# Bioprocessing Safety

Worker and Community
Safety and Health Considerations

Worren C. Hyer, Jr. editor



### **STP 1051**

# Bioprocessing Safety: Worker and Community Safety and Health Considerations

Warren C. Hyer, Jr., editor



#### Library of Congress Cataloging-in-Publication Data

Bioprocessing safety worker and community safety and health considerations/Warren C Hyer, Jr, editor

(STP: 1051)

Papers presented at the First International Symposium on Large-Scale Bioprocessing Safety: Worker and Community Safety and Health

Considerations, held 6-8 Oct 1987 in Washington, DC

Includes bibliographies and index

ISBN 0-8031-1264-5

1 Biotechnology—Safety Measures—Congresses. 2. Biotechnology— Health aspects—Congresses I. Hyer, Warren C., 1941–

II American Society for Testing and Materials

TP248 14 B54 1990

660',6'0289—dc20

89-18140

CIP

Copyright © by American Society for Testing and Materials 1990

#### NOTE

The Society is not responsible, as a body. for the statements and opinions advanced in this publication

#### **Peer Review Policy**

Each paper published in this volume was evaluated by three peer reviewers. The authors addressed all of the reviewers' comments to the satisfaction of both the technical editor(s) and the ASTM Committee on Publications

The quality of the papers in this publication reflects not only the obvious efforts of the authors and the technical editor(s), but also the work of these peer reviewers. The ASTM Committee on Publications acknowledges with appreciation their dedication and contribution of time and effort on behalf of ASTM

## **Foreword**

This publication, Bioprocessing Safety Worker and Community Safety and Health Considerations, contains papers presented at the First International Symposium on Large-Scale Bioprocessing Safety. Worker and Community Safety and Health Considerations, which was held on 6–8 Oct 1987 in Washington, DC The symposium was sponsored by ASTM Committee E-48 on Biotechnology, in cooperation with the following organizations American Biological Safety Association, American Industrial Hygiene Association, American Society for Microbiology, Association of Biotechnology Companies, Biotechnology Science Coordinating Committee (BSCC), Conservation Foundation, Department of Professional Employees—AFL/CIO, Environmental Defense Fund, National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), Society for Industrial Microbiology, United Food and Commercial Workers International Union—AFL/CIO & CLC, and the U S. Department of Energy Warren C. Hyer, Jr., of the American Biotechnology Association, presided as chairman of the symposium and also served as editor of this publication

## Contents

Introduction	1
Overview of Safety in the Bioprocessing Industry	
The NIH Recombinant DNA Advisory Committee: An Example of the Self-Regulatory Process—GERARD J. MCGARRITY	5
Safety in Bioprocessing: An Industrial Perspective—MARK A. FOGLESONG	14
Perspectives on Opportunities Toward a Hazard-Free Bioprocessing Environment—LARRY J ELLIOTT, WILLIAM E. HALPERIN, AND PHILIP J. LANDRIGAN	20
Accepting Risk: Responsibility Versus Liability—ANN N. JAMES AND GAIL E PAPERMASTER	27
Design Criteria for Safety	
Containment and Regulations for Safe Biotechnology—S P. VRANCH	39
The Biological Production Facility—Design for Protection of the Worker and the Community—PHILIP G DAMM	58
Design Criteria for Safety in the Isolation and Purification of Antibiotics and Biologically Active Compounds—EDWARD L. PAUL	65
SAFETY PLAN—PERSONNEL	
Industrial Safety for the Biotechnology Industry—JOHN H KEENE	77
General Considerations for Work Practices and Personal Protective Equipment in Biotechnology Industries—Kenneth F Martinez, Larry J elliott, and James H Jones	83
Safe and Effective Spill Control Within Biotechnology Plants— JOSEPH VAN HOUTEN	91

Biotechnology: Is There a Role for Medical Surveillance?—Daniel F Liberman, alan M. Ducatman, and richard fink	101
SAFE WASTE DISPOSAL—MINIMIZING COMMUNITY ENVIRONMENTAL IMPACT	
Public Perception of Biotechnology: Green Revolution or Green Monster?— REBECCA J GOLDBURG AND RICHARD A DENISON	113
COMMUNITY AWARENESS AND EMERGENCY RESPONSES	
Community Awareness: Cooperation or Confrontation—WARREN C HYER, JR	129
Facing Frankenstein: The Importance of Public Participation—A JAMES BARNES	135
Township Review of a New Bioprocessing Facility in Henrietta, New York— JAMES R BREESE	140
REGULATORY ASPECTS OF BIOPROCESSING—INTERNATIONAL, NATIONAL, AND LOCAL	
Minimal Guidelines for Biotechnology Safety—Activities of the United Nations Specialized Agencies—VINSON R. OVIATT	147
FDA Enforcement in Bioprocessing Facilities—BARBARA-HELENE SMITH	152
Biotechnology Facility Approval at the Local Level: The Cambridge, Massachusetts, Experience—MELVIN H CHALFEN	158
Indexes	
Author Index	165
Subject Index	167