Certification of Electrical Medical Devices

When Is It Considered a Medical Device?

ME Equipment Definition

Per 60601-1, ME is Electrical Equipment having:

- An applied part or,
- Transferring energy to or from a patient or,
- Detecting such energy transfer to or from the patient
- And which is intended to be used:
  - In the diagnosis, treatment, or monitoring of a Patient or,
  - For compensation or alleviation of disease, injury or disability

The Consequences

- ME Equipment uses 60601 standards
  (AAMI ES60601, CSA60601, EN60601, IEC60601)
- Many more requirements = RA, RMS, Usability, etc.
- A “grey area” for some products that might benefit by avoiding the ME certification process
- A legitimate way to “avoid” the FDA for those that are searching for that option

There is a Grey Area

- Products with similar functionality intended for non-medical applications:
  - For example, devices that monitor EKG or provide other data about the human body for “wellness” purposes
- Products used in and around a medical facility

What Does the Manual Say?

- Product manual is 1st consideration
- Manual should clearly indicate product's purpose
- If not intended for medical purposes, clearly state this
- Should not present misleading information

Grey Area Alternatives

"Wellness" Product Safety Standards:

- Massage & Exercise: UL1647, CSA68, EN60335
- Personal Hygiene & Health Care: UL1431, CSA68, EN60335
- The manual and advertising = consistent with FDA Guidelines on Wellness Devices

Product Use Location

- Can create an incorrect assumption
- Location of use is not part of the ME definition
  - Use in a hospital is not automatically ME
  - Use on a patient is clearly ME
  - Use in the “patient vicinity” may be questioned
  - Non-medical products used in the patient vicinity = meet some aspects of medical compliance
    - But that doesn’t make it ME

Product Use Location

- Use in medical facility outside the patient areas
  - Appropriate standard for type of product
- Laboratory Equipment standard (61010) for equipment used in the hospital lab
- Physical therapy is often questioned
  - Meets the ME definition but often uses general exercise equipment, not ME

In-Vitro Diagnostic (IVD)

- Laboratory equipment that detects disease, conditions, and infections that are critical to patient care decisions
- In-Vitro Diagnostic Equipment (IVD) is to be evaluated using the 61010 standard series

FDA Consideration

- Required to be approved by the FDA?
- FDA consensus standard for the product
- FDA expects either
  - A very large report on how the product complies with the medical standards and all supporting information or,
  - An FDA-ASCA report

Next – the required elements of ME certification
Followed by – the *new* FDA-ASCA program

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When Is It Considered a Medical Device?

Summary

The Required Elements of ME Certification

Risk Assessment

- Method to identify all hazards and quantify their level of risk within a product
- Covering all potential risks including potential hazards identified in 60601-1 and any applicable 60601-2 Particular Standard
- Documented analysis and numerical assessment
  - *Likelihood of Occurrence* and *Severity of Injury*
- Documents the hazard mitigation methods and shows that the risks have been reduced to an acceptable level

Risk Assessment

Pre-Mitigation | Mitigation | Post-Mitigation

ID	Hazard and Cause of Hazard	Initial Rating			Pre-Mitigation Risk Discussion And Mitigation Activity If Required	Rating After Mitigation					
		Severity	Occurrence	RPN		Severity	Occurrence	RPN	Mitigation Cause New Hazard? (Y/N)	Acceptable Residual Risk? (Yes/No)	Follow-up Action Required (Yes/No)
1	Pinch Fingers from user reaching into chamber while carriages are rotating.	2	1	2	1. Add door switch that turns off carriage rotation when door is opened. This makes likelihood of occurrence smaller. 2. Use a drive belt that slips so torque to carriage is limited. This mitigation is just an extra precaution in case door switch doesn't work or if user opens door and manually presses the door switch. This makes the severity smaller.	1	1	1	No	Yes	No
2	Machine rolls out of position due to uneven floor, due to being bumped, or due to vibration caused during operation.	2	1	2	1. Use locking casters on wheels. No change to rating but added to improve design.	2	1	2	Yes (see ID No. 3)	Yes	No
3	If caster locks engaged pushing on machine could cause it to tip over.	2	1	2	No mitigation required. (Machine base is heavy enough to prevent tipping.)	2	1	2	No	Yes	No

Hazards listed

Severity

Likelihood

RPN

Mitigations listed

Process Repeated

Cause New Problem?

Acceptable?

Risk Management Checklist

- Checklist template provided by the certification lab
- Provides details how the product complies with ISO14971 and the RMF Requirements within 60601-1
- Clause by clause review – how the product complies or why the clause is N/A
- Reference quality and operational documents that demonstrate compliance with each clause = by document name, page number, and paragraph

Risk Management File (RMF)

- Contains the documents utilized to demonstrate product quality and compliance
- Includes documents referenced in the RMF Checklist
- Build the RMF while completing the RMF Checklist – each time you reference a document, add it to the RMF (binder or e-folder)

General Product Safety

- Per AAMI ES 60601-1 (and CSA, EN, IEC versions)
- Protecting the Patient and the Operator from Electrical and Mechanical Hazards
- Shock Hazard Protection = 2 MOPP for Patients (60601-1) and 2 MOOP for Operators (60950-1)
- Includes PEMS (Programmable Electrical Medical Systems) per Section 14 when applicable
- Requires Essential Performance definition

Particular Standards

- 60601-2-#
- Requirements provided by specific medical product type or product feature
- There is a long list of Particular Standards to review for each product
- All applicable particular standards must be included
- Some medical products have no particular standard

Particular Standards

- Written to coincide with a specific version of the 60601-1 standard
- Modify, remove, & add requirements to the -1
- Important to evaluate the -2 standard with the -1 standard
  - Clause by clause: Look at the -1, then the -2 = then assess compliance of the product design

Particular Standards

- When the -1 standard is updated, the technical committees for the -2 standards update to coincide
  - Takes a year or two, sometimes even longer
- Update compliance when the -1 updates, and note the need to re-evaluate after the -2 updates

Collateral Standards

- 60601-1-#
- Requirements cover additional areas of compliance that apply to some types of ME

EMC/Immunity

- ME must comply with the EMC & Immunity requirements of 60601-1-2
- EMC = Radiated and Conducted Emissions, Harmonic Distortion, Voltage Fluctuation & Flicker
- Immunity = Ability to Withstand External Electrical Interference = ESD, EFT, Surges, RF, Voltage Dips, Conducted Disturbances, Magnetic Field

Diagnostic X-Ray

- Radiation Protection for Diagnostic X-ray per 60601-1-3
- Include when this is the type of product or is an included product feature
- May also need to be considered for products used in conjunction with diagnostic x-ray

Usability

- All ME must have a Usability report per 60601-1-6
- Sometimes referred to as Human Factors
- Compliance with ISO62366 – Usability Engineering of Medical Devices

Alarm Safety

- Safety critical alarms must comply with 60601-1-8
- Not intended for all visible and audible alarms
  - What risks in your RA are mitigated with alarms?
- Minimize reliance on alarms
- In most cases, the visible and audible “notifications” are not being “relied upon” to ensure safety

Home Healthcare

- ME intended for use in the home and wearable ME must comply with 60601-1-11 for home healthcare devices
- A very Environmental Test intensive standard
- Not for wellness devices used in the home, evaluated to UL1431 for Hygiene and Health Care

Emergency Medical

- EMS Equipment must comply with 60601-1-12
- Only applies to EMS equipment
- A very Environmental Test intensive standard – shock, vibration, thermal shock, ingress protection (water), & drop tests

Medical Device Software Safety

- Safety critical software must comply with IEC62304 - covering the software lifecycle process
- Not all software is safety critical
  - What risks in your RA are mitigated with software?
- Minimize reliance on software for safety – rely on repeatable, reliable certified devices when possible
- *Now included in the 60601-1 TRF for the CB Scheme*

Biocompatibility

- Parts/materials in contact with the Patient's body
- Evaluated/tested for biocompatibility per ISO10993-1
- Manufacturers frequently use materials that are already ISO10993-1 compliant

Sterilization

- Sterilized medical products must comply with the applicable ISO standard
- The standard varies by product type, sterilization method, and whether the device is one-time sterilization (disposable) or repeatedly sterilized

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Elements of Medical Certification

60601-1 General Safety	60601-2-X Particular Standards
Risk Assessment	Alarm Safety 60601-1-8
Risk Management File	Home Healthcare 60601-1-11
RMF Checklist	Emergency Medical 60601-1-12
EMC/Immunity 60601-1-2	Software Safety IEC62304
Diagnostic X-Ray 60601-1-3	Biocompatibility ISO10993-1
Usability 60601-1-6	Sterilization ISO Standards

Key ME Certification Prep Questions

1) Have a Risk Assessment?
   - All residual risk mitigated to an acceptable level?
2) Have a complete RMF that is compliant with ISO14971 & the RMF requirements of 60601-1?
3) Completed the RMF Checklist?
   - Your RMF include all documentation referenced in the checklist?

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Key ME Certification Prep Questions

4) Identified all applicable ME Certification elements?
   - List of applicable standards?
4) Identified all applicable 60601-2 Particular Standards?
5) Have compliance reports for Usability, PEMS, Alarms, Biocompatibility, Software Safety, & Sterilization?
6) Has an expert done a pre-compliance review? It saves time and money to find/fix problems pre-compliance

The Required Elements of ME Certification

Summary

The Certification Process using the FDA-ASCA program

ME Certification Background

- Prior to the 3rd edition of 60601-1:
  - UL Certification process and FDA process were completely separate
- 3rd edition of 60601-1:
  - AAMI standard
  - Entire process shifted onto the Certification review = RA, RMF, Usability, EMC/Immunity, etc. = all but medical safety of the device

ME Certification Background

- FDA - inadequately staffed and funded
- Many new ME products, pharma, concerns (Covid)
- FDA shifting their focus to high-risk medicine
- FDA shifting review of low-risk to private sector
- 1st is ME equipment under FDA-ASCA program
  - Accredit labs to review product and issue an FDA-ASCA summary report and Declaration of Conformity

FDA-ASCA Program

- Saves manufacturers considerable time and expense
  - Reduced Q&A = shorter review period
  - Much smaller submittal package
- FDA accepts certified FDA-ASCA report
  - In lieu of hundreds of pages of compliance reports
- No more FDA questions on compliance
  - FDA states this previously delayed 100% of submittals!
- US Certification + FDA-ASCA are now done together!

FDA-ASCA Program

- FDA-ASCA program = overwhelming success
- Now permanent FDA policy
- Important for all ME manufacturers
- From now on:

ALL ME certifications should include an FDA-ASCA report

FDA-ASCA Process

1) Identify 60601-1 and 60601-2 standards that apply
2) Verify the -2 standards are ASCA
   - Most -2's are part of the program
3) Perform Certification project with FDA-ASCA Lab
   - Agree on Test Plan
4) Plan FDA submission elements

FDA-ASCA Process

5) Obtain Test Results and Summary ASCA Test Report
6) Prepare the FDA Submission using the ASCA Test Report & Documentation

A box of certification reports and a lot of back-and-forth questions from the FDA have been replaced by a single FDA-ASCA Summary Test Report!!

FDA-ASCA Test Plan

- Most important step = Development of the Test Plan
- FDA consistently found problems with the Test Plan in *most* Premarket Submissions = a BIG delay!
- FDA-ASCA ensures
  - The Test Plan is correct
  - The FDA receives consistent information/format

FDA-ASCA Test Plan Development

- Much more than just a “Test Plan”
- Now a collaborative process:
  - Medical Device Manufacturer + Experienced Lab Staff
- FDA-ASCA requires Test Plan agreement before testing
  - FDA-ASCA Lab and ME Manufacturer must agree

Common Test Plan Mistakes

1) Creating a Test Plan from a List of Tests
   - The Standard doesn't contain just a list of tests
   - The Standard contains compliance requirements
   - Some requirements specify performing a test to determine compliance
   - Must conduct a complete review of the standard before preparing the Test Plan

Common Test Plan Mistakes

2) Missing an applicable Particular Standard
   - Particular Standards are intended to be used in conjunction with the -1
   - The -2 standard may modify, remove, or add tests
   - Missing particular standards during the product review process will result in an incomplete and incorrect Test Plan

Common Test Plan Mistakes

3) Failing to include EP considerations
   - Pass/fail criteria for several tests includes Essential Performance (EP)
   - This mistake often coincides with a missed Particular standard since EP comes from the -2s

Common Test Plan Mistakes

4) Ignoring Product Configuration Specs
   - Some products have multiple configurations
   - In many cases, multiple configurations must be tested for compliance
   - Missing test configurations will result in an incomplete Test Plan

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Common Test Plan Mistakes

5) Not including Environmental Considerations
   - 60601 standards specify temperature, humidity, and atmospheric pressure ranges for ME
   - Any extended environmental ratings must be considered – some tests will need to be performed under the extended conditions

Common Test Plan Mistakes

6) Leaving out Home Healthcare Testing
   - Applies to any medical device prescribed for use outside a medical facility
   - Home healthcare has some of the most severe test conditions
   - Missing these tests could cause you to miss non-compliant issues

Certification Process with FDA-ASCA

- FDA-ASCA process with US & Canadian certifications
- Use an in-scope FDA-ASCA accredited lab that is also US-NRTL and Canadian-SCC accredited
- CertifiGroup was the 1st FDA-ASCA Lab
- MET Lab was the 1st US-NRTL
- Now combined under Eurofins E&E
  - Eurofins is the world's largest test and certification lab

Certification Process with FDA-ASCA

Part 1: Detailed review of the product to 60601-1 and the applicable 60601-2 standards:

- Tests identified and test configurations determined
- Test parameters specified
- Device loading conditions and support equipment
- EP & tests requiring EP identified
- Test plan prepared stating exactly how the tests will be performed = discussed and agreed with client

Certification Process with FDA-ASCA

Part 2: Testing per the Test Plan & Report Preparation.

Once the product has been verified to be compliant:

- Final report for Certification
- FDA-ASCA Submission Cover Letter
- FDA-ASCA Declaration of Conformity (DoC)
- FDA-ASCA Summary Test Report

Benefits of FDA-ASCA

Large Document Package plus Endless Questions is replaced by:

- FDA-ASCA report
- Ready to send your FDA submittal immediately
- Safety Certifications at the same time

Why would anyone not use the new FDA-ASCA program?

ME Certification Summary

What is considered a Medical Device?

The Required Elements of ME Certification

Certification using the FDA-ASCA Program

Thank you
for your attendance

Please provide any input to Bill

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