

# IEC 60601 Amendments Updates

## WHAT STANDARDS UPDATING?

60601-1 <i>Electro Med</i>	60601-1-2 <i>EMC</i>	60601-1-6 <i>Usability</i>	60601-1-8 <i>Alarms</i>
60601-1-9 <i>Environ ... Dsgn</i>	60601-1-10 <i>Closed loop cntrls</i>	60601-1-11 <i>Home Use Environ</i>	60601-1-12 <i>EMS Environ</i>

## 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](mailto:Leo@EisnerSafety.com)*

*[www.EisnerSafety.com](http://www.EisnerSafety.com)*