

TABLE OF CONTENTS

CHAPTER 1 – ADMINISTRATIVE

- SUBCHAPTER 1.1 - ADMINISTRATION NOTES
- SUBCHAPTER 1.2 - OII TRAVEL
- SUBCHAPTER 1.3 - TRAVELER' HEALTH
- SUBCHAPTER 1.4 - DIVISION OF TRAVEL OPERATIONS
- SUBCHAPTER 1.5 - VEHICLE ACCIDENTS
- SUBCHAPTER 1.6 - TRANSPORTATION
- SUBCHAPTER 1.7 - MEDIA INTERACTIONS DURING INSPECTIONS
- SUBCHAPTER 1.8 - EQUIPMENT
- SUBCHAPTER 1.9 - OFFICAL IDENTIFICIATION SUBCHAPTER 1.10 BUSINESS CARDS
- SUBCHAPTER 1.10 - ETHICS AND INTEGRITY
- SUBCHAPTER 1.12 - QUALITY MANAGEMENT
- SUBCHAPTER 1.13 - OII TIME REPORTING

CHAPTER 2 – NOTES, RECORDS, AND INFORMATION

- SUBCHAPTER 2.1 - REGULATORY NOTES
- SUBCHAPTER 2.2 - RECORDS MANAGEMENT
- SUBCHAPTER 2.3 INFORMATION DISCLOSURE
- SUBCHAPTER 2.4 - ENGLISH LANGUAGE REQUIREMENT
- SUBCHAPTER 2.5 - FULL NAME REQUIREMENT

CHAPTER 3 - REGULATORY

- SUBCHAPTER 3.1 - PURPOSE
- SUBCHAPTER 3.2 - STATUTORY AUTHORITY
- SUBCHAPTER 3.3 - EVIDENCE
- SUBCHAPTER 3.4 - ADVISORY ACTIONS AND OTHER NOTICES OF VIOLATIONS
- SUBCHAPTER 3.5 - ADMINISTRATIVE ACTIONS
- SUBCHAPTER 3.6 - PROCEDURAL STEPS FOR EXECUTION OF DETENTION AT A FIRM
- SUBCHAPTER 3.7 - DENATURING
- SUBCHAPTER 3.8 - JUDICIAL ACTIONS
- SUBCHAPTER 3.9 - COMPLIANCE ACHIEVEMENTS FOR VOLUNTARY CORRECTIVE ACTIONS
- SUBCHAPTER 3.10 - REGULATORY SUBMISSIONS
- SUBCHAPTER 3.11 – REFERENCES

CHAPTER 4 - SAMPLING

- SUBCHAPTER 4.1 - GENERAL
- SUBCHAPTER 4.2 - DEALER RELATIONS
- SUBCHAPTER 4.3 - COLLECTION TECHNIQUE
- SUBCHAPTER 4.4 - DOCUMENTS COLLECTED WITH SAMPLE
- SUBCHAPTER 4.5 - BIORESEARCH MONITORING SAMPLES
- SUBCHAPTER 4.6 - REPORTING SAMPLE COLLECTIONS
- SUBCHAPTER 4.7 - SAMPLING: PREPARATION, HANDLING, SHIPPING

CHAPTER 5 - INSPECTIONS

- SUBCHAPTER 5.1 - GENERAL INSPECTION INFORMATION
- SUBCHAPTER 5.2 - PRE-INSPECTION ACTIVITIES
- SUBCHAPTER 5.3 - SAFETY DURING INSPECTIONS
- SUBCHAPTER 5.4 - CONFIDENTIAL SOURCES
- SUBCHAPTER 5.5 - INSPECTIONAL ACTIVITIES
- SUBCHAPTER 5.6 - EVIDENCE DEVLOPEMENT
- SUBCHAPTER 5.7 - REPORTING
- SUBCHAPTER 5.8 - HUMAN AND ANIMAL FOODS
- SUBCHAPTER 5.9 - COSMETICS
- SUBCHAPTER 5.10 - DRUGS
- SUBCHAPTER 5.11 - ANIMAL & VETERINARY

SUBCHAPTER 5.12 - MEDICAL DEVICE AND ELECTRONIC RADIATION PRODUCT CONTROL (EPRC)

SUBCHAPTER 5.13 - BIOLOGICS

SUBCHAPTER 5.14 - BIORESEARCH MONITORING (BIMO)

SUBCHAPTER 5.15 - TOBACCO PRODUCTS

SUBCHAPTER 5.16 - COMBINATION PRODUCTS

CHAPTER 6 - IMPORTS

SUBCHAPTER 6.1 - IMPORT GENERAL

SUBCHAPTER 6.2 - ENTRY REVIEW

SUBCHAPTER 6.3 - FIELD EXAMINATION

SUBCHAPTER 6.4 - IMPORT SAMPLE COLLECTION

SUBCHAPTER 6.5 - IMPORT PROCEDURES AFTER EXAMINATION / SAMPLING

SUBCHAPTER 6.6 - IMPORT INVESTIGATIONS

SUBCHAPTER 6.7 - FILER EVALUATIONS

SUBCHAPTER 6.8 - FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

SUBCHAPTER 6.9 - GLOSSARY OF IMPORT TERMS

CHAPTER 7 - RECALL ACTIVITIES

SUBCHAPTER 7.1 - PURPOSE OF RECALLS

SUBCHAPTER 7.2 - RESPONSIBILITIES DURING RECALLS

SUBCHAPTER 7.3 - RECALLS AND INSPECTIONS

SUBCHAPTER 7.4 - FDA'S RECALL MONITORING ACTIVITIES

SUBCHAPTER 7.5 - RECALL COMPLETION AND TERMINATION

CHAPTER 8 - INVESTIGATIONS

SUBCHAPTER 8.1 - INVESTIGATIONS AND INSPECTIONS

SUBCHAPTER 8.2 - HUMAN AND ANIMAL FOOD INVESTIGATIONS

SUBCHAPTER 8.3 - DRUG INVESTIGATIONS

SUBCHAPTER 8.4 - DEVICE INVESTIGATIONS

SUBCHAPTER 8.5 - BIOLOGICS INVESTIGATIONS

SUBCHAPTER 8.6 - BIORESEARCH MONITORING INVESTIGATIONS

SUBCHAPTER 8.7 - TOBACCO INVESTIGATIONS

CHAPTER 9 – PUBLIC HEALTH COLLABORATION

SUBCHAPTER 9.1 - PUBLIC HEALTH COLLABORATION

SUBCHAPTER 9.2 - ROLES AND RESPONSIBILITIES OF OTHER FEDERAL AGENCY

SUBCHAPTER 9.3 - STATE LOCAL, TRIBAL AND TERRITORIAL INTERACTIONS

SUBCHAPTER 9.4 - INTERNATIONAL AGREEMENTS

SUBCHAPTER 9.5 - NON-GOVERNMENT AGREEMENTS

SUBCHAPTER 9.6 - TRIBAL AFFAIRS

CHAPTER 10 – SAFETY

SUBCHAPTER 10.1 - PURPOSE

SUBCHAPTER 10.2 - UNACCEPTABLE RISK

SUBCHAPTER 10.3 - PERSONAL SAFETY

SUBCHAPTER 10.4 - EMPLOYER/EMPLOYEE SAFETY RESPONSIBILITIES

SUBCHAPTER 10.5 - FOLLOWING FIRM SAFETY REQUIREMENTS

SUBCHAPTER 10.6 - SAFETY RISK ASSESSMENT FRAMEWORKS

SUBCHAPTER 10.7 - ADDITIONAL SAFETY INFORMATION

SUBCHAPTER 10.8 - HIERARCHY OF CONTENTS

SUBCHAPTER 10.9 - PPE

SUBCHAPTER 10.10 - REGULATORY OPERATIONS SAFETY STAFF (ROSS)

SUBCHAPTER 10.11 - RESOURCES

SUBCHAPTER 10.12 - SPECIAL SAFETY SITUATIONS

SUBCHAPTER 10.13 - BIOLOGICAL HAZARDS

SUBCHAPTER 10.14 - CHEMICAL HAZARDS

SUBCHAPTER 10.15 - PHYSICAL AND RADIATION HAZARDS

SUBCHAPTER 10.16 - ERGONOMIC

SUBCHAPTER 10.17 - EMPLOYEE AND TRAVELER HEALTH AND SAFETY

APPENDIX

APPENDIX A - PRINCIPAL STORED GRAIN INSECTS

APPENDIX B - PERPETUAL JULIAN CALENDAR

APPENDIX C - BLOOD SERUM CHEMISTRY

APPENDIX D - CONVERSION TABLES

APPENDIX E - DIVISION MAPS (OBIMO, OBPO, OMDRHO, OPQO, OHAFO, OEIO, TOBACCO, ORS)

Note: Certain links in this chapter are only available to FDA employees via the FDA Intranet site and cannot be accessed by individuals outside the FDA internal network. Requests for information can be made through the Freedom of Information Act (FOIA) process described in IOM Section 8.1.3 and also at <https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request>.