to participate. Congress did not establish a "no less stringent" standard for these States. EPA will identify those States that elect to opt out in a later **Federal Register** notice.

3. Other States

States not mentioned above may elect to participate in the demonstration program. The Governor of a State electing to participate must petition EPA by April 24, 1989 to be included on the list of Covered States. The definition of "State" in RCRA section 1004(31) includes the several States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands. EPA interprets the term "Governor" to include the Governor in any of the several States, or the equivalent head of the executive branch of the government for those other governmental entities. The Act specifies that EPA must determine whether to include a petitioning State in the program within 30 days of receipt of the petition (RCRA section 11001(c)). American Samoa has already petitioned to be included in the program, and EPA will make a determination regarding American Samoa and any other petition-in States after the 30 day period.

The Agency is planning to publish the final list of Covered States in the **Federal Register** shortly after the April 24, 1989, opt-out/petition-in deadline.

*D. Subpart D—Regulated Medical Waste*

Section 11002 of RCRA requires EPA to develop and promulgate a list of medical wastes to be tracked under the demonstration program. The statute provides the basic components of the list by identifying five waste types that must be included: (1) Cultures and stocks of infectious agents and associated biologicals; (2) pathological waste; (3) human blood and blood products; (4) used sharps (e.g., syringes, needles, and surgical blades); and (5) contaminated animal carcasses. The statute also identifies five additional waste types that EPA is authorized to exclude from the demonstration program if the Agency determines that mismanagement of such wastes would not pose a substantial threat to human health or the environment; (6) surgery or autopsy waste; (7) laboratory wastes; (8) dialysis wastes; (9) discarded medical equipment; and (10) isolation wastes. The Act also gives EPA authority to add other medical wastes to the list if the Agency determines that such wastes may pose a substantial threat to human health or the environment.

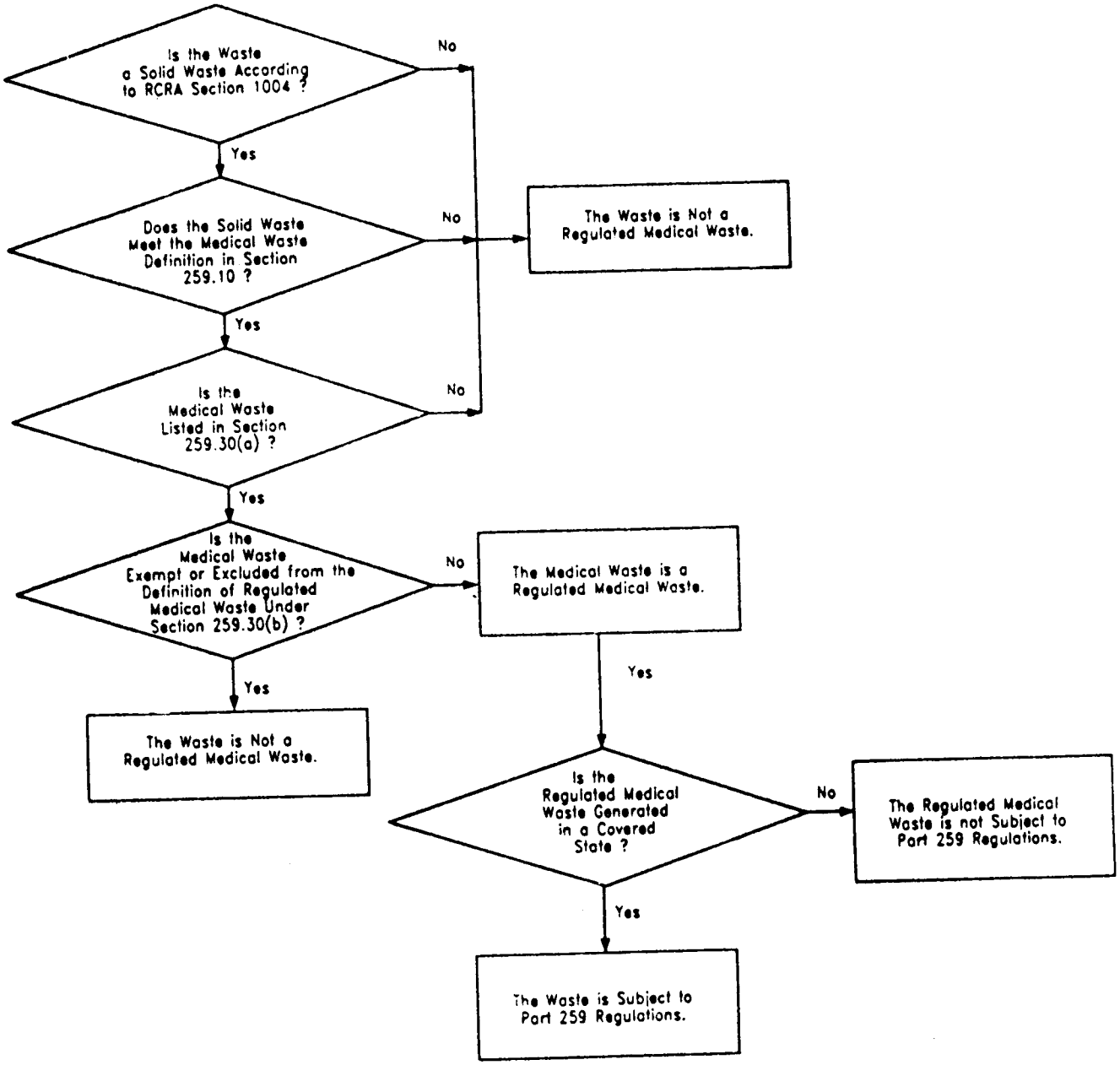
The Act's designation of two different "universes" of medical waste originates, in part, from EPA's *Guide for Infectious Waste Management* (1986). In that document, the Agency identified two universes of medical waste: "infectious" medical waste and "miscellaneous contaminated wastes." The first universe, "infectious" medical wastes, included those wastes listed in the Act as waste types 1, 2, 3, 4, 5, and 10. The Agency, at the time, believed that all of these wastes should be specially managed. The second universe included those wastes listed in the Act as waste types 6, 7, 8, and 9. EPA recognized that, depending on the specific characteristics of the "miscellaneous contaminated wastes," they could be handled appropriately as "infectious" medical wastes or noninfectious medical wastes based on the determination of a responsible infection control practitioner.

Clearly, one of the most controversial aspects of EPA's guidance document has been its inclusion of isolation wastes (waste type 10 in the Act) in the first universe of "infectious" medical wastes. The health care community, medical professionals, and public health officials have strongly criticized this aspect of the guidance document stating that, except under special circumstances, isolation wastes are unlikely to pose a significant hazard to human health or the environment. Thus, EPA believes that Congress, in formulating the statutory list of medical wastes subject to the demonstration program, relied on the basic format of the original waste listing as set forth in the 1986 guidance document (i.e., separating the universe of medical waste into "infectious" and "miscellaneous contaminated waste" categories). However, EPA also believes that Congress concurred with prevailing scientific opinion concerning the relative threat posed by isolation patient waste (listed in the EPA guidance document as an infectious waste category) and designated this as a category that the Administrator may exclude from the demonstration program based on the authority of section 11002(b).

In today's rule, medical wastes to be tracked under the demonstration program are referred to as "regulated medical waste." Regulated medical waste is a subset of medical waste which, in turn, is a subset of "solid waste" as defined in RCRA section 1004. This relationship is illustrated in Figure 1. The term "regulated medical waste" includes the list of medical wastes, as determined by EPA, and certain mixtures of these wastes with other types of wastes. This section of the Preamble discusses the criteria used to define or designate medical waste as "regulated medical waste," explains the content and rationale behind the regulatory listing of regulated medical waste, and describes the conditions under which waste classes may be exempted from regulation.

BILLING CODE 6560-50-M

FIGURE 1
REGULATED MEDICAL WASTE COVERED BY PART 259




BILLING CODE 6560-50-C

1. Definition of Solid Waste

Solid waste, as defined in section 1004 of RCRA, includes discarded solid, liquid, semisolid, or contained gaseous material, among other materials. Specifically excluded from the meaning of the term "solid waste" is domestic sewage, because Congress did not intend for materials that are legally discharged to sewers to be regulated under RCRA. Such discharge is subject to the Clean Water Act and also may be subject to State and local controls. Similarly, materials which health care facilities discharge to sewers flowing to a publicly owned treatment works (POTW) are not "solid waste" and are not subject to the demonstration program. For purposes of the demonstration program, the term "domestic sewage" has the same specific meaning as in the Subtitle C (hazardous waste management) program (i.e., untreated sanitary wastes and other materials which flow through a sewer system to a POTW). See 40 CFR 261.4(a)(1).

2. Definition of Medical Waste

Medical waste is a subset of solid waste. Section 1004(40) of RCRA, as amended by the MWTA, defines medical waste as follows:

Except as otherwise provided in this paragraph, the term "medical waste" means any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste identified or listed under Subtitle C or any household waste as defined in regulations under Subtitle C.

Following is EPA's interpretation of this definition.

a. *General.* EPA interprets "diagnosis, treatment, or immunization" to include waste generated during the provision of medical services such as surgery, dialysis, obstetrical procedures, routine checkups, and health maintenance activities. (Treatment in the statutory definition refers to the provision of patient care; EPA also interprets treatment to mean the preparation of human and animal remains before interment or cremation. Treatment when used in the context of medical waste management means to reduce or eliminate a medical waste's disease-causing potential.) However, EPA does not interpret "medical waste" to include waste generated as a result of activities ancillary to patient care, such as general refuse from administrative offices, or cafeteria waste.

Solid waste generated during "research pertaining to" the diagnosis, treatment, or immunization of humans or animals is "medical waste" if it results from one of the following practices: (1) Diagnosis research—waste generated by facilities engaged in pathology research, the development of diagnostic procedures, and the evaluation of health effects of various pharmaceuticals and chemicals; and (2) Treatment research—waste generated during research pertaining to the treatment of patients and in the evaluation of the effectiveness of such treatment; and (3) Immunization research—waste generated during research pertaining to the development of new or improved vaccines, evaluation of the effectiveness of the vaccines, or in the development and evaluation of immunization techniques. Biotechnology wastes are medical wastes only if the end-product is a biological intended for use in diagnosing, immunizing, or treating humans or animals or in research pertaining to these activities. Solid waste that is generated as a result of biotechnology activities producing microorganisms for pesticide or industrial applications (e.g., mineral extraction, oil recovery, chemical production, and chemical degradation) is not medical waste and is, therefore, not subject to the requirements of the demonstration program.

In summary, EPA interprets the universe of medical waste generators to include, but not be limited to, hospitals, physicians' offices, dental offices, veterinary practices, funeral homes, research laboratories that perform health-related analyses or services, nursing homes, and hospices. However, as discussed later in this section, only a portion of the medical waste generated by these facilities is "regulated medical waste" and thus subject to the demonstration program.

b. *Exclusions.* In developing this definition, Congress determined that both hazardous waste and household waste (as defined under the Subtitle C regulations, 40 CFR 261.4(b)(1)) should not be regulated under the demonstration program and, thus, specifically excluded them from the meaning of medical waste in the statutory definition (section 1004(40) of RCRA). The terms "hazardous waste" and "household waste" have specific meanings in the Subtitle C (hazardous waste management) program (see 40 CFR Part 261). For purposes of the demonstration program, they retain those meanings.

Hazardous waste listed or identified in 40 CFR Part 261 is not "medical waste" but may be subject to Part 259 requirements when mixed with regulated medical waste. EPA interprets the term "hazardous waste identified or listed under Subtitle C" to include any hazardous waste as generated. Accordingly, mixtures of hazardous waste and medical waste are not excluded from the definition of "medical waste" by virtue of the hazardous waste mixture rule (40 CFR 261.3). Under today's regulation, only mixtures of hazardous waste and medical waste that are subject to the Subtitle C manifest requirements are excluded from Part 259 requirements. Mixtures of hazardous waste and medical waste are discussed later in this Preamble section.

Household waste, as defined in the Subtitle C regulations (40 CFR 261.4(b)), is not medical waste, and is not subject to the requirements of the demonstration program. The Agency has stated that the exclusion is limited to waste generated by individuals on the premises of a residence for individuals and composed primarily of materials found in waste generated by consumers in their homes. 49 FR 44978 (November 13, 1984). Thus, if the waste is domestic waste generated at a residence, it is "household waste" and thus excluded from this program.

As a result, the wastes generated by health care providers in private homes where they provide medical services to individuals would be "household waste." Because the household *wastestream* is excluded, the waste generated by the health care provider in private homes would not be subject to the tracking or management requirements even when removed from the home and transported to the physician's place of business.

Although the Agency believes that nursing homes are "residential" in some ways, their primary purpose is the provision of health care services. Because such facilities are primarily for the purpose of providing health care and, like a hospital, the residential aspects are a necessary incident of the health care, and because such facilities are expected to generate amounts and types of medical waste significantly different from waste generated by consumers in their homes, such wastes are not considered "household waste" under § 261.4, and must be managed as regulated medical waste. EPA will be studying the effects of this household waste exclusion as part of its Report to Congress under section 11008, and will consider regulatory and nonregulatory options for dealing with any mismanagement problems associated with such waste.

3. Definition of Regulated Medical Waste

Regulated medical waste is medical waste that has not been specifically excluded in the provisions and is either (a) a listed medical waste, or (b) a mixture of a listed medical waste and a solid waste. EPA has listed seven (7) classes of medical waste that must be tracked under the demonstration program and has described the items included in each class. The regulated items have been grouped by waste class so that generators can easily identify those wastes that are subject to the tracking requirements.

Today's rule requires these substances to be tracked under the demonstration program only if they are waste materials and are being shipped off-site for treatment or disposal. When these substances are being transported from site to site for analysis or as a commercial product (e.g., pathological specimens or blood), they are not subject to the requirements of the demonstration program, as a result of that shipment, because they are not waste materials. However, if these materials become waste and they meet the definition of regulated medical waste, they will be subject to these regulations if generated in a Covered State.

Of the seven (7) waste classes listed below, the first six parallel six (6) of the first 10 waste types identified in section 11002 of the statute. The seventh has been added by EPA under the authority of section 11002(a)(11). The descriptions for each of the first six (6) waste classes presented in Subpart D of today's rule are based on EPA's interpretation of the statute and the authority provided in section 11002(b) and section 11002(a)(11). The remainder of this section discusses each class of regulated medical waste and explains EPA's interpretations regarding the items included in each class. EPA based these descriptions, in part, on discussions held during meetings with various representatives of the health care and solid waste management communities on November 14–16, 1988, and with State representatives on December 19 and 20, 1988.

a. *Class 1—Cultures and stocks.* EPA includes, within this class, those wastes (cultures and stocks of infectious agents) meeting the statutory description of section 11002(a)(1), described below:

> 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.

As guidance in determining what "infectious agents" are, those agents listed in Classes 2 through 4 of the Centers for Disease Control's (CDC's) *Classification of Etiologic Agents on the Basis of Hazard* (July, 1974) would be included. EPA believes that these guidelines are suitable to indicate which medical wastes warrant regulation. Also, EPA has interpreted the term "biological" to mean preparations made from organisms, or from products of their metabolism, intended for use in diagnosing, immunizing, or treating humans or animals, or in research pertaining thereto. See the definition in § 259.10. EPA notes that under the definition of "infectious agents" and "biologicals," agents that cause disease in non-human animals, but not in humans, are not covered under this class, however, agents that cause disease in both humans and non-human animals are covered. The main concern with this class is potential hazard to human health.

Examples of wastes that may fall in this category include cultures of medical specimens, stocks of infectious agents used to produce vaccines, vaccines that are off-specification, culture dishes, and swabs used to inoculate cultures.

b. *Class 2—Pathological wastes.* EPA's regulatory description of Class 2 is based on the language in the section 11002(a)(2) definition, and reads as follows:

> Human pathological wastes, including tissues, organs, body parts, and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.

As described above, the pathological waste class includes wastes of human origin only. Thus, except for those specific animal wastes included in Classes 5 and 6, described below, and except for certain items that meet the conditions of waste Class 1, pathological wastes from veterinary practices are specifically excluded from regulation under this part. As explained previously, the 10 medical waste types listed in the Act are virtually identical to the infectious medical wastes identified in the 1986 EPA Guide for Infectious Waste Management. However, the guidance was intended to include only human pathological wastes, and thus all examples of pathological waste in the guidance are of human origin. Although the statute and legislative history are unclear as to whether Congress intended to include all pathological waste, under this class, EPA believes Congress intended to include the same wastes that were included in the *EPA Guide for Infectious Waste Management.* Thus, EPA interprets the Act to include pathological wastes of human origin only.

While EPA is aware that some arguments can be made that animal pathological wastes should be included in Class 2 (e.g., it may be difficult, in some cases, to distinguish between human and animal pathological wastes), animal wastes that are known to be contaminated and thus potentially harmful to human health are already regulated under waste Class 5. Other animal wastes are regulated under Class 6. For all of the above reasons, the Agency has determined that waste Class 2, pathological waste, should include wastes of human origin only. The Agency requests specific comments on this decision.

EPA has added the phrase, "other medical procedures," to account for pathological wastes generated from procedures not normally considered surgery (e.g., obstetrical procedures). Also being included under this waste class are discarded body fluids and discarded specimens of body fluids and their containers. These are included at the recommendation of health professionals who regard the potential for causing health effects posed by such fluids to be the same as for other pathological wastes.

c. *Class 3—Human blood and blood products.* The regulatory description of Class 3 is based on section 11002(a)(3). Class 3 includes:

> (1) *Liquid* waste human blood; (2) products of blood; (3) *items saturated and/or dripping with human blood;* or (4) *items that were saturated and/or dripping with human blood that are now caked with dried human blood;* including serum, plasma, and other blood components, *and their containers, which were used or intended for use in either patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.*

This waste class covers bulk waste human blood and products derived from blood, such as discarded units of blood and other licensed blood products. EPA has also included in this class the containers used to hold blood (e.g., blood bags and blood vials) because these containers may be contaminated by blood, and thus present the same hazards as the blood itself. In addition, the mismanagement of these containers may result in the type of serious environmental degradation that closed beaches in past summers. The legislative history indicates that the

MWTA was clearly intended to address this type of degradation.

Intravenous bags are being included in this category because they may continue to resemble blood bags even after certain treatment processes. Although intravenous bags may not have come into contact with any pathogenic microorganisms, the aesthetic degradation of the environment caused when they are mismanaged warrants their inclusion in the demonstration tracking program. EPA is using the authority under RCRA section 11002(a)(11) to list these items, and is including these items in this part of the regulation for convenience.

Class 3 also includes items that are saturated and/or dripping with human blood or that were saturated and/or dripping but have since dried. These wastes are aesthetically objectionable and, while they may present low potential for causing adverse health effects, in certain instances they pose a potential health threat if mishandled in the presence of other waste material such as sharps. This concern should only be present if the blood is in liquid form. Items with large quantities of dried blood are not likely to transmit disease. The blood is generally not present in a form (i.e., liquid) likely to pose a significant hazard to the persons handling the waste, but blood-caked items may still cause environmental (aesthetic) degradation, so these items are included in Class 3 as described above.

d. *Class 4—Used Sharps.* EPA's regulatory description of Class 4, used sharps, is based on section 11002 (a)(4), and reads as follows:

> Sharps that have been used in *animal or human* patient care *or treatment* or in medical, research, or industrial laboratories, including hypodermic needles, syringes (*with or without the attached needle*), pasteur pipettes, scalpel blades, *blood vials, test tubes, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of* broken *or unbroken* glassware that were in contact with infectious agents, such as used slides and cover slips.

Sharps, with the exception of certain glassware, as explained below, are universally recognized as requiring stringent regulation under this program, given the unique bio and physical hazards as well as environmental degradation problems associated with used sharps (unused sharps are addressed in a separate class). The statutory waste type description has been modified slightly to clarify that sharps generated in care of both humans and animals are covered. It also includes the word "treatment" to cover sharps generated from the preparation of human and animal remains for burial or cremation. Syringes are included under this class regardless of whether a needle is attached because EPA believes that this interpretation is consistent with the intent of Congress under the Medical Waste Tracking Act to minimize further improper disposal of aesthetically offensive medical wastes in the natural environment. Blood vials and culture dishes, which may also meet the descriptions of Waste Classes 3 and 1, respectively, were included in this class because the packaging requirements for sharps are more protective of waste handlers. Needles with attached tubing are included because of the physical and biohazard that may be present with the needle.

EPA has included in Class 4 certain wastes from RCRA section 11002(a)(7). These wastes are slides and cover slips that were in contact with infectious agents. In general, laboratory glassware that was not in contact with infectious agents does not pose the same kinds of aesthetic concerns as other sharps and is already adequately managed as general refuse. Therefore, only slides and cover slips that were in contact with infectious agents are listed in Class 4.

Finally, because the physical and aesthetic concerns are independent of the nature of medical service provided, EPA interprets Class 4 to cover sharps used in veterinary services as well as human patient care.

e. *Class 5—Animal waste.* EPA's description of Class 5 is based on section 11002(a)(5), and reads as follows:

> Contaminated animal carcasses, body parts, and bedding of animals that were *known to have been* exposed to infectious agents during research (*including research in veterinary hospitals*), production of biologicals, or testing of pharmaceuticals.

Two modifications were made to the statutory language to clarify the wastes included in this class. First, the phrase "known to have been" was added to emphasize that only wastes from animals known to have been exposed to infectious agents during research are regulated medical waste. Without this phrase, it would be difficult for generators to identify accurately those wastes that should be regulated, which would make both compliance with and enforcement of this regulation problematic. This definition does not include household pets, farm animals, or wastes from farm animals unless they were exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals.

The second clarification includes veterinary hospitals as an example of a research facility. This was suggested by attendees at EPA's medical waste meetings, because such facilities may generate contaminated animal waste. Wastes generated by general veterinary practices (e.g., small animals) are not covered in Class 5. However, the reader should note that sharps from veterinary services are covered under Class 4.

As guidance in determining what organisms are "infectious agents", the reader may use those agents identified in Classes 2 through 4 of the CDC's *Classification of Etiologic Agents on the Basis of Hazard* (July, 1974, available in the docket). Because EPA's definition of "infectious agent" in § 259.10 is limited to those organisms that cause disease or adverse health impacts in humans, only animal wastes potentially posing a hazard to *human* health are covered in Class 5.

f. *Class 6—Isolation wastes.* EPA's regulatory description of this class is identical to section 11002(a)(10) in all but one respect, and reads as follows:

> Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from *highly* communicable diseases, or isolated animals *known to be infected with highly* communicable diseases.

Although the statute refers to "communicable diseases" generally, the Agency believes that only certain *highly* communicable diseases should be included in the demonstration program. Health care professionals recommend that the scope of this class be limited to only those specific diseases that are sufficiently communicable to pose a potential threat to public health (for example, diseases caused by those agents listed in Classification 4 by the CDC in *Classification of Etiologic Agents on the Basis of Hazard* (1974)).

The Agency considered regulating all wastes from isolation patients, but concluded that many of the waste items are already covered under other waste classes, and that regulating all wastes from isolation patients would needlessly subject large amounts of waste to handling and packaging according to the requirements of the tracking program even though the large majority of such waste would be neither infectious nor aesthetically objectionable. For example, health care facilities have the option of assessing which isolation wastes, in addition to those required by these regulations, should be managed as regulated medical waste. EPA requests

comments on its approach and recommendations on any alternative approaches.

g. *Class 7—Unused sharps.* Under the authority provided by section 11002(a)(11) of the MWTA, EPA has elected to include the following unused, discarded sharps as a class of regulated medical waste: hypodermic needles, suture needles, syringes, and scalpel blades. The improper disposal of sharps has, in some areas, presented sufficient potential health hazard and environmental degradation for local officials to restrict public access to beaches. When inappropriate appearances of sharps occurs, as in the example of beach wash-ups, it is neither practical nor necessary to try to distinguish used from unused sharps for several reasons. First, both used and unused sharps present the same physical hazard in terms of the potential for puncture injuries. Second, time usually does not allow for the testing of improperly disposed sharps to determine the presence of infectious agents. Additionally, unused sharps present the same possibility of aesthetic degradation of the environment as do used sharps. Given the legislative history indicating serious Congressional concern over environmental degradation caused by sharps, the Agency believes the combination of physical hazards and aesthetic concerns are sufficient reasons to list certain unused sharps as regulated medical waste.

4. Determination To Exclude Certain Waste Types

EPA has made a determination that certain wastes listed in section 11002(a) of RCRA do not pose a substantial present or potential hazard to human health or the environment when improperly managed. EPA made this determination after numerous discussions with public health experts and a thorough review of the available information, including contact with Dr. William Rutala, a researcher who conducts an annual literature review to locate documented cases of disease transmission. EPA has concluded that items in waste types (1)–(5) have some potential to cause harm, and has structured today's rule so that the wastes in sections 11002(a) (6)–(9) which may pose a present or potential threat to human health are regulated medical wastes subject to Part 259 requirements. The remaining wastes (those not included within the waste classes listed in the regulation) do not pose substantial health or environmental hazards. This determination is described in more detail in the *Background Document for Part 259 Subpart D, Listing of Medical Waste,* available in the docket for this rulemaking.

Under section 11002(b) of RCRA, the Administrator is authorized to exempt from the requirements of the demonstration program any of the wastes, by type or by item, listed in sections 11002(a) (6)–(10) of the statute if he determines that such wastes do not pose a substantial present or potential threat to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed. The sections 11002(a) (6)–(9) waste descriptions are based on a waste's source and contain a variety of items. Many of the individual items in sections 11002(a) (6)–(9) are, under certain conditions, already included in the sections 11002 (a) (1)–(5) waste types. For example, surgery wastes such as scalpels and suture needles are already included in section 11002(a)(4), and laboratory wastes such as discarded tissue specimens are already included in section 11002(a)(2). EPA examined the remaining items in sections 11002(a) (6)–(9) that are not identified in section 11002(a) (1)–(5), and has specifically listed in the regulation certain items that may pose a substantial health or environmental hazard. As explained previously, used slides and cover slips (from laboratories) that were in contact with infectious agents are examples of items from sections 11002(a) (6)–(9) that were included in the regulation. Thus, EPA has determined it is not necessary to list sections 11002(a) (6)–(9) specifically in today's rule.

For the remaining wastes included in sections 11002(a) (6) through (9), in comparison to the wastes that Congress mandated to be subject to the tracking program due to their potentially harmful physical properties (e.g., sharps) and/or biological properties (e.g., blood or cultures), the items to be excluded do not exhibit either property sufficiently to warrant inclusion in the demonstration program. (In evaluating the potential for wastes to present an infection hazard, factors such as the presence of a pathogen at its infecting dose, the pathogen's portal of entry to the body, and the host's resistance to infection must be considered.) EPA also conducted a thorough review of available information and consulted with representatives of the Centers for Disease Control, the National Institutes of Health, other health care professionals, and State officials; based on these consultations, EPA did not find evidence that the handling of those remaining wastes included in sections 11002(a) (6) through (9), not already addressed in EPA regulated medical waste Classes 1 through 7, present a substantial hazard to human health or the environment when mismanaged. On this basis, the Agency believes that wastes in sections 11002(a) (6) through (9) that are not already included in the EPA Classes 1 through 7 should not be included in the demonstration program.

In certain instances, EPA recognizes that a health care professional may determine that some wastes in sections 11002(a) (6) through (9) should be handled as infectious wastes based on the professional's experience and knowledge of the waste in light of the specific conditions necessary to transmit disease (presence of a pathogen of sufficient virulence; dose; portal of entry; and resistance of host). In these instances, consistent with the Agency's 1986 guidance document, EPA encourages the health care provider to manage such wastes as regulated medical waste. However, EPA believes that the decision on how to manage such wastes is appropriately made by the generator on a case-by-case basis according to its established infection control procedures.

In summary, as described above, EPA believes that the demonstration program and its tracking requirements are targeted to those wastes that have been improperly managed and on those likely to pose a substantial threat to human health and the environment. If, as a result of the demonstration program and other studies required by the Act, the Agency determines that additional wastes are posing a substantial threat to human health or the environment, EPA may expand the list of regulated medical waste to ensure strict management of problem wastes.

5. Unregulated Medical Wastes

Certain wastes generated in a medical setting or research laboratories that are not covered in the listing of regulated medical waste are not subject to the Part 259 regulations, except for mixtures described below. EPA nonetheless recommends that any waste that an individual practitioner or health care professional believes may pose a risk of disease transmission should be handled as a regulated medical waste.

6. Mixtures

EPA is requiring mixtures of regulated medical waste and other nonhazardous solid waste, including non-regulated medical waste, to be regulated under today's requirements. This requirement is established to prevent parties from avoiding regulation through mixing. Also, the physical and aesthetic

properties that caused Congress' concern over many of these wastes are not removed by mixing and such mixture would be inconsistent with the Congressional mandate that medical wastes be segregated to the extent practicable.

However, mixtures of regulated medical waste with hazardous waste that is subject to the hazardous waste manifest requirements are subject to regulation as hazardous waste, not medical waste (See § 259.31). EPA has determined that when regulated medical waste is mixed with hazardous waste, and the resulting mixture is otherwise subject to the hazardous waste manifesting requirements, it is unnecessary to require an additional tracking form for the medical waste component of the mixture.

7. Exclusions and Exemptions

Section 259.30(b) of today's rule identifies seven provisions under which medical wastes are not subject to the requirements of the demonstration program. This section of the Preamble explains five of those provisions. The provisions for household and hazardous waste exclusions are discussed elsewhere in the Preamble.

a. *Incinerator ash and treatment/destruction residue.* Regulated medical waste that has been both treated, so as to substantially reduce or eliminate its potential for causing disease, and destroyed, is no longer regulated medical waste, but generators who both treat and destroy regulated medical waste on-site are subject to certain recordkeeping requirements under this Part while they conduct the treatment and destruction. In addition, section 11003(a) specifically excludes waste which has been incinerated from the tracking program. In today's regulation, these two types of residues cease to be regulated medical waste at the point where the incineration has been completed, or at the point where both treatment and destruction processes have been conducted.

Processes such as incineration involve reducing or eliminating the biological and physical hazard of the wastes, as well as their visually offensive nature, to the extent that they are no longer likely to pose a substantial threat to human health or the environment in the event of mismanagement. Residues from wastes that have been treated and destroyed (e.g., waste that has been decontaminated and ground up) and incinerator ash are no longer "regulated medical waste" and can be managed under other applicable requirements for such residues. The Agency believes that it is sound policy to encourage treatment to reduce the biologic and physical hazard of regulated medical wastes as early in the waste management chain as possible, thereby minimizing the potential impacts resulting from mismanagement of the waste.

Under § 259.30(b)(1)(iv) the first criterion, treatment, is satisfied if the waste is processed by a means designed to reduce levels of infectious agents. The purpose of this provision is to ensure that the concentration of microorganisms capable of causing disease in humans is reduced so as to render such waste noninfectious or less infectious and, thus, safer to handle, transport, and dispose of. However, waste need not be sterilized. The treatment processes commonly available are not 100% effective in inactivating microorganisms. Complete inactivation is unnecessary, since any refuse is expected to support some level of bacterial activity.

In the context of medical waste management, "treatment" is defined as any method, technique, or process designed to change the biological character or composition of medical waste so as to eliminate or reduce its potential for causing disease. EPA's 1986 guidance document, *EPA Guide for Infectious Waste Management* (U.S. EPA, Office of Solid Waste and Emergency Response, EPA/530-SW-86-014, May 1986), describes many of the techniques available for adequately treating regulated medical waste. As the guidance document explains, incineration and steam sterilization (autoclaving) are the most common treatment methods for medical wastes. There are, however, several other less commonly used treatment methods that are acceptable for certain waste types, such as chemical disinfection, thermal inactivation, and irradiation. Not all of these processes will meet the treat and destroy criteria, but some combinations (e.g., chemical disinfection followed by grinding) may indeed meet both criteria.

EPA strongly encourages operators of treatment devices to become familiar with these guidelines. Further, the Agency recognizes that methods and technologies other than those discussed in the guidance document may be available for treating medical waste and does not want to discourage emerging or innovative technologies. Regardless of the method chosen, the important point is that the operator should understand the factors affecting the effectiveness of the treatment method used and establish a program to ensure that the treatment objectives are met. Specifically, EPA recommends:

i. Using standard operating procedures for each process employed for treating regulated medical waste;

ii. Monitoring all treatment processes to ensure efficient and effective treatment;

iii. Using biological indicators to monitor treatment (other indicators may be used, provided that their effectiveness has been successfully demonstrated); and

iv. Selecting treatment methods appropriate for the waste types being treated.

The lack of an objective treatment standard for determining whether a waste has been disinfected is problematic. Data are not currently available to establish objective standards. A long-term goal of EPA's medical waste program is to evaluate the effectiveness of various treatment alternatives and either to issue additional guidance or promulgate treatment standards. Additionally, generators and treatment facility owners and operators are advised to consult with the waste management agency in their State to determine if additional requirements apply. States may require operating plans or specify operating conditions or monitoring methods.

The second criterion in § 259.30(b)(1)(iv), destruction of the waste, is satisfied when the waste is ruined, torn apart, or mutilated so that it is no longer generally recognizable as medical waste. EPA has determined that when waste has been both treated (substantially removing or reducing any biological hazard) and destroyed, all of the Agency's concerns (i.e., biological and physical hazards, and aesthetic degradation) have been addressed, and tracking of the waste is unnecessary.

Processes capable of destroying medical wastes include incineration, grinding, shredding, crushing, or melting. EPA recognizes that a determination of when a medical waste is "destroyed" is somewhat subjective, but believes this standard is workable in practice for owners or operators of treatment and destruction facilities, and for generators. Moreover, Congress acknowledged the validity of the "rendered unrecognizable" standard, in section 11008(a)(6), with respect to medical waste treatment and the protection of human health and the environment.

One currently used method that meets both conditions involves the combination of chemical disinfection and grinding. Another process that could achieve the same results involves steam sterilization followed by shredding. EPA notes that for grinding processes, "destruction" can generally be assessed

by use of a mesh size determination for the ground particles. The processes currently in use can generally achieve a ½ inch mesh size (i.e., the resulting particles will pass through screening having one-half inch wide openings). This standard is only being used as a guide, however, because no grinding process that EPA is aware of can achieve a ½ inch particle size for 100% of the material.

It should be noted that the exclusion applies to wastes at the point in the waste management chain when the waste has been both treated and destroyed. If wastes are treated and destroyed on-site by the generator, they typically enter the general refuse waste stream directly and are not subject to the substantive requirements of the demonstration tracking program. Regulated medical waste that is shipped off-site for treatment is subject to the requirements of the demonstration program up to the point it is treated and destroyed. After it has been treated and destroyed, it is no longer regulated medical waste.

Finally, EPA has included a requirement for persons claiming that they have caused regulated medical waste to meet the terms of the exclusion to maintain records of the amounts of waste treated and destroyed (and therefore excluded from regulation). The records could be simply a log onto which entries are made on a regular basis (i.e., daily, per batch, etc.). Generators who use on-site incinerators must keep these records under § 259.61, discussed elsewhere in the Preamble, in which case no additional recordkeeping is required. Generators using processes other than incineration are not subject to § 259.61, but, nonetheless, must keep records to qualify for the exclusion under § 259.54(c).

EPA believes such a recordkeeping provision is necessary to ensure the exclusion is not abused by persons who do not track their waste and do not really meet the terms of the exclusion. EPA notes that when a broad remedial scheme is established, such as Subtitle J, the burden of proof should fall on persons claiming any available exclusions or exemptions from that scheme.

b. *Human remains.* The regulation provides that human remains (e.g., corpses and anatomical parts) that are stored, transported, or otherwise managed for purposes of interment or cremation, are not subject to any requirements of this part, because such human remains are not "regulated medical waste". Inclusion of this provision in the regulation is for purposes of clarification.

c. *Etiologic agents.* The Agency recognizes that etiologic agents are being transported interstate between facilities according to regulations set by the U.S. Department of Transportation and the U.S. Department of Health and Human Services. The Agency believes that those existing regulations ensure safe packaging, handling, and transport of these materials and, thus, these materials should be exempt from today's rule. However, when etiologic agents that are regulated medical waste are intended for discard and are not being transported according to DOT and HHS regulations, they are subject to all of the requirements of today's rule.

d. *Enforcement samples.* Samples of regulated medical waste obtained during enforcement procedures by authorized EPA personnel or States using Federal authorities are exempt from the requirements of this Part. These samples, typically small in volume, temporarily taken out of the waste management system for evaluation, and subject to the oversight of government agencies involved in legal proceedings, are unlikely to be mismanaged. However, when such evaluations or legal proceedings are concluded, the sample will again be subject to all of the requirements of today's rule.

8. Relationship to Previous EPA Definition

In addition to providing guidance on waste management practices, the *EPA Guide for Infectious Waste Management* provides a definition of "infectious waste." The recommended definition includes six waste types that should be managed according to the guidelines and four "optional" types that could be managed as either infectious waste or general refuse at the discretion of the generator.

Today's rule does not define infectious waste; rather, it defines those medical wastes that are subject to the requirements of the demonstration program, regardless of infectiousness. Actual or potential infectiousness of a waste is only one criterion the Agency used to determine which wastes must be tracked under this program; physical hazard and potential aesthetic degradation of the environment are also major considerations.

Generators may continue to follow EPA guidelines for waste management within their facilities; however, when regulated medical wastes are generated in Covered States, such wastes are subject to the requirements of the demonstration tracking program described in these provisions. Any suggestions in the *EPA Guide for Infectious Waste Management* that are not completely consistent with the Part 259 requirements would be superseded by today's regulations. Generators in non-Covered States should continue to rely on the *EPA Guide*, and must comply with applicable State and local rules.

In summary, regulated medical waste that has been treated and destroyed is exempt from all but certain recordkeeping requirements under today's rule. The reader should note that waste that is treated, but not destroyed, must be tracked but is subject to certain reduced requirements. (This is discussed later in the Preamble.) Also, generators are required to classify their wastes as "untreated" or "treated" on the tracking form, and transporters must report quantities of such wastes transported. As explained later in the Preamble, EPA will be collecting information to determine changes in treatment practices over the life of the demonstration program.

The Agency welcomes comments on the general definition of regulated medical wastes, on the appropriateness and content of the list of regulated medical wastes, and on the exclusions and exemptions provided. EPA also requests comments or suggestions for a more objective method of determining what constitutes "treated and destroyed."

*E. Subpart E Pre-transport Requirements*

The Act requires EPA to include specific requirements for segregation, packaging, and labeling of medical waste regulated in the demonstration program. As a result, today's rule includes pre-transport requirements for medical waste, including requirements for segregating regulated medical wastes from other types of solid waste (e.g., general refuse, hazardous wastes), separating medical wastes by category (untreated and treated), packaging the medical wastes, and labeling and marking the packaged materials. The requirements of Subpart E generally apply to those regulated medical wastes generated in a Covered State that are transported, or offered for transport, off-site. Wastes that are treated and/or disposed of on-site at a generator's facility are subject only to the general storage requirements of § 259.42. Most of these requirements are applicable to, and must be complied with by, the generator. Several of the requirements may also apply to transporters and treatment facilities (e.g., storage).

Generators must ensure that all medical waste subject to these regulations meets all pre-transport requirements prior to shipment or being