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

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Foreword

User input has been considered in the development of this Standards Publication. The Standards Publication was developed by the Nuclear Section of the National Electrical Manufacturers Association, which will periodically review it for any revisions necessary to keep it up to date with advancing technology. Proposed or recommended revisions should be submitted to:

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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.