Changed or Modified

1. Seed Strength Calibration form
2. Seed Strength Calibration form for Seed of Known U ("One Seed Order")
3. Vial Label
4. Vial Label for Seed of Known U
5. Pig Label
6. Notice/ "Attention" Flyer

List of New Items

1. Vial Warning Label
2. Pig Warning Label
3. TheraSeed® Ordering Protocol: Calibration System Option, August 20, 2001

List of Items Deleted

1. "Calibration Letter to Customer" for Cd -109 System Seed of Known Activity



Check List for clients currently ordering in U_{NIST}

1. Review current radioactive material license and decide if new Pd-103 possession limits are needed regarding the numerical increase in the listed mCi for seed strength and total activity under the corrected 1999 NIST WAFAC standard, (i.e., approximately 25% higher total activity in your typical possession quantity); obtain approved license amendment on or before August 20, 2001 and communicate new amendment to Theragenics or your distributor for transmittal to Theragenics.
2. Items Related to New Certification Form
 - Update institution procedures and practice because of new seed strength certification format.
3. Items Related to New Seed of Known U (One seed order)
 - Update institution procedures and practice to calculate strength of seed on dose calibrator / well chamber adjustment date using seed strength data for the implant date on the seed strength certification. (Eliminate procedure elements using letter, "Dear Customer", containing date and time of Theragenics assay and mCi activity value; i.e., procedure element to decay seed strength to institution measurement date.)
 - Update procedures and practice as needed to accommodate changes in elements on associated vial label (i.e., air kerma strength range and total activity in units of corrected 1999 NIST WAFAC, seed strength not typically in middle of range identified.)
4. Items Related to New Labels
 - Update procedures and practice as needed to accommodate changes in elements on associated vial label (i.e., air kerma strength range and total activity in units of corrected 1999 NIST WAFAC.)
5. Items Related to New Fax Confirmations
 - Alert ordering staff that Fax Confirmations will be adjusted on August 20, 2001. (Confirm any changes with your distributor.)
6. Continue to assure consistency in seed strength units between treatment planning functions, ordering functions, receiving functions (seed strength verification measurements with a calibrated dose calibrator / well chamber) and post-implant dosimetry efforts.
7. Monitor FedEx shipping label on box for ship date. Monitor box contents (see Attachment VII) beginning September 10, 2001 to identify orders shipped under the changes identified in this Notification of Change. Use new procedures and practice as appropriate on such shipments. (On orders shipped prior to September 10, 2001, use previous procedures and practices.)



Check List for Cd Calibration System Users Switching to the Corrected NIST 1999 WAFAC Standard:

Please note the following transition items and the referenced check list attached.

**FOR CLIENTS CURRENTLY USING THE THERAGENICS
INTERNAL ^{109}Cd CALIBRATION STANDARD**

IMPORTANT INFORMATION FOR CLIENTS USING THE INTERNAL ^{109}Cd CALIBRATION STANDARD AND CHOOSING TO TRANSITION TO THE NIST 1999 WAFAC STANDARD (CORRECTED):

Transition Items:

The majority of our clients have already transitioned from the ^{109}Cd calibration standard to the NIST 1999 WAFAC standard as originally implemented by NIST. On March 5, 2001, Theragenics implemented a correction to the NIST standard as directed by the AAPM and NIST. This transition was addressed in "THERASEED[®] NOTIFICATION OF CHANGE FOR CLIENTS CURRENTLY USING THE NIST 1999 WAFAC STANDARD", dated December 27, 2000, and sent to clients outlining our plans for correction of the NIST 1999 WAFAC standard. This notification included a report by Theragenics' consultants, J. Williamson, Ph.D. and R. Nath, Ph.D., dated December 15, 2000 (see Attachment VIII - (B-1)). (An additional copy of that notification may be obtained by calling TheraSeed's Customer Service at 877-960-1234.) In order to assist the transition from our internal ^{109}Cd standard to this new calibration standard, please review Attachment VIII - (B-2) containing an example for converting seed strengths based on the ^{109}Cd calibration standard to the corrected NIST 1999 WAFAC air kerma strength standard.

Please note that the AAPM and the ABS have previously provided recommendations regarding prescribed dose and dose rate constant. References to these recommendations are provided on our current calibration certification sheet. However, these references precede the change in the NIST system identified above. Please note that the Attachment to the December 27, 2000 notification (i.e., the December 15, 2000 report by Theragenics' consultants, Attachment VIII - (B-1) provides several recommended adjustments to the previous guidance for dose rate constant and prescribed dose, when using the corrected NIST 1999 WAFAC calibration standard.

Attachment VIII - (B-3) provides a suggested list to include in your check list of items for this transition.



EVALUATION OF EFFECT OF CORRECTED NIST 1999 WAFAC STANDARD ON PREVIOUSLY
RECOMMENDED DOSE RATE CONSTANT OF 0.665 AND ON RECOMMENDED PRESCRIBED
DOSES --- RE: MODEL 200 THERASEED® Pd-103 BRACHYTHERAPY SOURCE

December 15, 2000

BY THERAGENICS CONSULTANTS:

Ravinder Nath, Ph.D.
Professor and Chief
Radiological Physics Division
Yale University School of Medicine

Jeffrey Williamson, Ph.D.
Professor of Radiology
Mallinckrodt Institute of Radiology
Washington University Medical Center

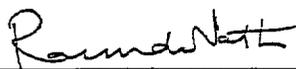
As dosimetry consultants to Theragenics, we have reviewed the amended NIST 1999 air kerma strength calibration reports ($S_{K,N99}$) which were based upon WAFAC measurements performed in 1999. Our review indicated that the corrected NIST-traceable air kerma strength is approximately 5% lower. In a previous publication¹, the dose rate constant value was determined to be $0.65 \pm 0.05 \text{ cGy h}^{-1} \text{ U}^{-1}$ where $1 \text{ U} = 1 \mu\text{Gy}\cdot\text{m}^2\cdot\text{h}^{-1}$. This measurement was performed using lithium fluoride (LiF) thermoluminescent dosimeters (TLDs) in a water equivalent solid phantom and was based upon air-kerma strengths traceable to NIST calibrations supplied in 1999. In addition, another publication² reported the dose rate constant as $0.68 \pm 0.02 \text{ cGy h}^{-1} \text{ U}^{-1}$. This value was calculated by Monte Carlo photon-transport (MCPT) simulation, which is consistent with corrected NIST 1999 standard. Consequently, in a third publication³ the AAPM recommended the dose rate constant which was an average of these two values as $0.665 \pm 0.03 \text{ cGy h}^{-1} \text{ U}^{-1}$. Use of corrected NIST 1999 WAFAC air kerma strength affects only the measurement by Dr Nath. Dr. Nath recommends that the previously reported value of $0.65 \pm 0.05 \text{ cGy h}^{-1} \text{ U}^{-1}$ to be revised to 0.687. Averaging the corrected measured value and the Monte Carlo value, as done in the prior AAPM publication³, yields a new consensus value of $0.68 \pm 0.03 \text{ cGy h}^{-1} \text{ U}^{-1}$. Therefore, our recommendation to your clients is to adopt this value, $0.68 \pm 0.03 \text{ cGy h}^{-1} \text{ U}^{-1}$, for treatment planning but only with seeds calibrated against the corrected NIST 1999 WAFAC air kerma strength standard. Theragenics has

¹ R. Nath, N. Yue, K. Shahnazi, and P.J. Bongiorni, "Measurement of dose-rate constant for ¹⁰³Pd seeds with air-kerma strength calibration based upon a primary national standard," *Med. Phys.* 27, 665-658 (2000).

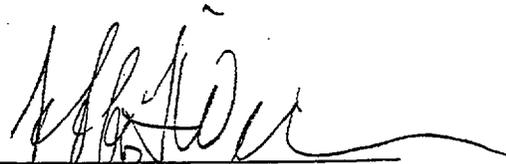
² J.F. Williamson, "Monte Carlo modeling of the transverse-axis dose distribution of the Model 200 ¹⁰³Pd interstitial brachytherapy source," *Med. Phys.* 27, 643-654 (2000).

³ J.F. Williamson, B.M. Coursey, L.A. DeWerd, W.F. Hanson, R. Nath, M.J. Rivard, and G. Ibbott, "Recommendations of the American Association of Physicists in Medicine on ¹⁰³Pd interstitial source calibration and dosimetry: implications for dose specification and prescription," *Med. Phys.* 27, 634-642 (2000).

indicated an intent to provide this corrected air kerma strength for shipments received beginning on a date to be announced by Theragenics. The date for the transition will be as early as the first quarter of 2001 and will be announced by Theragenics to allow a timely transition by all parties. At this time, we recommend that the prescribed dose remain unchanged as a consequence of the changes above. We recommend that physicians and physicists continue to use the prescribed-to-administered dose ratios recommended by the AAPM in April 2000³ as the basis for selecting the appropriate prescribed dose. Thus, the ABS recommendations⁴, which endorse prescribed doses of 125 Gy and 100 Gy for monotherapy and boost, respectively, should not be modified at this time. However, we recognize that by using the corrected NIST 1999 WAFAC air kerma strength standard in conjunction with the corrected dose rate constant and using identical prescribed dose as previously selected with the original 1999 WAFAC calibration, the "actual" delivered dose may be approximately 2-3% higher. We note that our recommendation to leave prescribed dose unchanged at this time is consistent with the views of the AAPM subcommittee on Low Energy Interstitial Brachytherapy Dosimetry (chair: Dr. Williamson). The Subcommittee will review the need for revising the published prescribed-to-administered dose ratios when our ongoing measurements to provide definitive two-dimensional TG43 dose ratios are available.



Ravinder Nath, Ph.D.
Professor and Chief
Radiological Physics Division
Yale University School of Medicine



Jeffery Williamson, Ph.D.
Professor of Radiology
Mallinckrodt Institute of Radiology
Washington University Medical Center

⁴ Beyer et al "American Brachytherapy Society (ABS) Recommendations for clinical implementation of NIST-1999 standards for ¹⁰⁵Pd brachytherapy," Int. J. Radiat. Oncol. Biol. Phys. 47, 273-275 (2000).

For implants scheduled with TheraSeed® orders shipped on or after September 10, 2001

Using the corrected NIST 1999 WAFAC Standard instead of the Theragenics' internal ^{109}Cd calibration system

Step 1	Change Dose Rate Constant in Treatment Planning Software to $0.68 \text{ cGy hr}^{-1} \text{ U}^{-1}$ (See attached report by J. Williamson, Ph.D. and R. Nath, Ph.D., dated December 15, 2000).
Step 2	For Monotherapy - Change Prescribed Dose to 125 Gy (see attached report by J. Williamson, Ph.D. and R. Nath, Ph.D., dated December 15, 2000) or equivalent prescription. For Boost - Change Prescribed Dose to 100 Gy (see attached report by J. Williamson, Ph.D. and R. Nath, Ph.D., dated December 15, 2000) or equivalent prescription.
Step 3	Order seeds based on corrected NIST 1999 WAFAC Standard

Converting Previous Orders in $A_{\text{app},T97}$ to corrected $S_{K,N99}$ (U_{NIST})

REFERENCE ONLY:

For the case of 1.4 mCi (^{109}Cd system) order used for a 115 Gy monotherapy,

$$(1.4\text{mCi}) * (1.293\text{U} / \text{mCi}) * \left(\frac{1}{0.767}\right) * \left(\frac{1}{1.05}\right) * \left(\frac{125\text{Gy}}{135\text{Gy}}\right) * \left(\frac{0.68}{0.665}\right) = (2.13\text{U})$$

For the case of 1.0 mCi (^{109}Cd system) order used for a 90 Gy boost therapy,

$$(1.0\text{mCi}) * (1.293\text{U} / \text{mCi}) * \left(\frac{1}{0.767}\right) * \left(\frac{1}{1.05}\right) * \left(\frac{100\text{Gy}}{105\text{Gy}}\right) * \left(\frac{0.68}{0.665}\right) = (1.56\text{U})$$

where the number in the brackets are

$$\left(A_{\text{app},T97}\right) * \left(\frac{S_{K,T97}}{A_{\text{app},T97}}\right) * \left(\frac{S_{K,N99}}{S_{K,T97}}\right) * \left(\frac{S_{K,N99}^{\text{corrected}}}{S_{K,N99}}\right) * \left(\frac{\text{Dose to Deliver with } S_{K,N99}^{\text{corrected}}}{\text{Dose Delivered with } S_{K,T97}}\right) * \left(\frac{\Lambda_{N99}^{\text{corrected}}}{\Lambda_{N99}}\right) = \left(S_{K,N99}^{\text{corrected}}\right)$$

Please refer to *References 3 and 4* in the attached report by J. Williamson, Ph.D. and R. Nath, Ph.D., dated December 15, 2000, and note that all treatment plans differ and should be verified by the qualified medical physicist and radiation oncologist.



Considerations for Transition from Theragenics' Internal Cd-109 Standard to Corrected NIST 1999 WAFAC Standard

User Facility Actions:

- **Change dose rate constant** in treatment planning system to $0.68 \text{ cGy h}^{-1} \text{ U}^{-1}$ per recommendation in Theragenics' Consultants Report, dated December 15, 2000, by J. Williamson, Ph.D. and R. Nath, Ph.D. (Attachment VIII-(B-1)).
- **Obtain ADCL calibrated dose calibrator** based on new calibration data in 2000 from NIST 1999 WAFAC Standard for institution measurement of seeds. Alternatively, adjust previous ADCL calibrated dose calibrator (based on NIST 1999 data) readings with instructions from ADCL for new calibration data in 2000 from NIST 1999 WAFAC standard. Verify seed strength order in terms of corrected NIST 1999 WAFAC standard.
- **Change your facility's procedures and practice** from Cd-109 based calibration system to NIST 1999 WAFAC standard based on NIST 2000 data. This change should include ordering seeds and confirming your order in units of U_{NIST} .
- **Select seed strength ordering value** to achieve prescribed dose (see advice included in Attachment VIII-(B-1) references, "References" contained on seed strength certification and Attachment VIII-(B-2) example).

Your appropriate transition efforts are needed concerning your time period to switch from the Cd system to the corrected 1999 NIST WAFAC system for a given case such as coordinating: 1) treatment planning and seed ordering (possibly in Cd system units), followed by 2) order receipt and seed strength verification measurements, implant, and post-implant treatment planning (all, possibly in corrected NIST 1999 WAFAC standard units).

Please note the following:

- Vials will remain labeled in units of $A_{\text{app},T97}$ until shipments on or after September 10, 2001, when label units will change to the corrected NIST 1999 WAFAC standard.
- See "References" and "Notes" identified on calibration certification.
- Following these changes to implement the corrected NIST 1999 WAFAC system and before August 20, 2001, implement changes noted in Attachment VIII- (A).



Checklist for Those Cd Users Continuing To Use Theragenics' Internal Cd-109 Standard:

1. Review current radioactive material license and decide if new Pd-103 possession limits are needed regarding the numerical increase in the listed mCi for seed strength and total activity under the corrected NIST 1999 WAFAC standard, i.e., approximately 25% higher total activity in your typical possession quantity. Obtain approved license amendment on or before August 20, 2001 and transmit new amendment to Theragenics, either directly or through your distributor.
2. Items Related to New Certification Form
 - Update institution procedures and practice because of new seed strength certification format - seed strength information based on the internal historical Cd-109 calibration system located in certification form footnote. DO NOT USE mCi VALUE LOCATED IN RECTANGLE.
3. Items Related to New Seed of Known U (One seed order)

Update institution procedures and practices to calculate strength of seed on dose calibrator / well chamber adjustment date using seed strength data for the implant date on the seed strength certification. (Eliminate procedure elements using letter, "Dear Customer", containing date and time of Theragenics assay and mCi activity value, i.e., procedure element to decay seed strength to institution measurement date. Note internal historical Cd-109 calibration system seed strength value in certification form footnote.) DO NOT USE mCi VALUE LOCATED IN RECTANGLE.

 - Update procedures and practice to accommodate changes in elements on associated vial label (i.e., air kerma strength range and total activity in units of corrected NIST 1999 WAFAC, seed strength not typically in middle of range identified).
 - Please be advised that the change in seed strength mCi value on certification and label will typically result in a change in dose calibrator "pot" setting or well chamber calibration factor for Model 200, Pd-103, if adjusting to the mCi value stated in units of the corrected NIST 1999 WAFAC standard.
 - In general, previous dose calibrator / well chamber adjustments with a seed of known activity are not expected to be valid (i.e., correlated) with measurements of new seeds of known U (one seed orders), related to their labeled Total Activity in mCi, but only to the mCi value in the footnote on the associated certification form.
4. Items Related to New Labels
 - Update procedures and practice, as needed, to accommodate changes in elements on associated vial label (i.e., air kerma strength range and total activity in units of corrected NIST 1999 WAFAC).
5. Items Related to New Fax Confirmations
 - Alert ordering staff that fax confirmations will be modified on August 20, 2001. (Confirm any changes with your distributor.) The new fax confirmations will confirm in corrected NIST 1999 WAFAC units; however, the basic Cd-109 system units will be included as a footnote.



6. Items Related to Seed Strength Ordering Value

- Develop an internal procedure or practice to convert the seed strength, determined in your treatment planning process in units of mCi based on the historical Theragenics' internal Cd-109 system, to units of corrected NIST 1999 WAFAC units for the purpose of placing the order and verifying the order with the fax confirmation. The relationship between mCi Cd system and the U_{NIST} system is that $S_{k, N99} = 1.6 X A_{app, T97}$. The numerical relationship between $S_{k, N99}$ and $A_{app, T97}$ varies slightly week to week and the magnitude can be verified using the information on the seed strength certification form.
- Develop an internal procedure or practice to associate the fax confirmation footnote information regarding mCi Cd system with the desired seed strength in units of $A_{app, T97}$.

7. Monitor FedEx shipping label for ship date. Beginning September 10, 2001, monitor box contents (See Attachment VII) to identify orders shipped under the changes identified in this Notification of Change and use new procedures and practice as appropriate on such shipments. (Use prior procedures and practice on orders shipped before September 10, 2001.) Be advised that the labels on shipments after September 10, 2001 will display different seed strength units.



Check list for International Cd-109 users:

1. If you choose to switch to the corrected NIST 1999 WAFAC standard, you should implement the changes identified in Attachment VIII-(B) and then in Attachment VIII-(A). Your current seed strength certification form and labels will remain unchanged until the dates indicated in Attachment VI. Please review the timing of your actions with the schedule in Attachment VI.
 - Beginning August 20, 2001, you will need to begin ordering in units of U for the corrected 1999 NIST WAFAC system.
 - If such orders are shipped before September 10, 2001, the seed strength certification and labels will remain in the Cd-109 mCi system.
 - You are expected to coordinate use of calibration system units in treatment planning, ordering, receipt inspections or seed strength verification measurements, post implant dosimetry, etc. For example, you may: 1) choose a traditional dose prescription and perform treatment planning for a case and then order all seeds in the Cd-109 calibration system, and 2) if the shipment is made on or after September 10, 2001, the order will arrive with information primarily based on the corrected NIST 1999 WAFAC system and you may choose to alter your treatment planning dosimetry, Δ , and your prescribed dose.
 - Request a seed of known strength in units of corrected NIST 1999 WAFAC system for your first implant associated with shipment on or after September 10, 2001 or provide an alternate seed strength verification method.
2. If you choose to stay with the Cd-109 calibration system, you should follow guidance in Attachment VIII-(C). Please note the changes to the seed strength certification form and the labels as identified in this Notification of Change. You will need to begin ordering seeds in units of U in corrected 1999 NIST WAFAC system beginning August 20, 2001 and for such orders shipped on or after September 10, 2001, you will need to use the seed strength information in the footnote on the seed strength certification.
3. U.S. versions of seed strength certifications and labels indicate use of mCi units for activity; however, international copies will use MBq, as appropriate. (Note: the footnote information concerning the Cd-109 calibration system on seed strength certifications and any FAX confirmations will remain in units of mCi.)
4. Please contact Theragenics or your Distributor for assistance or clarification. TheraSeed® Customer Service telephone number is 1-877-960-1234.



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