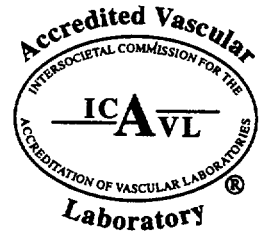




*CARDIOVASCULAR RADIOLOGY INSTITUTE*

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TEL: 787-268-1015 / FAX: 787-268-5511



August 20, 2001

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, D.C. 20555

**RE: Reply to a Notice of Violation.**

A. The violation is accepted.

1. The two existing syringe shields broke at some undetermined point; the nuclear medicine technologist failed to inform anyone so as to repair/purchase new shields.
2. The corrective steps that have been taken-at the time of writing, the desired result has been achieved, since a new syringe arrived at the site on July 6 and one of the old shields was repaired. The technologist is using them, as is expected to.
3. To avoid further violations, the technologist will inform management and the consultant physicist on any problem she may have with their use so as to correct the problem on one, while using the other.
4. Full compliance has been achieved as of July 6, 2001.

B. and C. since the two are connected to the same finding the reply is the same for both.

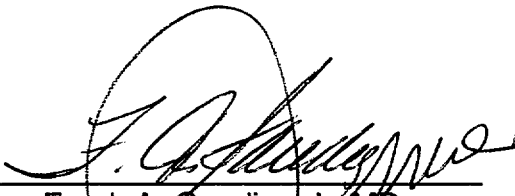
Several years ago, the same inspector visited one of the nuclear medicine laboratories in Puerto Rico and verbally pointed out to our consultant physicist that the Victoreen DWTC Model 05-578 had to have its calibration checked annually. Our physicist claimed that the procedure he was mentioning was not necessary because the instrument was used in the PASS/FAIL mode only and the procedure labeled " Calibration for TC-99m", Section 3.4 page 7 of the manufacturer's instruction manual was been done frequently. (Enclosed please find a copy of this calibration form).

JE07

At that time, the inspector agreed to consult his boss at NRC. The answer then was that this was acceptable.

At some point between then and now, the NRC must have concluded that the procedure labeled by the manufacturer as calibration was not acceptable and that what would be acceptable would be the procedure labeled "Tc-99m Calibration Check", Section 8, page 14 of the instruction manual. It would have been in the best interest of all concerned if NRC would have informed that the decision given years ago was no longer valid.

1. The described situation explains the reason for the violation
2. The corrective steps taken: Enclosed please find a copy of the Calibration Check performed on the Victoreen DWTC on August 16, 2001. According to the manufacturer, if one has performed the Tc-99m calibration check and it passes the test, "then the NRC requirement for efficiency determination has been satisfied".
3. The corrective steps that will be taken to avoid further violations—the test will be performed annually.
4. Full compliance was achieved on August 16, 2001.



Frank A. Gaudier, Jr. MD  
Owner/Radiation Safety Officer

cc: Regional Administrator, Region II

# Deluxe Wipe Test Counter Calibration for Tc-99m

Date: \_\_\_\_\_

Procedure:

1. Press the BKGND key (the LED will light this last 20 minutes).
  
2. When the BKGND light goes out. Press the ACTIVITY key ( the red LED will light which indicates that the DWTC is in the DATA ENTRY MODE).
  
3. If the display is at some value other than **zero** (0), adjust it to zero using the CHANGE DIGIT keys.
  
4. Press the THRESHOLD key to exit the DATA ENTRY MODE (the activity light will go out).
  
5. Place the Cs-137 test source in the large opening of the tray, slide it under the unit (label side down), and press the CALIB key (this test will last for one minute).
  
6. Remove the Cs-137 test source. Press the THRESHOLD key and enter a value of 2.0 using the CHANGE DIGIT keys.
  
7. Press the ACTIVITY key to complete the entry and the THRESHOLD light will go out.

Comments:

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Done by:

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# DWTC Tc-99m Calibration Check

## Procedure:

Date: August 16, 2001

ATT. 2

- 1. Select KDPM mode
- 2. Perform Calibration Steps:

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## Procedure:

- a) Press the BKGND key (the LED will light this last 20 minutes).
  - b) When the BKGND light goes out. Press the ACTIVITY key (the red LED will light which indicates that the DWTC is in the DATA ENTRY MODE).
  - c) If the display is at some value other than zero (0), adjust it to zero using the CHANGE DIGIT keys.
  - d) Press the THRESHOLD key to exit the DATA ENTRY MODE (the activity light will go out).
  - e) Place the Cs-137 test source in the large opening of the tray, slide it under the unit (label side down), and press the CALIB key (this test will last for one minute).
  - f) Remove the Cs-137 test source. Press the THRESHOLD key and enter a value of 2.0 using the CHANGE DIGIT keys.
  - g) Press the ACTIVITY key to complete the entry and the THRESHOLD light will go out.
- 3. Prepare a Tc-99m concentration of 0.1mCi/ml in a 10 ml vial. This is 1 mCi in 10 ml of saline.
  - 4. Using a microliter syringe with 0.2 microliter graduations, draw off a sample of the Tc-99m solution and drop one (1)  $\mu$ liter onto the center of a 1/2" wipe pad. Allow to dry.
  - 5. Place the contaminated wipe into the small opening of the tray under the instrument.
  - 6. Press COUNT and note the audio counting. After a few moments, a value should be displayed. Compare this value to the actual contamination.

Displayed Contamination = 323.1

$$\text{Contamination} = (2220 \text{ kdpm}/\mu\text{Ci}) \times C \times V$$

C = 130 ( $\mu$ Ci/ml) Tc-99m Concentration in Vial

V = 0.001 (ml) volume drop onto wipe pad.

$$\text{Contamination} = \frac{288.6}{\text{kdpm}}$$

- 7. Calculate % error between displayed and calculated contamination.

$$\% \text{ error} = \frac{11.95}{\text{}}$$

## RESULT:

Calibration is OK

If the % error exceeds 30% and is reproducible, then refer to manufacturer's manual and calibrate the DWTC as per 3.5.

Performed by: *[Signature]*

# Deluxe Wipe Test Counter Calibration for Tc-99m

Date: \_\_\_\_\_

Procedure:

- 1. Press the BKGND key (the LED will light this last 20 minutes).
  
- 2. When the BKGND light goes out. Press the ACTIVITY key ( the red LED will light which indicates that the DWTC is in the DATA ENTRY MODE).
  
- 3. If the display is at some value other than **zero (0)**, adjust it to zero using the CHANGE DIGIT keys.
  
- 4. Press the THRESHOLD key to exit the DATA ENTRY MODE (the activity light will go out).
  
- 5. Place the Cs-137 test source in the large opening of the tray, slide it under the unit (label side down), and press the CALIB key (this test will last for one minute).
  
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- 7. Press the ACTIVITY key to complete the entry and the THRESHOLD light will go out.

Comments:

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Done by:

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# DWTC Tc-99m Calibration Check

## Procedure:

Date: August 16, 2001

ATT. 2

- 1. Select KDPM mode
- 2. Perform Calibration Steps:

*Cardiovascular Radiology Institute.*

## Procedure:

- a) Press the BKGND key (the LED will light this last 20 minutes).
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  - c) If the display is at some value other than zero (0), adjust it to zero using the CHANGE DIGIT keys.
  - d) Press the THRESHOLD key to exit the DATA ENTRY MODE (the activity light will go out).
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Contamination = 288.6 kdpm

- 7. Calculate % error between displayed and calculated contamination.

% error = 11.95

## RESULT:

Calibration is OK

If the % error exceeds 30% and is reproducible, then refer to manufacturer's manual and calibrate the DWTC as per 3.5.

Performed by: *[Signature]*