

# FDA Repair vs ISO 13485:2016 - OEM vs Servicers, Independent Service Organizations

FDA Terminology:

**Repair action on a nonconforming** product or service to *make it acceptable for the intended use*.

A successful repair of a nonconforming product or service does not necessarily make the product or service conform to the requirements. It may be that, in conjunction with a repair, a concession is required.

Repair includes remedial action taken on a previously conforming product or service to restore it for use, for example, as part of maintenance.

Repair can affect or change parts of the nonconforming product or service.

**Rework action on a nonconforming** product or service to *make it conform to the requirements*. Rework can *affect or change parts of the nonconforming product or service*.

*FDA: Rework means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution. (This typically means before the first product release.)*

Intended use: The general purpose of the device or its function, which encompasses the indications for use.

Manufacturers (Manufacturers, OEMs, or Remanufacturers): A manufacturer is any person who designs, manufactures, fabricates, assembles, or processes a finished device. A remanufacturer is any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use. Remanufacturers are considered to be manufacturers. For electronic products, a manufacturer is any person engaged in manufacturing, assembling, or importing such products.

**Performance specifications:** The performance characteristics of a device established by the OEM for the device to perform as intended, including those listed in device labeling or in finished product release specifications. Some examples include measurement accuracy, output accuracy, energy output level, and stability criteria.

**Recondition/Refurbish/Rebuild:** Restores a medical device to the OEM's original specifications, comparable to when new. The device is brought into compliance with current specifications if the change(s) made to the device do not significantly alter the finished device's performance or safety specifications, or its intended use. These activities include repair of components, installation of OEM-provided updates and upgrades, and replacement of worn parts.

**Remanufacture:** Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

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**Repair:** A type of servicing that returns a component to the OEM's original specifications, including replacing non-working components or parts *outside of preventive or routine maintenance*.

**Reprocess:** With respect to reusable devices, means validated processes used to render a medical device that has been previously used or contaminated fit for a subsequent single use on a patient. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization.

**Safety specifications:** The safety characteristics of a device established by the OEM for the safe use of the device, including those incorporated into the device design and finished product release specifications, generally including the device's compensating controls and risk mitigations. Some examples include alarms, sensors, and locking or fail-safe mechanisms.

**Service:** Repair and/or preventive or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing excludes activities that significantly change the finished device's safety or performance specifications, or intended use.

Third-party servicers and Independent Service Organizations (ISOs): Entities, other than the OEM or healthcare delivery organizations, that **maintain, restore, refurbish, repair, or service a finished device after distribution, for purposes of returning it to the OEM's original safety and performance specifications and to meet its original intended use.**

*They are interchangeable. I would lean on the repair terminology for third-party servicers, depending on the medical device being repaired.*

ISO Terminology:

**Rework:** The act of reprocessing non-complying articles, through the use of original or equivalent processing, in a manner that assures full compliance of the article with applicable drawings or specifications.

*(not always able to do this as an independent service organization)*

**Repair:** The act of restoring the functional capability of a defective article in a manner that precludes compliance of the article with applicable drawings or specifications.

Repairs are generally changes to an unacceptable end product to make it acceptable in accordance with the original functional requirements.

**Modification:** The revision of the functional capability of a product to satisfy new acceptance criteria.

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Modifications are usually required to incorporate design changes, which are controlled by drawings, change orders, etc. Modifications should only be performed when specifically authorized and described in detail in controlled documentation.

ISO Standard requirements:

## 8.3.4 Rework

*The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure.*

*After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.*

### *Intent*

The new section separates the requirements related to the rework of nonconforming product to conformance with specification.

### *Guidance*

The clause requires that a determination of any adverse effect of the rework upon the product be made, whether there is repeated rework or not. The intent is that such a determination is made with any rework, given the potentially harmful effect rework could have on the product. Having the same review and approval also means using the same verification/validation process as would be applied to a product that has not undergone rework.

*Information cited from;*

*ISO 13485:2016 Practical Guide.*

*ISO 9000:2015 Standard Vocabulary*

*FDA 21 CFR 820*

*FDARA 710 Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices. FDA.gov*

*FDA White Paper MDSR Docket No. FDA-2018-N-3741 by January 25, 2019.*

*<https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendments/totheFDCA/FDARA/UCM607469.pdf>.*