

# USAMMA

National  
Maintenance  
Program

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**[CHANGES TO NFPA 99]**

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## **Introduction-**

**In 2012, after seven years since the last edition, the ninth edition of NFPA 99 was published. The Handbook version of this edition listed in SUPPLEMENT 5 significant technical changes and a brief comment. However, SUPPLEMENT 5 does not list changes when a chapter is totally rewritten, as in the new Chapter 10 on Electrical Equipment, nor does it provide information on Chapters that are removed, such as the old Chapter 10 on Manufacturer Requirements. Therefore our review, focused on a comprehensive analysis of the new Chapter 10, to determine what items were changed, and their impact, which is contained in Section 1. Then we reviewed the old Chapter 10, Manufacturers Requirements to determine what topics were kept in the 2012 edition, albeit in other chapters. That work is contained in Section 2.**

## Section 1

### Changes in the 2012 edition of NFPA 99

A comprehensive review was conducted to determine among the 8 new or entirely rewritten chapters and the hundreds of other changes made to the newly published 2012 Edition of NFPA 99 *Health Care Facilities Code* which of those might have some ramifications for the U.S. Army medical maintenance community. Therefore these comments focus on changes that may have an impact on the Medical Maintenance Community, either tangentially or directly. Additionally, specific comment was made to any notional impact to the training of Medical Maintenance personnel at the Medical Equipment Training Center (METC)

The comments are arranged in chapter order and the referenced page numbers are from the 2012 HANDBOOK version of the code. A copy of the Handbook will provide the reader with a valuable reference.

(NOTE: when a specific paragraph is shown, and then followed by “vice (and a paragraph number)” that vice paragraph number is from the NFPA 99 (2005 edition) which is provided to give the reader a basis for comparison.)

#### Chapter 1 Administration

##### Page 8 – Para 1.3 .1 **Application**

CHANGE: Added the phrase “Other than home care” – Home care setting equipment is not included. The previous versions of NFPA 99 did not exclude homecare.

IMPACT on Field: Home care is now specifically excluded from NFPA 99 requirements. Less stringent testing and maintenance requirements if enacted, may lessen the maintenance workload and may require modification to contracts that provide home care equipment.

IMPACT on METC: None

#### Chapter 3- Definitions

##### Page 19 – Para 3.2.2 **Authority Having Jurisdiction.**

CHANGE: The previous versions of NFPA 99 were guidelines, the 2012 is now a “CODE”. Therefore, in practical terms for the U.S. Army, it has the same weight as a federal law.

IMPACT on Field: The AMEDD has for a number of years formally recognized the NFPA in the AR40-61, in effect making it mandatory for our activities. Therefore, this change although significant in a broader sense, its impact on the day-to-day AMEDD Medical Maintenance community is insignificant.

IMPACT on METC: May require a POI change.

##### Page 54 – Para 3.3.138 – **Patient Care Rooms**

CHANGE: New criteria to define the criticality of patient locations. The new code utilizes a risk assessment approach. Previously, areas were generally defined by their location, and not by associated risk. Further explained in Chapter 4.

IMPACT on Field: This risk-assessment approach will likely tie directly to the risk assessment analysis that we will develop for our risk-assessment based maintenance criteria. Its impact on the day-to-day AMEDD Medical Maintenance community is significant.

IMPACT on METC: Significant if METC teaches any management. Should be significant to the 670A Warrant Basic Course.

## Chapter 4- Fundamentals

### Page 67 – Para 4.1 **Building System Categories**

CHANGE: A totally new chapter. Describes Risk to Patient and how to categorize the facility system requirements. Basically, the system requirements are defined by the procedure and not the location. Previously, NFPA 99 used occupancy definitions to determine system requirements, not so with this revision. Now, a patient undergoing a procedure in an office setting must have the same level of “building systems” (O2, Electrical, etc) as a patient undergoing that procedure in a level 3 hospital.

IMPACT on Field: This risk-assessment approach to building and facility systems, will likely tie directly to the risk assessment analysis that we will develop for our medical device risk-assessment maintenance criteria. Its impact on the day-to-day AMEDD Medical Maintenance community is significant.

IMPACT on METC: Significant if METC teaches any management. Should be significant to the 670A Warrant Basic Course.

Further comment – Knowledge and an understanding of this new fundamental analysis is critical to an medical device maintainer/manager. Why? Because the facility systems risk category determination will have a significant influence on the analysis of risk and the risk categories assigned to medical devices. This analysis will need to be done for equipment and the facility.

For general information, a summary of the categories follows:

Category 1 - Failure of this system (includes facility and equipment) is likely to cause major injury or death

Category 2 - Causes minor injury

Category 3 - Not likely to cause injury but can cause discomfort.

Category 4 – No impact on patient care.

## Chapter 6 – Electrical Systems

### Page 268 - Para 6.3.2.2.1.3 **Access to Overcurrent Protective Devices.**

Change: Category 1 and 2 locations must restrict access to the circuit breakers. (NEW) Only “Authorized Personnel” Additionally code now states they cannot be located in Public access spaces.

IMPACT on Field: General information

IMPACT on METC: Significant in safety training at METC. May be significant to the 670A Warrant Basic Course.

Page 273 Para 6.3.2.2.8.4 **Wet Procedure Locations.**

CHANGE: By default operating rooms “shall” be considered a wet procedure location, unless a risk assessment conducted by the health care governing body determines otherwise.

IMPACT on Field: Considerably more frequent and stringent inspections, the risk assessment is critical to the proper identification of “truly” wet procedure locations. Impact to be determined. Recommended risk assessment procedure is located in attachment below:



Eval\_OR\_Wet\_Classification.docx

IMPACT on METC: Significant in safety training at METC. Should be significant to the 670A Warrant Basic Course.

Page 274 – Para 6.3.2.2.8.5(B)(4) **Wet Procedure Locations** (as referenced in 6.1.2(4))

Further requires new and existing testing of Receptacles, and “EQUIPMENT” connected by cord and plug, and fixed equipment at intervals not exceeding six months.

Page 274 Para 6.3.2.2.8.7 **Wet procedure locations.**

CHANGE: Wet locations require a GFCI or isolated power. (In both new and existing facilities.)

IMPACT on Field: General information

IMPACT on METC: Significant in safety training at METC. May be significant to the 670A Warrant Basic Course.

## **Chapter 7 – IT and Communication Systems for Healthcare Facilities**

Note: Entirely new chapter for NFPA 99 2012. Of interest to the medical maintenance community are references to “biomedical systems” and the “electronic health record”. (EHR)

Page 337 Para 7.3.1.2.1.4(F) and 7.3.1.2.2.5(E) **EF and TER**

Requires 12 foot minimum distance from telecom equipment room (TER) and IT/ telecom entrance facility (EF) and any permanent source of electromagnetic interference.(i.e.,Imaging equipment, high voltage transformers and motors)

Page 346 - Note: The following paragraphs are reserved in this chapter and may be significant to the medical maintenance community once they are published.

7.3.3.4 Equipment and Asset Tracking

7.3.3.10 Material Management Information System

7.3.3.12 Medical Imaging Systems

## Chapter 8 - Plumbing

Note: Entirely new chapter for NFPA 99 2012. Portion of this chapter that is applicable to the medical maintenance community is:

Page 354, Para 8.3.11.1 **Clear Waste Water**

Code permits the use of non-potable water for things like – sterilizer jacket, MRI and LINAC cooling.

## Chapter 9 - HVAC

Note: Entirely new chapter for NFPA 99 2012.

Of interest to the medical maintenance community is:

Page 357 - Para 9.2 **System Category Criteria**

HVAC systems must use the same risk analysis criteria as other facility systems.

Page 364 - Para 9.3.9, **Medical Plume Evacuation**

Requires a special handling system for the removal of vaporized, coagulate, and cut tissue, vapors, smoke, and particulate debris. Such as those produced during electrosurgical and laser usage.

## Chapter 10 - Electrical Equipment

This is an entirely rewritten chapter combining some portions of two previous chapters of the 2005 NFPA99, specifically Chapter 8 *Electrical Equipment* and Chapter 10 *Manufacturers Requirements*. Why were these two chapters shuffled around and rewritten? NFPA's contention is that some of the previously included manufacturer's requirements, from chapter 8 are now adequately controlled and published via the:

1. FDA,
2. Center for Devices and Radiological Health (CDRH)
3. International Electrotechnical Commission (IEC). (Primarily IEC 60601-1-2 *Medical Electrical Equipment*).

Consequently, medical maintenance managers should familiarize themselves with these other references.

Page 370 - Para 10.1.1 - **Applicability**

Excludes home healthcare devices from the requirements provided in Chapter 10. (See Para 1.3.1)

IMPACT on Field: If the medical maintenance activity is responsible for the home health care equipment these changes may require some action.

IMPACT on METC: Minimal, except as safety requirement awareness

Page 371- Para 10.2.2.1.2 (**Grounding of Appliances**) vice 8.4.1.2.12

New Requirement: “Double insulated appliances shall be permitted to have 2 conductor cords and shall be rated as Class II devices.” Note: Underlined portion of the preceding sentence was added.

IMPACT on Field: Undetermined. If this is IEC Class II or FDA Class II many, many medical devices are double insulated and not rated FDA Class II. We believe this refers to the IEC, as they use the term “Class II” as an indicator for a double insulated device. This adds an additional reference and furthers the harmonization between the USA and international standards.

IMPACT on METC: Undetermined.

Page 374 - Para 10.2.3.3.1 (**Separable Cord Sets**) vice 10.2.2.3

Change/ Requirement: Changed word from separable to detachable. The term detachable is now used for consistency within International Standards. Added “unacceptable” in front of the word “hazard”.

IMPACT on Field: Further defined as mechanisms that prevent inadvertent connection of the cord set. Specifically prohibits friction type devices.

IMPACT on METC: Minimal, except as safety requirement awareness.

Page 374 - Para 10.2.3.6 (**Multiple Outlet Connection**) vice 8.4.1.2.4.2

Change: Added the word “cart-mounted”.

IMPACT on Field: None

IMPACT on METC: None

Page 375 - Para 10.2.3.6 (**Multiple Outlet Connection**) vice 8.4.1.2.4.2

Changes:

- (1) Removed the words “integral part”.
- (2) Changed “receptacle” to “outlets”
- (4) Deleted “through an ongoing maintenance program”
- (5) Means are to be employed that ensure additional devices are not connected after leakage current has been verified as safe.

IMPACT on Field: If medical maintenance activity is responsible for the creation or modification of crash carts these changes require some action to assure compliance.

IMPACT on METC: Minimal, except as safety requirement awareness

Page 376 - Para 10.3.1 (**Physical Integrity**) vice 8.4.1.3.1

Deletion: Deleted “or other applicable tests”

IMPACT on Field: None

IMPACT on METC: None

Page 379 - Para 10.3.3.3 (***Techniques of Measurement***) vice 8.4.1.3.3.2

Change: Added the word “separable” in front of “transformer.”

IMPACT on Field: None

IMPACT on METC: None

Page 380 - Para 10.3.4.2 (***Leakage Current Fixed Equipment***) vice 8.4.1.3.4.2

Went from 5 mA to 10 mA with all ground lifted.

IMPACT on Field: New testing standard.

IMPACT on METC: May require POI change.

Page 380 - Para 10.3.5 (***Touch Current- Portable Equipment***) vice 8.4.1.3.5

New term for “leakage current” is “touch current”. Reason? To remain consistent with International Standards (IEC).

IMPACT on Field: New testing term.

IMPACT on METC: May require POI change.

Page 380 - Para 10.3.5.1 (***Touch Current Limits***) vice 8.4.1.3.5.1

Change: Touch current limit is lowered from 300  $\mu\text{A}$  to 100  $\mu\text{A}$  grounded. And increased from 300 $\mu\text{A}$  to 500 $\mu\text{A}$  with ground lifted. Removed requirement for a maintenance schedule of 500 $\mu\text{A}$  items. To remain consistent with other international standards.

IMPACT on Field: New testing limits. Educational requirement.

IMPACT on METC: May require POI change.

Page 381- Fig 10.3.5.4 (***Test Circuit for measuring Touch Leakage Current***)

Change: Fig 10.3.5.4 is identical to the old Fig 8.4.1.3.5.5. However, the NFPA 99 (2005) illustration, Fig 8.4.1.3.6.1 (*Test Circuit for Measuring Leakage Current between patient leads and ground, Non-isolated*) is not in the 2012 edition. However, the 2012 edition requires testing of patient leads to ground, and inaccurately references the test configuration shown at 10.3.5.4 which we think will not provide those results.

IMPACT on Field: We think it is a mistake by the NFPA. We have prepared a correction/suggestion and are awaiting internal vetting.

IMPACT on METC: To be determined.

Page 382- Para 10.4.2.1 (***Cord and Plug Connected – Portable Equipment in Patient Care Room***) vice 8.4.2.2

Change: Nonpatient Care-related equipment, facility or patient owned, shall be visually inspected by staff or “other personnel”

Further states reference PAGE 382 – Para 10.4.2.2

This is a new initiative, basically a common-sense approach. If it appears not to be safe or inoperable it shall be removed or reported.

And Page 382 Para 10.4.2.3

Allows household and office appliances without a ground, are allowed, just not in the patient care vicinity, while double-insulated appliances are permitted in the patient care vicinity.

IMPACT on Field: Represents a major departure from previous policy that often required any devices in the Patient care room to be tested and meet the same standards as Patient Care Equipment.

IMPACT on METC: To be determined.

Page 383 - Para 10.5.2.1.1 (***Administration***) vice 8.5.2.1.2.1

Change: Old edition said “each appliance”; new version states “for patient-care related electrical equipment”

Further reference PAGE 383 – Para 10.5.2.1.2

Change: Removed the previously required 12 and 6 month testing intervals. Now, testing is required before being put into service for the first time and following any repair or modification that might compromise electrical safety.

IMPACT on Field: Represents a major departure from previous policy that often required a safety test every 6 months, in a critical or wet location, and every 12 months in a General location.

IMPACT on METC: To be determined.

Page 383 - Para 10.5.2.2 (***Protection of Patients with Direct Electrical Pathways to the Heart***) vice 8.5.1.5.1

Change: Adds specific reference to IEC terminology, “Cardiac Floating” (CF) for such devices.

IMPACT on Field: New standard to be aware of during procurement of such equipment.

IMPACT on METC: NONE

Para 8.5.2.1.5.1 (NFPA 99 (2005)) has been removed. It mandated a requirement to have a policy prohibiting external pacemakers.

IMPACT on Field: None

IMPACT on METC: None

Page 384 - Para 10.5.2.4 (**Devices Likely To Be Used During Defibrillation**) vice 8.5.2.1.8

CHANGE: Mandates that when a device critical to patient safety, is likely to be attached to the patient during defibrillation, then it shall be rated as “defibrillator proof”. (Not certain where the term is defined, we believe it to be an IEC term)

IMPACT on Field: New standard to be aware of when evaluating proper device application, and during procurement of such equipment.

IMPACT on METC: Education and awareness of the standard.

Page 384 - Para 10.5.2.5 (**System Demonstration**) vice 8.5.2.1.11.1

CHANGE: Removed the reference to the “vendor” having responsibility to demonstrate compliance.

IMPACT on Field: None

IMPACT on METC: None

Page 385 – Para 10.5.3.1 (**Servicing and Maintenance of Equipment**) vice 8.5.2.1.10 and 10.2.8.1.1

Change: The NFPA 99 (2005 edition) required the vendor to provide the following:

1. Installation and Operating instructions
2. Inspecting and testing procedures
3. Maintenance details to include:
  - a. Operator’s Manual
  - b. Maintenance Manual
  - c. Repair Manual

- i. And further defined by 13 ea sub paragraphs (10.2.8.1.2)

The NFPA 99 (2012 edition) states “The manufacturer of the appliance shall furnish documents containing at least a technical description, instructions for use, and a means of contacting the manufacturer.” It also includes the 13 ea sub paragraphs.

Page 386 -, Para 10.5.3.1.1 (**Servicing and Maintenance of Equipment**) vice 10.2.8.1.2

Specifically sub-paragraphs:

(8) Requirement to provide a “Functional Description of the Circuit” (In the 2005 edition) was removed. In the 2012 edition, (8) requires “Instructions for cleaning, disinfecting, or sterilization”

(10) Requirement to provide a “The limits of Electrical Supply variations...” (In the 2005 edition) was removed. In the 2012 edition, (10) requires “Explanation of the figures, symbols ...etc.”

(11) Requirement to provide “Technical performance specifications...to include design leakage current levels.” (In the 2005 edition) was changed. In the 2012 edition, (11) requires “Technical performance specifications” (Reference to leakage levels removed)

(13) Requirement to provide “Comprehensive preventive and corrective maintenance and repair procedures” (In the 2005 edition) was changed. In the 2012 edition the word “Comprehensive” was removed.

Page 386 – Para 10.5.3.1.2

New paragraph. States that OEM literature should be considered in the development of a program for maintenance of equipment.

IMPACT on Field: Significantly reduces the code requirements for the manufacturers to provide adequate, or for that matter any repair or maintenance manuals. While at the same time, emphasizing its utilization in the development of maintenance plans. Contractual specifications to provide adequate literature will be essential going forward.

IMPACT on METC: None

Page 389 - Para 10.5.4.5 (**Electrical Equipment in Oxygen-Enriched Atmosphere**) vice 8.5.2.4.5  
CHANGE: Added a new reference to the “ANSI/AAMI ES 60601-1”

IMPACT on Field: New standard to be aware of when evaluating proper device application, and during procurement of such equipment.

IMPACT on METC: Education and awareness of the standard.

## Chapter 11 – Gas Equipment

Page 402 - Para 11.3.3.3 (**Cylinder and Container Storage Requirements**)

NEW: Added a requirement specific to the proper storage of small-sized cylinders.

IMPACT on Field: New standard to be aware of when evaluating proper crash cart application, and during procurement of such equipment.

IMPACT on METC: Education and awareness of the standard.

Page 405 - Para 11.4.3.3 (**Gas Equipment – Laboratory**)

NEW: Added a requirement specific to medical devices not for patient care, and require oxygen USP. Provides a list of 5 each - do’s and don’ts.

IMPACT on Field: New standard to be aware of when evaluating proper installation of ozone sterilizers or similar systems, and during procurement of such equipment.

IMPACT on METC: Education and awareness of the standard.

Page 407 - Para 11.5.1.3.3 (**Servicing and Maintenance of Equipment**) vice 8.5.2.2.3

Change: Removed the prohibition that no other equipment could be repaired in an area designated for the service of oxygen equipment.

IMPACT on Field: New standard to be aware of when evaluating shop space utilization.

IMPACT on METC: Education and awareness of the standard.

Page 414 - Para 11.6.5.2.1 (**Special Precautions – Storage of Cylinders and Containers**)

NEW: Added a requirement specific to cylinders with an integral pressure gauge. Activities shall establish the threshold at which a cylinder is considered empty.

IMPACT on Field: New standard to be aware of when evaluating and testing devices that utilize an integral pressure gauge.

IMPACT on METC: Education and awareness of the standard.

Page 414 - Para 7.1 (**Liquid Oxygen Equipment**)

NEW SECTION: Basically requires the manufacturer to provide instructions for the use, storage and refill of these devices and requires the users to follow those instructions. Further restricts storage locations, transportation methods, requires a drip pan, and restricts a maximum of 31.6 gallon in proper fire barriered patient locations.

IMPACT on Field: New standard to be aware of when evaluating proper installation and utilization of LOX systems, and during procurement of LOX equipment or service contracts.

IMPACT on METC: Education and awareness of the standard.

## **Chapter 12 - Emergency Management**

Page 417 – CHAPTER REWRITTEN to aligned with The Joint Commission. Contains a new requirement to have a robust Emergency Management Plan, if the Health Care Facility is required to provide care during an emergency or disaster. The Plan shall provide for the protection of visitors and staff. Although staff positions are not specifically designated, it is likely that the referenced “Medical Device Unit Leader” would be a Medical Maintenance manager. Likewise medical maintenance manager is a natural candidate for the Hazard Vulnerability Analysis team and its work which are also contained in this chapter.

IMPACT on Field: New standard – ramification to be determined.

IMPACT on METC: Education and awareness of the standard.

## **Chapter 13 - Security Management**

Page – 453 - This is another new chapter. Although not a Medical Maintenance responsibility it will certainly impact staff, and their access to medical devices to perform services.

IMPACT on Field: New standard – ramification to be determined.

IMPACT on METC: Education and awareness of the standard.

## **Chapter 14 - Hyperbaric Facilities**

### **Page 474 – Para 14.2.1.2 (Construction and Equipment)**

NEW: Extends the requirement to have a sprinkler system from only Class A chambers, to also Class B and C chambers.

IMPACT on Field: New standard to be aware of when evaluating proper installation and utilization and servicing of hyperbaric chambers, as well as during the procurement of hyperbaric equipment or service contracts.

IMPACT on METC: Education and awareness of the standard.

### **Page 478 – Para 14.2.2.5 (Fabrication of the Hyperbaric Chamber)**

NEW: Restricts the material to be used as a finish coating on Class A Chambers.

IMPACT on Field: New standard to be aware of when performing maintenance or servicing a class A hyperbaric chambers, as well as during the procurement of hyperbaric equipment or service contracts.

IMPACT on METC: Education and awareness of the standard.

Page 492 – Para 14.2.7.3.6 (**Wiring and Equipment inside Class A Chambers**)

NEW: Specifies the UL and CSA wire coating/insulation standard that are allowed to be inside a class A chamber.

IMPACT on Field: New standard to be aware of when performing maintenance or servicing a class A hyperbaric chambers, as well as during the procurement of hyperbaric equipment or service contracts.

IMPACT on METC: Education and awareness of the standard.

Page 496 – Para 14.2.7.3.17.5 (**Battery Operated Devices**)

NEW: Specifies restriction for battery usage in a chamber. Specifically, there is a new prohibition on Lithium or Lithium Ion batteries in chambers.

IMPACT on Field: New standard to be aware of when performing maintenance or servicing a class A hyperbaric chambers, as well as during the procurement of hyperbaric equipment or service contracts.

IMPACT on METC: Education and awareness of the standard.

Page 500 – Para 14.2.8.6.4 (**Chamber Gas Supply Monitoring**)

NEW: Specifies that when providing breathing air to a Class A or Class B chamber, the breathing air shall be medical air USP.

IMPACT on Field: New standard to be aware of when performing maintenance or servicing of class A or B hyperbaric chambers..

IMPACT on METC: Education and awareness of the standard.

Page 508 – Para 14.3.1.5.4.1 (**Chamber Gas Supply Monitoring**)

NEW: Prohibits silk, wool, or synthetics fabrics in a Class A or Class B chamber.

IMPACT on Field: New standard to be aware of when performing maintenance or servicing a class A or B hyperbaric chambers.

IMPACT on METC: Education and awareness of the standard.

Page 516 – Para 14.3.6.2.1.4 (**Maintenance**)

NEW: Lubricants shall be oxygen compatible.

IMPACT on Field: New standard to be aware of when performing maintenance or servicing hyperbaric chambers.

IMPACT on METC: Education and awareness of the standard.

## **Chapter 15 – Features of Fire Protection**

Page 519 – New Chapter. Provides an overview specific to NFPA 101 *Life Safety Codes* and fire protection program in a Health Care Facility.

IMPACT on Field: New standard to be aware and gain an understanding of the interaction between the things we analyze in a risk assessment and the impact of life safety codes and ultimately how they interact with the fire protection program.

IMPACT on METC: Education and awareness of the standard.

## Section 2

### 2005 edition topics that were omitted from the 2012 edition

#### Preface

The 2005 edition of NFPA 99 Chapter 8 (Electrical Equipment) was completely rewritten and is now Chapter 10 (Electrical Equipment) in the 2012 edition. The 2005 edition of NFPA 99 contained a chapter (Chapter 10) specifically addressing Manufacturer Requirements; this chapter was not included in the 2012 edition. The NFPA felt that this chapter was no longer necessary and was not within the scope of this code. Although some of the specifications/requirements were incorporated into other chapters of the 2012 edition.

The NFPA's comment regarding the removal of Manufacturer Requirements:

“For the 2012 edition of NFPA 99, the Technical Correlating Committee on Health Care Facilities decided that the chapter addressing manufacturer requirements was no longer necessary and was not within the scope of the code. Manufacturer requirements for medical equipment are now well covered by the regulations of the U.S Food and Drug Administration, Center for Devices and Radiological Health, as well as consensus standards – most notably those published by the International Electrotechnical Commission (IEC), Primarily IEC 60601-1, *Medical Electrical Equipment – Part 1 :General Requirements for Basic Safety and Essential Performance.*”

Therefore, it was necessary to perform a paragraph by paragraph review of the 2005 edition specifically focusing on Chapters 8 & 10 to determine what items were omitted in the newly published 2012 edition of NFPA 99 and their impact on the field.

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The comments are arranged in chapter order and the referenced page numbers are from the 2005 edition of the NFPA 99. A copy of the 2005 NFPA 99 Standard will provide the reader the ability to view the omitted items that are listed below.

### **Chapter 8 Electrical Equipment**

#### **Page 99-83 – Para 8.1.1 Applicability**

MOVED to Annex A – A.10.1

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-83 – Para 8.2.3; 8.2.4; 8.2.5; 8.3; 8.4 Burns; Interruption of Power; RF Interference; Electrical System; Performance Criteria and Testing**

REMOVED: These were references to other chapters in the 2005 edition of NFPA 99.

IMPACT on Field: None  
IMPACT on METC: None

**Page 99-84 – Para 8.4.1.2.4 Line Voltage Equipment – Anesthetizing Location**

REMOVED: Anesthetizing location is now affiliated with Oxygen-Rich Atmospheres.  
IMPACT on Field: Minimal  
IMPACT on METC: None

**Page 99-84 – Para 8.4.1.2.4.1 Foot –treadle Operated Controllers**

REMOVED foot-treadle specifications for anesthetizing locations.  
IMPACT on Filed: Minimal  
IMPACT on METC: None

**Page 99-84 – Para 8.4.1.2.4.3 Overhead Power Receptacles**

REMOVED specifications concerning requirements for overhead power receptacles..  
IMPACT on Field: Minimal  
IMPACT on METC: None

**Page 99-84 – Para 8.4.1.3.3.3 Frequency of Leakage Current**

MOVED to Annex A – A10.3.3  
IMPACT on Field: Minimal  
IMPACT on METC: Minimal

**Page 99-84- Para 8.4.1.3.3.4(3) Leakage Current in Relation to Polarity**

REMOVED requirement to have “all operating controls in the position to cause maximum leakage current readings.”  
IMPACT on Field: Significant change to testing procedures.  
IMPACT on METC: May require POI change.

**Page 99-85 – Para 8.4.1.3.6.2 & Para 8.4.1.3.6.3 Lead to Ground – Isolated Input & Isolation Test – isolated Input**

REMOVED requirements for isolated lead leakage testing, no longer required.  
IMPACT on Field: Significant change to lead leakage testing requirements.  
IMPACT on METC: May require POI change.

**Page 99-86 – Para 8.4.1.3.6.4 & 8.4.1.3.6.5 Between Leads – Non-isolated and Isolated**

REMOVED requirements for non-isolated and isolated leakage testing between leads, no longer required.

IMPACT on Field: Significant change to testing procedures.

IMPACT on METC: May require POI change.

**Page 99-86 – Para 8.4.2.2.2.1; 8.4.2.2.2.2; 8.4.2.2.2.3; 8.4.2.2.2.4; 8.4.2.2.2.5 Laboratory**

REMOVED requirements for laboratory over temperature -limit control, flammable/combustible hazard, and heating element disconnect by fan interlock control. These requirements covered by NFPA 45 (Standard on Fire Protection for Laboratories Using Chemicals) and College of American Pathologists (CAP).

IMPACT to Field: Minimal, except education for where requirements are now located.

IMPACT to METC: Minimal, except as safety requirement awareness.

**Page 99-86 – Para 8.5.2.1.1 General**

REMOVED no longer applies.

IMPACT to Field: Minimal

IMPACT on METC: None

**Page 99-87- Para 8.5.2.1.4 Testing Intervals – Fixed Equipment**

REMOVED the terms general and critical care areas. These are now risk categories.

IMPACT to Field: Minimal

IMPACT to METC: Minimal

**Page 99-87- Para 8.5.2.1.6 Controls**

REMOVED as this falls under patient care risk assessment.

IMPACT to Field: Minimal

IMPACT to METC: Minimal

**Page 99-87- Para 8.5.2.1.8 Appliances Intended to Deliver Electrical Energy**

REMOVED

IMPACT to Field: None

IMPACT to METC: None

**Page 99-87- Para 8.5.2.1.9 Specification of Conditions of Purchase**

REMOVED

IMPACT to Field: Removed the vendors' responsibility and puts it back onto the person purchasing the equipment.

IMPACT on METC: None

#### **Page 99-87- Para 8.5.2.2.4 Servicing and maintenance of Equipment - Tagging**

REMOVED the requirement for tagging the defective piece of equipment.

IMPACT on Field: Educational.

IMPACT on METC: Minimal.

#### **Page 87- Para 8.5.2.2.5 Servicing and maintenance of Equipment – Monitoring of Electrical Interference**

REMOVED or it is possibly relocated to another chapter

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-87- Para 8.5.2.3.1 During Surgery - Securing**

REMOVED requirement for securing active electrodes when not in use.

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-88 – Para 8.5.2.3.2 During Surgery – Contamination**

REMOVED requirement for removing contained cable on electrosurgical generator.

IMPACT on Field: None

IMPACT on METC: None

## **Chapter 10 Manufacturer Requirements**

#### **Page 99-93 – Para 10.2.1.1 Separation of Patient Circuits**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-94 – Para 10.2.1.2 Mechanical Stability**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-94 – Para 10.2.2.2.3.3 Grounding Conductor- Cord Set / Receptacle Polarization**

REMOVED: This specification is relinquished to NFPA 70 National Electrical Code (NEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-94 – Para 10.2.2.2.6 Separable Cord Sets – Testing**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.3.1; 10.2.3.2; 10.2.3.3 Protection of Wiring in Appliances; Grounding of Exposed Conductive Surfaces; Replacement Connection**

REMOVED: These specifications are relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.3.4.1; 10.2.3.4.2; 10.2.3.4.3; 10.2.3.4.4 Connection of the Grounding Conductor**

REMOVED: These specifications are relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.3.6.1; 10.2.3.6.2; 10.2.3.6.3; 10.2.3.6.4; 10.2.3.6.5 Overcurrent Protection**

REMOVED: These specifications are specific to the manufacturer.

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.3.7.1; 10.2.3.7.2; 10.2.3.7.3; 10.2.3.7.4 Primary Power-Control Switch**

REMOVED: These specifications are specific to the manufacturer.

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.3.8.1; 10.2.3.8.2 Rack- or- Cart- Mounted Equipment**

REMOVED: These specifications are specific to the manufacturer.

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 - Para 10.2.4.1.1; 10.2.4.1.2 Indexing of Receptacles for Patient Leads**

REMOVED: These specifications are specific to the manufacturer.

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.4.2 Distinctive Receptacles for Patient Leads**

REMOVED: These specifications are specific to the manufacturer.

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.4.3.1 Lead Termination**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.4.3.2 Isolated Patient Lead**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-95 – Para 10.2.5 Line Voltage Variations and Transients – General**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.6.1.1; 10.2.6.1.2 Thermal Standards**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.6.2.1; 10.2.5.2.2 Toxic Materials**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.6.3 Chemical Agents**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.6.4 Electromagnetic Compatibility**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.6.5.1 General**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.6.5.2.1; 10.2.6.5.2.2 Power Transfer**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.6.5.3.1; 10.2.6.5.3.2; 10.2.6.5.3.3 Programmable Appliances**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.7.1.1; 10.2.7.1.2 Fire and Explosion Hazards- Material and Supplies**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-96 – Para 10.2.8.1.3 Manuals**

REMOVED the requirement for the manufacturer to provide operating and service manuals.

IMPACT on Field: The softening of the NFPA requirement for the manufacture to provide operator and service literature may cause issues with proper operation and maintenance/repair of the equipment.

IMPACT on METC: May affect ability to get literature and may affect training.

**Page 99-96 – Para 10.2.8.2 Operating Instructions on Appliances**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-97 – Para 10.2.8.3.1; 10.2.8.3.2; 10.2.8.3.3; 10.2.8.3.4; 10.2.8.3.5; 10.2.8.3.6; 10.2.8.3.7 Labeling**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-97 – Para 10.2.9.1.1 General**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-97 – Para 10.2.9.1.2 Outdoor Signal Transmission**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-97 – Para 10.2.9.2.1 Conditions for Meeting Safety Requirements**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-97 – Para 10.2.9.2.2.1 Electrically Powered Transducers**

REMOVED requirement of testing exposed metal parts of transducers.

IMPACT on Field: Minimal, testing no longer required.

IMPACT on METC: None

#### **Page 99-97 – Para 10.2.9.2.2.2 Inadvertent Interchange**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

#### **Page 99-97 – Para 10.2.9.2.2.3 patient Impedance Measuring Devices**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-97 – Para 10.2.9.2.2.4 Electrotherapeutic Devices**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-97 – Para 10.2.9.2.2.5 Electrosurgery**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-97 – Para 10.2.9.2.2.6 Cardiac Defibrillation**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-97 – Para 10.2.10.1; 10.2.10.2; 10.2.10.3 General; Rechargeable Appliance; Low-Voltage Connectors**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 97-99 – Para 10.2.10.4.1; 10.2.10.4.2 Isolation of Low-Voltage Circuits**

REMOVED: This specification is relinquished to NFPA 70 National Electrical Code (NEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-98 – Para 10.2.12 Direct Electrical Pathways to the Heart**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-98 – Para 10.2.12.1.1; 10.2.12.1.2; 12.2.12.1.2.1; 10.2.12.1.2.2; 10.2.12.1.2.3; 10.2.12.1.2.4; 10.2.12.1.3; 10.2.12.1.4 Cardiac Electrodes**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-98 – Para 10.2.12.2.1; 10.2.12.2.2 Liquid-Filled Catheters**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-99 – Para 10.2.12.2.3.1; 10.2.12.2.3.2; 10.2.12.3 Conductive Cardiac Catheters – Angiographic Catheters**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-99 – Para 10.2.13.1; 10.2.13.2(1)(2) Manufacturers’ Test for Safety of Patient-Care-Related Electrical Appliances- General – Grounding Circuit Continuity-Measurement of Resistance**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-99 – Para 10.2.13.3.1 Techniques of Measurement**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-99 – Para 10.2.13.3.2.1; 10.2.13.3.2.2 Frequency of Leakage Current**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-99 – Para 10.2.13.3.3 Leakage Current in Relation to Polarity**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-100 & 101 – Para 10.2.13.5.1; 10.2.13.5.1.1; 10.2.13.5.1.2; 10.2.13.5.1.3; 10.2.13.5.1.4 Lead to Ground (Non-isolated Input)**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-101 – Para 10.2.13.5.2.1; 10.2.13.5.2.2; 10.2.13.5.2.3 Lead to Ground (Isolated Input)**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-101- Para 10.2.13.5.3.1; 10.2.13.5.3.2; 10.2.13.5.3.3; 10.2.13.5.3.4; 10.2.13.5.3.5 Isolation Test (Isolated Input)**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-102 - Para 10.2.13.5.4.1; 10.2.13.5.4.2 Between Lead (Non-isolated Input)**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None

**Page 99-102 - Para 10.2.13.5.5.1; 10.2.13.5.5.2 Between Leads (Isolated Input)**

REMOVED: This specification is relinquished to one of the following regulatory organizations: U.S Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), International Electrotechnical Commission (IEC).

IMPACT on Field: None

IMPACT on METC: None