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Cleanrooms and Associated Controlled Environments - Part 4: Design, Construction and Start-up (ISO 14644-4:2001) I.S. EN ISO 14644-4 (Cleanrooms and Associated Controlled Environments Developments in Surface Contamination and Cleaning, Volume 4 ISO 14644 28 Success Secrets - 28 Most Asked Questions on ISO 14644 - What You Need to Know *Clean Room Technology in ART Clinics* **Regenerative Medicine and Tissue Engineering** *Handbook of Pharmaceutical Manufacturing Formulations, Third Edition* Exposure to Microbiological Agents in Indoor and Occupational Environments The Certified Pharmaceutical GMP Professional Handbook **Healthcare Sterilisation Metric Handbook** *Control of Particulate Matter Contamination in Healthcare Manufacturing* **Handbook of Pharmaceutical Manufacturing Formulations** *Decontamination in Hospitals and Healthcare* **Guide to Cell Therapy GxP DS/EN ISO 14644-4** *Contamination Control in Practice* **Medical Device** Materials for Medical Application Microbial Contamination Control in Parenteral Manufacturing Microbial Limit and Bioburden Tests **Introduction to Contamination Control and Cleanroom Technology Sterilisation of Polymer Healthcare Products** *Isolation Technology* **Sterilization of Medical Devices Compounding Sterile Preparations Biocontamination Control for Pharmaceuticals and Healthcare** *Pharmaceutical Manufacturing Handbook Robotics for Electronics Manufacturing Handbook of Filter Media* **Design in Modular Construction Validation of Pharmaceutical Processes Guidelines for Safe Handling of Powders and Bulk Solids** *Environmental Monitoring for Cleanrooms and Controlled Environments* **CleanRooms Contamination and ESD Control in High-Technology Manufacturing** Quality (Pharmaceutical Engineering Series) **Emerging Chemical Risks in the Work Environment** Handbook for Critical Cleaning: Applications, processes, and controls

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This book gives an introduction to the highly interdisciplinary field of biomaterials. It concisely summarizes properties, synthesis and modification of materials such as metals, ceramics, polymers or composites. Characterization, in vitro and in vivo testing as well as a selection of various applications are also part of this inevitable guide. Contamination control is being used by more and more industries where the highest level of cleanliness and hygiene is of vital importance. This book covers the basic principles of contamination control and cleanroom technology from a holistic point of view. It deals with cleanliness and hygiene and their effects on the outcome of a process, reflecting the latest results from both scientific and practical points of view. The following topics are covered: contaminants and how they are measured cleanrooms and clean zones cleaning and decontamination cleanroom clothing the impact of people on cleanliness. Intended as an introduction to the area of contamination control, the text is also an excellent source of knowledge for people with both theoretical and practical experience. The Swedish version has been used for a long time within the Nordic countries as a basic training textbook within the pharmaceutical, microelectronics, food and beverage, optics and many other industries. The ways of sterilisation begin as far back as biblical and roman times, from early beginnings to standardization. Sterilisation evolution has gone through a series of trials and wizardry before it achieved the status of science. And even with a scientific approach, some of its modalities frequently has been referred to as an art (an imaginary focus), while most have achieved a certain scientific standardization. This book provides a drawbridge between history, terminology, environmental and fundamentals of sterilisation that beginners to sterilisation should recognize, but continues with advancements, which supervisors and managers should know and apply. So while providing historical and current sterilisation information, the book also provides interfacial areas with design practices, development, environmental control, material compatibility, microbiology, packaging, process selection, statistics, technical information and validation. This book consists of two volumes (Healthcare Sterilisation, Introduction and Standard Practices: Volume 1, and Healthcare Sterilisation, Challenging Practices: Volume 2). Volume 1 provides an introduction, and an overview of sterilisation on early and classical sterilisation principles such as absolutism and overkill, and steadfast and standard methods. It will help answer some healthcare sterilisation queries such as: what are the origins and evolution of sterilisation? How does environmental control and microbiology affect sterilisation? What are some of the classical as well as standard sterilisation methods? What are the most consistent and reliable sterilisation methods? Is sterilisation in your future? An ounce of prevention is worth a pound of cure. Without sterilisation, infectious disease

and contamination would run rampant. Consequently, sterilisation has tremendous value and disease control, and this book provides a three dimensional view of it. In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility. The most significant changes in isolation technology during the past five years have not been in the technology itself but in its increased acceptance. This acceptance is clearly demonstrated by the series of monographs, guidelines, and standards produced by regulatory bodies to describe best practice in the design and operation of isolators. Thoroughly revised and updated, Isolation Technology: A Practical Guide, Second Edition provides an in-depth overview of new standards and new technology. Here's what's new in the Second Edition: " Descriptions of and comments on new guidelines and standards " Technological advances - such as the new breed of sanitizing gas generators " Updates that reflect current thinking and new information Drawing on his vast experience in this field, the author delineates practical ways to improve product standards, increase operator productivity, efficiency and safety, and cut costs. Carefully designed for easy understanding by readers from multiple fields, the book reviews the how-tos for setting up clean rooms and techniques for maintaining sterility, and includes case studies, resource listings, and numerous photographs. The combination of up-to-date information and the author's clear writing style make this the ideal resource for both experienced and beginning professionals. This book is meant to be a guide to all who want to learn about a highly regulated industry. My approach is to give you, the reader, an example of a fictitious device, and we will take it from a conceptual idea all the way to launch and beyond. My intention is to incorporate the best experiences that I and other contributors have had into this book and convert them into laymans terms for those who are in need. These experiences can and will be indispensable to beginners and professionals alike who are trying their hand in the medical device industry and to those who have not been out of their silo to help see how each of the systems relate to each as a whole. However, it should be noted that the contents of this book should be taken only as information and is not intended to demonstrate how companies can be in compliance. In some instances, there are multiple ways to go through the maze of regulations that are documented and made by agencies because the regulations are pretty much made and designed to be flexible and high level so that companies can adopt their systems, which are solely designed for their purposes. Therefore, this book will try to avoid complicated words and complex technical details of engineering and statistics. This book will strive to be an embodiment of the honest-to-goodness, everyday experiences and issues that folks experience while working in the medical device industry. Around the world, the production and use of nanomaterials, as well as carcinogenic, mutagenic, reprotoxic substances (CMR) and endocrine disruptors has systematically increased. The increase in production has exposed workers to hazardous substances in practically all branches of the world economy. Readers will have access to up-to-date and comprehensive knowledge on

emerging risks related to nanomaterials, endocrine disruptors, reprotoxic, carcinogenic and mutagenic substances, which are related to the development of technologies and workplaces. The book will provide the tools for occupational risk assessment of chemical substances for which there are no safety levels of exposure as well as an indication of methods and measurements to protect human health and reduce chemical risks at the workplace. This book creates awareness for employers, employees and safety experts about emerging risks related to chemical agents resulting in the reduction of cancer, reproductive system diseases, cases of abnormal child development, hormonal system disorders leading to abnormal metabolism, obesity, and diabetes. Features: Comprehensive information on emerging and newly identified chemical hazards Delivers the latest data on methods and tools for identification, assessing and reducing health risks Provides practical occupational safety advice and recommendations Real life examples from measurements carried out in the workplaces "The monograph, due to the high universality of its considerations, can be addressed to a very wide audience. It is an important compendium of knowledge, which can be used by health and safety services, employers, people designing new technologies and those interested in this issue. It is a valuable and up-to-date study, among others because it uses the latest literature and quotes current legal acts." —Sławomir Czerczak, Nofer Institute of Occupational Medicine, Poland An Introduction to Filter Media -- Textiles -- Filter Papers and Filter Sheets -- Media for air and gas filters -- Screens and Meshes -- Porous Sheets and Tubes (excluding Membranes) -- Membranes -- Cartridges and Special Fabrications -- Loose Powders, granules and fibres -- Testing filter media. Empower your staff to improve safety, quality and compliance with the help of new guidelines and standards. We've updated every chapter of this popular review of the fundamentals of preparing sterile products in hospital, home-care, and community pharmacy settings to reflect the most recent revisions to USP . Included are the latest guidelines for the compounding process, quality assurance methods, and comprehensive coverage of all aspects of the dispensing process. Comprehensive documentation for the guidelines is included in the appendices.Chapters new to this edition focus on: Gap analysis and action plans Safe use of automatic compounding devices Cleaning and disinfecting Radiopharmaceuticals as CSPs Allergen extracts as CSPs. This book presents vital information on international sterilization standards and guidance on practical application of these standards in the manufacturing process. It covers validation, industrial sterilization methods, emerging sterilization techniques, laboratory testing, manufacturing of sterile devices, and device reuse. Excerpted from The Validator, edited by Anne F. Booth, more than fifty experts share their knowledge of current technologies in easy-to-understand articles that establish methods to ensure compliance. Contents include reviews of ISO sterilization standards, industrial sterilization methods and technologies, and support testing methodologies. Decontamination in Hospitals and Healthcare, Second Edition, enables users to obtain detailed knowledge of decontamination practices in healthcare settings, including surfaces, devices, clothing and people, with a specific focus on hospitals and dental clinics. Offers in-depth coverage of all aspects of decontamination in healthcare Examines the decontamination of surgical equipment and endoscopes Expanded to include new information on behavioral principles in decontamination, control of microbiological problems, waterborne microorganisms, pseudomonas and the decontamination of laundry Modular construction can dramatically improve efficiency in construction, through factory production of pre-engineered building units and their delivery to the site either as entire buildings or as substantial elements. The required technology and application are developing rapidly, but design is still in its infancy. Good design requires a knowledge of modular production, installation and interface issues and also an understanding of the economics and client-related benefits which influence design decisions. Looking at eight recent projects, along with background information, this guide gives you coverage of: generic types of module and their application vertical loading, stability and robustness dimensional and spacial planning hybrid construction cladding, services and building physics fire safety and thermal and acoustic performance logistical aspects – such as transport, tolerances and safe installation. A valuable guide for professionals and a thorough introduction for advanced students. The purpose of this handbook is to assist individuals for the Certified

Pharmaceutical Good Manufacturing Practices Professional (CPGP) examination and provide a reference for the practitioner. The second edition reflects the Body of Knowledge which was updated in 2015. This edition has also incorporated additional information including updated references. The updates reflect the current trends and expectations of the evolving pharmaceutical industry driven by consumer expectations and regulatory oversight. This handbook covers compliance with good manufacturing practices (GMPs), as regulated and guided by national and international agencies for the pharmaceutical industry. It covers finished human and veterinary drugs and biologics, and combination devices, as well as their component raw materials (including active pharmaceutical ingredients (APIs) and excipients), and packaging and labeling operations. A critical technology in the science of contamination control, environmental monitoring is a technique that provides important data on the quality of a process, processing environment, and final product, which can aid scientists in identifying and eliminating potential sources of contamination in cleanrooms and controlled environments. In response Contamination control has received great interest and found increasing use within several industrial branches including microelectronics, pharmaceuticals, food and beverages using various concepts of contamination control in their production, purification or packaging process. The book supplies a holistic view of contamination control, presenting the different types of contaminants in a summarized form. The focus is on how to protect products and processes from external contamination and also on different ways to take care of and control contaminants generated in the process. The aim is to eliminate them from a product or a process flow (e.g. through filtration), or to render them harmless (e.g. through sterilisation by moist heat). Product purity or the cleanliness of process flows are often complex matters and hard to define in easily understood terms. This book covers a variety of different techniques used in order to achieve and maintain certain overall cleanliness levels for both microbiological or inanimate particle contaminants. It supplies basic knowledge including validation aspects for industrial branches working with increased demands of cleanliness, for instance water purification, steam, pressurized gases and different flows in a process together with finished products. This book deals with all the principal building types, ranging from airports, factories and warehouses, offices, shops and hospitals. For each such building type, the basic design requirements and all the principal dimensional data is given. Regulatory agencies worldwide have issued directives or such requirements for air quality standards in embryology laboratories. This practical guide reviews the application of clean room technology or controlled environments specifically suited for Assisted Reproductive Technology (ART) Units. Its comprehensive coverage includes material on airborne particles and volatile organic compounds, including basic concepts, regulation, construction, materials, certification, clinical results in humans, and more. Biocontamination Control for Pharmaceuticals and Healthcare outlines a biocontamination strategy that tracks bio-burden control and reduction at each transition in classified areas of a facility. This key part of controlling risk escalation can lead to the contamination of medicinal products, hence necessary tracking precautions are essential. Regulatory authorities have challenged pharmaceutical companies, healthcare providers, and those in manufacturing practice to adopt a holistic approach to contamination control. New technologies are needed to introduce barriers between personnel and the environment, and to provide a rapid and more accurate assessment of risk. This book offers guidance on building a complete biocontamination strategy. Provides the information necessary for a facility to build a complete biocontamination strategy Helps facilities understand the main biocontamination risks to medicinal products Assists the reader in navigating regulatory requirements Provides insight into developing an environmental monitoring program Covers the types of rapid microbiological monitoring methods now available, as well as current legislation In this series Rajiv Kohli and Kash Mittal have brought together the work of experts from different industry sectors and backgrounds to provide a state-of-the-art survey and best-practice guidance for scientists and engineers engaged in surface cleaning or handling the consequences of surface contamination. The expert contributions in this volume cover important fundamental aspects of surface contamination that are key to understanding the behavior of specific types of contaminants. This understanding is essential to develop preventative and mitigation

methods for contamination control. The coverage complements the treatment of surface contamination in vol.1, Fundamental and Applied Aspects. This volume covers: Sources and Generation of Particles; Manipulation Techniques for Particles on Surfaces; Particle Deposition and Rebound; Particle Behavior in Liquid Systems; Biological and Metallic Contamination; and includes a comprehensive list of current standards and resources. Comprehensive coverage of innovations in surface contamination and cleaning Written by established experts in the contamination and cleaning field Each chapter is a comprehensive review of the state of the art Case studies included Understand the design, testing, and application of cleanroom robotics and get real-world examples and design tips with this practical guide. Tissue Engineering may offer new treatment alternatives for organ replacement or repair deteriorated organs. Among the clinical applications of Tissue Engineering are the production of artificial skin for burn patients, tissue engineered trachea, cartilage for knee-replacement procedures, urinary bladder replacement, urethra substitutes and cellular therapies for the treatment of urinary incontinence. The Tissue Engineering approach has major advantages over traditional organ transplantation and circumvents the problem of organ shortage. Tissues reconstructed from readily available biopsy material induce only minimal or no immunogenicity when reimplanted in the patient. This book is aimed at anyone interested in the application of Tissue Engineering in different organ systems. It offers insights into a wide variety of strategies applying the principles of Tissue Engineering to tissue and organ regeneration. Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va A central resource of technology and methods for environments where the control of contamination is critical. "Nearly all companies which manufacture or fabricate high-value physical objects (components, parts, assemblies) perform critical cleaning at one or more stages. These range from the giants of the semiconductor, aerospace, and biomedical world to a host of small to medium to large companies producing a dizzying array of components"-- The Pharmaceutical Engineering Series is a comprehensive reference for the pharmaceutical professional covering all aspects from quality, documentation and validation through manufacturing processes to facility design and management. In 'Quality', Dr Kate McCormick provides the reader with comprehensive coverage of this vital subject, including the quality life cycle, management and cost of quality, GMP, auditing and inspections. This book with the others in the series will become a unique source of reference and educational material for the readership. Case studies and examples make the book of direct practical relevance to the professional in the pharmaceutical industry Find the answers you are looking for quickly and easily with clear indexing and referencing Reference to international standards and practice mean this book will be useful wherever you are working This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear. This book intends to provide information about detection and health effects due to bacteria, fungi and viruses in indoor environments. The book will cover also information about preventive and protective measures to avoid health-hazardous. Case studies will be also addressed to enrich the book with the expertise of each invited author. The book also intends to fill a gap regarding information about all biologic agents, since most of the books available are dedicated to only one type of microorganisms. For various different biologic agents and metabolites this book will compile information about indoors presence, detection methods, exposure assessment and health effects. Several problems regarding the exposure of biologic agents will be presented through case studies, and also the implementation of preventive and protective measures to avoid/minimize exposure. Besides, all the book will focus on occupational health and/or public health point of view. Here comes ISO 14644. There has

never been a ISO 14644 Guide like this. It contains 28 answers, much more than you can imagine; comprehensive answers and extensive details and references, with insights that have never before been offered in print. Get the information you need--fast! This all-embracing guide offers a thorough view of key knowledge and detailed insight. This Guide introduces what you want to know about ISO 14644. A quick look inside of some of the subjects covered: ISO 14644-4, ISO 14644-9, Institute of Environmental Sciences and Technology - International standards, IEST, Kennedy Space Center - Facilities, ISO 14644-6, University of Texas, Dallas - Research, ISO 14644-5, Cleanroom suitability, ISO 14644-3, ISO 14644-1, ISO 14644-8, ISO 14644-2, Cleanroom - Cleanroom classifications, ISO 14644-7, ISO 1750 - ISO 10000 - ISO 14999, FED-STD-209E, Cleanroom suitability - Testing, The University of Texas at Dallas - Research, List of International Organization for Standardization standards - ISO 10000 - ISO 14999, and much more... The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Six, Sterile Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this sixth volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author’s own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines Sterilisation has always been challenging but sterilisation of healthcare products and polymers, especially together is an even greater challenge - how do you sterilise without adversely affecting the end use or the end user? This book discusses all the sterilisation methods used for polymeric healthcare products both traditional and new. This reference surveys emerging trends, concepts, and procedures used in the characterization and control of contaminants; the sterile production of traditional drugs and biologics; the design, construction, and validation of new parenteral facilities; and the monitoring of clean environments-vividly illustrating the routes by which products, proce Guide to Cell Therapy GxP is a practical guide to the implementation of quality assurance systems for the successful performance of all cell-based clinical trials. The book covers all information that needs to be included in investigational medicinal product dossier (IMPD), the launching point for any clinical investigation, and beyond. Guide to Cell Therapy GxP bridges a knowledge gap with the inclusion of examples of design of GLP-compliant preclinical studies; design of bioprocesses for autologous/allogeneic therapies; and instruction on how to implement GLP/GMP standards in centers accredited with other quality assurance standards. Guide to Cell Therapy GxP is an essential resource for scientists and researchers in hospitals, transfusion centers, tissue banks, and other research institutes who may not be familiar with the good scientific practice regulations that were originally designed for product development in corporate environments. This book is also a thorough resource for PhD students, Post-docs, Principal Investigators, Quality Assurance Units, and Government Inspectors who want to learn more about how quality standards are implemented in public institutions developing cell-based products. Easy access to important information on current regulations, state-of-the-art techniques, and recent advances otherwise scattered on various funding websites, within conference proceedings, or maintained in local knowledge Features protocols, techniques for trouble-shooting common problems, and an explanation of the advantages and limitations of a technique in generating conclusive data Includes practical examples of successful implementation of quality standards No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities

than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing ster A practical "how to" guide that effectively deals with the control of both contamination and ESD This book offers effective strategies and techniques for contamination and electrostatic discharge (ESD) control that can be implemented in a wide range of high-technology industries, including semiconductor, disk drive, aerospace, pharmaceutical, medical device, automobile, and food production manufacturing. The authors set forth a new and innovative methodology that can manage both contamination and ESD, often considered to be mutually exclusive challenges requiring distinct strategies. Beginning with two general chapters on the fundamentals of contamination and ESD control, the book presents a logical progression of topics that collectively build the necessary skills and knowledge: Analysis methods for solving contamination and ESD problems Building the contamination and ESD control environment, including design and construction of cleanrooms and ESD protected environments Cleaning processes and the equipment needed to support these processes Tooling design and certification Continuous monitoring Consumable supplies and packaging materials Controlling contamination and ESD originating from people Management of cleanrooms and ESD protected workplace environments Contamination and ESD Control in High-Technology Manufacturing conveys a practical, working knowledge of contamination and ESD control strategies and techniques, and it is filled with case studies that illustrate key principles and the benefits of contamination and ESD control. Moreover, its straightforward style makes the material, which integrates many disciplines of engineering and science, clear and accessible. Written by three leading industry experts, this book is an essential guide for engineers and designers across the many industries where contamination and ESD control is a concern. Powders and bulk solids, handled widely in the chemical, pharmaceutical, agriculture, smelting, and other industries present unique fire, explosion, and toxicity hazards. Indeed, substances which are practically inert in consolidated form may become quite hazardous when converted to powders and granules. The U.S. Chemical Safety and Hazard Investigation Board is currently investigating dust explosions that occured in 2003 at WestPharma, CTA Acoustics, and Hayes-Lemmerz, and is likely to recommend that companies that handle powders or whose operations produce dust pay more attention to understanding the hazards that may exist at their facility. This new CCPS guidelines book will discuss the types of hazards that can occur in a wide range of process equipment and with a wide range of substances, and will present measures to address these hazards. This book offers practical applications addressing the specifics of contamination, including particle origination, characterization, identification, and elimination, with a special focus on quality considerations. Written by an industry expert, this material offers a clear and concise understanding of particle populations and their control in stability, efficacy, and predictability in the manufacture of healthcare products. Complete with a full-color insert of micrographs illustrating commonly encountered particulate matter and over eighty figures, tables, and charts. Features

- Exposure To Microbiological Agents In Indoor And Occupational Environments
- The Certified Pharmaceutical GMP Professional Handbook
- Healthcare Sterilisation
- Metric Handbook
- Control Of Particulate Matter Contamination In Healthcare Manufacturing
- Handbook Of Pharmaceutical Manufacturing Formulations
- Decontamination In Hospitals And Healthcare
- Guide To Cell Therapy GxP
- DS EN ISO 14644 4
- Contamination Control In Practice
- Medical Device
- Materials For Medical Application
- Microbial Contamination Control In Parenteral Manufacturing
- Microbial Limit And Bioburden Tests
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