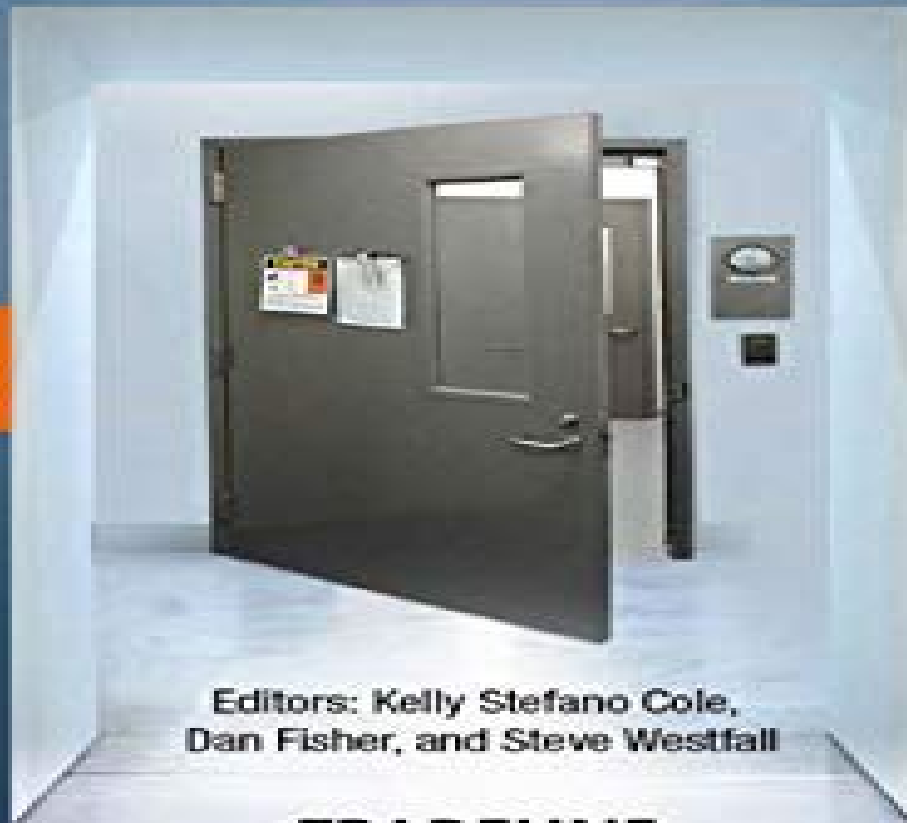


# Management Principles for Building and Operating Biocontainment Facilities

Ten years of planning and management lessons learned



Editors: Kelly Stefano Cole,  
Dan Fisher, and Steve Westfall

**TRADELINE**

# Management Principles For Building And Operating Biocontainment Facilities

**United States. Congress. House.  
Committee on Appropriations.  
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## **Management Principles For Building And Operating Biocontainment Facilities:**

**Management Principles for Building and Operating Biocontainment Facilities** Kelly Stefano Cole, 2013-04-10 This practical highly focused book is intended to be an authoritative planning and management reference for anyone associated with capital projects or facility operations involving biocontainment facilities for research on potentially dangerous biological pathogens and toxins. The emphasis is on research facilities that are designed to operate at biosafety containment Levels 3 or 4 which in the U S is designated BSL 3 or BSL 4 as defined by the CDC and NIH. Level 3 and 4 biocontainment is referred to in this book as high containment. The book is directed especially to people of all disciplines who are new to high containment to managers or program leaders undertaking new initiatives to expand build new or modernize high containment facilities to administrators who need a clear picture of the level of institutional commitment that high containment facilities entail and to veterans in the field who have yet to codify their thinking on the elements of their successes or possibly even failures. This is not a book about design details specific floor plans or detailed procedural protocols. Nor is it about science facilities in general. Rather it is about the management of capital projects and operational programs that have specific high containment program elements. This book distills and codifies the experience insights and lessons learned of seasoned practitioners facility planners project directors owners end users science program managers and facility operators who are immersed in the field of high containment facility planning construction operation and program management. They have experienced at first hand the remarkable advancement that has occurred in the ten year period 2002-2012 in the thinking and practice of delivering and operating safe environments for research involving dangerous biological pathogens and toxins. They share their management experiences insights and lessons learned in the form of 55 management principles for developing and operating successful high containment facilities important background information personal testimonies and counsel and guidelines and templates for planning and operations. The management principles put forth in this book come in two types Normative Principles things to do or not to do and Descriptive Principles if you do or don't do this expect the following outcome. It is intended that these principles will spur productive discussion among future project and management team members to shape successful project and management outcomes. Appendices list all 55 of the book's management principles and a glossary of terminology pertaining to high containment facilities. The ten year period 2002 to 2012 represents the most active aggressive and well funded decade of high containment facility growth in history. In this decade major biocontainment laboratory facilities have been built or have undergone major upgrades in North America Europe Asia Australia and Africa and hundreds of research universities and hospitals government research agencies private sector biopharmaceutical firms diagnostic companies and research institutes have completed or are currently modernizing or putting in place new facility capacity for high containment research programs. Many of these facilities have now accumulated significant start up commissioning and operational experience which this book seeks to codify and chronicle for the benefit of future high containment research.

programs All book royalties received by Tradeline are being donated to biocontainment facility operations training programs in Africa to offset the costs of visiting subject area experts who conduct special training courses in high containment facilities management maintenance and operations      *Management Principles for Building and Operating Biocontainment Facilities*, 2013      *Developing Norms for the Provision of Biological Laboratories in Low-Resource Contexts* National Academies of Sciences, Engineering, and Medicine, Division on Earth and Life Studies, Board on Life Sciences, Policy and Global Affairs, 2019-05-01 On June 27 28 2018 the U S National Academies of Sciences Engineering and Medicine the National Academies convened an international workshop in Amsterdam the Netherlands on developing norms for the provision of laboratories in low resource contexts The U S Department of State s Biosecurity Engagement Program requested that the National Academies organize this workshop to engage an international group of organizations that provide funding for construction upgrades and maintenance of biological laboratories in countries without the means to build such labs themselves Twenty one people from 19 organizations participated The intent was to advance the conversation about the identification and application of guiding principles and common norms for use by these organizations in their grants partnerships and aid This publication summarizes the presentations and discussions from the workshop      *Biosafety and Biosecurity* Jonathan Jaime G. Guerrero, Rohani Cena-Navarro, Raul V. Destura, Marian P. De Leon, Kin Israel Notarte, Mark Angelo O. Balendres, 2024-07-15 There are many guidelines protocols and advisories that outline how biosafety and biosecurity can be adopted by institutions around the world Whilst helpful many of these are tailored to affluent Western nations This leaves developing nations far behind since their laboratories and institutions are resource scarce and biosafety and biosecurity are not mainstreamed entirely among the different laboratory workers healthcare professionals researchers and academics Biosafety and Biosecurity Practical Insights and Applications for Low and Middle Income Countries aims to bridge this gap by comprehensively summarizing the state and development of biosafety and biosecurity in developing and developed nations in a comparative analysis This book includes basic concepts and principles of biosafety and biosecurity including certification and legal frameworks both international and local and biosafety and biosecurity across disciplines including environmental medical and special topics that are relevant to countries with comparable conditions This proposed book solves the problem of the lack of a prescribed professional title that comprehensively summarizes the state and development of biosafety and biosecurity throughout the world allowing the reader a 360 view of the subject area This book will appeal to a global audience of biorisk officers health and safety professionals and specialists in the life sciences health and allied fields environmental science engineering and plant and animal agriculture      **Process Architecture in Biomanufacturing Facility Design** Jeffery Odum, Michael C. Flickinger, 2018-01-26 Essential information for architects designers engineers equipment suppliers and other professionals who are working in or entering the biopharmaceutical manufacturing field Biomanufacturing facilities that are designed and built today are radically different than in the past The

vital information and knowledge needed to design and construct these increasingly sophisticated biopharmaceutical manufacturing facilities is difficult to find in published literature and it is rarely taught in architecture or design schools This is the first book for architects and designers that fills this void Process Architecture in Biomanufacturing Facility Design provides information on design principles of biopharmaceutical manufacturing facilities that support emerging innovative processes and technologies use state of the art equipment are energy efficient and sustainable and meet regulatory requirements Relying on their many years of hands on design and operations experience the authors emphasize concepts and practical approaches toward design construction and operation of biomanufacturing facilities including product process facility relationships closed systems and single use equipment aseptic manufacturing considerations design of biocontainment facility and process based laboratory and sustainability considerations as well as an outlook on the facility of the future Provides guidelines for meeting licensing and regulatory requirements for biomanufacturing facilities in the U S A and WHO especially in emerging global markets in India China Latin America and the Asia Pacific regions Focuses on innovative design and equipment to speed construction and time to market increase energy efficiency and reduce footprint construction and operational costs as well as the financial risks associated with construction of a new facility prior to the approval of the manufactured products by regulatory agencies Includes many diagrams that clarify the design approach Process Architecture in Biomanufacturing Facility Design is an ideal text for professionals involved in the design of facilities for manufacturing of biopharmaceuticals and vaccines biotechnology and life science industry including architects and designers of industrial facilities construction equipment vendors and mechanical engineers It is also recommended for university instructors advanced undergraduates and graduate students in architecture industrial engineering mechanical engineering industrial design and industrial interior design

**Healthcare-Associated Infections in Australia** Ramon Z. Shaban, Brett G. Mitchell, Deborah Macbeth, Philip Russo, 2023-04-01 Infection prevention and control IPC is everybody's responsibility Healthcare associated Infections in Australia is the first Australian text to address the challenges posed by infectious diseases and healthcare associated infections HAIs for all members of the multidisciplinary healthcare team Drawing on the expertise of a wide author team and based on current research this important and comprehensive text provides a clear pathway for the reader to increase their knowledge and understanding of IPC The text is designed for both students and practising clinicians and is presented in two sections Principles and Practice for ease of use With IPC principles and guidelines now embedded into all health related curricula and mandated by standards and guidelines across all areas of healthcare this is a book no health professional should miss Includes practice tips case studies and video based learning materials providing real life examples across more than 20 health professions Suitable for increasing IPC knowledge across all members of the multidisciplinary team Content is pitched at different levels with examples ranging from novice to expert Aligned to the Australian National Infection Control Guidelines 2019 and the NSQHS Standard Preventing and Controlling

Healthcare Associated Infections as well as the nine hospital acquired complication HAC HAIs addressed in specific chapters Endorsed by the Australian College for Infection Prevention and Control ACIPC and the Australian Society for Infectious Diseases ASID Supported by a companion text Epidemiology of Healthcare associated Infections in Australia providing data on the epidemiology of healthcare associated surveillance in Australia Instructor and Student resources on Evolve Multiple Choice Questions Case Studies Abbreviations and Glossary Useful Websites Resources Video based learning materials

**National Bio and Agro-Defense Facility**, 2008 *Introduction to Homeland Security* George Haddow, Jane Bullock, Damon Coppola, 2015-05-29 *Introduction to Homeland Security Principles of All Hazards Risk Management* Fifth Edition provides users with a substantially updated version of previous versions clearly delineating the bedrock principles of preparing for mitigating managing and recovering from emergencies and disasters while also offering a balanced account of all aspects of homeland security This new edition features coverage of the Boston Marathon bombing analysis of the NIST Cybersecurity Framework for critical infrastructure protection and examines the DHS Blue Campaign to stop human trafficking To provide added perspective this edition features additional another voice sections and examines the emergence of social media as a tool for reporting on homeland security issues Provides users with a comprehensive understanding of the bedrock principles of preparing for mitigating managing and recovering from emergencies and disasters Features coverage of the Boston Marathon bombing and analysis of the NIST Cybersecurity Framework for critical infrastructure protection Examines the emergence of social media as a tool for reporting on homeland security issues **Emerging Infectious Diseases**, 2008 *Fundamentals of Laboratory Animal Science* Enqi Liu, Jianglin Fan, 2017-07-28 Laboratory animals are becoming increasingly important for biomedical research It is said that approximately 70% of biomedical research is associated with the use of experimental animals Laboratory animal research not only expands our knowledge of science but also greatly improves human and animal health The field of laboratory animal science is ever growing and changing as new experimental techniques are developed and new animal models are created It is essential to know not only the biological features of each laboratory animal but also how to use and care for them responsibly in order to perform high quality experiments Courses in beginning Laboratory Animal Science are starting to be offered in many universities throughout the world However a practical introductory textbook that contains state of the art techniques is still lacking *Fundamentals of Laboratory Animal Science* provides comprehensive information on the principles and practices of using laboratory animals for biomedical research Each individual chapter focuses on a key sub discipline of laboratory animal science animal welfare and best humane care practices in the laboratory the quality control of laboratory animals the anatomy physiology and husbandry of commonly used species the principles of creating and using animal models for studying human diseases practical techniques used for laboratory animal experiments experimental design and animal experimentation management Knowledge of this broad spectrum of concepts and skills will ensure research goes smoothly while greatly reducing animal

pain and distress Well illustrated and thoroughly referenced this book will serve not only as a standard textbook but also as a handy guide for veterinarians researchers animal care staff administrators and other professionals who are involved in laboratory animal science

**Molecular Therapeutics** Mr. Rohit Manglik, 2024-05-07 Focuses on molecular level drug development gene therapy and personalized medicine

*Mycobacterium Tuberculosis: Molecular Infection Biology, Pathogenesis, Diagnostics and New Interventions* Seyed Ehtesham Hasnain, Nasreen Z. Ehtesham, Sonam Grover, 2019-11-30 This book reviews recent advances in the molecular and infection biology pathology and molecular epidemiology of Mycobacterium tuberculosis as well as the identification and validation of novel molecular drug targets for the treatment of this mycobacterial disease Despite being completely curable tuberculosis is still one of the leading global causes of death M tuberculosis the causative organism one of the smartest pathogens known adopts highly intelligent strategies for survival and pathogenesis Presenting a wealth of information on the molecular infection biology of M tuberculosis as well as nontuberculous mycobacteria NTM the book provides an overview of the functional role of the PE PPE group of proteins which is exclusive to the genus Mycobacteria of host pathogen interactions and virulence It also explores the pathogenesis of the infection pathology epidemiology and diagnosis of NTM Finally it discusses current and novel approaches in vaccine development against tuberculosis including the role of nanotechnology With state of the art contributions from experts in the respective domains this book is an informative resource for practitioners as well as medical postgraduate students and researchers

**Anthology of Biosafety** Jonathan Y. Richmond, 1999 *Biological Safety* Dawn P. Wooley, Karen B. Byers, 2020-07-02 Biological safety and biosecurity protocols are essential to the reputation and responsibility of every scientific institution whether research academic or production Every risk no matter how small must be considered assessed and properly mitigated If the science isn't safe it isn't good Now in its fifth edition Biological safety Principles and Practices remains the most comprehensive biosafety reference Led by editors Karen Byers and Dawn Wooley a team of expert contributors have outlined the technical nuts and bolts of biosafety and biosecurity within these pages This book presents the guiding principles of laboratory safety including the identification assessment and control of the broad variety of risks encountered in the lab the production facility and the classroom Specifically Biological Safety covers protection and control elements from biosafety level cabinets and personal protection systems to strategies and decontamination methods administrative concerns in biorisk management including regulations guidelines and compliance various aspects of risk assessment covering bacterial pathogens viral agents mycotic agents protozoa and helminths gene transfer vectors zoonotic agents allergens toxins and molecular agents as well as decontamination aerobiology occupational medicine and training A resource for biosafety professionals instructors and those who work with pathogenic agents in any capacity Biological safety is also a critical reference for laboratory managers and those responsible for managing biohazards in a range of settings including basic and agricultural research clinical laboratories the vivarium field study insectories and greenhouses

**Department of Homeland Security Appropriations for 2015** United States. Congress. House. Committee on Appropriations. Subcommittee on Homeland Security, 2014

*Laboratory Animal Welfare* Kathryn Bayne, Patricia V. Turner, 2013-09-02 Laboratory Animal Welfare provides a comprehensive up to date look into the new science of animal welfare within laboratory research Animals specifically considered include rodents cats and dogs nonhuman primates agricultural animals avian animals and aquatic animals The book examines the impact of experiment design and environment on animal welfare as well as emergency situations and euthanasia practices Readers will benefit from a review of regulations and policy guidelines concerning lab animal use as well as information on assessing animal welfare With discussions of the history and ethics of animals in research and a debate on contemporary and international issues this book is a go to resource for laboratory animal welfare

*Understanding Tuberculosis* Pere-Joan Cardona, 2012-02-15 Mycobacterium tuberculosis is a disease that is transmitted through aerosol This is the reason why it is estimated that a third of humankind is already infected by Mycobacterium tuberculosis The vast majority of the infected do not know about their status Mycobacterium tuberculosis is a silent pathogen causing no symptomatology at all during the infection In addition infected people cannot cause further infections Unfortunately an estimated 10 per cent of the infected population has the probability to develop the disease making it very difficult to eradicate Once in this stage the bacilli can be transmitted to other persons and the development of clinical symptoms is very progressive Therefore the diagnosis especially the discrimination between infection and disease is a real challenge In this book we present the experience of worldwide specialists on the diagnosis along with its lights and shadows

*Handbook of Laboratory Animal Science, Volume I* Jann Hau, Steven J. Schapiro, 2010-12-02 Laboratory animal testing provides most of our current knowledge of human physiology microbiology immunology pharmacology and pathology From studies of genetics in fruit flies to studies of cellular processes in genetically modified mice to recent dramatic developments in genetics translational research and personalized medicines biomedical

*Planning and Designing Research Animal Facilities* Jack Hessler, Noel Lehner, 2011-04-28 Research institutions have or are planning to build expand and renovate animal research facilities to keep up with the demands of biomedical research caused in part by growth in the use of genetically altered rodents and the upsurge of research in infectious diseases Properly designed facilities greatly facilitate effective management and high quality day to day animal care that is required to optimally support animal research and testing There are multiple solutions to address the myriad of factors that influence the design and construction of animal research facilities There is no best design applicable for all facilities and arguably not even a single best design for a given facility For this reason Planning and Designing Research Animal Facilities is not intended to be a how to book The goal is to cover the basic programmatic requirements of animal research facilities provide ideas for meeting those requirements while hopefully stimulating the creative process in which designers in consultation with those who work in animal research facilities generate even better ideas That is how progress has been made and will continue to be made



Facilitates communication between the parties involved in planning and designing animal facilities by providing contemporary information and stimulating creativity that will help lead to wise decisions and advance the knowledge base for planning design and constructing animal research facilities

**Department of Homeland Security Appropriations for 2010, Part 1C, 111-1 Hearings ,2009**

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## **Table of Contents Management Principles For Building And Operating Biocontainment Facilities**

1. Understanding the eBook Management Principles For Building And Operating Biocontainment Facilities
  - The Rise of Digital Reading Management Principles For Building And Operating Biocontainment Facilities
  - Advantages of eBooks Over Traditional Books
2. Identifying Management Principles For Building And Operating Biocontainment Facilities
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Management Principles For Building And Operating Biocontainment Facilities
  - User-Friendly Interface
4. Exploring eBook Recommendations from Management Principles For Building And Operating Biocontainment Facilities
  - Personalized Recommendations
  - Management Principles For Building And Operating Biocontainment Facilities User Reviews and Ratings
  - Management Principles For Building And Operating Biocontainment Facilities and Bestseller Lists

5. Accessing Management Principles For Building And Operating Biocontainment Facilities Free and Paid eBooks
  - Management Principles For Building And Operating Biocontainment Facilities Public Domain eBooks
  - Management Principles For Building And Operating Biocontainment Facilities eBook Subscription Services
  - Management Principles For Building And Operating Biocontainment Facilities Budget-Friendly Options
6. Navigating Management Principles For Building And Operating Biocontainment Facilities eBook Formats
  - ePub, PDF, MOBI, and More
  - Management Principles For Building And Operating Biocontainment Facilities Compatibility with Devices
  - Management Principles For Building And Operating Biocontainment Facilities Enhanced eBook Features
7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Management Principles For Building And Operating Biocontainment Facilities
  - Highlighting and Note-Taking Management Principles For Building And Operating Biocontainment Facilities
  - Interactive Elements Management Principles For Building And Operating Biocontainment Facilities
8. Staying Engaged with Management Principles For Building And Operating Biocontainment Facilities
  - Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Management Principles For Building And Operating Biocontainment Facilities
9. Balancing eBooks and Physical Books Management Principles For Building And Operating Biocontainment Facilities
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Management Principles For Building And Operating Biocontainment Facilities
10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
11. Cultivating a Reading Routine Management Principles For Building And Operating Biocontainment Facilities
  - Setting Reading Goals Management Principles For Building And Operating Biocontainment Facilities
  - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Management Principles For Building And Operating Biocontainment Facilities
  - Fact-Checking eBook Content of Management Principles For Building And Operating Biocontainment Facilities
  - Distinguishing Credible Sources

13. Promoting Lifelong Learning
  - Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
  - Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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