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FDA issues new requirements to improve defibrillator safety

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The Food and Drug Administration said Wednesday it will require makers of heart-zapping defibrillators to submit more data on the emergency devices after years of recalls and manufacturing problems.

Under the new requirements, manufacturers will have to submit more data on the reliability of their devices and components, including batteries, adapters and electrodes. Additionally, the FDA will inspect manufacturing plants before companies can begin marketing new devices. The rules take effect for new defibrillators July 2016. Accessories already on the market will have until January 2020 to meet the new standards.

Defibrillators use electric shocks to jolt the heart back to normal after cardiac arrest or other life-threatening heart problems. Once used exclusively in emergency rooms, they are now found in schools, office buildings and other public places.

The devices have been plagued by design and manufacturing flaws for years. The FDA says it has received 72,000 reports of defibrillator problems between 2005 and September 2014. Since 2005, manufacturers have issued 111 recalls involving more than 2 million defibrillators.

"These changes to the way these devices are reviewed will allow us to more closely monitor how they are designed and manufactured," said Dr. William Maisel, the FDA's deputy director for science, in a statement.

"This will go a long way towards correcting long-standing problems and ultimately improving the reliability of these devices."

Companies that make external defibrillators include Philips Medical Systems, Zoll Medical Corp. and Cardiac Science, among others.