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Department SECTION OF HEALTH FACILITY SERVICES AND SYSTEMS

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ACT 41 of 1992

Intended
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CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance With Act 434 of 1967 As Amended.

Charles McGrew/skj
SIGNATURE

Charles McGrew
Director, Section of Health Facility Services & Systems

TITLE

8-4-92

DATE

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RULES AND REGULATIONS
PERTAINING TO

WILLIAM M. MOOREHEAD
GOVERNOR OF STATE
LITTLE ROCK, ARKANSAS

THE MANAGEMENT OF
REGULATED MEDICAL WASTE FROM HEALTH CARE
RELATED FACILITIES

Promulgated Under the Authority of

Act 96 of 1913
as amended, and
Act 41 of 1992

ARKANSAS DEPARTMENT OF HEALTH

LITTLE ROCK, AR

July 28, 1992

RULES AND REGULATIONS PERTAINING TO
THE MANAGEMENT OF REGULATED MEDICAL WASTE FROM HEALTH CARE RELATED FACILITIES

Section I - AUTHORITY

These Rules and Regulations pertaining to the definition, segregation, treatment, packaging, labeling, storage, transport and disposal of regulated medical waste from health care related facilities are hereby promulgated pursuant to the authority conferred by Act 96 of 1913, as amended, the same being A.C.A. 20-7-109 and Act 41 of 1992. These Rules and Regulations are in consonance with the Occupational Safety and Health Administration Standard 29 CFR Part 1910. 1030; Friday, December 6, 1991, "Occupational Exposure to Bloodborne Pathogens."

Section II - PURPOSE

The purpose of these sections is to provide a definition of regulated medical waste from health care related facilities, identify entities that are subject to provisions of these sections and to establish criteria for proper management of such waste materials in order to protect public health. The disposal of chemical and radioactive wastes is not included since the proper disposal of these items is governed by other regulations.

Section III - DEFINITIONS

- A. Commercial regulated medical waste - any regulated medical waste transported for profit from a generator to an off-site facility for treatment and/or disposal, and such off-site treatment and/or disposal facility is operated for profit.
- AA. A commercial disposer is an entity that receives regulated medical waste from various sources for treatment and disposal for a profit.
- B. Department - The Arkansas Department of Health
- C. Disposal - The final place of rest of regulated medical waste or the residue remaining after treatment of regulated medical waste.
- D. Facility - all contiguous land and structures, other appurtenances, and improvements on the land, used for treating, destroying, storing, or disposing of regulated medical waste. A facility may consist of several treatment, destruction, storage, or disposal operational units.
- E. Generator - any person or source institution producing regulated medical waste as defined in these sections.
- F. Labeling - to write on or affix a label to a regulated medical waste package that is water resistant, legible and readily visible.
- G. Off-site - any facility which is not on site.
- H. On-site - a facility on the same or adjacent property with adjacent meaning real property within four hundred (400) yards from the property boundary of the existing facility.

- I. Packaging – containing of regulated medical waste in disposable or reusable containers in such a manner as to prevent exposure to the waste material.
- J. Person – any individual, partnership, company, corporation, association, firm, organization, Federal and State government, or any other group of individuals, or any officer or employee thereof.
- K. Regulated Waste – means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

The term "regulated waste" refers to the following categories of waste which require special handling, at a minimum.

- 1. Pathological waste – all human unfixed tissues, organs and anatomical parts (other than intact skin) which emanate from surgery, obstetrical procedures, dental procedures, autopsy and laboratory. Such waste shall be exclusive of bulk formaldehyde and other preservative agents.
- 2. Liquid or semiliquid blood such as human blood, human blood components and products (e.g., serum, plasma) made from human blood and other potentially infectious materials, to include regulated human body fluids such as semen, vaginal secretions, cerebrospinal fluid, pleural fluid, pericardial fluid, synovial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood and all body fluid where it is difficult or impossible to differentiate between body fluids.
- 3. Contaminated items, to include dressings, bandages, packings, gauze, sponges, wipes, cotton rolls and balls, etc., which cannot be laundered or that would release blood or regulated body fluids in a liquid or semi-liquid state if compressed or that are caked with dried blood or regulated body fluids and are capable of releasing these materials during handling.

All patient care items from hospital isolation rooms and end-stage renal dialysis units, or from patients with communicable diseases, which cannot be laundered and which are contaminated with regulated body fluids or blood or potentially infectious material, must be considered a contaminated item.
- 4. Microbiological waste – includes, but is not limited to, cells and tissue cultures, culture medium or other solutions and stocks of infectious agents, organ cultures, culture dishes, devices used to transfer, inoculate and mix cultures, paper and cloth which has come in contact with specimens or cultures and discarded live vaccines.

- 5. Contaminated sharps – any contaminated object that can penetrate the skin, e.g., needles, scalpels, broken glass, broken capillary tubes, dental wires. (Breakable container of blood, regulated body fluid, microbiological waste, or infectious material must be treated as contaminated sharps.)
- L. Reprocessing – the handling of regulated medical waste at the generating facility after its segregation by the procedures of treatment, packaging, labeling, storing, transporting and disposal.
- M. Segregation – the separation of regulated medical waste from other routine regular waste at the time waste is generated within the generating facility.
- N. Storage – the containment of regulated medical waste in such a manner as not to constitute disposal.
- O. Transport – the movement of regulated medical waste from the point of generation to any intermediate points and finally to the point of ultimate disposal.
- P. Treatment – any method, technique, or process designed to change the character or composition of any regulated medical waste so as to either neutralize such waste or to render it potentially noninfectious.

Section IV – APPLICATION

All requirements of these sections shall apply, without regard to the quantity of regulated medical waste produced per month, to any person generating regulated medical waste, to include but not be limited to, the following health care related facilities:

- A. ambulatory surgical centers;
- B. abortion clinics;
- C. birthing centers;
- D. blood banks and blood drawing centers;
- E. clinics, including but not limited to, medical, dental and veterinary;
- F. educational institution health centers and research facilities;
- G. emergency medical services and minor emergency centers;
- H. employee health clinics;
- I. funeral establishments;
- J. health maintenance organizations;
- K. home health agencies;
- L. hospices;
- M. hospitals;
- N. laboratories, including but not limited to clinical, diagnostic, pathological, veterinary and biomedical research;
- O. long term care facilities;
- P. mental health and mental retardation facilities;
- Q. pharmacies;
- R. pharmaceutical manufacturing plants and research facilities;
- S. professional offices, including but not limited to, the offices of physicians, dentists and veterinarians;

- T. public health units;
- U. renal dialysis centers; and
- V. special residential care facilities.

Section V – EXEMPTIONS

These sections do not apply to waste generated by the operation of the following entities:

- A. single or multi-family dwellings; and
- B. hotels, motels or other accommodations which provide lodging for the public.

Home Health personnel, physicians and dentists treating patients in the home often generate infectious medical waste during their visit or waste is generated as a result of their prescribing treatment and medication which occurs during their absence.

It is the responsibility of the health care provider to instruct the patient and family members in the proper disposal of infectious waste generated during their absence. Particular attention should be given to infectious wastes from patients with highly infectious conditions and/or with multiple resistant organisms, to include but not limited to, methicillin resistant Staphylococcus infections, hepatitis B, hepatitis C, HIV, etc. Health care providers are required to disinfect such wastes when they are present in the home and should properly instruct household members concerning the treatment and disposal of infectious waste items from all type of patient during their absence.

Rigid leak proof containers should be available for the disposal of sharps which should be chemically disinfected before disposal as regular waste.

Section VI – SEGREGATION, TREATMENT, PACKAGING, LABELING, STORAGE, TRANSPORTING AND DISPOSAL OF REGULATED MEDICAL WASTE

THIS SECTION IS APPLICABLE AS REQUIREMENTS FOR GENERATORS

- A. Segregation of regulated medical waste
 - 1. Regulated medical waste must be segregated from other regular wastes at the point of its generation in the producing facility.
 - 2. Segregation of regulated medical waste must be made into containers (paper or plastic bags, metal or plastic rigid containers) which are in compliance with the OSHA standard (Section I) and may then be utilized in satisfaction of these Rules and Regulations.
- B. Treatment of regulated medical waste shall be by one of the following methods:
 - 1. Incineration – burning of waste in conformance with the standards prescribed by the Arkansas Department of Pollution Control and Ecology (ADPC&E). A permit must be obtained from ADPC&E to operate an incinerator in compliance with all functional and operational requirements of the ADPC&E.

Inspections of incinerators shall be conducted by ADPC&E in compliance with the Air Pollution Control Act, Act 472 of 1949; ACA 8-4-103 "Penalties" and 8-4-310 "Unlawful Actions."

2. Sterilization Technology - procedure utilized must be performed properly to be effective and the adequacy of sterilization cycles must be verified by the periodic use of biological monitoring (spore-strips). Approved procedures are:
 - a. Steam Under Pressure (Autoclaving) - steam at 248°F (120°C), at 15 psi for 30 minutes.
 - b. Dry Heat - heat at 320°F (160°C) at atmospheric pressure for 2 hours (at effective temperature).
 - c. Chemical vapor - approved chemical mixture at 260°F (127°C) at 20 psi for 30 minutes.
 - d. Ethylene Oxide - 4 to 5 hour cycle using 11-12% ethylene oxide.
3. Disinfection
 - a. Technology - procedure must be performed properly and the adequacy of disinfection verified by biological monitoring (spore-strips). Approved procedures are:
 - 1) Steam-Microwave
 - 2) Steam-Dielectric Energy
 - b. Chemical - the use of a chemical agent to significantly reduce microbial activity. One part household bleach to ninety-nine parts water (1:100 dilution) for 10 minutes or other EPA-approved chemical disinfectant or sterilant may be used according to manufacturer's directions. Excess liquid should be drained prior to disposal.
4. Discharge into the collection system of a publicly owned treatment works (POTW) - grinding and/or flushing of waste into a POTW within the generating facility, except as prohibited by the department or the superintendent/manager of the POTW.
5. Encapsulation - complete encapsulation of the contents of a container of regulated medical waste in a solid matrix (e.g. plaster) which will significantly reduce the possibility of exposure.
6. Other available technology - technology other than listed above and available after the effective date of these Rules and Regulations shall be evaluated by the department and approved by the Board of Health.

C. Packaging and Labeling

1. Regulated medical waste, except for sharps capable of cutting or puncturing, shall be contained for reprocessing at the site of generation in disposable plastic bags which are impervious to moisture and have a strength sufficient to preclude ripping, tearing, or bursting under normal conditions of usage. Full bags shall be securely closed (tied, fastened, taped) so as to prevent leakage or loss of solid or liquid wastes.
2. Contaminated sharps shall be packaged for reprocessing at the site of generation in containers that are leakproof on the bottom and sides, ridged and puncture resistant.

If body fluids are present in the container whether free or in other breakable containers it must be sealed to prevent leakage during transport.

3. All bags and containers used for packaging, treatment and disposal of regulated medical waste shall be either red or orange-red in color or conspicuously labeled as required in Section VI, C4. Rigid containers of contaminated sharps shall be colored or labeled in the same way.
4.
 - a. Effective October 1, 1994, U.S. Department of Transportation regulations will require infectious medical waste to be prominently labeled with lettering indicating "Infectious/Substance Medical Waste" and contain the universal biohazard symbol. The label shall be fluorescent orange or orange red or red on a white background. The label must also state "in case of damage or leakage immediately notify public health authority. In U.S.A., notify Director of C.D.C., Atlanta, Georgia, (404) 633-5313."
 - b. Prior to October 1, 1994, identification of infectious medical waste may be as follows: Each package shall be prominently labelled with lettering indicating "Regulated Medical Waste" or "Biohazardous Waste" or "Infectious Waste" or the universal biohazard symbol. The label shall be fluorescent orange or orange red or red with lettering or symbols in a contrasting color.



- c. When treated or untreated regulated medical waste leaves the facility where it was generated, it must also state on the label the name and address of the generator and state whether the waste is treated or untreated. The label must be water resistant and legible.

- d. Treated regulated medical waste cannot be disposed in a sanitary landfill if in a red or orange-red container. It must be further over-packed in a different color container (e.g., brown paper, green or black or brown plastic bag), then, labeled treated infectious medical waste and the name and address of the generator.

D. Storage

1. Regulated medical waste packaged in disposable containers as described in Section VI, C, shall be placed for storage or transport in disposable or reusable pails, cartons, drums, dumpsters or portable bins. Reusable systems shall be leakproof, have tight-fitting covers and be kept clean and in good repair. Disposable systems shall be leakproof and sealed for storage prior to transport or disposal. The containers shall be of any color and shall be conspicuously labeled as required in Section VI, C4.
2. Storage of regulated medical waste shall be in a manner and location which affords protection from, unauthorized entry, animals, rain and wind, does not provide a breeding place or food source for insects and rodents, and minimizes exposure.
3. Storage time within the generating facility should be kept at a minimum. If is necessary to hold regulated medical waste, it must be held at room temperature in a secure location with limited access as specified in Section VI, D2.

E. Transport

1. The generator of regulated medical waste may transport such waste to an off-site treatment or disposal facility in a leakproof, fully enclosed container, as required in Section VI, D1, within a vehicle compartment. (See Section VI.I.)
2. For transport purposes, the generator shall transfer custody of untreated regulated medical waste only to a transporter who is registered as a regulated medical waste transporter by the department as required in Section VII, C.
3. The generator of regulated medical waste shall maintain a log of all untreated waste that is transported by a registered transporter for treatment and disposal. The log must include a description of the waste, its quantity, the date and the name of the registered transporter.

F. Disposal of regulated medical waste shall be by one of the following methods:

1. Disposition in a sanitary landfill - disposition in a sanitary landfill in accordance with the most current Solid Waste Management Codes of ADPC&E. Material considered as regulated medical waste in Section III must be treated as in Section VIB and, where applicable (i.e., not B1 or B4), packaged and labeled as in Section VI, C, prior to landfilling.

2. Discharge from the health care related facility into a POTW.
 3. Interment - the disposition of pathological waste by burial or cremation.
 4. Other available technology - if approved by the Board of Health as meeting the intent of these regulations.
- G. Table 1 describes which methods are approved for treatment and disposal of each specific category of regulated medical waste.
Note: Not all methods of treatment and disposal are approved for all categories of regulated medical waste.
- H. If the generator of regulated medical waste has treated the waste by an accepted method and if it is packaged and labeled as in Section VI, C1-4, then it may be included in the normal regular waste stream of the facility. Sanitary landfills are not allowed to accept liquids for disposal.
- I. A health care related facility with an ADPC&E permit for incinerator operation may accept regulated medical waste for treatment/disposal by incineration from a generator of another health care related facility only on a non-commercial, not-for-profit and cost-only basis.
- J. Treated regulated medical waste that has been disinfected and rendered unrecognizable is not required to have special packaging or labelling when transported to landfills or other destinations.

Section VII - REQUIREMENTS FOR TRANSPORTERS OF COMMERCIAL REGULATED MEDICAL WASTE

- A. The transporter shall deliver commercial regulated medical waste for treatment or disposal only to a facility that is registered as a regulated medical waste treatment, storage or disposal facility by the department as required in Section VIII, A.
- B. No person may transport commercial regulated medical waste for a generator, other than the generator itself, without first obtaining a permit from the department. The transporter shall submit each of the following:
1. A medical waste transporter permit from the Highway Department.
 2. An application fee of two hundred fifty dollars (\$250.00) to accompany the request for Health Department permit.
 - a. Upon issuance of the permit, the transporter shall pay a fee of no more than five (\$5.00) per ton hauled.
 - b. The department shall issue permits for a period of one (1) year.

- c. If the transporter has a history of non-compliance with any law or regulation of this state or any other jurisdiction, particularly those laws or regulations pertaining to the environment and the protection of the health and safety of the public, the department may refuse to issue a permit.

If a history of non-compliance is discovered after the permit has been issued, the department may revoke the permit.

3. A completed and signed application for permit on forms provided by the department. These forms shall contain the following:
 - a. A statement certifying that the registrant understands and will comply with the applicable requirements of this section;
 - b. A list of all vehicles and containers to be used by the registrant for transporting regulated medical waste, and
 - c. A copy of the registrant's insurance company certificate of coverage of liability due to accidents, etc.
 - d. A statement that transporting vehicles shall be marked with letters 4" tall either as Regulated Medical Waste or with the universal biohazard symbol.



4. An operation plan for the handling and transport of commercial regulated medical waste. The operation plan shall include the following:
 - a. A method of handling regulated medical waste separately from other waste which prevents unauthorized persons from having access to or contact with the waste.
 - b. A method of loading and unloading of regulated medical waste which limits the number of persons handling the wastes and minimizes the possibility of exposure of employees and the public to regulated medical waste.
 - c. A method of decontaminating emptied reusable regulated medical waste containers, transport vehicles or facility equipment which are known or believed to be contaminated with regulated medical waste.
 - d. The provision and required use of personal protective equipment for persons manually loading or unloading containers of regulated medical waste on or from transport vehicles. Soiled protective gear shall be disposed of at the facility or decontaminated.

- e. Means of decontamination of any person having had bodily contact with regulated medical waste while transporting the waste to the treatment or disposal site or while handling or disposing of the waste at the site.
- 5. A statement of assurance that each truck, trailer, semitrailer, vacuum tank, cargo tank or container used for transporting regulated medical waste shall be designed and constructed, and its contents so limited, that under conditions incident to transportation, there shall be no release of regulated medical waste to the environment.
- 6. Proof of bonding in a sufficient amount to cover accidents and other non-conformances.
- C. Transporters will keep a log of their daily pick-ups of regulated medical waste. The log will show the generator, date, quantity (e.g., size of container), type of waste and the delivery point. Manifests (e.g., tracking document) will also accompany each shipment. Log records and manifests will be kept on record for 2 years and will be subject to inspection as deemed necessary.
- D. Transporter personnel will be properly trained in identification and handling regulated medical waste for their own protection and others. They must be familiar with the Rules and Regulations in force in the state. Management has the responsibility for proper training. Training will include protective measures to be taken to prevent disease transmission. All training programs and training frequency must be approved by the department.

Section VIII – REQUIREMENTS FOR COMMERCIAL REGULATED MEDICAL WASTE TREATMENT, STORAGE AND DISPOSAL FACILITIES

- A. Any person operating a commercial regulated medical waste treatment, storage or disposal facility, not to include a POTW, shall register with the Department by submitting each of the following:
 - 1. A completed and signed registration on forms provided by the Department. These forms shall contain the following:
 - a. A statement certifying that the registrant understands and will comply with the applicable requirements of this chapter, and
 - b. Proof of any appropriate permits as required by ADPC&E or other State or Federal agencies.
 - c. Proof of bonding in ssufficient amounts to cover accidents and other non-conformance.
 - 2. An operation plan for the handling and disposal of regulated medical waste. The operation plan shall include the following:

- a. A method of receiving wastes which ensures that regulated medical waste is handled separately from other waste until treatment or disposal is accomplished and which prevents unauthorized persons from having access to or contact with the waste.
 - b. A method of unloading and processing of regulated medical waste which limits the number of persons handling the waste and minimizes the possibility of exposure of employees to the waste and the public using or visiting the facility.
 - c. A method of decontaminating emptied reusable regulated medical waste containers, transport vehicles or facility equipment which are known or believed to be contaminated with regulated medical waste.
 - d. The provision and required use of personal protective equipment to provide protection of employees against exposure to regulated medical waste. Soiled protective gear shall be disposed of at the facility or decontaminated.
 - e. Means of decontamination of any person having had bodily contact with regulated medical waste while transporting the waste to the treatment or disposal site or while handling or disposing of the waste at the site.
3. The disposal unit is required to maintain a log of regulated medical waste received by: truck name, number, date, the type of regulated medical waste and the quantity received. Copies of the manifests showing as a minimum the same information will be kept on file for at least 2 years.
- B. Disposal personnel will be properly trained by management. They must be familiar with the regulated medical waste Rules and Regulations and understand proper storage, handling and disposal procedures. Training will include protective measures to be taken to prevent disease transmission. All training programs and training frequency must be approved by the Department.

Section IX - RESPONSIBILITY

Any person generating regulated medical waste, or registering with the Department as a commercial regulated medical waste transporter or a commercial regulated medical waste treatment, storage and disposal facility, shall be responsible for compliance with these Rules and Regulations and all other State and local laws.

1. a. Any generator, transporter or disposer who illegally dumps regulated medical waste in landfills, rivers, vacant lots, etc., is guilty of a felony, under the Arkansas Department of Pollution Control and Ecology Litter Control Act 883 of 1977 "Unlawful to Litter," A.C.A. 8-6-406 and "Penalties," A.C.A. 8-6-404.

- b. When the Department (Division of Health Facility Services) is notified of the presence and location of illegally dumped regulated medical waste, inspection will be made in an effort to determine the generator or transporter responsible for the dumping.

If the offender is identified, it will be the offender's responsibility to clean up the area and properly dispose of the waste.

In instances where responsibility cannot be fixed, Department representatives will be responsible for arranging that properly trained personnel clean up the area.

2.
 - a. Any person who violates any provision of this act shall be guilty of a felony. Upon conviction, that person shall be subject to imprisonment for not more than one (1) year or a fine of not more than twenty-five thousand dollars (\$25,000) or both.
 - b. In addition, any person who violates any provision of this act may be subject to a civil penalty by the Board of Health. The penalty shall not exceed ten thousand dollars (\$10,000) for each violation.
 3. The Arkansas State Police and the enforcement officers of the Arkansas Highway Policy Division of the Arkansas State Highway and Transportation Department are authorized to stop vehicles suspected of transporting commercial regulated medical waste to assure that all required permits for transporting the commercial regulated medical waste have been obtained and to enforce all laws and regulations relating to the transportation of commercial regulated medical waste.

NOTE: Transporters and disposers of commercial regulated medical waste must register with THE DIVISION OF HEALTH FACILITY SERVICES, ARKANSAS DEPARTMENT OF HEALTH, 4815 WEST MARKHAM, LITTLE ROCK, AR 72205 - PHONE (501) 661-2201.

TABLE 1

METHODS FOR TREATMENT AND DISPOSAL OF REGULATED MEDICAL WASTE

Any one of the treatment methods listed for a given type of waste may be used; however, a disposal method is generally dependent on the treatment method used.

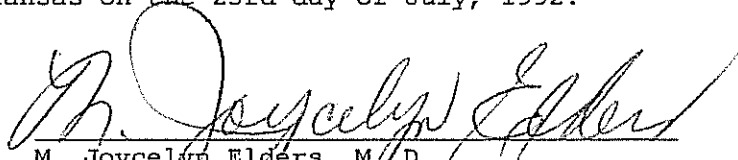
METHODS FOR TREATMENT

Type of Regulated Medical Waste	Incineration	Sterilization	Disinfection Tech. or Chem.	Discharge To POTW	Encapsulation	Other (Treatment By Disposal)
(1) <u>PATHOLOGICAL WASTES</u>						
(a) Material from surgical, obstetric, dental, autopsy and laboratory procedures						
(i) Body parts, bones	A					C
(ii) Teeth	A				A	C
(iii) Tissues, fetuses, organs	A					C
(b) Laboratory specimens - blood and tissue	A	A, B		B		B
(c) Spontaneous human abortion products	A					C
(d) Anatomical human remains	C					C
(2) <u>LIQUID/SEMI-LIQUID BLOOD</u>						
Blood, blood components and products; regulated body fluids	A	A, B	B	B	B	B
(3) <u>CONTAMINATED ITEMS</u>						
Sponges, cotton rolls, gloves, dressings, wraps	A	A	A			
(4) <u>MICROBIOLOGICAL WASTES</u>						
Cells and tissue cultures, stocks of infectious agents	A	A	A	A		
(5) <u>CONTAMINATED SHARPS</u>						
Needles, scalpels, broken glass, breakable containers	A	A	A	A	A	

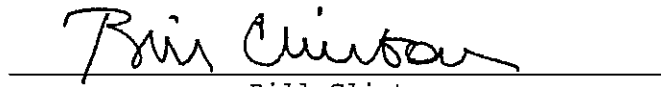
METHODS FOR DISPOSAL

- A. Managed in such a manner that final disposition shall be a sanitary landfill in accordance with the most current ADPC&E Solid Waste Management Codes.
- B. Discharge at the health care related facility into a POTW.
- C. Interment in accordance with mortuary regulations and may involve cremation service.

This is to certify that the foregoing Rules and Regulations Pertaining To The Management Of Regulated Medical Waste From Health Care Related Facilities were adopted by the Arkansas State Board of Health at a regular session of said Board held in Little Rock, Arkansas on the 23rd day of July, 1992.


M. Joycelyn Elders, M. D.
Secretary of Arkansas State Board of Health
Director, Arkansas Department of Health

The foregoing Rules and Regulations, copy having been filed in my office, are hereby approved on this 8th day of August, 1992.


Bill Clinton
Governor