Definitions		
Term	**Definition**	**Regulation**
Accompanying documentation	Materials accompanying a medical device and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the medical device, particularly regarding safe use. *Note: the accompanying documentation can consist of the instructions for use, technical description, installation manual, quick reference guide, etc. Accompanying documentation is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.*	ISO 14971:2019
Ambulatory surgical facility (ASF)	A distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.	21 CFR Part 803
Become aware	An employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred. (1) if you are a device user facility, you are considered to have "become aware" when medical personnel, as defined in this section, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event. (2) if you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with § 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable mdr event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. (3) if you are an importer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported by you within 30 days.	21 CFR Part 803
Benefit	Positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health. *Note: benefits can include positive impact on a clinical outcome, the patient's quality of life, outcomes related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or positive impact on public health.*	ISO 14971:2019
Caused or contributed	A death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) failure, (2) malfunction, (3) improper or inadequate design, (4) manufacture, (5) labeling, or (6) user error.	21 CFR Part 803
Complaint	Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.	21 CFR Part 820
Critical Task	A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care.	FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices
Decommissioning	To remove from user or service	N/A
Design history file (DHF)	A compilation of records which describes the design history of a finished device.	21 CFR Part 820
Design review	A documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems	21 CFR Part 820
Device history record (DHR)	A compilation of records containing the procedures and specifications for a finished device.	21 CFR Part 820
Device user facility	A hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician's office, as defined in this section. School nurse offices and employee health units are not device user facilities.	21 CFR Part 803
Distributor	Any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.	21 CFR Part 803
Expected life of a device	The time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified "end of life" (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time.	21 CFR Part 803
FDA, we, us, or Agency	The Food and Drug Administration.	21 CFR Part 803
Five-day report	A medical device report that must be submitted by a manufacturer to us under § 803.53 within 5 work days.	21 CFR Part 803
Formative Study/Evaluation	Assessing, at one or more stages during the device development process, a user interface or user interactions with the user interface to identify the interface's strengths and weaknesses and to identify potential use errors that would or could result in harm to the patient or user.	FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices
Harm	Injury or damage to the health of people, or damage to property or the environment.	ISO 14971:2019

Definitions		
Term	**Definition**	**Regulation**
Hazard	Potential source of harm.	ISO 14971:2019
Hazardous situation	Circumstance in which people, property or the environment is/are exposed to one or more hazards.	ISO 14971:2019
Human factors	"…the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations…."	ANSI/AAMI HE75:2009
Human Factors Validation Testing / Summative Studies	Testing conducted at the end of the device development process to assess user interactions with a device user interface to identify use errors that would or could result in serious harm to the patient or user. Human factors validation testing is also used to assess the effectiveness of risk management measures. Human factors validation testing represents one portion of design validation.	FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices
Importer	Any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.	21 CFR Part 803
Intended use/intended purpose	Use for which a product, process or service is intended according to the specifications, instructions, and information provided by the manufacturer. *Note: the intended indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.*	ISO 14971:2019
Life cycle	Series of all phases in the life of a medical device, from the initial conception to final decommissioning and disposal .	ISO 14971:2019
Malfunction	The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4 of this chapter.	21 CFR Part 803
Manufacturer	Natural or legal person with responsibility for the design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name, whether or not such a medical device is designed and/or manufactured by that person himself or on behalf by another person.	ISO 14971:2019
Manufacturer	Any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either: (1) repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture; (2) initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; (3) manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or (4) is the U.S. agent of a foreign manufacturer.	21 CFR Part 803
Manufacturer	Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.	21 CFR Part 820
Manufacturer Or Importer Report Number	This number uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of the following three parts: (1) the FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. If the manufacturing site or the importer does not have an establishment registration number, we will assign a temporary MDR reporting number until the site is registered in accordance with part 807 of this chapter. We will inform the manufacturer or importer of the temporary MDR reporting number; (2) the four-digit calendar year in which the report is submitted; and (3) the five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear as follows: 1234567–2011–00001.)	21 CFR Part 803
MDR	Medical Device Report	21 CFR Part 803
MDR reportable event (or reportable event)	(1)An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or (2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices: (i) May have caused or contributed to a death or serious injury, or (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.	21 CFR Part 803
Medical Device	Instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: -diagnosis, prevention, monitoring, treatment or alleviation of disease, -diagnosis, monitoring, treatment, alleviation of or compensation for an injury, -investigation, replacement, modification, or support of the anatomy or of a physiological process, -supporting or sustaining life, -control of conception, -disinfection of medical devices, -providing information by means of an in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.	ISO 14971:2019

Definitions		
Term	**Definition**	**Regulation**
Medical Personnel	An individual who: (1) is licensed, registered, or certified by a state, territory, or other governing body, to administer health care; (2) has received a diploma or a degree in a professional or scientific discipline; (3) is an employee responsible for receiving medical complaints or adverse event reports; or (4) is a supervisor of these persons.	21 CFR Part 803
Nursing Home	(1) an independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing: (i) skilled nursing care and related services for persons who require medical or nursing care; (ii) hospice care to the terminally ill; or (iii) services for the rehabilitation of the injured, disabled, or sick. (2) a nursing home is subject to this regulation regardless of whether it is licensed by a federal, state, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature or location of the medical service provided by the nursing home.	21 CFR Part 803
Objective Evidence	Data supporting the existence or verity of something.	ISO 14971:2019
Outpatient Diagnostic Facility	(1) a distinct entity that: (i) operates for the primary purpose of conducting medical diagnostic tests on patients, (ii) does not assume ongoing responsibility for patient care, and (iii) provides its services for use by other medical personnel. (2) outpatient diagnostic facilities include outpatient facilities providing radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in vitro testing. An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a federal, state, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.	21 CFR Part 803
Outpatient Treatment Facility	A distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or in a home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include the following: cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse. An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a federal, state, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.	21 CFR Part 803
Patient Of The Facility	Any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.	21 CFR Part 803
Physician's Office	A facility that operates as the office of a physician or other health care professional for the primary purpose of examination, evaluation, and treatment or referral of patients. Examples of physician offices include: dentist offices, chiropractor offices, optometrist offices, nurse practitioner offices, school nurse offices, school clinics, employee health clinics, or freestanding care units. A physician's office may be independent, a group practice, or part of a health maintenance organization.	21 CFR Part 803
Post-Production	Part of the life cycle of the medical device after the design has been completed and the medical device has been manufactured.	ISO 14971:2019
Procedure	Specified way to carry out an activity or a process.	ISO 14971:2019
Process	Set of interrelated or interacting activities that use inputs to deliver an intended result.	ISO 14971:2019
Reasonably Foreseeable Misuse	Use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behavior.	ISO 14971:2019
Record	Document stating results achieved or providing evidence of activities performed.	ISO 14971:2019
Remanufacturer	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.	21 CFR Part 820
Remedial Action	Any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.	21 CFR Part 803
Residual Risk	Risk remaining after risk control measures have been implemented.	ISO 14971:2019
Risk	Combination of the probability of occurrence of harm and the severity of that harm.	ISO 14971:2019
Risk Analysis	Systematic use of available information to identify hazards and to estimate the risk.	ISO 14971:2019
Risk Assessment	Overall process comparing a risk analysis and a risk evaluation.	ISO 14971:2019

Definitions		
Term	**Definition**	**Regulation**
Risk Control	Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels.	ISO 14971:2019
Risk Estimation	Process used to assign values to the probability of occurrence of harm and the severity of that harm.	ISO 14971:2019
Risk Evaluation	Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk.	ISO 14971:2019
Risk Management	Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.	ISO 14971:2019
Risk Management File	Set of records and other documents that are produced by risk management.	ISO 14971:2019
Safety	Freedom from unacceptable risk.	ISO 14971:2019
Serious Injury	An injury or illness that: (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.	21 CFR Part 803
Severity	Measure of the possible consequences of a hazard.	ISO 14971:2019
State of the art	Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience.	ISO 14971:2019
Task	Action or set of actions performed by a user to achieve a specific goal.	FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices
Top management	Person or group of people who directs and controls as a manufacturer at the highest level.	ISO 14971:2019
Trend	The general movement over time of a statistically detectable change. The general direction in which something is developing or changing. A negative trend indicates a systematic error that is occurring over time.	N/A
Unique device identifier (UDI)	An identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of: (1) A device identifier—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and (2) A production identifier—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: (i) The lot or batch within which a device was manufactured; (ii) The serial number of a specific device; (iii) The expiration date of a specific device; (iv) The date a specific device was manufactured. (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.	21 CFR Part 803
Usability	Characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY, ease of USER learning and USER satisfaction.	ISO/IEC 62366:2007
Use error	User action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user.	ISO 14971:2019
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.	ISO 14971:2019
Work Day	Monday through Friday, except federal holidays.	21 CFR Part 803