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

offered for shipment off-site, either from the generator's facility or from any intermediate site of treatment and/or storage. Wastes treated on-site prior to being transported off-site for disposal must meet all pre-transport requirements before being shipped off-site. However, as discussed above, medical wastes that are incinerated or otherwise "treated and destroyed" on-site are exempt from these regulations under § 259.30(b)(2). Regulated medical wastes retained on-site prior to incineration or other treatment or disposal processes must be stored in a manner that will prevent unauthorized access to the waste and will keep the waste free of animals and pests. The regulated medical wastes to be incinerated on-site are not subject to any other pre-transport requirements. Incinerator ash is exempt from Part 259 requirements, but must be managed in accordance with applicable Federal, State, or local requirements. Regulated medical wastes that will be incinerated off-site must meet all pre-transport requirements prior to transport.

EPA's intent, in establishing segregation, packaging, labeling, and marking requirements for regulated medical wastes, is to ensure proper containment of the waste and to protect workers, handlers, and the general public from exposure to these materials. EPA intends for all packages containing regulated medical wastes to be labeled and marked and, therefore, easily identified as medical waste. Generator compliance with these rules will alert workers and waste handlers to take necessary precautions when handling or transporting the waste to protect themselves and the environment. As discussed below, the generator's signature on the tracking form is the generator's certification that the waste is packaged, labeled, and marked properly.

1. Segregation Requirements (Section 259.40)

a. *General.* This section requires generators of medical waste to segregate all categories of medical waste, to the extent practicable, prior to transport off-site. EPA believes it is generally necessary to segregate sharps, including sharps containing residual fluids, and fluids in quantities greater than 20 cubic centimeters (cc) from all other medical waste, as well as to segregate these wastes from each other. EPA believes that sharps and fluids pose special problems in waste handling and are best managed if placed in special containers. If not segregated, these items can contaminate other medical waste. Segregating sharps and fluids should increase the integrity and safety of all medical waste packaging and protect those persons handling the waste. Used needles, syringes, and other sharps, including the residual fluids contained therein, must meet more stringent packaging requirements than all other waste. In addition, fluids in quantities greater than 20 cubic centimeters (cc) must meet certain packaging requirements. Other regulated medical waste must be segregated, to the extent practicable, from other waste (e.g., hazardous, radioactive, or general refuse), as well as from sharps and fluids.

b. *Mixing of regulated medical waste.* When regulated medical waste cannot be segregated from other waste (i.e., it is not practicable), the generator must ensure that the waste is packaged and marked according to the applicable packaging requirements. For example, if general refuse is placed in the same container as fluids, then the packaging must meet the requirements for fluids. Further, if "untreated" regulated medical waste is mixed and co-packaged with "treated" regulated medical waste the package must be labeled and identified on the tracking form as "untreated medical waste." The scheme outlined above provides incentives for segregation when it is advantageous for the generator to do so, but still does not preclude co-packaging when the generator determines it to be necessary or appropriate.

2. Packaging Requirements (Section 259.41)

Section 11003 of the MWTA requires that the demonstration program include requirements for packaging medical waste that will protect waste handlers and the public from exposure to the dangers posed by medical waste. Under today's rule, generators must make certain that all medical waste is packaged prior to being transported or offered for transport off-site to ensure the containment of the waste, the protection of workers and waste handlers from exposure to the waste, and the protection of human health and the environment.

Today's rule requires that all regulated medical waste to be managed off-site must be packaged in rigid, leak-resistant packaging. Any number of containers may be used to satisfy the basic performance requirements; for instance the combination of a plastic bag and a rigid cardboard box generally could satisfy the performance standards of "leak-resistance" and "rigid." Although the plastic bags and other containers commonly used for waste collection within the facility are generally able to withstand the stresses of handling and transport within the facility, the Agency believes that additional, rigid containerization is required to ensure integrity of the packaging during transit off-site. The generator must ensure that the § 259.41 packaging requirements are met prior to the waste's being transported off-site. In a hospital setting, this means that wastes could be placed in containers (such as bins) meeting the requirements in a central location, such as a loading area.

The Agency believes that these packaging requirements are an effective way to containerize waste that has been accumulated according to the common established collection and handling practices utilized in the health care setting. Comments submitted by an association representing waste handlers in response to the June 2, 1988 **Federal Register** notice (53 FR 20140) support the requirement for rigid packaging for waste that is transported off-site.

The Agency recognizes that, if the generator decides to double package the waste to meet the requirements, increased handling and disposal costs may result. To increase the options available to the generator and transporter, today's regulations provide for the utilization of reusable containers, such as bins and drums, provided a liner is used or the container is decontaminated prior to reuse.

The Agency has not established special packaging standards for bulk materials (e.g., animal bedding) that are classified as regulated medical waste, since it is uncertain that a need exists for transport of such regulated medical wastes in bulk. The Agency requests comment on whether generators of regulated medical waste foresee the need to provide for bulk transport and any special packaging requirements that might be considered.

Today's rule also specifies special packaging requirements for sharps and fluids. EPA's basic objectives in establishing these packaging requirements are: (a) To ensure that all wastes are properly contained, without leakage or release into the environment; and (b) to provide flexibility in how parties may meet the standards.

The Agency has been requested to establish specific performance standards by some interested parties for specific types of containers (i.e., plastic bags, sharps containers, and boxes) when used for containment of regulated medical waste during transport. However, the Agency believes that it is inappropriate to specify specific performance standards for such

containers, since packaging materials vary extensively in their physical and mechanical properties. For instance, it is quite possible that a 1-mil-thick film of one polymer material will be more puncture, impact, and abrasion resistant than a 2-mil-thick film of a different polymeric material. The physical properties can be affected further by the manufacturing process, such as extrusion and injection molding. The most appropriate manner of determining the suitability of a particular container with respect to its ability to resist puncture, leaking, and/or breaking under individual usage conditions is to subject the container to those conditions. Therefore, in today's rule, the Agency has set general performance standards for packaging of regulated medical waste. EPA requests comment on the appropriateness of these standards. The standards, discussed next, include general requirements for all regulated medical waste, and additional requirements for sharps and fluids.

a. *General packaging requirements.* In all cases, regulated medical waste intended for transport offsite must be placed in a single container or a combination of containers that is rigid and leak resistant. For example, a box, pail, drum, or other container that can be closed or secured to prevent leakage during shipment could satisfy the "rigid" performance standard, and in some cases could satisfy the "leak-resistance" requirement as well. In other cases, a plastic bag used as an inner liner may be necessary to satisfy the "leak-resistance" requirement, or even more protective packaging may be necessary. The rule does not specify the containers' composition or size, thus providing as much flexibility in packaging as possible. If untreated regulated medical waste is packaged in plastic bag(s), the bag(s) must be red in color or display the universal biohazard symbol. The bag(s) must be sufficiently sturdy to prevent tearing or breaking and must be sealed securely to prevent leakage. When treated regulated medical waste, other than sharps and fluids, is packaged in plastic bag(s), it must be packaged similarly to untreated regulated medical waste, except the bag(s) does not need to be labeled. Labeling requirements are discussed in section V.E.5. Reusable containers may be used, as well as containers that can be loaded on pallets and moved by forklift or mechanical means, as long as the handling procedures do not subject the containers to undue mechanical stress or compaction.

b. *Sharps and fluids packaging requirements.* EPA is requiring that all sharps, including those that contain residual fluids, be placed in packaging that is rigid, leak-resistant, and puncture-resistant. If the container(s) cannot be sealed to prevent leakage, it must be placed in a plastic bag or other leak-resistant container that can be sealed to prevent leakage. The intent is to ensure that sharps and associated residual fluids (often blood) are securely contained and the integrity of the packaging is maintained from the time the waste leaves the generator's site until the time the waste is disposed of or is treated and destroyed.

The rule specifies that fluids in quantities greater than 20 cubic centimeters shipped off-site for treatment and/or disposal be packaged in packaging that is rigid, leak-resistant, and break-resistant to guard against spillage. All vessels or containers must be tightly sealed or stoppered to prevent leakage or spillage during transport. Fluids should not be placed in glass containers, since these containers may break during transport or handling. Blood bags and other non-rigid containers of fluids that contain more than 20 cc of fluid are required to be packaged as fluids (see § 259.41(b)(2)), since these items contain quantities of fluid which could be released during waste handling, contaminating other waste and posing a hazard for waste handlers.

Syringes and other containers such as vials and blood bags that contain fluids in quantities of greater than 20 cubic centimeters (cc) may be emptied prior to packaging. EPA has established a fluid residual level of up to 20 cc's that may remain in syringes, tubing, vessels, and containers and still allow the waste to be packaged under the requirements of § 259.41 (a) and (b)(1) only. This 20 cc level has been established based on the State of New Jersey's regulations, as a conservative estimate of the residual volume of fluid that will remain in a container after it has been emptied. The Agency is concerned that attempts to remove all remaining fluids may expose health care workers to additional risk, and such small volumes of fluid should not present any significant potential for contaminating other wastes or waste handlers.

c. *Packaging requirements for oversized medical waste.* EPA has not established specific packaging requirements for "oversized" medical waste as defined in § 259.10. Wastes falling into this category include regulated medical waste too large to be adequately packaged in accordance with the above standards (i.e., the waste will not fit in standard-sized plastic bags or containers). These wastes should be managed to protect the waste handler and public from exposure.

3. Storage Requirements (Section 259.42)

Although an optimal medical waste management plan might involve the same-day collection and treatment of regulated medical waste, many generating facilities are unable to accommodate this management scheme. This is particularly true for parties generating relatively small quantities of regulated medical waste. Thus, regulated medical waste intended for disposal off-site may require storage prior to transport off-site.

The Agency, in referring to on-site storage prior to transport, is referring specifically to that area of the facility where waste is stored or accumulated prior to off-site transport or disposal (or incineration or treatment/destruction on-site). Typically, it is the area within a generator's facility where waste is put into secondary containers, packages are marked and labeled, and where the medical waste tracking form is completed. As explained previously, the Agency is not regulating intermediate accumulation areas, such as the area of the facility where waste is first generated (e.g., patient rooms, operating rooms, laboratories and waste holding areas (areas of the facility where waste is accumulated and temporarily held)) until it is moved to the facility's final on-site storage and packaging area.

The storage requirements in today's rule are also applicable to regulated medical waste during transport and prior to treatment and disposal. These requirements will reduce the potential number of occurrences where the public could be exposed to the waste.

EPA has established limited requirements to provide a minimum standard of safety and to ensure containment of the medical waste under the general authorities of section 11003(a)(4)(A) and (B), which require segregation and proper containment of waste to protect the public from exposure. EPA recognizes that individual States or localities may determine that additional requirements, or more specific requirements, are necessary. EPA is considering developing guidance (e.g., as part of a Model State Program) to aid States in the development of storage standards. Under today's rule, regulated medical waste must be stored in accordance with the following requirements: (a) Regulated medical waste must be stored in a manner and location that maintains

the integrity of the packaging and affords protection from water, rain, and wind; (b) regulated medical waste must be maintained in a nonputrescent state to avoid becoming a nuisance to workers and the public. Refrigeration may be necessary depending on the type of waste stored and the length of the storage period; (c) regulated medical waste can be stored in outside storage areas (e.g., dumpsters, sheds, tractor trailers) only if the areas are locked to prevent unauthorized access; (d) regulated medical waste stored on-site must be contained in a secure, locked area, with access limited to authorized waste handlers and employees in order to prevent exposure to the public; and (e) regulated medical waste must be stored in a manner that affords protection from animals and does not provide a breeding place or a food source for insects and rodents.

EPA believes these are good housekeeping practices which are necessary to maintain proper sanitary conditions and which will protect the public from exposure. Comments are requested on these requirements and on the need for additional requirements.

4. Decontamination Standards for Reusable Containers (Section 259.43)

EPA is promulgating in today's rule general requirements for the decontamination of packaging/shipping containers to allow for their reuse without compromising the safety of waste handlers. Any rigid container which is reused must be decontaminated prior to reuse if the container is visibly contaminated. If, for any reason, a container cannot be decontaminated and rendered free of visible contamination, the container will be considered regulated medical waste and must be handled, treated, and disposed of as such. Inner liners used in conjunction with reusable containers must be disposed of with the regulated medical waste they contain. EPA's goal is to ensure protection of all waste handlers. Therefore, any non-rigid package liners must remain intact and be disposed of with the waste, and may not be reused.

Section 259.43(b) requires containers to be free of any visible signs of contamination prior to reuse. Under § 259.43(c), any container that cannot be rendered free of visible contamination must be managed as regulated medical waste. The Agency is not requiring waste handlers to utilize any specific method to decontaminate containers in these regulations because there was insufficient time to conduct technical studies to determine the effectiveness of various methods. EPA suggests that reusable containers be thoroughly washed and decontaminated each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable inner liners, bags or other packaging devices removed with the waste. Review of State standards indicates that suggested methods of decontamination include, but are not limited to, agitation to remove visible contaminants combined with one of the following procedures: (a) Exposure to hot water of at least 82 °C (180 °F) for a minimum of 15 seconds; or (b) exposure to chemical disinfection in accordance with the EPA-approved label directions for hypochlorite, iodoform, or quaternary ammonium antimicrobial products. The Agency requests comment on the appropriateness of these suggested decontamination methods and other methods which may be in use.

5. Labeling Requirements (Section 259.44)

Section 11003 of the MWTA requires EPA to establish appropriate requirements for the labeling of regulated medical waste containers or packages. The purpose is to ensure that regulated medical waste can be easily identified as such during shipment and disposal. Under today's rule, EPA is requiring that each package containing untreated regulated medical waste be imprinted or affixed with a label including the words "Infectious Waste," "Medical Waste," or a label displaying the universal biohazard symbol. When a red bag is used as a container, however, the color red is recognized as an indicator that the bag contains untreated regulated medical waste and serves the same function as the label. However, a label is always required on the outer surface of an untreated regulated medical waste package, regardless of the color of the package.

Regulated medical waste categorized as "treated medical waste", discussed above, does not require a label on the package. Such waste poses a substantially reduced risk of disease transmission, and a label indicating "infectiousness" would not be appropriate.

6. Marking (Identification) Requirements (Section 259.45)

Today's rule requires generators to ensure that all packages of regulated medical waste, including treated medical wastes and oversized medical wastes, that are shipped off-site be marked clearly to identify both the generator and transporter of the medical waste. The purpose of this requirement is to facilitate identification of the generator and transporter of any regulated medical waste that is found to be mismanaged or disposed of improperly. All containers must be marked with the identity of the generator. The marking(s) placed on the outer surface of the package, once it has been prepared for shipment, must also include the identity of the transporter, the date that the waste is removed from the generator's site, and identification of the package's contents as medical waste. In conjunction with the date, other markings may be used to indicate or establish the unique shipment (e.g., the tracking form number, a bar-code label, or some other assigned box number). All such tags or markings must be water resistant to ensure survival of the information in the event the package(s) or container(s) becomes wet.

The marking, affixed to or placed on the package must specify the name of the generator and the generator's State permit or identification number. If the State does not issue permit or identification numbers, then the generator's address must be used. Because EPA will not be issuing any generator identification numbers under this demonstration program, the generator's permit or identification number will be any such identification number that is required by the State. Generators can use pre-printed markings or have the marking printed directly on the package. The identification tags must be of sufficient dimensions to contain all of the information required and should be printed with lettering sufficiently large to be read easily.

Markings placed on the outermost surface of the package must contain, in addition to the generator identification information, similar information for all transporters (i.e., transporter's name, address, and/or State permit or identification number). Generators should obtain this information from transporters; transporters may provide generators with pre-printed tags, or may mark the packages for the generator prior to acceptance. The marking also must include the date the package was shipped in order to facilitate tracking of individual shipments.

When regulated medical waste is handled by more than one transporter, each subsequent transporter must affix an additional, separate identification tag to the outermost surface of the package with the transporter's name, address and/or State permit or identification number, and the date of transfer (see § 259.70(e)). All such tags should be placed on the secondary package so a

not to obscure previously placed tags or markings.

*F. Subpart F—Generator Requirements*

The generator's role in tracking medical waste is vital since he is responsible for packaging, labeling, and marking the waste and for initiating the tracking process. The following paragraphs describe major sections of the generator regulations in Subpart F of Part 259.

1. Applicability and General Requirements (Section 259.50)

a. *General.* The rule requires all health care providers or other affected facilities located in the Covered States to determine whether the wastes they generate are regulated medical wastes. The Agency will work with the States, trade associations, and other Federal agencies to inform generators in the Covered States of their new responsibilities under today's rule. Generators who generate mixtures of regulated medical waste and hazardous waste may be subject to today's rule for those mixtures if the waste is not subject to the manifesting requirements of Subtitle C. Mixtures of regulated medical waste and radioactive wastes are subject to today's rule (see Section VII.A of the Preamble).

Under today's rule, vessels (including foreign-flagged ships) must manage any regulated medical waste according to these regulations when at port in a Covered State, and when such waste is to be removed from the vessel for transport and disposal. In situations where a ship is docked at a shore base, the shore base may perform the generator functions, such as maintaining records and initiating the tracking form, if waste is to be sent off-site, provided that the waste is stored at all times in compliance with the on-site storage provisions in § 259.42. In this situation, the ship operator and shore base operator are "co-generators" of the waste, and either may assume generator responsibilities. However, both parties remain liable for compliance.

Wastes managed at the generator's site through incineration, disposal to the sewer, or burial, are not subject to the segregation, packaging, labeling, marking, or tracking requirements. These wastes are subject, however, to storage requirements (§ 259.42) prior to on-site disposal. Additionally, all medical wastes incinerated on-site are subject to a Congressionally-mandated recordkeeping and reporting requirement, discussed below. As discussed above, persons who claim the "treated and destroyed" exemption must also maintain certain records.

b. *Generator exemptions according to quantity.* Generators who will be sending their medical waste off-site must estimate quantities that will be shipped off-site to determine if they may be subject to reduced tracking requirements, as discussed below.

Section 11003(b) allows EPA to establish an exemption from the tracking requirements for generators of small quantities of regulated medical waste based on the quantity generated per calendar month. EPA has determined that some form of exemption from the full tracking requirements is appropriate for generators of less than 50 pounds per calendar month, because the paperwork burden resulting from tracking each shipment individually would overwhelm generators, transporters, treaters and disposers, making the whole tracking system virtually impossible to administer and thus ineffective. This would be especially problematic in a program of short duration that affects persons not formerly subject to similar regulation where Congress clearly envisioned expeditious implementation. Discussions with State officials and health care organizations indicate that under the definition of "regulated medical waste" in today's rule, the universe of generators in the less than 50 pounds per month category would be extremely large (in excess of 100,000). EPA considered an outright exemption under which waste from this category of generators could be disposed of in the normal (e.g., general refuse) solid waste stream. (This would be similar to the "small quantity" hazardous waste generator exemption under 40 CFR 261.5.) EPA rejected this option because some problems have been caused by relatively small quantities of medical waste being improperly managed.

For the reasons discussed above, under today's rule, generators of less than 50 pounds per month of regulated medical waste are responsible for: proper packaging, labeling, and marking of waste; use of transporters who have notified EPA; and use of a log to record when waste is transported off-site (see § 259.50(e)(2)). These generators are not required to complete a tracking form for each shipment, nor are they required to comply with the associated exception reporting requirements. These two exemptions should result in a significant reduction of the paperwork burden for medical waste managers. EPA believes this limited exemption achieves the appropriate balance between the need to ensure that even very small quantities of medical waste are properly managed and the need to develop a program that can be quickly and easily implemented. Comments are requested on the approach described above.

There are two further considerations related to generators of less than 50 pounds per month. First, wastes disposed on-site (e.g., land-filled or sewer-disposed) are not counted towards the 50 pound limit. Since these wastes would not be subject to the tracking requirements of today's rule, it is not appropriate to change a generator's regulatory status based on the amount of material not sent off-site. (EPA notes that a similar concept is used in the hazardous waste rules at 40 CFR 261.5.) Also, the reader should note that a generator need not count the weight of the packaging materials against the 50 pound per month limit.

Second, the tracking requirements of today's rule apply in full to a generator of less than 50 pounds per month, if he accumulates his waste on-site and ships a package or packages with a total weight of 50 pounds or more at any one time or in any calendar month. The small generator exemption is thus limited to persons who generate less than 50 pounds per month and ship less than 50 pounds at any time. The purpose of the 50 pound shipment rule is to overcome the difficulties in ensuring compliance with the generator's determination that he generates less than 50 pounds per month. Thus, the shipment rule establishes a clear measure for generators and transporters as to when a tracking form must accompany individual shipments of waste.

Under Subpart H of today's rule, transporters who pick up wastes from generators producing less than 50 pounds per month will be responsible for initiating a tracking form for those wastes. However, transporters are allowed to initiate a single tracking form to cover all of the waste present on each truck that is generated by generators of less than 50 pounds per month. A separate tracking document for each generator is not required. Therefore, while the generator is relieved of some of the paperwork burden, his waste still will be responsibly tracked and handled. This is somewhat different from the approach under the hazardous waste regulations. In the hazardous waste regulations, EPA does not regulate waste from generators of less than 100 kilograms (220 pounds) per month (except for acutely hazardous waste; see 40 CFR 261.5). Since the medical waste tracking regulations essentially regulate all listed medical wastes, the Agency determined some flexibility was necessary for managing so many very small shipments, and