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NEMA/IEC STANDARDS PUBLICATION NO. 601-1

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Medical Electrical Equipment—Part 1, General Requirements for Safety

NEMA

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION ■ 2101 L STREET, N.W., WASHINGTON, D.C. 20037

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MEDICAL ELECTRICAL EQUIPMENT—PART 1, GENERAL REQUIREMENTS FOR SAFETY

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Foreword

IEC Publication 601-1, *Medical Electrical Equipment—Part 1, General Requirements for Safety*, includes in its scope all electro-medical devices. All products falling within the product scope of NEMA's Diagnostic Imaging and Therapy Systems Division are covered by this IEC document.

The Food and Drug Administration (FDA) has indicated that medical devices meeting the requirements of 601-1 will satisfy FDA concerns with electrical safety.

IEC has recommended and continues to encourage adoption of the text of IEC documents by the individual national committees. NEMA adoption of the IEC 601-1 document is a first step in this direction.

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Scope

NEMA's adoption of IEC 601-1 is limited to all magnetic resonance, nuclear, ultrasound, or X-ray equipment, components, and accessories used for medical diagnostic imaging, and all equipment, components, and accessories used in executing radiation therapy.

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Medical Electrical Equipment

Part 1—General Requirements for Safety

The International Electrotechnical Commission (IEC) issued the second edition of the 601-1 document, *Medical Electrical Equipment, Part 1—General Requirements for Safety*, in 1988.

On January 23, 1990, the NEMA Codes and Standards Committee approved the recommendation to adopt IEC 601-1, Second Edition, 1988, as a NEMA Adoptive Standards Publication.

Copies of IEC 601-1 are available from the following source:

American National Standards Institute
1430 Broadway
New York, NY 10018

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NEMA STANDARDIZATION

The purpose of NEMA Standards, their classification and status, are set forth in certain clauses of the NEMA *Standardization Policies and Procedures* manual and are referenced below.

Purpose of Standards

National Electrical Manufacturers Association standards are adopted in the public interest and are designed to eliminate misunderstandings between the manufacturer and the purchaser and to assist purchasers in selecting and obtaining the proper product for their particular needs. Existence of a National Electrical Manufacturers Association standard does not in any respect preclude any member or nonmember from manufacturing or selling products not conforming to the standard. *(Standardization Policies and Procedures, p. 1)*

Definition of a Standard

A standard of the National Electrical Manufacturers Association defines a product, process, or procedure with reference to one or more of the following: nomenclature, composition, construction, dimensions, tolerances, safety, operating characteristics, performance, rating, testing, and the service for which they are designed.

(Standardization Policies and Procedures, p. 2)

Dimensions

Where dimensions are given for interchangeability purposes, alternate dimensions satisfying the other provisions of the Standards Publication may be capable of otherwise equivalent performance.

(Standardization Policies and Procedures, p.8)

Categories of Standards

National Electrical Manufacturers Association Standards are of three classes:

1. NEMA Standard, which relates to a product, process, or procedure commercially standardized and subject to repetitive manufacture, which standard has been approved by at least 90 percent of the members of the Subdivision eligible to vote thereon;
2. Suggested Standard for Future Design, which may not have been regularly applied to a commercial product, but which suggests a sound engineering approach to future development, which standard has been approved by at least two-thirds of the members of the Subdivision eligible to vote thereon.
3. Adoptive Standard, which is adopted in whole or in part from the standards of another organization, either domestic, regional, or international.

(Standardization Policies and Procedures, pp. 7 & 16)

Authorized Engineering Information

Authorized Engineering Information consists of explanatory data and other engineering information of an informative character not falling within the classification of NEMA Standard or Suggested Standard for Future Design, which standard has been approved by at least two-thirds of the members of the Subdivision eligible to vote on the standard.

(Standardization Policies and Procedures, pp. 7 & 16)

Official Standards Proposal

An Official Standards Proposal is an official draft of a proposed standard which is formally recommended to an outside organization(s) for consideration, comment, and/or approval, and which has been approved by at least 90 percent of the members of the Subdivision eligible to vote thereon.

(Standardization Policies and Procedures, pp. 7 & 16)

Identification of Status

Standards in NEMA Standards Publications are identified in the foreword or following each standard as "NEMA Standard" or "Suggested Standard for Future Design." These indicate the status of the standard. These words are followed by a date which indicates when the standard was adopted in its present form by the Association.

The material identified as "Authorized Engineering Information" and "Official Standards Proposal" is designated similarly.

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