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The Medical Devices (Amendment Etc.) (EU Exit) Regulations 2019 Jan 21 2020 Enabling power: European Union (Withdrawal) Act 2018, s. 8 (1), sch. 4, para. 7 (2), sch. 7, para. 21. Issued: 04.02.2019. Sifted: -. Made: -. Laid: -. Coming into force: In accord. with reg. 1. Effect: S.I. 2002/618 amended. Territorial extent & classification: E/W/S/NI. For approval by resolution of each House of Parliament. EC note: Part 1 of these regs amends the existing Medical Devices Regulations 2002 ('the 2002 Regulations') which implemented three European Union Directives which aimed to ensure the safety and quality of general medical devices, active implantable medical devices and in vitro diagnostic medical devices ('the three Directives'). Part I also makes certain transitional and savings provisions and amends EU tertiary legislation which relates to the regime implemented by the 2002 Regulations and revokes certain tertiary legislation along with the two EU Regulations insofar as they are retained EU law. Parts 2 and 3 restate (by inserting restated new provisions into the 2002 Regulations) the provisions of two EU Regulations: Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (the two EU Regulations). Rights, powers, liabilities, obligations restrictions, remedies and procedures contained in the two Regulations were retained by virtue Section 4 of the Withdrawal Act and limited provisions were retained by virtue of section 3 of that Act
Medical Devices Law and Regulation Answer Book Oct 22 2022 This title walks you through the current regulatory requirements and provides in-depth coverage of individual FDA programs that cover everything from conducting clinical trials, preparing successful premarket submissions, adhering to quality system requirements, and fulfilling post-market obligations.
NILECJ Report on Test Procedures for Night Vision Devices Nov 11 2021
Biaxial Testing for Fabrics and Foils Apr 04 2021 This book offers a well-structured, critical review of current design practice for tensioned membrane structures, including a detailed analysis of the experimental data required and critical issues relating to the lack of

a set of design codes and testing procedures. The technical requirements for biaxial testing equipment are analyzed in detail, and aspects that need to be considered when developing biaxial testing procedures are emphasized. The analysis is supported by the results of a round-robin exercise comparing biaxial testing machines that involved four of the main research laboratories in the field. The biaxial testing devices and procedures presently used in Europe are extensively discussed, and information is provided on the design and implementation of a biaxial testing rig for architectural fabrics at Politecnico di Milano, which represents a benchmark in the field. The significance of the most recent developments in biaxial testing is also explored.

Procedures in Cosmetic Dermatology: Lasers, Lights, and Energy Devices Jul 07 2021 Offering a step-by-step, practical approach to this challenging area of dermatology, Procedures in Cosmetic Dermatology: Lasers, Lights, and Energy Devices, 5th Edition, enables you to master the up-to-date cosmetic techniques that produce the superior results your patients expect. Edited by expert clinicians Drs. Elizabeth L. Tanzi, Jeffrey S. Dover, and Leah K. Spring, it provides an overview of the underlying scientific principles of lasers and lights in dermatology, as well as the latest treatment options—all abundantly illustrated and evidence based. A substantial video library demonstrating applications and technical aspects helps you successfully incorporate the latest procedures into your practice. Provides current, authoritative guidance on popular procedures including laser hair removal, tattoo removal, vascular lesions, pigmented lesions, non-ablative fractional laser rejuvenation, ablative laser resurfacing, tissue tightening, and body contouring. Contains five new chapters: Treatment of Skin with Intense Pulsed Light Sources, Radiofrequency Microneedling, Photodynamic Therapy, Muscle Toning and Contouring, and Treatment of Acne with Light and Energy-Based Devices. Features a greatly expanded video library with more than three dozen new videos, demonstrating modalities such as photodynamic therapy, IPL, radiofrequency microneedling, a wide range of lasers, and cryolipolysis. Covers special considerations when treating skin of color, as well as complications and legal considerations of laser, light, and energy-based treatments. Includes procedural how-to's, step-by-step advice on proper techniques, case studies, and pearls and pitfalls.

Silicon Devices and Process Integration Nov 30 2020 Silicon Devices and Process Integration covers state-of-the-art silicon devices, their characteristics, and their interactions with process parameters. It serves as a comprehensive guide which addresses both the theoretical and practical aspects of modern silicon devices and the relationship between their electrical properties and processing conditions. The book is compiled from the author’s industrial and academic lecture notes and reflects years of experience in the development of silicon devices. Features include: A review of silicon properties which provides a foundation for understanding the device properties discussion, including mobility-enhancement by straining silicon; State-of-the-art technologies on high-K gate dielectrics, low-K dielectrics, Cu interconnects, and SiGe BiCMOS; CMOS-only applications, such as subthreshold current and parasitic latch-up; Advanced Enabling processes and process integration. This book is written for engineers and scientists in semiconductor research, development and manufacturing. The problems at the end of each chapter and the numerous charts, figures

and tables also make it appropriate for use as a text in graduate and advanced undergraduate courses in electrical engineering and materials science.

Reliable Design of Medical Devices Jan 01 2021 As medical devices increase in complexity, concerns about efficacy, safety, quality, and longevity increase in stride. Introduced nearly a decade ago, Reliable Design of Medical Devices illuminated the path to increased reliability in the hands-on design of advanced medical devices. With fully updated coverage in its Second Edition, this practical guide continues to be the benchmark for incorporating reliability engineering as a fundamental design philosophy. The book begins by rigorously defining reliability, differentiating it from quality, and exploring various aspects of failure in detail. It examines domestic and international regulations and standards in similar depth, including updated information on the regulatory and standards organizations as well as a new chapter on quality system regulation. The author builds on this background to explain product specification, liability and intellectual property, safety and risk management, design, testing, human factors, and manufacturing. New topics include design of experiments, CAD/CAM, industrial design, material selection and biocompatibility, system engineering, rapid prototyping, quick-response manufacturing, and maintainability as well as a new chapter on Six Sigma for design. Supplying valuable insight based on years of successful experience, Reliable Design of Medical Devices, Second Edition leads the way to implementing an effective reliability assurance program and navigating the regulatory minefield with confidence.

Rare Diseases and Orphan Products Sep 09 2021 Rare diseases collectively affect millions of Americans of all ages, but developing drugs and medical devices to prevent, diagnose, and treat these conditions is challenging. The Institute of Medicine (IOM) recommends implementing an integrated national strategy to promote rare diseases research and product development.

Contextual Inquiry for Medical Device Design Apr 16 2022 Contextual Inquiry for Medical Device Design helps users understand the everyday use of medical devices and the way their usage supports the development of better products and increased market acceptance. The text explains the concept of contextual inquiry using real-life examples to illustrate its application. Case studies provide a frame of reference on how contextual inquiry is successfully used during product design, ultimately producing safer, improved medical devices. Presents the ways contextual inquiry can be used to inform the evaluation and business case of technology Helps users understand the everyday use of medical devices and the way their usage supports the development of better products Includes case studies that provide a frame of reference on how contextual inquiry is successfully used during the product design process

Medical Device Regulations Sep 21 2022 Medical Device Regulations: A Complete Guide describes a brief review of various regulatory bodies of major developed and developing countries around the world. The book covers the registration procedures of medical devices for pharmaceutical regulatory organizations. Sections provide guidance on dealing with the ethical considerations of medical device development, compliance with patient confidentiality using information from medical devices, the interoperability

between, and among devices outside of healthcare, and the dynamics of implementation of new devices to ensure patient safety. The author brings forth relevant issues, challenges and demonstrates how management can foster increased clinical and non-clinical relations to enhance patient outcomes and the bottom-line by demystifying the regulatory impact on operational requirements. Provides clear information on regulatory pathways for the design and commercialization of Medical Devices in different countries Explains the difference between standards and mandatory regulations for each region, along with discussions of regulations from USFDA (USA), CDSCO (India), EMEA (European Union), SFDA (China) and PMDA (Japan) Compiles regulations for medical devices and pharmaceuticals worldwide, helping readers create globally compliant products

Use of Spirit-based Solutions During Surgical Procedures Requiring the Use of Electrosurgical Equipment May 17 2022

The Changing Economics of Medical Technology Aug 28 2020 Americans praise medical technology for saving lives and improving health. Yet, new technology is often cited as a key factor in skyrocketing medical costs. This volume, second in the Medical Innovation at the Crossroads series, examines how economic incentives for innovation are changing and what that means for the future of health care. Up-to-date with a wide variety of examples and case studies, this book explores how payment, patent, and regulatory policiesâ€"as well as the involvement of numerous government agenciesâ€"affect the introduction and use of new pharmaceuticals, medical devices, and surgical procedures. The volume also includes detailed comparisons of policies and patterns of technological innovation in Western Europe and Japan. This fact-filled and practical book will be of interest to economists, policymakers, health administrators, health care practitioners, and the concerned public.

Medical Device Design and Regulation Aug 20 2022 The intent of this book (MDDR, for short) is to present an introduction to, and overview of, the world of medical device regulation by the United States Food and Drug Administration (FDA), and the relationship of this regulatory scheme to the design and development of medical devices. In providing this information, the book covers the broad range of requirements, which are presented within eight major topics: background and regulatory environment, device design control, nonclinical testing, clinical testing, marketing applications, post-market requirements, quality systems/GMPs, and compliance/enforcement. This book provides students and professionals in the medical device industry with a road map to the regulation of medical devices. It provides a broad understanding of the breadth and depth of medical device regulation by collecting in one textbook coverage of the regulatory scheme for medical devices in terms that are suitable for engineers, scientists, and healthcare providers. The vast amount of information available on the subject is distilled into a concise and coherent presentation. There also are problems and projects at the end of each chapter. In addition to the usual questions requiring specific answers, the projects include the drafting of a device control plan, the development of a nonclinical test procedure, the resolution of a recall, the response to a Warning Letter, and the creation of a CAPA for a device deficiency. A solutions manual for these exercises is available to teachers who adopt the textbook for classroom use or for employee training. Medical Device Design and Regulation (MDDR) also makes available over

100 complimentary live hyperlinks to web pages with additional relevant information, and offers users the opportunity to join and participate in the “MDDR Users Group” on LinkedIn.

The Role of Human Factors in Home Health Care Jun 18 2022 The rapid growth of home health care has raised many unsolved issues and will have consequences that are far too broad for any one group to analyze in their entirety. Yet a major influence on the safety, quality, and effectiveness of home health care will be the set of issues encompassed by the field of human factors research-the discipline of applying what is known about human capabilities and limitations to the design of products, processes, systems, and work environments. To address these challenges, the National Research Council began a multidisciplinary study to examine a diverse range of behavioral and human factors issues resulting from the increasing migration of medical devices, technologies, and care practices into the home. Its goal is to lay the groundwork for a thorough integration of human factors research with the design and implementation of home health care devices, technologies, and practices. On October 1 and 2, 2009, a group of human factors and other experts met to consider a diverse range of behavioral and human factors issues associated with the increasing migration of medical devices, technologies, and care practices into the home. This book is a summary of that workshop, representing the culmination of the first phase of the study.

Registries for Evaluating Patient Outcomes Dec 12 2021 This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Improper Medicare Billing by Hospitals Nationwide for Investigational Devices and Procedures Jan 13 2022 Excerpt from Improper Medicare Billing by Hospitals Nationwide for Investigational Devices and Procedures: Hearing Before the Permanent

Subcommittee on Investigations of the Committee on Governmental Affairs, United States Senate, One Hundred Fourth Congress, Second Session, February 14, 1996 Additionally, the clinical hospitals and doctors are positioned to corner the market for millions of dollars in patient referrals and revenues if the fda approval is received. About the Publisher Forgotten Books publishes hundreds of thousands of rare and classic books. Find more at www.forgottenbooks.com This book is a reproduction of an important historical work. Forgotten Books uses state-of-the-art technology to digitally reconstruct the work, preserving the original format whilst repairing imperfections present in the aged copy. In rare cases, an imperfection in the original, such as a blemish or missing page, may be replicated in our edition. We do, however, repair the vast majority of imperfections successfully; any imperfections that remain are intentionally left to preserve the state of such historical works.

Medicare: Divided Authority for Policies on Coverage of Procedures & Devices Results in Inequities Oct 10 2021

Clinical Evaluation of Experimental Orthotic Devices and Procedures Feb 02 2021

Technological Innovation Mar 15 2022

Code of Federal Regulations Jul 27 2020

Medical Device Design Sep 28 2020 Medical Device Design: Innovation from Concept to Market, Second Edition provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones; this book fills that need. It addresses medical devices' regulatory (FDA and EU) requirements, shows the essential methodologies medical designers must understand to ensure their products meet requirements, and brings together proven design protocols, thus enabling engineers and medical device manufacturers to rapidly bring new products to the marketplace. This book is unique because it takes the reader through the process of medical device development, from very early stages of conceptualization, to commercialization on the global market. This rare resource can be used by both professionals and newcomers to device design. Provides a reference to standards and regulations that have been updated, including ISO 13485:2016, FDA regulations and the European Medical Device Regulation Includes new case studies in the areas of classifying medical devices, the design process, quality, labeling, instructions for use, and more Presents additional content around software and biocompatibility concerns

Clinical Evaluation of Medical Devices Dec 20 2019 The original edition of this text, Clinical Evaluation of Medical Devices: Principles and Case Studies, provided the first overview of key pr- ciples and approaches to medical device clinical trials, illustrated with a series of detailed, real-world case studies. The book is designed as a resource for clinical professionals and regulatory specialists working in the field of new medical device development and marketing. Since the first edition of this text was published in 1997, the rapid pace of inno- tion in health care technologies continues to yield exciting and important new products. The regulatory landscape has also evolved, reflecting some of the changes and needs within the medical device industry. The purpose of Clinical

Evaluation of Medical Devices: Principles and Case Studies, Second Edition is to provide an updated and expanded presentation of the scientific methods and regulatory requirements applied to the study of new significant risk medical devices. The text now includes (1) new information on the requirements and process for gaining reimbursement of new products from Medicare and private insurers, with case studies of research specifically designed for this p- pose as well as health care technology assessment methods; (2) infor- tion on new statistical methodologies applied to medical device trials; and (3) all new case studies, including examples of combination pr- ucts, three-phase development models (i. e. , feasibility, FDA approval, Medicare reimbursement), and novel study designs.

Authentication Devices and Procedures Feb 26 2023 This paper contains summary descriptions and analysis of authentication devices, procedures, and technologies. Also included are performance comparisons, relative costs, and current areas of research and development. Special emphasis and study is placed on passwords, card systems, and identity verification devices since they are the primary instruments used to provide identification in access control schemes. Finally, recommendations are made for authentication procedures to be used in the Navy Supply System to help alleviate both current and potential problems related to user identification. This report was prepared under contract N00173-78-C-0455, Task No. 10 for the Navy Ship Research and Development Center (NSRDC) for use in the Navy Supply environment. (Author).

Medical Devices Apr 28 2023 Medical Devices and Regulations: Standards and Practices will shed light on the importance of regulations and standards among all stakeholders, bioengineering designers, biomaterial scientists and researchers to enable development of future medical devices. Based on the authors' practical experience, this book provides a concise, practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards. Provides readers with a global perspective on medical device regulations Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards Includes a useful case study demonstrating the design and approval process

Public Health Effectiveness of the FDA 510(k) Clearance Process Feb 20 2020 The Food and Drug Administration (FDA) is responsible for assuring that medical devices are safe and effective before they go on the market. As part of its assessment of FDA's premarket clearance process for medical devices, the IOM held a workshop June 14-15 to discuss how to best balance patient safety and technological innovation. This document summarizes the workshop.

Medical Device Regulations Roadmap Nov 23 2022 For the Engineer or scientist starting out in Medical devices, the array of regulation across the globe can be daunting. Many companies also need to fulfill regulation from multiple jurisdictions. Some requirements of Design, GMP and manufacturing are common. FDA and European market requires provide a framework for medical device manufacturers to certain requirements that ensure patient safety. This short book introduces the key themes associated with Medical Device Regulation. While the online world provides a detailed and perrinial source of current information and regulations, it is often hard to know where to start. This concise book provides that introduction and provides in a physical format that is a useful

companion for the Engineer or Medical Device Professional. (Page Count 112)

Medical Device Regulation Dec 24 2022 Medical Device Regulation provides the current FDA-CDRH thinking on the regulation of medical devices. This book offers information on how devices meet criteria for being a medical device, which agencies regulate medical devices, how policies regarding regulation affect the market, rules regarding marketing, and laws and standards that govern testing. This practical, well-structured reference tool helps medical device manufacturers both in and out of the United States with premarket application and meeting complex FDA regulatory requirements. The book delivers a comprehensive overview of the field from an author with expertise in regulatory affairs and commercialization of medical devices. Offers a unique focus on the regulatory affairs industry, specifically targeted at regulatory affairs professionals and those seeking certification Puts regulations in the context of contemporary design Includes case studies and applications of regulations

Proceedings Jun 06 2021

Needs Assessment for Medical Devices Jul 19 2022 WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas: * policy framework for health technology * medical device regulations * health technology assessment * health technology management * needs assessment of medical devices * medical device procurement * medical equipment donations * medical equipment inventory management * medical equipment maintenance * computerized maintenance management systems * medical device data * medical device nomenclature * medical devices by health-care setting * medical devices by clinical procedures * medical device innovation, research and development. These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels. Needs assessment is a complex process, incorporating a number of variables, that provides decision-makers with the information necessary to prioritize and select appropriate medical devices at a national, regional or hospital level. This document describes and illustrates the objective, the general approach and the process of such a needs assessment. The main section, Specific Approach (Section 4), demonstrates in seven steps how to identify related needs, consider the requirements of baseline information, analyze the gathered information, appraise the options, and prioritize the specific requirements. Tools are being continuously developed to support this decision-making process, and this document also includes information on useful tools that will help in the execution of these steps.

Modern Methods of Clinical Investigation May 05 2021 The very rapid pace of advances in biomedical research promises us a wide range of new drugs, medical devices, and clinical procedures. The extent to which these discoveries will benefit the public, however, depends in large part on the methods we choose for developing and testing them. Modern Methods of Clinical Investigation focuses on strategies for clinical evaluation and their role in uncovering the actual benefits and risks of medical innovation. Essays explore

differences in our current systems for evaluating drugs, medical devices, and clinical procedures; health insurance databases as a tool for assessing treatment outcomes; the role of the medical profession, the Food and Drug Administration, and industry in stimulating the use of evaluative methods; and more. This book will be of special interest to policymakers, regulators, executives in the medical industry, clinical researchers, and physicians.

Medical Device Design Oct 30 2020 This book provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones. It addresses medical devices' regulatory (FDA and EU) requirements--some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products' commercial prospects. This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements. It brings together proven design protocols and puts them in an explicit medical context based on the author's years of academia (R&D phase) and industrial (commercialization phase) experience. This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly. The medical device market is a multi-billion dollar industry. Every engineered product for this sector, from scalpelsstents to complex medical equipment, must be designed and developed to approved procedures and standards. This book shows how Covers US, and EU and ISO standards, enabling a truly international approach, providing a guide to the international standards that practicing engineers require to understand Written by an experienced medical device engineers and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products

Procedures for the Performance Detection Devices Including Preliminary Test Methods Apr 23 2020

Technological Innovation Jan 25 2023

Medical Device Design for Six Sigma Feb 14 2022 The first comprehensive guide to the integration of Design for Six Sigma principles in the medical devices development cycle Medical Device Design for Six Sigma: A Road Map for Safety and Effectiveness presents the complete body of knowledge for Design for Six Sigma (DFSS), as outlined by American Society for Quality, and details how to integrate appropriate design methodologies up front in the design process. DFSS helps companies shorten lead times, cut development and manufacturing costs, lower total life-cycle cost, and improve the quality of the medical devices. Comprehensive and complete with real-world examples, this guide: Integrates concept and design methods such as Pugh Controlled Convergence approach, QFD methodology, parameter optimization techniques like Design of Experiment (DOE), Taguchi Robust Design method, Failure Mode and Effects Analysis (FMEA), Design for X, Multi-Level Hierarchical Design methodology, and Response Surface methodology Covers contemporary and emerging design methods, including Axiomatic Design Principles, Theory of Inventive Problem Solving (TRIZ), and Tolerance Design Provides a detailed, step-by-step implementation process for each DFSS tool included Covers the

structural, organizational, and technical deployment of DFSS within the medical device industry Includes a DFSS case study describing the development of a new device Presents a global prospective of medical device regulations Providing both a road map and a toolbox, this is a hands-on reference for medical device product development practitioners, product/service development engineers and architects, DFSS and Six Sigma trainees and trainers, middle management, engineering team leaders, quality engineers and quality consultants, and graduate students in biomedical engineering.

Improper Medicare Billing by Hospitals Nationwide for Investigational Devices and Procedures Aug 08 2021 This work has been selected by scholars as being culturally important, and is part of the knowledge base of civilization as we know it. This work was reproduced from the original artifact, and remains as true to the original work as possible. Therefore, you will see the original copyright references, library stamps (as most of these works have been housed in our most important libraries around the world), and other notations in the work. This work is in the public domain in the United States of America, and possibly other nations. Within the United States, you may freely copy and distribute this work, as no entity (individual or corporate) has a copyright on the body of the work.As a reproduction of a historical artifact, this work may contain missing or blurred pages, poor pictures, errant marks, etc. Scholars believe, and we concur, that this work is important enough to be preserved, reproduced, and made generally available to the public. We appreciate your support of the preservation process, and thank you for being an important part of keeping this knowledge alive and relevant.

Public Health Effectiveness of the FDA 510(k) Clearance Process May 25 2020 The Food and Drug Administration (FDA) is responsible for ensuring that medical devices are safe and effective before they go on the market. Section 510(k) of the Federal Food, Drug, and Cosmetic Act requires a manufacturer of medical devices to notify FDA of its intent to market a medical device at least 90 days in advance. That window of time allows FDA to evaluate whether the device is substantially equivalent to a product already legally on the market (called a predicate), in which case the device does not need to go through the premarket approval (PMA) process. As part of its assessment of the FDA's premarket clearance process for medical devices, the Institute of Medicine (IOM) held a workshop on July 28, 2010 to discuss how medical devices are monitored for safety after they are available to consumers. Its primary focus was on monitoring the safety of marketed medical devices, including FDA's postmarket surveillance activities, analysis of safety concerns that resulted in medical device recalls, and non-FDA sources of adverse-event information. Public Health Effectiveness of the FDA 501(K) Clearance Process summarizes the views of the workshop participants.

Improper Medicare Billing by Hospitals Nationwide for Investigational Devices and Procedures Mar 27 2023