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Performance Measurements and Quality Control Guidelines for Non-Imaging Intraoperative Gamma Probes

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CONTENTS

Section 1  PURPOSE, SCOPE, AND RATIONALE
1.1  Purpose.................................................................................................................. 1
1.2  Scope...................................................................................................................... 1
1.3  Introduction .......................................................................................................... 1
1.3.1  Applications...................................................................................................... 2
1.3.2  Basic Probe Design ......................................................................................... 3
1.4  Rationale for Non-imaging Intraoperative Gamma Probe Measurements .......... 3
1.4.1  Rationale for Sensitivity and Spatial Resolution Measurements .................. 3
1.4.2  Rationale for Sensitivity to Scatter Measurements ........................................ 4
1.4.3  Rationale for Sensitivity to Distributed Activity in Water Measurements .......... 4
1.4.4  Rationale for Short-Term Sensitivity Stability in Air Measurements ................ 4
1.4.5  Rationale for Count-Rate Capability with Scatter Measurement .................... 5
1.4.6  Rationale for Energy Resolution Measurement ............................................... 5
1.4.7  Rationale for Side and Back Shielding Measurement ...................................... 5
1.4.8  Probe Response Time ....................................................................................... 5
1.4.9  Rationale for Radioisotope Used for Testing .................................................... 5

Section 2  REFERENCED PUBLICATIONS, DEFINITIONS, AND TEST EQUIPMENT
2.1  References ............................................................................................................ 7
2.2  General Definitions ............................................................................................... 7
2.3  Terminology .......................................................................................................... 9
2.4  Test Equipment, Conditions, and Results .............................................................. 9
2.4.1  Source Holders and Test Fixtures ................................................................... 9
2.4.2  Radiation Sources ........................................................................................... 9
2.4.3  Equipment Setup and Test Conditions .............................................................. 10
2.4.4  Reporting ......................................................................................................... 11
2.4.5  Measurements ................................................................................................. 11

Section 3  PERFORMANCE MEASUREMENT TESTS
3.1  Sensitivity in Air .................................................................................................. 12
3.1.1  Test Conditions ............................................................................................... 12
3.1.2  Measurement Procedure ................................................................................ 12
3.1.3  Calculations and Analysis ............................................................................. 12
3.1.4  Reporting ........................................................................................................ 12
3.2  Sensitivity in a Scatter Medium ........................................................................ 13
3.2.1  Test Conditions ............................................................................................. 13
3.2.2  Measurement Procedure ............................................................................... 13
3.2.3  Calculations and Analysis ............................................................................. 13
3.2.4  Reporting ....................................................................................................... 13
3.3  Sensitivity through Side Shielding in Air ............................................................ 14
3.3.1  Test Conditions ............................................................................................. 14
3.3.2  Measurement Procedure ............................................................................... 14
3.3.3  Calculations and Analysis ............................................................................. 14
3.3.4  Reporting ....................................................................................................... 14
3.4  Sensitivity to Scatter .......................................................................................... 15
3.4.1  Test Conditions ............................................................................................. 15
3.4.2  Measurement Procedure ............................................................................... 15
3.4.3  Calculations and Analysis ............................................................................. 15
3.4.4  Reporting ....................................................................................................... 16
<table>
<thead>
<tr>
<th>Section</th>
<th>Quality Control Tests</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>General</td>
<td>24</td>
</tr>
<tr>
<td>4.2</td>
<td>Sensitivity</td>
<td>24</td>
</tr>
<tr>
<td>4.2.1</td>
<td>Test Conditions</td>
<td>24</td>
</tr>
<tr>
<td>4.2.2</td>
<td>Measurement Procedure</td>
<td>25</td>
</tr>
<tr>
<td>4.2.3</td>
<td>Calculations and Analysis</td>
<td>25</td>
</tr>
<tr>
<td>4.2.4</td>
<td>Reporting</td>
<td>25</td>
</tr>
<tr>
<td>4.2.5</td>
<td>Recommended Test Frequency</td>
<td>25</td>
</tr>
<tr>
<td>4.3</td>
<td>Visual and Physical Inspection</td>
<td>26</td>
</tr>
<tr>
<td>4.3.1</td>
<td>Inspection</td>
<td>26</td>
</tr>
<tr>
<td>4.3.2</td>
<td>Frequency</td>
<td>26</td>
</tr>
<tr>
<td>4.4</td>
<td>Power Source (for Internally-Powered Systems)</td>
<td>26</td>
</tr>
<tr>
<td>4.4.1</td>
<td>Checks</td>
<td>26</td>
</tr>
<tr>
<td>4.4.2</td>
<td>Frequency</td>
<td>26</td>
</tr>
<tr>
<td>4.4.3</td>
<td>Performance Measurement Datasheet (example)</td>
<td>27</td>
</tr>
<tr>
<td>4.4.4</td>
<td>Quality Control Datasheet (example)</td>
<td>28</td>
</tr>
</tbody>
</table>

© Copyright 2004 by the National Electrical Manufacturers Association.
Tables
Table 1-1 Common Radionuclides and Examples of their Surgical Applications ........................................ 2
Table 1-2 Recommended Frequencies for Gamma Probe Tests .............................................................. 3
Table 1-3 Changes in Test Results Between Using $^{99m}$Tc and $^{57}$Co ................................................... 6
Table 2-1 Recommended Radiation Test Sources ..................................................................................... 10

Figures
Figure 3-1 Sensitivity Test Configuration ................................................................................................ 12
Figure 3-2 Water Bath Test Configuration for Sensitivity ......................................................................... 13
Figure 3-3 Sensitivity Test Configuration .................................................................................................. 14
Figure 3-4 Sensitivity to Scatter Test Configuration .............................................................................. 15
Figure 3-5 Determination of FWHM and FWTM .................................................................................. 16
Figure 3-6 Count Rate Capability and Linearity .................................................................................... 19
Figure 3-7 Angular Resolution Test Configuration ................................................................................. 20
Figure 3-8 Energy Resolution Calculation ............................................................................................. 21
Figure 3-9 Side Shielding Test Configuration ........................................................................................ 22
Figure 4-1 Sensitivity Test Configuration ................................................................................................ 24
Foreword

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CAUTION: Persons using this measurement standard must be in compliance with all applicable federal and state regulations (Ref: NRC Regulatory Guide 10.8, Guide for the Preparation of Applications for Medical Programs) for the use, handling, and possession of radioactive material.
Section 1
PURPOSE, SCOPE, AND RATIONALE

1.1 PURPOSE
The purpose of this standards publication is to provide uniform criteria for conducting and reporting performance measurements and quality control tests of non-imaging intraoperative gamma probes. They are simple, inexpensive to perform, not time consuming and do not require exotic or costly equipment. This Standard identifies parameters and test methods by which a manufacturer may specify the performance of a device and, when doing so, reference NEMA standards publication No. NU 3, *Performance Measurements and Quality Control Guidelines for Non-Imaging Intraoperative Gamma Probes*. These Quality Control Tests are recommended to ensure diagnostic accuracy in clinical practice. This standard does not establish minimum performance levels or minimum acceptance criteria for quality control tests.

1.2 SCOPE
This standards publication establishes definitions and describes quantitative measurements of performance characteristics and quality control tests for non-imaging intraoperative gamma probes.

Performance measurement tests are as follows:

a) Sensitivity in Air  
b) Sensitivity in a Scatter Medium  
c) Sensitivity through Side Shielding in Air  
d) Sensitivity to Scatter  
e) Spatial Resolution in a Scatter Medium  
f) Volume Sensitivity to Distributed Activity in a Scatter Medium  
g) Short Term Sensitivity Stability  
h) Count Rate Capability in a Scatter Medium  
i) Angular Resolution in a Scatter Medium  
j) Energy Resolution  
k) Side and Back Shielding

Quality Control Tests are set forth for the following:

a) Sensitivity  
b) Visual Inspection  
c) Source of Power  

A serious and concerted effort has been made to include non-imaging intraoperative gamma probes of every design under the scope of this Standard. Included are probes that contain scintillating (CsI, NaI) detectors and solid-state (CdTe, CZT) detectors.

This Standard does not apply to non-imaging intraoperative probes that are designed to detect beta particles, such as from positron emitters including FDG. This Standard does apply to non-imaging intraoperative probes intended to detect photons emitted from positron annihilation.

In general, this Standard does not apply to hand-held or other small field of view (SFOV) imaging probes, although many of these performance measurements may apply to these devices when used in a targeting (i.e. non-imaging) manner.

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## CONTENTS

*Page iv*

### Section 1  PURPOSE, SCOPE, AND RATIONALE

1.1  Purpose .......................... 1
1.2  Scope ............................ 1
1.3  Introduction .................... 1

1.3.1  Applications .................. 2
1.3.2  Basic Probe Design .......... 3

1.4  Rationale for Non-imaging Intraoperative Gamma Probe Measurements .......... 3

1.4.1  Rationale for Sensitivity and Spatial Resolution Measurements .......... 3
1.4.2  Rationale for Sensitivity to Scatter Measurements ............................. 4
1.4.3  Rationale for Sensitivity to Distributed Activity in Water Measurements ...... 4
1.4.4  Rationale for Short-Term Sensitivity Stability in Air Measurements .......... 4
1.4.5  Rationale for Count-Rate Capability with Scatter Measurement .............. 4
1.4.6  Rationale for Energy Resolution Measurement .................................... 5
1.4.7  Rationale for Side and Back Shielding Measurement ............................ 5
1.4.8  Probe Response Time ............ 5
1.4.9  Rationale for Radioisotope Used for Testing ...................................... 5

### Section 2  REFERENCED PUBLICATIONS, DEFINITIONS, AND TEST EQUIPMENT

2.1  References ........................ 7
2.2  General Definitions ............... 7
2.3  Terminology ........................ 9

2.4  Test Equipment, Conditions, and Results ................................................. 9

2.4.1  Source Holders and Test Fixtures ....................................................... 9
2.4.2  Radiation Sources ................................................................. 9
2.4.3  Equipment Setup and Test Conditions ............................................. 10
2.4.4  Reporting ................................................................. 11
2.4.5  Measurements ................................................................. 11

### Section 3  PERFORMANCE MEASUREMENT TESTS

3.1  Sensitivity in Air .................. 12

3.1.1  Test Conditions .................. 12
3.1.2  Measurement Procedure ........ 12
3.1.3  Calculations and Analysis .......... 12
3.1.4  Reporting ........................ 12

3.2  Sensitivity in a Scatter Medium .............................................................. 13

3.2.1  Test Conditions .................. 13
3.2.2  Measurement Procedure ........ 13
3.2.3  Calculations and Analysis .......... 13
3.2.4  Reporting ........................ 13

3.3  Sensitivity through Side Shielding in Air ................................................ 14

3.3.1  Test Conditions .................. 14
3.3.2  Measurement Procedure ........ 14
3.3.3  Calculations and Analysis .......... 14
3.3.4  Reporting ........................ 14

3.4  Sensitivity to Scatter ............... 15

3.4.1  Test Conditions .................. 15
3.4.2  Measurement Procedure ........ 15
3.4.3  Calculations and Analysis .......... 15
3.4.4  Reporting ........................ 16

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3.5 Spatial Resolution in a Scatter Medium
3.5.1 Test Conditions
3.5.2 Measurement Procedure
3.5.3 Calculations and Analysis
3.5.4 Reporting

3.6 Volume Sensitivity to Distributed Activity in a Scatter Medium
3.6.1 Test Conditions
3.6.2 Measurement Procedure
3.6.3 Calculations and Analysis
3.6.4 Reporting

3.7 Short-Term Sensitivity Stability
3.7.1 Test Conditions
3.7.2 Measurement Procedure
3.7.3 Calculations and Analysis
3.7.4 Reporting

3.8 Count Rate Capability in a Scatter Medium
3.8.1 Test Conditions
3.8.2 Measurement Procedure
3.8.3 Calculations and Analysis
3.8.4 Reporting

3.9 Angular Resolution in a Scatter Medium
3.9.1 Test Conditions
3.9.2 Measurement Procedure
3.9.3 Calculations and Analysis
3.9.4 Reporting

3.10 Energy Resolution
3.10.1 Test Conditions
3.10.2 Test Equipment
3.10.3 Measurement Procedure
3.10.4 Calculations and Analysis
3.10.5 Reporting

3.11 Side and Back Shielding
3.11.1 Test Conditions
3.11.2 Measurement Procedure
3.11.3 Calculations and Analysis
3.11.4 Reporting

Section 4 QUALITY CONTROL TESTS
4.1 General
4.2 Sensitivity
4.2.1 Test Conditions
4.2.2 Measurement Procedure
4.2.3 Calculations and Analysis
4.2.4 Reporting
4.2.5 Recommended Test Frequency

4.3 Visual and Physical Inspection
4.3.1 Inspection
4.3.2 Frequency

4.4 Power Source (for Internally-Powered Systems)
4.4.1 Checks
4.4.2 Frequency

Performance Measurement Datasheet (example)
Quality Control Datasheet (example)
Tables
Table 1-1 Common Radionuclides and Examples of their Surgical Applications ............................................. 2
Table 1-2 Recommended Frequencies for Gamma Probe Tests ................................................................. 3
Table 1-3 Changes in Test Results Between Using $^{99m}$Tc and $^{57}$Co ...................................................... 6
Table 2-1 Recommended Radiation Test Sources .......................................................................................... 10

Figures
Figure 3-1 Sensitivity Test Configuration ............................................................................................... 12
Figure 3-2 Water Bath Test Configuration for Sensitivity ........................................................................ 13
Figure 3-3 Sensitivity Test Configuration .................................................................................................. 14
Figure 3-4 Sensitivity to Scatter Test Configuration ................................................................................ 15
Figure 3-5 Determination of FWHM and FWTM .................................................................................... 16
Figure 3-6 Count Rate Capability and Linearity ....................................................................................... 19
Figure 3-7 Angular Resolution Test Configuration .................................................................................. 20
Figure 3-8 Energy Resolution Calculation ............................................................................................... 21
Figure 3-9 Side Shielding Test Configuration ......................................................................................... 22
Figure 4-1 Sensitivity Test Configuration ............................................................................................... 24
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