

IEC 60601 Amendments Updates

WHAT STANDARDS UPDATING?

| | | | |
|-------------------------------|----------------------------------|--------------------------------|---------------------------|
| 60601-1 Electro Med | 60601-1-2 EM Disturbances | 60601-1-6 Usability | 60601-1-8 Alarms |
| 60601-1-9 Environ ... Dsgn | 60601-1-10 Closed loop cntrls | 60601-1-11 Home Use Environ | 60601-1-12 EMS Environ |

WHEN WILL UPDATES PUBLISH?

Estimated August / September 2020

LOTS OF CHANGES

TOUGHER REQUIREMENTS TO MEET (I.E. 60601-1-2)

WILL YOU BE READY FOR THE CHANGES?

3 YR TRANSITION PERIOD EXPECTED

NO GRANDFATHERING

1. New reports for EU MDR, product changes for FDA & update HC Cert's may be impacted.

2. Will your designs need to be updated?

3. What design documents need to be updated?

4. What test lab documents need to be updated (RMF, Usability, S/W, EMC, etc.)?

5. Will your test plans be ready in time?

Do you have the internal resources to conduct a thorough Gap Assessment against the appropriate standards?



Are your internal resources part of the standards committees that developed these standards updates and understands the changes in depth? Leo "The IEC 60601 Guy" is one of those experts.

What are you waiting for?

Invest in your business...

START NOW!

1. Join a public webinar!

2. We can tailor training for your Co.

3. We can do product & document reviews

4. Do you need a Gap Assessment?

Contact us @ 503-244-6151 or Leo@EisnerSafety.com

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