Electrical Safety Manual 2015

A Comprehensive Guide to Electrical Safety Standards For Healthcare Facilities

Matthew F. Baretich, PE, PhD
SPECIAL NOTE

This manual contains references to generally accepted, national standards relating to electrical safety. It is important to note that many state, county, and city codes/standards may be more rigid and enforced by the local authority having jurisdiction (AHJ). The healthcare facility employee designated as responsible for electrical safety policy and procedures will need to identify the AHJ and determine if additional laws or ordinances apply.

Published by
Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2015 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI at 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Phone: +1-703-525-4890; Fax: +1-703-525-1067.

Printed in the United States of America

ISBN 1-57020-582-5
# Table of Contents

**FOREWORD** ................................................................. vii

**INTRODUCTION TO THE 2015 EDITION** .............................. ix
- Target audience .............................................................. ix
- Responsibility ............................................................... ix
- Manual organization ...................................................... ix
- Changes from the 2008 edition ......................................... ix
- Reference sources and citations ........................................ ix

**CHAPTER 1: THE ELECTRICAL SAFETY PROGRAM** ............... 1
- Rationale ........................................................................ 1
- Elements ........................................................................ 2
- Implementation ................................................................ 2
- Classification of areas .................................................... 3

**CHAPTER 2: EQUIPMENT-RELATED SAFETY REQUIREMENTS** .... 5
- Definitions ....................................................................... 5
- Portable medical equipment ............................................ 6
- Testing—power cord and general condition ....................... 8
- Testing—ground resistance ............................................. 8
- Testing—touch current ................................................... 9
- Testing—lead leakage .................................................... 10
- Fixed electrical equipment ............................................. 10
- Non—patient care equipment ......................................... 10

**CHAPTER 3: FACILITY-RELATED SAFETY REQUIREMENTS** ....... 11
- Emergency power systems ........................................... 11
- Testing—emergency power systems .............................. 12
- Isolated power systems ............................................... 12
- Testing—isolated power systems .................................. 14
- Electrical receptacles .................................................. 16
- Testing—electrical receptacles ...................................... 16
- Extension cords and relocatable power taps ...................... 16
# CHAPTER 4: CODES, STANDARDS, AND REGULATIONS

- Association for the Advancement of Medical Instrumentation ........................................... 19
- American National Standards Institute .................................................................................. 20
- Facility Guidelines Institute ................................................................................................ 20
- International Electrotechnical Commission ......................................................................... 20
- The Joint Commission ......................................................................................................... 21
- National Fire Protection Association ..................................................................................... 21
- Occupational Safety and Health Administration ..................................................................... 22

## QUICK VIEW 1: GROUND RESISTANCE AND LEAKAGE CURRENT LIMITS ............................ 23

## QUICK VIEW 2: POWER LINE COLOR CODES ........................................................................ 27

## QUICK VIEW 3: POWER PLUG WIRING PROCEDURE ............................................................ 29

## QUICK VIEW 4: EQUIPMENT MODIFICATIONS ................................................................. 31

## QUICK VIEW 5: THE SAFE MEDICAL DEVICES ACT ......................................................... 33

- Medical device reporting ....................................................................................................... 33
- Medical device tracking ......................................................................................................... 34

## QUICK VIEW 6: SPECIAL CASES ..................................................................................... 35

- Electrical safety testing of plastic-encased devices ............................................................... 35
- Electrical safety testing of multiple-device assemblies ......................................................... 35
- Use of equipment with high leakage currents ....................................................................... 36
- Use of unlisted or unlabeled devices ................................................................................... 36

## POLICY GUIDE 1: MANAGING MEDICAL DEVICE–RELATED INCIDENTS ......................... 37

- Take care of the patient ......................................................................................................... 37
- Report to risk management ................................................................................................... 37
- Sequester the device and associated materials .................................................................... 37
- Preserve patient data ........................................................................................................... 37
- Investigate the incident ......................................................................................................... 38
- Report to the FDA ................................................................................................................ 38
- Avoid recurrences ................................................................................................................ 38

## POLICY GUIDE 2: MANAGING MEDICAL DEVICE ALERTS AND RECALLS ..................... 39

- Policy .................................................................................................................................. 39
- Responsibilities of the safety officer ...................................................................................... 39
- Responsibilities of the HTM department ................................................................................. 39

## POLICY GUIDE 3: MANAGING RENTED AND LEASED MEDICAL EQUIPMENT .............. 41

- Purpose ................................................................................................................................ 41
- Responsibilities of the clinical department ............................................................................. 41
- Responsibilities of the purchasing department ...................................................................... 41
- Preferred vendors .................................................................................................................. 41
- Alternate vendors .................................................................................................................. 41
- Responsibilities of the HTM department ............................................................................... 41
### POLICY GUIDE 4: MANAGING PERSONALLY-OWNED ELECTRICAL DEVICES . . . .43
- Policy ...........................................................................................................43
- Responsibilities .........................................................................................43
- Patient notification ..................................................................................44
- Handling exceptions ................................................................................44

### POLICY GUIDE 5: ISOLATED POWER SYSTEM RISK ASSESSMENT ..............45
- Risk assessment process .........................................................................45
- References ..................................................................................................45
- Risk assessment factors ............................................................................46
- Preparing for the risk assessment .............................................................46

### POLICY GUIDE 6: LOCKOUT/TAGOUT REQUIREMENTS ...........................47
- General .......................................................................................................47
- Purpose ......................................................................................................47
- Compliance ................................................................................................47
- Sequence of lockout ...................................................................................48
- Restoring equipment to service .................................................................48

### GLOSSARY ................................................................................................49

### FURTHER READING ...................................................................................57

### REFERENCES ..............................................................................................59
PREVIEW COPY

This is a preview edition of an AAMI document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
Foreword

Most of the general populace know the basic rules of electrical safety, such as don’t stand in water while handling live electrical equipment or exposed wires are dangerous. Most of them also take for granted that electricity is safe when these basic rules are followed. They have little appreciation for all the engineering years of experience and safety standards that have helped to make it so safe for the general population. As this Electrical Safety Manual so ably illustrates, there are many aspects of electrical safety beyond these few basic principles.

In spite of the best efforts of those who write standards on electrical safety—myself included—those in the healthcare field charged with implementing and interpreting the various standards need some help. The different standards sometimes overlap, and may even conflict. Even definitions may differ.

In addition, electrical safety thinking has changed over the years. The 2012 version of NFPA 99, for example, removed many of the “nice to have” aspects of the earlier editions as the document was transformed from a voluntary standard into a “code” on an equal footing with the National Electrical Code and the Life Safety Code.

Matt Baretich has done an excellent job of pulling together this Electrical Safety Manual and making it accessible to readers. As Matt has shown with this latest edition, there is definitely a need to refresh.

With the aid of this manual, I hope that you will be able to help your organization comply with relevant sections of the various standards on electrical safety. Keep in mind that this manual is not intended to be the final authority, rather a guide to the pertinent standards. When compliance with a pertinent standard is essential, go back to the source standard.

Alan Lipschultz, PE, CCE, CSP
President, HealthCare Technology Consulting LLC
North Bethesda, MD
Introduction to the 2015 Edition

TARGET AUDIENCE

This document is directed toward those who are responsible for electrical safety in healthcare facilities. A healthcare facility may be a clinic, an outpatient surgery center, a nursing home, a hospital, or a complex healthcare system incorporating any combination of facilities that provide patient care. To simplify the presentation, the Electrical Safety Manual (ESM) uses the term “healthcare facility” to represent any of these units.

RESPONSIBILITY

Departments within the healthcare facility that may be responsible for electrical safety include clinical engineering, biomedical equipment technology, healthcare technology management (HTM), healthcare facilities engineering, or other technically qualified components of the organization. In each healthcare facility, one or more of these departments are responsible for application of this manual in accordance with facility policies and applicable electrical safety codes, standards, and regulations.

Healthcare facilities must have access to appropriate technical expertise to effectively apply this manual. When such expertise is not available on staff, the healthcare facility should work with an external service organization or consultant that has appropriate technical qualifications.

In most cases, the recommended testing procedures can be carried out by the healthcare facility’s technical personnel. It should be noted that electrical safety procedures for medical devices and healthcare environments are not intended to be separate from other equipment maintenance activities. They should be integrated into a comprehensive equipment inspection and maintenance program for the facility.

In addition, accreditation and regulatory agencies expect clinical unit managers and equipment operators to be aware of their roles in ensuring compliance with appropriate codes and standards, and to have access to documents that demonstrate compliance.

MANUAL ORGANIZATION

The ESM contains four chapters that provide a range of information regarding electrical safety, including discussions of codes, standards, regulations, and general concepts upon which the manual is based. The chapters also include recommendations for organizing an electrical safety program and descriptions of electrical safety-related procedures to be used in the program.

The manual also contains several Quick Views that summarize key information for easy reference and Policy Guides that provide recommendations for developing policies and procedures for use in an electrical safety program.

For further reference, the manual includes a Glossary of key terms, a References list of cited material, and a Further Reading section for additional resources.
CHANGES FROM THE 2008 EDITION

The most fundamental difference between the 2008 and 2015 editions is the incorporation of material from the latest codes and standards (listed below). Reference sources used for the 2008 edition of the ESM have had significant updates and, in some cases, have been superseded by new documents. A key objective of the manual is to provide a single publication that pulls together critical material from the full range of applicable codes and standards.

Two major areas of change in the 2015 edition of the ESM are these:

• There is additional material regarding facility-related electrical safety. In particular, new material regarding isolated power systems (IPSs) has been added. Material regarding facility-related safety requirements has been brought together in a single chapter (Chapter 3) to distinguish it from material regarding equipment-related safety requirements (Chapter 2).

• The 2012 edition of NFPA 99: Health Care Facilities Code represents a fundamental rewriting of the 2005 edition. New and revised material, particularly with regard to IPSs and risk-based building system categories, has been incorporated into this edition of the ESM.

And, as with every edition, efforts have been made to clarify and expand various topics to enhance the value of the ESM for its readers. A few topics that, over time, have become of limited interest have been removed.

REFERENCE SOURCES AND CITATIONS

The ESM is based on material from organizations that have developed codes, standards, and regulations applicable to healthcare facilities in the United States. Chapter 4 of the ESM describes these organizations and their requirements. These reference sources are national in scope; however, individual states or other government jurisdictions may have exceptions or additions. Moreover, various authorities having jurisdiction (AHJs) may enforce earlier editions of these references. Therefore, readers of the ESM should make themselves aware of local requirements.

For simplicity, citations of the reference sources used will be abbreviated as shown in the examples below.

The Joint Commission (TJC) document listed below addresses accreditation of hospitals. TJC offers several distinct accreditation programs; however, the hospital accreditation program is the most comprehensive with regard to the topics in the ESM. There are also other hospital accreditation organizations, including the Healthcare Facilities Accreditation Program (www.hfap.org), DNV GL Healthcare (www.dnvglhealthcare.com), and the Center for Improvement of Healthcare Quality (www.chq.org), all with very similar requirements regarding the topics of the ESM.

Finally, it should be noted that the 2015 edition of NFPA 99 has already been published. However, with regard to the topics in the ESM, there are only minor differences between the 2012 and 2015 editions. The ESM uses the 2012 edition rather than the 2015 edition because CMS (Centers for Medicare and Medicaid Services) and TJC have indicated their intent to adopt the 2012 edition of NFPA 99.

<table>
<thead>
<tr>
<th>Full Reference (Example)</th>
<th>Abbreviated Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSI/AAMI ES60601-1:2005(R)2012 (IEC 60601-1:2005 MOD) Medical electrical equipment—Part 1: General requirements for basic safety and essential performance, clause 3.2</td>
<td>AAMI 60601-1 3.2</td>
</tr>
<tr>
<td>2015 Comprehensive Accreditation Manual for Hospitals, Standard EC.02.04.03, Element of Performance 1</td>
<td>CAMH EC.02.04.03 EP 1</td>
</tr>
<tr>
<td>NFPA 70: National Electrical Code, 2014 edition, paragraph 517.18</td>
<td>NFPA 70 517.18</td>
</tr>
<tr>
<td>NFPA 70E: Standard for Electrical Safety in the Workplace, 2015 edition, paragraph 120.1</td>
<td>NFPA 70E 120.1</td>
</tr>
<tr>
<td>NFPA 99: Health Care Facilities Code, 2012 edition, paragraph 10.2.2</td>
<td>NFPA 99 10.2.2</td>
</tr>
</tbody>
</table>
Rigel Medical, part of Seaward Group, has over five decades of experience in electrical safety and brings innovative, game-changing electromedical test equipment to their customers. Rigel’s core competency in electrical test equipment has led to their active involvement in several IEC committees, developing international standards for electrical safety.

The Rigel 288 safety analyzer is relied upon by leading healthcare providers across the globe to deliver a solution for accurate, fast and handheld electrical safety to comply with test standards including IEC 62353, 60601-1, and NFPA-99.

In addition to electrical safety testing products, Rigel Medical manufactures a range of other electromedical test and analysis equipment as well as a vast selection of technical resources and guides, available as free downloads from www.rigelmedical.com/rigel-downloads.
Electrical Safety Manual
2015
A Comprehensive Guide to Electrical Safety Standards for Healthcare Facilities

AAMI’s best-selling guide, the Electrical Safety Manual, is a mainstay resource for professionals, including those in healthcare technology management (HTM), who are responsible for electrical safety in healthcare facilities. The 2015 edition contains updated standards and fresh insights on the changing landscape.

Revised and expanded for the first time in more than six years, the Electrical Safety Manual pulls together crucial information from the full range of applicable codes and standards. It includes descriptions of the basic elements that should be contained in an electrical safety program and recommended steps for implementing a cost-effective program.

The 2015 edition of the Electrical Safety Manual includes:

- Recommendations based on ANSI/AAMI ES60601-1 and the 2012 editions of NFPA 70 and NFPA 99 that are used by The Joint Commission and other accreditation and regulatory bodies.

- Quick View sections with concise tables summarizing the key requirements of applicable standards.

- Policy Guide sections with information on developing and implementing key policies and procedures.

- Other new and updated material to help HTM professionals maintain the highest level of electrical safety, thus supporting patient safety.

About the Author

Matthew F. Baretich, PE, PhD, is president of Baretich Engineering, Inc., in Fort Collins, CO. He is a Certified Clinical Engineer (CCE), a Certified Healthcare Facility Manager (CHFM), and a Certified Professional in Healthcare Risk Management (CPHRM). He is a founder, past-president, and Fellow of the American College of Clinical Engineering (ACCE). Matt consults in the areas of performance improvement for healthcare technology management and investigation of medical technology-related incidents.