promulgation of regulations establishing the demonstration program under this subchapter, and the Administrator shall determine whether to include the State within 30 days after receipt of the State's petition.

(d) Expiration of demonstration program

The demonstration program shall expire on the date 24 months after the effective date of the regulations under this subchapter.

(Pub. L. 89–272, title II, § 11001, as added Pub. L. 100–582, § 2(a), Nov. 1, 1988, 102 Stat. 2950.)

§ 6992a. Listing of medical wastes

(a) List

Not later than 6 months after November 1, 1988, the Administrator shall promulgate regulations listing the types of medical waste to be tracked under the demonstration program. Except as provided in subsection (b) of this section, such list shall include, but need not be limited to, each of the following types of solid waste:

(1) Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.

(2) Pathological wastes, including tissues, organs, and body parts that are removed during surgery or autopsy.

(3) Waste human blood and products of blood, including serum, plasma, and other blood components.

(4) Sharps that have been used in patient care or in medical, research, or industrial laboratories, including hypodermic needles, syringes, pasteur pipettes, broken glass, and scalpel blades.

(5) Contaminated animal carcasses, body parts, and bedding of animals that were exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals.

(6) Wastes from surgery or autopsy that were in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves.

(7) Laboratory wastes from medical, pathological, pharmaceutical, or other research, commercial, or industrial laboratories that were in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats, and aprons.

(8) Dialysis wastes that were in contact with the blood of patients undergoing hemodialysis, including contaminated disposable equipment and supplies such as tubing, filters, disposable sheets, towels, gloves, aprons, and laboratory coats.

(9) Discarded medical equipment and parts that were in contact with infectious agents.

(10) Biological waste and discarded materials contaminated with blood, excretion, excudates[1] or secretion from human beings or animals who are isolated to protect others from communicable diseases.

(11) Such other waste material that results from the administration of medical care to a patient by a health care provider and is found by the Administrator to pose a threat to human health or the environment.

(b) Exclusions from list

The Administrator may exclude from the list under this section any categories or items described in paragraphs (6) through (10) of subsection (a) of this section which he determines do not pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed.

(Pub. L. 89–272, title II, § 11002, as added Pub. L. 100–582, § 2(a), Nov. 1, 1988, 102 Stat. 2951.)

§ 6992b. Tracking of medical waste

(a) Demonstration program

Not later than 6 months after November 1, 1988, the Administrator shall promulgate regulations establishing a program for the tracking of the medical waste listed in section 6992a of this title which is generated in a State subject to the demonstration program. The program shall (1) provide for tracking of the transportation of the waste from the generator to the disposal facility, except that waste that is incinerated need not be tracked after incineration, (2) include a system for providing the generator of the waste with assurance that the waste is received by the disposal facility, (3) use a uniform form for tracking in each of the demonstration States, and (4) include the following requirements:

(A) A requirement for segregation of the waste at the point of generation where practicable.

(B) A requirement for placement of the waste in containers that will protect waste handlers and the public from exposure.

(C) A requirement for appropriate labeling of containers of the waste.

(b) Small quantities

In the program under subsection (a) of this section, the Administrator may establish an exemption for generators of small quantities of medical waste listed under section 6992a of this title, except that the Administrator may not exempt from the program any person who, or facility that, generates 50 pounds or more of such waste in any calendar month.

(c) On-site incinerators

Concurrently with the promulgation of regulations under subsection (a) of this section, the Administrator shall promulgate a recordkeeping and reporting requirement for any generator in a demonstration State of medical waste listed in section 6992a of this title that (1) incinerates medical waste listed in section 6992a of this title on site and (2) does not track such waste under the regulations promulgated under subsection (a) of this section. Such requirement shall require the generator to report to the Administrator on the volume and types of medical waste listed in section 6992a of this title that the generator incinerated on site during the 6 months

[1] So in original. Probably should be ''exudates''.

following the effective date of the requirements of this subsection.

(d) Type of medical waste and types of generators

For each of the requirements of this section, the regulations may vary for different types of medical waste and for different types of medical waste generators.

(Pub. L. 89–272, title II, § 11003, as added Pub. L. 100–582, § 2(a), Nov. 1, 1988, 102 Stat. 2952.)

§ 6992c. Inspections

(a) Requirements for access

For purposes of developing or assisting in the development of any regulation or report under this subchapter or enforcing any provision of this subchapter, any person who generates, stores, treats, transports, disposes of, or otherwise handles or has handled medical waste shall, upon request of any officer, employee, or representative of the Environmental Protection Agency duly designated by the Administrator, furnish information relating to such waste, including any tracking forms required to be maintained under section 6992b of this title, conduct monitoring or testing, and permit such person at all reasonable times to have access to, and to copy, all records relating to such waste. For such purposes, such officers, employees, or representatives are authorized to—

(1) enter at reasonable times any establishment or other place where medical wastes are or have been generated, stored, treated, disposed of, or transported from;

(2) conduct monitoring or testing; and

(3) inspect and obtain samples from any person of any such wastes and samples of any containers or labeling for such wastes.

(b) Procedures

Each inspection under this section shall be commenced and completed with reasonable promptness. If the officer, employee, or representative obtains any samples, prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the sample obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained if giving such an equal portion is feasible. If any analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge of the premises concerned.

(c) Availability to public

The provisions of section 6927(b) of this title shall apply to records, reports, and information obtained under this section in the same manner and to the same extent as such provisions apply to records, reports, and information obtained under section 6927 of this title.

(Pub. L. 89–272, title II, § 11004, as added Pub. L. 100–582, § 2(a), Nov. 1, 1988, 102 Stat. 2952.)

§ 6992d. Enforcement

(a) Compliance orders

(1) Violations

Whenever on the basis of any information the Administrator determines that any person has violated, or is in violation of, any requirement or prohibition in effect under this subchapter (including any requirement or prohibition in effect under regulations under this subchapter) (A) the Administrator may issue an order (i) assessing a civil penalty for any past or current violation, (ii) requiring compliance immediately or within a specified time period, or (iii) both, or (B) the Administrator may commence a civil action in the United States district court in the district in which the violation occurred for appropriate relief, including a temporary or permanent injunction. Any order issued pursuant to this subsection shall state with reasonable specificity the nature of the violation.

(2) Orders assessing penalties

Any penalty assessed in an order under this subsection shall not exceed $25,000 per day of noncompliance for each violation of a requirement or prohibition in effect under this subchapter. In assessing such a penalty, the Administrator shall take into account the seriousness of the violation and any good faith efforts to comply with applicable requirements.

(3) Public hearing

Any order issued under this subsection shall become final unless, not later than 30 days after issuance of the order, the persons named therein request a public hearing. Upon such request, the Administrator shall promptly conduct a public hearing. In connection with any proceeding under this section, the Administrator may issue subpoenas for the production of relevant papers, books, and documents, and may promulgate rules for discovery procedures.

(4) Violation of compliance orders

In the case of an order under this subsection requiring compliance with any requirement of or regulation under this subchapter, if a violator fails to take corrective action within the time specified in an order, the Administrator may assess a civil penalty of not more than $25,000 for each day of continued noncompliance with the order.

(b) Criminal penalties

Any person who—

(1) knowingly violates the requirements of or regulations under this subchapter;

(2) knowingly omits material information or makes any false material statement or representation in any label, record, report, or other document filed, maintained, or used for purposes of compliance with this subchapter or regulations thereunder; or

(3) knowingly generates, stores, treats, transports, disposes of, or otherwise handles any medical waste (whether such activity took place before or takes place after November 1, 1988) and who knowingly destroys, alters, conceals, or fails to file any record, report, or other document required to be maintained or filed for purposes of compliance with this subchapter or regulations thereunder

shall, upon conviction, be subject to a fine of not more than $50,000 for each day of violation, or imprisonment not to exceed 2 years (5 years