

## BIOWASTE POLICY AND PROGRAM DEVELOPMENT

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Medical schools generate multiple waste streams from both research laboratories and medical clinics. The research laboratories generate both characteristic and listed chemical waste streams as defined by RCRA, as well as radioactive waste and biowaste from humans and animals. The medical clinics generate EPA regulated cytotoxic drugs and biowaste from humans.

It is imperative that the biowaste be handled and disposed of properly to ensure the health and safety of all faculty and staff. In order to ensure proper handling and disposal of biowaste, a written program on the correct procedures should be developed and implemented by facility management.

At Wake Forest University Health Sciences (WFUHS), approximately 91,000 pounds of biowaste is generated in 640 research laboratories (Biosafety Level 1 and 2), 30 medical clinics and nine animal resource program locations covering four campuses. The various biowaste streams generated from humans and animals include: microbiological, pathological, blood and body fluids, sharps, animal waste and carcasses and non EPA regulated cytotoxic drugs.

The existing biowaste programs at WFUHS were reviewed in order to ensure compliance with local, state and federal requirements. The existing biowaste programs were documented as a section of the Biosafety Process Manual as well as an appendix in the Bloodborne Pathogen – Exposure Control Plan. These biowaste documents differed as to coverage of the biowaste streams. In reviewing the existing biowaste documents, it was discovered that only the North Carolina Department of Environment and Natural Resources (NCDENR) Division of Waste Management, Medical Waste Regulations and OSHA Bloodborne Pathogen Regulations were covered. Further review of the documents noted that the existing biowaste documents were deficient in the following areas:

- Biowaste documentation contained within the Biosafety Process Manual and the Bloodborne Pathogen – Exposure Control Plan was confusing, limited and contradictory.
- The definitions of biowaste streams were limited to the NC Medical Waste and OSHA Bloodborne Pathogen Regulations.
- The existing documents allowed liquid blood to be disposed through the sanitary sewer.
- Manifests were not centrally managed.
- Record retention requirements were not being met per NCDENR Medical Waste Regulations.
- The amount of biowaste generated annually could not be accurately determined.

- Responsibilities were poorly defined.
- Training (for example, on proper handling and disposal of biowaste) was lacking.

A review of the pertinent regulations included the following:

- Local Ordinances
- State (NCDENR)
- Federal [(Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Center for Disease Control and Prevention (CDC), National Institutes of Health (NIH)].

Additionally, requirements from the biowaste disposal vendor were reviewed.

## **REGULATIONS**

The first step in developing the biowaste policy was to review the pertinent local, state and federal regulations governing biowaste. Listed below are review findings.

### **LOCAL**

Local regulations that govern the use of the sanitary sewer and landfill include:

- The Sewer and Water Policy Resolution of Winston-Salem, North Carolina states that no blood shall be disposed of through the sanitary sewer.
- The Solid Waste Disposal Policy Resolution of the City of Winston-Salem, North Carolina prohibits the disposal of infectious waste in the landfill. For disposal of animal carcasses, written permission must be obtained from the city.

### **STATE**

NCDENR Division of Waste Management is responsible for the regulation of medical waste. NCDENR differentiates biowaste into two categories:

- Regulated medical waste
- Medical waste

The major difference between regulated medical waste and medical waste pertains to the volume of blood and body fluids. If the volume of blood and body fluids is greater than 20 ml, the waste is considered regulated medical waste. If the volume is less than 20 ml, then the waste is considered medical waste. Medical waste can be disposed of via local sewer and solid waste options. However, regulated medical waste

requires treatment prior to disposal. Treatment methods include: steam sterilization, incineration, chemical or microwave treatment.

## MIXED WASTE STREAMS

Biowaste cannot contain any hazardous chemical or radioactive waste components. For a mixed waste, the biological component must first be treated; it can then be treated as chemical or radioactive waste. Medical waste incinerators will not accept chemical hazardous waste. Hazardous waste incinerators will not accept medical waste.

## FEDERAL

The federal requirements reviewed included:

- OSHA 29 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogen Standard.
  - The Bloodborne Pathogen Standard is the regulation for controlling exposure to bloodborne pathogens for personnel working in medical clinics and research laboratories.
  - The Bloodborne Pathogen Standard states that research laboratories generating biowaste shall either incinerate or autoclave the biowaste to effectively destroy bloodborne pathogens.
  
- Environmental Protection Agency (EPA) Resource Conservation and Recovery Act (RCRA) 40 CFR 261 Subpart D, Identification and Listing of Hazardous Waste.
  - This regulation differentiates characteristic and listed chemical waste streams.
  - At present, seven cytotoxic drugs are listed as hazardous chemical waste by EPA. **TABLE 1** lists the seven drugs along with their corresponding EPA Waste Number. These drugs and associated materials must be segregated from non-regulated chemotherapy waste or red sharps containers and placed into RCRA hazardous waste containers when present in bulk or residue amounts.

**TABLE 1 – REGULATED CYTOTOXIC AGENTS**

<b>Drug</b>	<b>EPA No.</b>
Chlorambucil (Leukeran)	U035
Cyclophosphamide (Cytosan, CTX)	U058
Daunomycin (Daunorubicin)	U059
Melphalan (Alkeran)	U150
Mitomycin-C (Mutarnycin)	U010
Streptozocin (Zanosar)	U206
Uracil Mustard	U237

- CDC, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4<sup>th</sup> Edition.
  - The BMBL serves as an enforceable reference under the Select Agent Rule, 42 CFR Part 73.
  - The *BMBL* states that all cultures, stocks and other regulated wastes shall be decontaminated before disposal by an approved decontamination method such as autoclaving.
  
- National Institutes of Health (NIH), NIH Recombinant DNA Guidelines.
  - Adherence to NIH Guidelines is a condition of all NIH grants.
  - NIH Recombinant DNA Guidelines state that level 2 and higher risk groups contaminated liquid or solid wastes must be decontaminated before disposal. Recommendations for decontamination prior to disposal are the use of standard practices used in microbiological laboratories.
  
- CDC 42 CFR 71.53 (g) Importation of Nonhuman Primates (NHPs).
  - CDC regulates the disposal of infectious and non-infectious nonhuman primates in accordance with the owner's and Director's arrangements.
  - In reality, CDC expects infectious NHPs and their waste to be incinerated.

Lastly, the biowaste vendor (Stericycle) requirements were reviewed. It was noted that Stericycle adapts their requirements from OSHA 29 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogen Standard and Department of Transportation (DOT) 49 CFR Part 173.197, Shippers General Requirements for Shipments and Packagings, Regulated Medical Waste.

## **BIOWASTE DEFINITIONS**

As a result of reviewing the various regulations pertinent to medical waste, the medical waste stream definitions were expanded from the previous biowaste document. The definition of each waste stream was revised to incorporate all the regulations, rather than just NCDENR and OSHA requirements; and to reflect the biowaste streams as actually generated by research laboratories, medical clinics and the animal resource program. The biowaste streams identified and defined included:

- Microbiological
- Pathological
- Blood and body fluids

- Sharps
- Animal waste and carcasses
- Isolation wastes
- Cytotoxic drugs
- Urine and feces

### MICROBIOLOGICAL

- Microbiological waste (cultures, stocks and biologicals) include the following:
  - Items infectious to humans (those that require Risk Group 2 and above containment): cultures and stocks from medical, pathological, or research laboratories, and their associated biologicals including bacteria, viruses, fungi and other parasites.
  - Human, primate and any other cell lines, even in the absence of overt contamination, may contain latent viruses and/or other opportunistic pathogens or zoonotic agents (capable of transmitting disease from animals to man).
  - Waste from the production of biologicals (e.g., biologicals defined as serums, vaccines, antigens, antitoxins, cell lines, and cultures), as well as materials used for spill cleanups.
  - Discarded live or attenuated vaccines and biological toxins.
  - Systems used to grow and maintain infectious agents in vitro, including but not limited to: nutrient agars, gels, and broths.
  - Culture dishes and devices used to transfer, inoculate or mix cultures, including but not limited to: plastic or glass plates, paper, gloves, growth media, gels, filters, stoppers, plugs, flasks, inoculation loops and wires, contaminated pipette tips, tubes, stirring devices, jars, etc.

### PATHOLOGICAL

- Pathological waste include the following:
  - Human pathological waste, including tissues, organs, body parts and body fluids that are removed during surgery, autopsy or other medical procedures. Human pathological waste also includes specimens of body fluids and their containers.
  - Human cadavers and other anatomical waste.
  - Organs and tissues fixed for histological or cytological examinations. These must be processed as hazardous waste since the fixatives used are considered to be hazardous chemicals.

### BLOOD AND BODY FLUIDS (Volumes greater than 20 ml)

- Blood and blood-product waste include the following:
  - Human blood, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, and any body fluid that is visibly contaminated with blood.
  - Waste human blood and products of blood, items saturated and/or dripping with human blood, or items saturated and/or dripping with human blood that are now caked with dried human blood; to include

serum, plasma and other blood components and their containers which were used or intended for use in patient care, testing, laboratory analysis, or the development of pharmaceuticals and intravenous bags.

- Containers and/or materials containing free-flowing blood or blood components, and materials saturated with blood or blood products, tissue, organs, body parts, body fluids removed during autopsy, or obtained during other medical procedures, specimens or body fluids and their containers and discarded material saturated with such body fluids (other than urine).
- Discarded waste blood and/or blood components (e.g., serum, plasma).

Excluded from blood products category are feminine hygiene products used to absorb menstrual flow and band-aids, bandages and gauze.

### SHARPS

- Sharps include the following:
  - Sharps that have been used in animal or human patient care in medical clinics or research laboratories, discarded used or unused needles (even if not exposed to any infectious agents), hypodermic needles, and complete syringes (needle & syringe body).
  - Pasteur pipettes, scalpel blades and razor blades in contact with infectious agents.
  - Broken glass, broken plastic petri dishes, rigid plastic culture tubes, flasks, beakers and other labware that has been in contact with infectious agents; and blood vials used in animal or human patient care, medical research, and clinical laboratories.
  - Broken or unbroken glass slides and their covers that have been in contact with infectious agents.
  - Syringe barrels.
  - Uncontaminated scalpel blades and razor blades.
  - Used or unused hypodermic needles and suture needles.
  - Exposed ends of dental or orthopedic wires.
  - Plastic speculums.

### ANIMAL WASTE AND CARCASSES

- Animal material and carcasses include the following:
  - Animal waste contaminated with a known infectious agent.
  - Contaminated animal carcasses, body parts, body fluids, blood, or bedding from animals known to be contaminated with infectious agents (e.g., zoonotic organisms); or from animals inoculated during research, production of biologicals, or pharmaceutical testing with infectious agents.

### ISOLATION

- Isolation waste from persons or animals infected with Risk Group 2 or above organisms include the following:
  - Patient isolation waste including biological waste and discarded materials contaminated with blood, excretion, exudates or secretions from humans who are isolated to protect others from highly communicable diseases (excludes linens, towels, etc.).
  - Isolated animals known to be infected with highly communicable diseases.
  - Waste from Quarantine of Imported Non Human Primates (NHPs) including: shavings, crates, paper, work clothing; personal protective equipment (PPE), medicines and animals. This is required as a control measure for preventing the spread of communicable diseases.

### CYTOTOXIC DRUGS

- Cytotoxic drugs include the EPA non-regulated cytotoxic agents. EPA regulated cytotoxic drugs must be disposed of through a chemical waste program.
  - The EPA regulated cytotoxic drugs include chlorambucil, cyclophosphamide, daunomycin, melphalan, mitomycin C, streptozotocin and uracil mustard.

### URINE AND FECES

- Urine and feces from animals and/or humans.
- Urine and feces can be disposed of via local sewer and solid waste options.

## **VALIDATION**

After developing definitions, the various biowaste streams were validated with housekeeping, chemotherapy team, animal resources personnel, clinic areas and a small percent of the research laboratories. Environmental Health and Safety (EH&S) Staff met with affected managers and refined the definitions to ensure comprehension by all involved parties.

## **DEFINING RESPONSIBILITIES**

Responsibilities were defined for all faculty and staff, ranging from principal investigators to the housekeeping personnel.

To fulfill their general responsibilities, all faculty and staff must:

- Participate in the initial and annual refresher training course.
- Receive Hepatitis B vaccines and/or demonstrate immunity.
- Use and wear appropriate PPE when handling biowaste.
- Package biowaste in containers designated for biowaste.
- Label all containers with pre-generated labels.
- Transport biowaste to accumulation area.

The University Environmental, Health and Safety staff should:

- Develop, validate and implement a University Biowaste Program.
- Develop and implement an initial and annual refresher training course.
- Determine which university organizations are to collect and dispose of biowaste.
- Ensure that all biowaste received is weighed and recorded by class.
- Issue biowaste receipts for all biowaste collected.
- Determine record retention policy and responsibilities.

Housekeeping staff should:

- Inspect biowaste accumulation area weekly.
- Disinfect biowaste storage area weekly.
- Schedule and complete periodic shipments.
- Maintain accumulation and storage facilities, accumulation container labeling and collection records.
- Send copies of the manifests to the record retention organization.

The Animal Resource Program personnel should:

- Collect animal waste and carcasses as required.
- Disinfect biowaste storage area weekly.
- Schedule and complete periodic shipments.
- Maintain accumulation and storage facilities, accumulation container labeling and collection records.
- Inspect biowaste accumulation areas weekly.
- Schedule and complete periodic shipments.
- Send copies of manifests to the record retention organization.

## **DOCUMENTATION**

A single document was written to define the waste streams and organizational responsibilities. The document detailed how each biowaste stream should be packaged and labeled. After the document was written, it was again reviewed with the affected organizations. As a result of the review, the document was changed to incorporate site-specific definitions for each waste stream and an accurate flow of the biowaste.

## **CHARTING**

After the document was finalized, the biowaste flow chart (**FIGURE 1**) was revised (**FIGURE 2**) to show how each particular waste stream would be processed from the user to the final disposal site. Biowaste flow charts were developed to cover the research laboratories, medical clinics and the Animal Resource Program.

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## WASTE STREAMS GUIDE

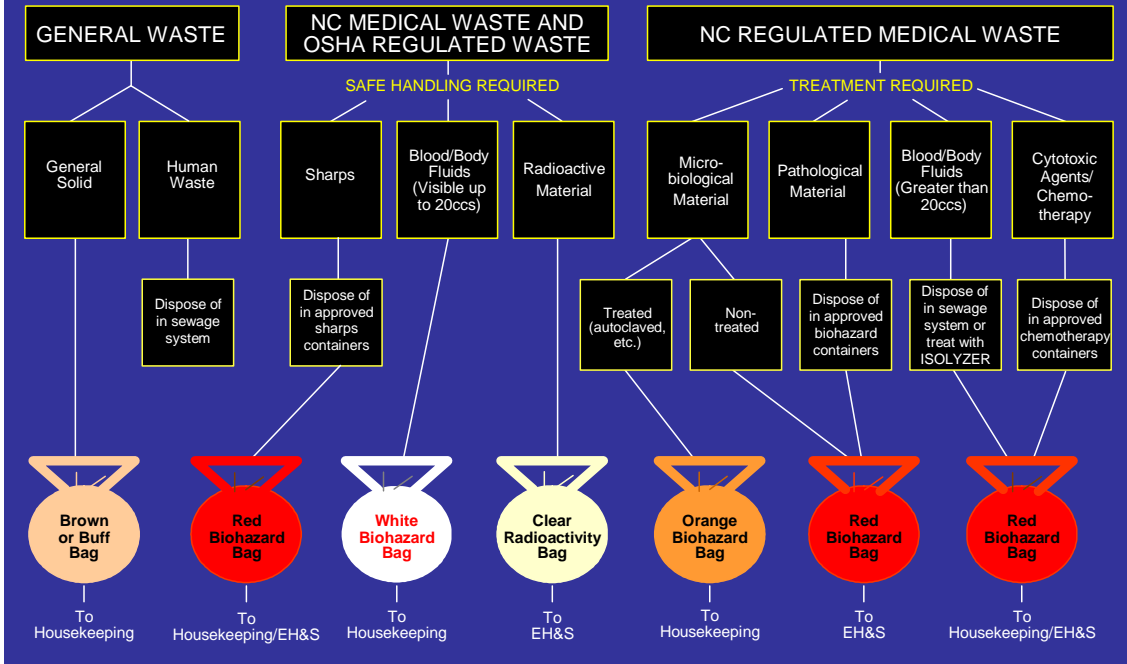


FIGURE 1 – BIOWASTE CHART

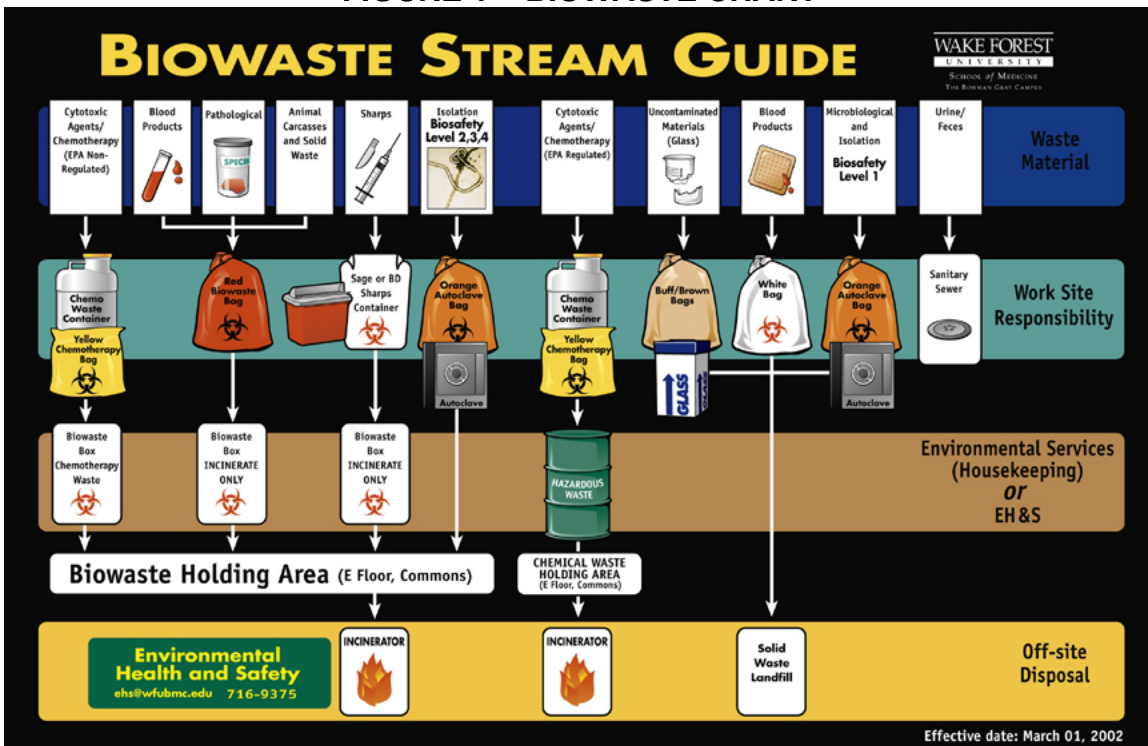


FIGURE 2 - REVISED BIOWASTE CHART

## **TRAINING**

A training program was developed for each customer. Training was conducted for the medical clinics, housekeeping and Animal Resource Program staff. Biowaste handling information was incorporated into basic lab safety training for new employees.

## **RESULTS**

Through the development of the biowaste program, the following items were identified and corrected:

- Proper signage was placed on the storage areas.
- Storage areas were inspected and cleaned weekly.
- Standard operating procedures were developed and implemented for using the autoclave.

## **PROGRAM AUDITS**

To further evaluate handling biowaste from cradle to grave, an audit of Stericycle was performed. During the course of the audit, it was discovered that Stericycle was in the process of coming into compliance with the Clean Air Amendments (CAA) of 1990 (Title V), as these standards apply to medical waste incinerators. As a result of this compliance activity, part of their waste stream was being diverted to another medical waste treatment facility. This audit led to another site visit.

The following documents were obtained from Stericycle: water permit, air and solid waste permits and the insurance liability statement. Each document was reviewed and evaluated for compliance. Other than the Clean Air Amendments (CAA), Stericycle was in compliance with other requirements. Stericycle sends a monthly departmental summary and a detailed report of the biowaste shipped from WFUHS and processed at Stericycle. These reports are reviewed and the amount of biowaste generated is calculated monthly.

Recently, an internal audit was performed on *The Biowaste Program*. The report has not been issued at this point.

## **CONCLUSION**

By using a team approach to develop a biowaste management plan, opportunities for participation, user input and acceptance or “buy-in” were provided. Improvements made by implementing a biowaste program included: a written autoclave procedure, tracking of biowaste and the storage of biowaste.

As the program implementation unfolded, the following areas for improvement were identified: manifest retention procedures, staff training and periodic program review.

Periodically, environmental programs must be reviewed and updated to ensure compliance with new and current regulations and internal procedures. After

reviewing the existing biowaste documents, discrepancies were found in both documents. These discrepancies lead to a review of requirements of pertinent agencies, requirements of the biowaste vendor and the needs of the internal generator. The result was the development and implementation of a single, cohesive biowaste management plan.

## REFERENCES

Water and Sewerage System Policy Resolutions City of Winston-Salem, North Carolina Codified through Resolution of March 8, 2004, (Supplement No. 14), <http://livepublish.municode.com/16/lpext.dll?f=templates&fn=main-hit-j.htm&2.0>

Solid Waste Disposal Policy Resolution City of Winston-Salem, North Carolina Codified through Resolution of March 8, 2004. (Supplement No. 4), [http://library.municode.com/gateway.dll/NC/north%20carolina/7599/7600?f=templates&fn=default.htm&npusername=13132&nppassword=MCC&npac\\_credentials\\_present=true&vid=default](http://library.municode.com/gateway.dll/NC/north%20carolina/7599/7600?f=templates&fn=default.htm&npusername=13132&nppassword=MCC&npac_credentials_present=true&vid=default)

North Carolina Department of Environment and Natural Resources, Section 1200, Medical Waste, <http://www.wastenotnc.org/SWHOME/12RUL.htm>

OSHA Bloodborne Pathogen Standard, 1910.1030, [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p\\_id=10051](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051)

Environmental Protection Agency (EPA) Resource Conservations Recovery Act (RCRA) 40 CFR 261 Subpart D, Identification and Listing of Hazardous Waste. (<http://frwebgate2.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=87109476847+7+0+0&WAISSaction=retrieve>)

Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4<sup>th</sup> Edition, Center for Disease Control and Prevention, U.S. Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health, Fourth Edition, May 1999, US Government Printing Office, Washington: 1999, <http://www.cdc.gov/od/ohs/biosfty/bmb4/bmb4toc.htm>

NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), April 2002, [http://www4.od.nih.gov/oba/rac/guidelines\\_02/NIH\\_Guidelines\\_Apr\\_02.htm](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm)

Center for Disease Control and Prevention, U.S. Department of Health and Human Services, Title 42, Section 71.543, Nonhuman Primates, [http://a257.g.akamaitech.net/7/257/2422/05dec20031700/edocket.access.gpo.gov/cfr\\_2003/octqtr/42cfr71.53.htm](http://a257.g.akamaitech.net/7/257/2422/05dec20031700/edocket.access.gpo.gov/cfr_2003/octqtr/42cfr71.53.htm)

Department of Transportation 49 CFR Part 173.197, Shippers General Requirements for Shipments and Packagings, Regulated Medical Waste, [http://a257.g.akamaitech.net/7/257/2422/05dec20031700/edocket.access.gpo.gov/cfr\\_2003/octqtr/49cfr173.197.htm](http://a257.g.akamaitech.net/7/257/2422/05dec20031700/edocket.access.gpo.gov/cfr_2003/octqtr/49cfr173.197.htm)

