IEC 60601-1 VERSION 3.2

AMENDMENT HIGHLIGHTS

RAM Technologies

Why has 60601-1 3.2 been introduced?

Medical electrical systems and equipment used to diagnose, monitor, or treat a patient, or alleviate or compensate for an injury, disease, or disability fall under IEC 60601 standards.

For this medical electrical equipment, an applied part either detects an energy transfer or transfers energy to or from the patient and provides up to one connection to supply mains. IEC 60601-1 includes the general requirements for all equipment that fall under this umbrella category.

For each version of the published standards, two amendments can be included before a new version is introduced. 60601-1 3.2 is version three of the 60601-1 standard, with Amendment 2 being published in August 2020 by the International Electrotechnical Commission (IEC).

The FDA listed 6060-1 3.2 as a recognized standard on May 30, 2022. This new amendment includes updates that were determined to be too urgent to wait for a new version to be published – IEC has stated that version 4 won't be published until after 2024.

DIFFERENCES BETWEEN IEC 60601-1 3.1 AND 3.2

Amendment 2 of IEC standard 60601-1 Version 3 mainly addresses the potential hazards that can happen to patients or operators in both normal and fault conditions when operating medical electrical equipment.

These hazards can be electrical, thermal, mechanical, or functional, and are considered unacceptable risks. 78 items were added in Amendment 2 and were determined too urgent to wait until Version 4.

CLAUSE 2 - NORMATIVE REFERENCES

When applying an updated standard, it's important to interpret the guidelines alongside other documents that provide supplementary information.

Version 3.2 includes more explicit language about making the connection between documents, as well as paying attention to subsequent collateral that comes out about the 60601-1 series after the publication of Amendment 2.

IEC 60950-1 reference replaced by IEC 62368-1:2018

10 normative references were introduced or altered on the list from 3.1 to 3.2.

One important change calls out IEC 60950-1 and replaces it with IEC 62368-1:2018 “Audio/video, information and communication technology equipment – Part 1: Safety requirements.”

This new standard replaces IEC 60950-1 as both a “hazard-based” standard and one that takes into account the blurring of lines between Information and Communications Technology (ICT) and traditional AV devices.

The set of guidelines applies to all video, audio, information, and communication technology.

IEC 62368-1:2018 is applicable to electronic and equipment safety for these devices that don’t exceed 600 volts. The standard works to outline safeguards against classified energy sources and when to apply these safeguards.

CLAUSE 3 -

TERMINOLOGY AND DEFINITIONS

Many of the definitions in Amendment 2 reference definitions included in ISO 14971:2019, including:

- Harm
- Hazard
- Hazardous situations
- Objective evidence
- Procedure (Note 1 has been deleted)
- Process
- Record
- Residual
- Risk definition
- Risk analysis
- Risk assessment
- Risk control
- Risk evaluation
- Risk management
- Risk management file
- Severity

CLAUSE 3 - TERMINOLOGY & DEFINITIONS

The definition of **harm** was also expanded to include animals in this latest version.

Intended use is separated from **normal use** by definition – intended use is meant to describe the medical purpose of a device, whereas normal use could also include non-medical use such as transport and maintenance.

CLAUSE 3 - TERMINOLOGY & DEFINITIONS

A manufacturer is defined as a “natural or legal” person who is responsible for:

- Designing medical electrical equipment (ME)
- Manufacturing ME equipment
- Packaging ME equipment
- Labeling ME equipment (which doesn’t include shipping)
- Assembling medical electrical (ME) systems
- Adapting ME equipment / ME systems (substantially modifying something already being used)
- Operations that could be performed by the person or on their behalf to be defined as a manufacturer

The definition of **verification** was clarified to include an explanation of what objective evidence would be needed to verify and that activities of verification are sometimes called a “qualification process,” with “verified” being the status of the outcome of that process.

CLAUSE 3 - TERMINOLOGY & DEFINITIONS

Definitions 3.148 to 3.154 were also introduced:

- Electromagnetic disturbance
- High priority
- Information signal
- Low priority
- Maximum equipment pressure
- Medium priority
- Safety sign

Clause 7 - Identification and Marking

Updates made to Clause 7 further specify markings and lights that should be used on devices.

Safety signs

The requirement for clearly legible markings has been extended to include safety signs on ME equipment. Safety signs or symbols should also be used to denote which accompanying documents should be consulted for additional safety information. Several references in labeling have been modified to specify requirements for safety signs.

Clause 7.5 that addresses safety signs has also been modified to include more clarification and specification on the definition for safety signs, as well as what is required of safety signs on different parts of equipment.

Alarm indicator and indicator lights

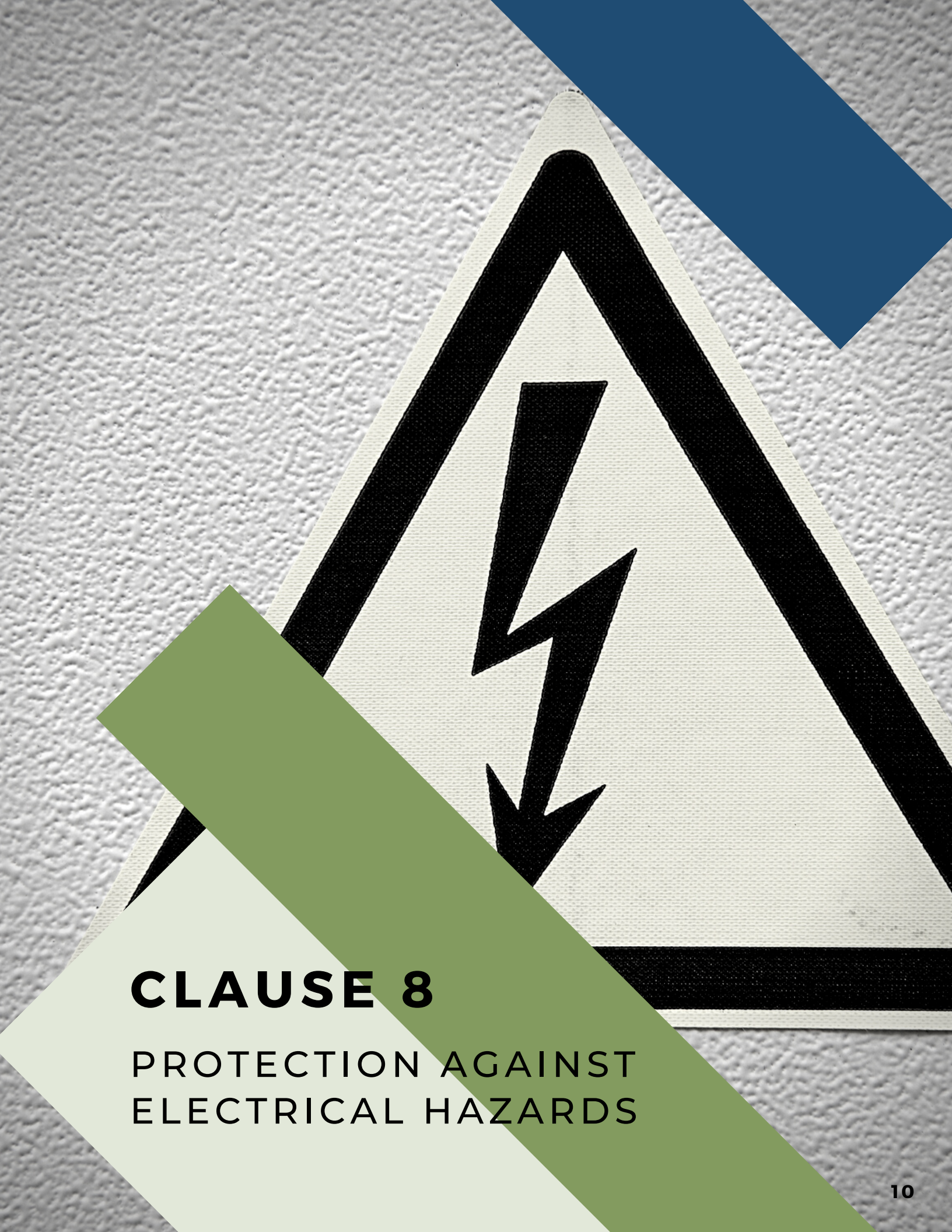
Clause 7 also includes a table (Table 2) that provides colors and meanings for alarm indicator and indicator lights to be used on ME equipment. This table offers details for the name of each light, when it should be on, the color of the light, and whether it should be accompanied by a sound.

CLAUSE 7 - IDENTIFICATION AND MARKING

Other updates and additions in Clause 7 include:

- IP classification – Clarification on when IP classification needs to be marked or not
- Batteries – Warnings via proper markings and references needed for equipment that incorporates lithium batteries or fuel cells that could become a hazardous situation if replaced incorrectly

Power Switches:
Specification of symbols that can be used for "on" and "off" on power parts of ME equipment, as well as a symbol for "stand-by"



CLAUSE 8

PROTECTION AGAINST ELECTRICAL HAZARDS

MANY PARTS OF CLAUSE 8 HAVE BEEN UPDATED, INCLUDING THE FOLLOWING:

Accessible Parts and Applied Parts

Gave instructions for measuring the voltage for ME equipment with SIP/SOP connectors or separate power supply outlet connectors and which currents need to be measured based on different conditions.

Y Capacitors

A note has been added on fitting Y capacitors across barriers and consideration of the dielectric strength requirement.

Means of Protection

Means of Protection will be categorized in accordance to the parts that are being protected from surpassing permitted limits. Figure 40 in the standards expands on this in a visual way with a flowchart that determines when means of protection (MOP), means of patient protection (MOPP), or means of operator protection (MOOP) requirements apply to certain parts of devices.

CLAUSE 8

PROTECTION AGAINST
ELECTRICAL HAZARDS

Opto-Couplers

Opto-couplers that comply with IEC 60747-5-5:2007 or later are deemed equivalent to 8.8.2 or 8.9.3 requirements depending on the insulation used – air clearance, creepage distance, and dielectric strength apply. This is the first time opto-couplers have been mentioned in IEC 60601-1, making it a new requirement for version 3.2. Previously, it was not necessary for opto-couplers to meet IEC requirements.

Means of Operator Protection

Insulation coordination requirements need to be met for solid insulation, creepage distances, and air clearances for means of operator protection, citing specific IEC standards for each. Additional requirements are listed for compliance for protective earthing.

Working voltage measurement

There is a working voltage measurement requirement for all circuits to be connected to the earth unless they are floating parts, which would require one means of protection to the earth. Figure 41 was also added for greater specification.

CLAUSE 8

Single patient connection

A few notes were made about applied parts with multiple patient connections all within the body and in close proximity to one another being treated as a “single patient connection.”

Impedance and current-carrying capability

Testing should be performed using a detachable power supply cord provided or specified by the manufacturer. The amendment also includes specification on how the highest rated current should be determined.

Allowable values

The leakage current shouldn’t exceed 10 mA r.m.s. in either normal conditions or single fault conditions.

Measuring supply circuits

Specifications were added for ME equipment when connected to supply mains or internally powered.

Conductive surface coatings

If these coatings are applied to non-metallic surfaces, flaking or peeling shouldn’t reduce air clearance or creepage distance.

CLAUSE 11 – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS

Clause 11 covers concerns about excessive temperatures and protecting patients and operators from the hazards that can come with these temperatures and similar situations. The terminology “accessible parts” was added in reference to allowable maximum temperatures for parts on Table 23. The same term was added in other parts of the clause as well.

A few updates were included for fire enclosure requirements on ME equipment, including the flammability classification requirement for insulated wire and connectors within fire enclosure, as well as printed circuit boards and insulating material that components are mounted on.

Amendment 2 also made changes to the fire enclosure requirements for the bottom and sides of the enclosure, with a note included about other design solutions for openings possibly being acceptable per solutions found in other standards.

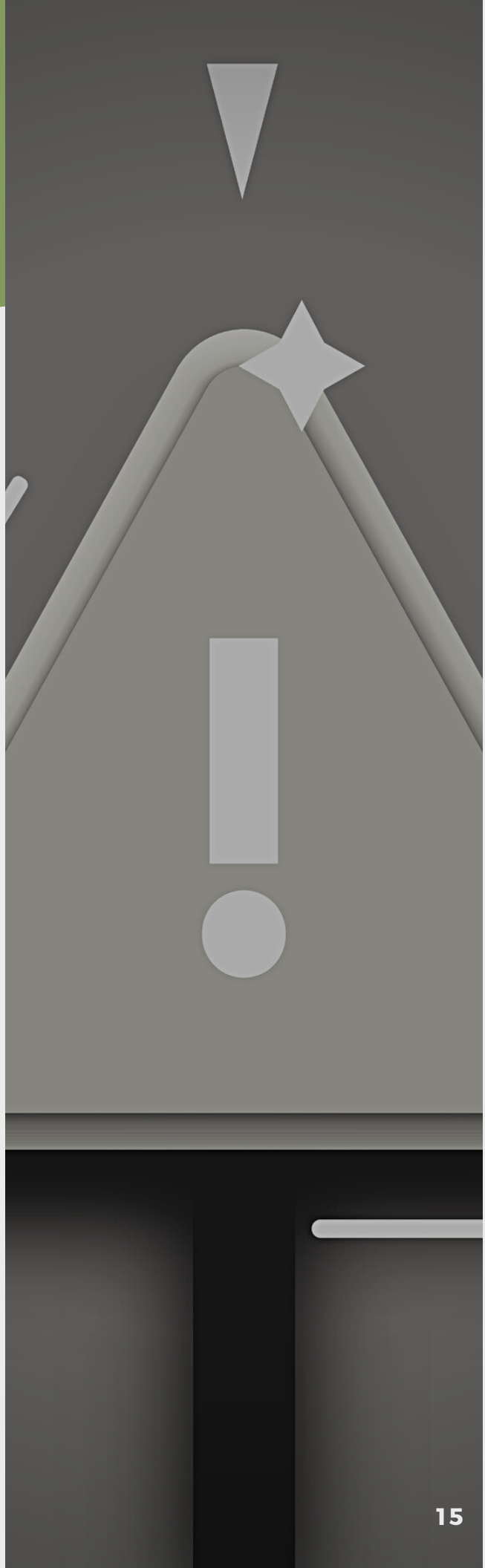
CLAUSE 13 -

HAZARDOUS SITUATIONS AND FAULT CONDITIONS

The biggest update in Clause 13 provided detail on temperature excesses that would be unacceptable and would pose a hazard.

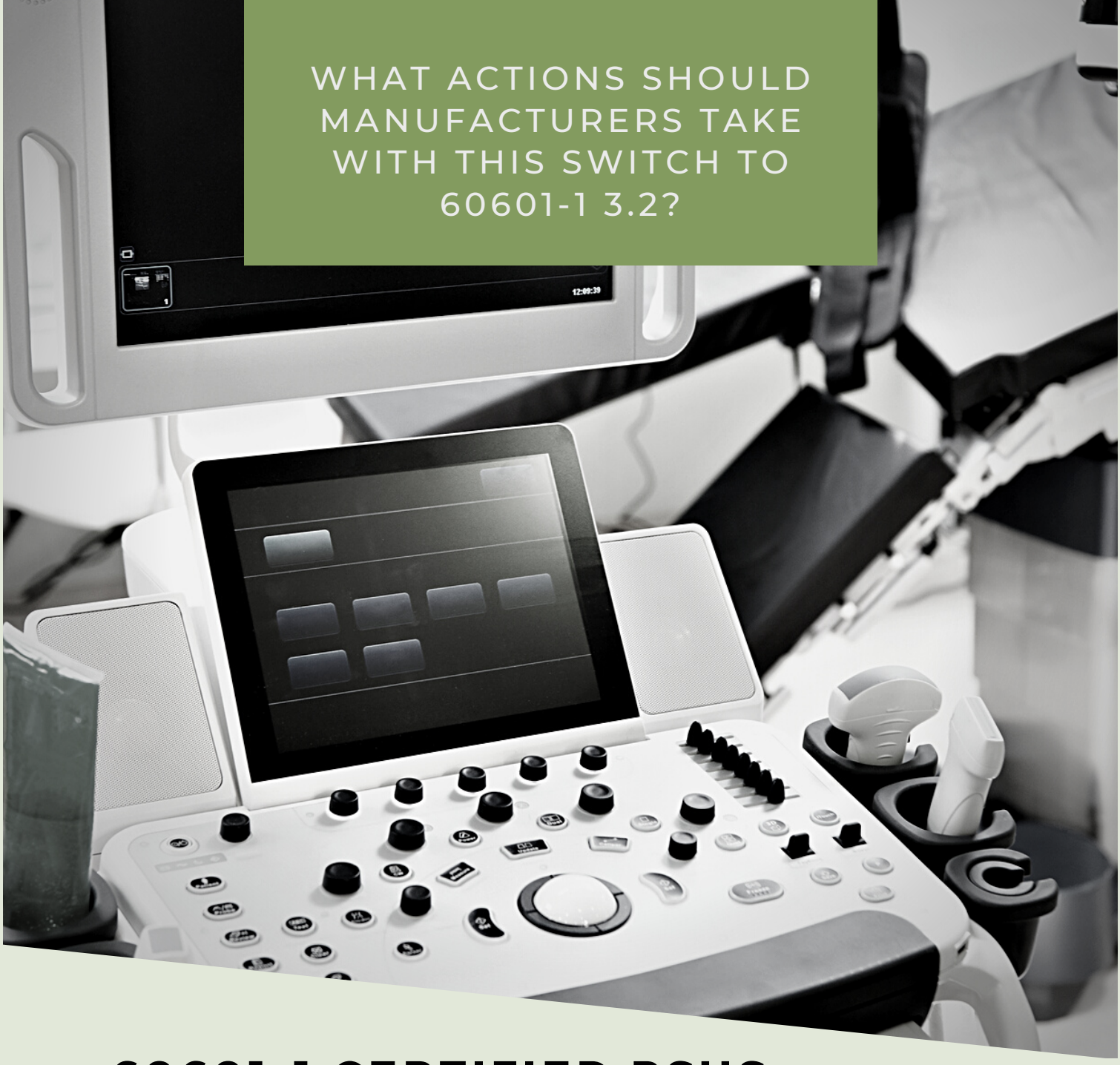
Table 34 in the standard is for accessible parts that are not likely to be touched. Table 23 is for parts that are.

Additional details on how compliance can be checked are also provided.



CLAUSE 14 - PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

The main update made to Clause 14 included a definition of SOUP (software of unknown provenance) as found in IEC 62304:2006/AMD1:2015.



WHAT ACTIONS SHOULD MANUFACTURERS TAKE WITH THIS SWITCH TO 60601-1 3.2?

60601-1 CERTIFIED PSUS

MAKE YOUR PATH TO MARKET SMOOTH WITH A CERTIFIED VENDOR

Any manufacturers working on ME equipment and expecting to seek clearance after December 17, 2023 should prepare to meet Version 3.2 standards.

RAM Technologies meets the requirements laid out by Amendment 2, and we're now certified.

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