Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

RECEIVED
IRRC
2013 AUG -5 AM 11:12

(1) Agency: Department of Environmental Protection

(2) Agency Number:
Identification Number: #7-480

IRRC Number: 3017

(3) PA Code Cite: 25 Pa Code Chapters 271, 272, 273, 284, 285, 287, 288, and 299

(4) Short Title: Regulated Medical and Chemotherapeutic Waste

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Michele Tate, (717) 783-8727, mtate@pa.gov
Secondary Contact: Patricia Allan, (717) 783-8727, pmallan@pa.gov

(6) Type of Rulemaking (check applicable box):

- ☒ Proposed Regulation
- ☐ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
- ☐ Certification by the Governor
- ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Department of Environmental Protection's (Department) Bureau of Waste Management regulates and oversees the management and disposal of wastes that are generated from diagnosis, treatment, immunization, or autopsy of human beings and animals.

The proposed regulation changes will bring Pennsylvania's regulated medical and chemotherapeutic waste provisions up to date and consistent with federal requirements and the requirements of surrounding states. This regulation will:

- Change the terminology from "infectious waste" to "regulated medical waste";
- Clarify and streamline the storage, transportation and shipment requirements of regulated medical waste to recognize business practices, and encourage labor and fuel efficiency;
- Incorporate permits-by-rule for processing and treatment of regulated medical waste;
- Allow the use of standard business documentation, including electronic tracking systems to record the proper processing and disposal of regulated medical waste;
- Allow the transportation of regulated medical and chemotherapeutic waste through the U.S. Postal Service (USPS); and
- Eliminate provisions that relate to areas governed by the Occupational Safety and Health Association (OSHA) to avoid inconsistencies and duplication.

(8) State the statutory authority for the regulation. Include specific statutory citation.

This proposed rulemaking is being made under the authority of the following:

The Solid Waste Management Act (SWMA) (35 P.S. §§ 6018.101 - 6018.1003), which in Section 105(a) (35 P.S. § 6018.105(a)) grants the Board the power and the duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the SWMA. Sections 102(4) and 104(6) of SWMA (35 P.S. §§ 6018.102 and 104), which provide the Department with the power and duty to regulate the storage, collection, transportation, processing, treatment, and disposal of solid waste to protect the public health, safety and welfare.

The Infectious and Chemotherapeutic Waste Disposal Law, which at Section 6019.4(b), (35 P.S. § 6019.4(b)) grants the Board the power and duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the law and which at Section 6019.2(b) (35 P.S. § 6019.2(b)) provides the Department with the authority to review and revise regulations as necessary.

The Administrative Code of 1929 (71 P.S. §§ 510-1 - 510-27), which at Section 1917-A (71 P.S. § 510-17) authorizes and requires the Department to protect the people of this Commonwealth from unsanitary conditions and other nuisances, including any condition that is declared to be a nuisance by any law administered by the Department. Section 1920-A (71 P.S. § 510-20), which grants the Board the power and duty to formulate, adopt and promulgate such rules and regulations as may be determined by the Board for the proper performance of the work of the Department.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

This regulation is not mandated by any federal law or federal regulation.

This regulation is not mandated by, or related to, any federal or state court decision.

The Pennsylvania Infectious and Chemotherapeutic Waste Disposal Law requires a manifest system to track the waste.

Regulated medical and chemotherapeutic wastes are solid wastes under the Solid Waste Management Act and must be managed in accordance with the rules and regulations pursuant to that Act.

There are no deadlines associated with these proposed amendments to the regulations.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The regulation of infectious waste (regulated medical waste) and chemotherapeutic waste is necessary to protect the overall health and safety of the public. Blood and bodily fluid have the ability to carry pathogenic microorganisms that can cause infections and diseases in humans or animals that come into contact with them. Chemotherapeutic drugs are inherently toxic substances. Their toxic effects can pose a threat to otherwise healthy individuals that come into contact with discarded medical devices or supplies used to administer drugs to cancer patients or contain residual amounts of chemotherapeutic substances.

Current regulations are not aligned with nationwide practices and place Pennsylvania at a disadvantage. New streamlined regulations will provide equivalent environmental protection with a more efficient process, which will benefit medical practitioners, medical facilities, transporters of and processors of regulated medical and chemotherapeutic waste (see number (15) for a breakdown of the number of facilities that will benefit). This rulemaking will allow an estimated 16,063 generators of regulated medical and chemotherapeutic waste to better understand Pennsylvania's requirements and eliminate duplicative and other outdated requirements, as elaborated below:

Labeling
Currently, medical facilities in Pennsylvania are required to have two labels on their waste receptacles, one that reads "infectious waste" to comply with Pennsylvania regulations, and one that reads "regulated medical waste" to comply with Federal requirements. These proposed amendments include a revision that would identify "infectious waste" as "regulated medical waste," making the terminology consistent with federal and other states' requirements and thus eliminating the need for two separate labels. This uniform practice should reduce the costs borne by waste generators and other persons managing regulated medical waste because the same containers and labels could be used to satisfy Pennsylvania requirements, federal requirements and the requirements imposed by other states.

Storage
In Pennsylvania, medical facilities are currently required to seal medical waste disposal containers, such as boxes or bags, for disposal within 30 days of placing the first waste item in the container. These amendments will allow generators to store regulated medical and chemotherapeutic waste for a longer time period: 30 days after the date the container is full or sealed, whichever occurs first. This will provide the generator with more control over the length of time the waste is stored onsite and promotes more efficient business practices by reducing the need to transport partially filled containers. This storage provision change encourages transporter labor savings and fuel efficiency, while maintaining the integrity of Pennsylvania's regulated medical waste management and disposal requirements.

Transportation and Shipping
These amendments streamline the transportation and shipment requirements for regulated medical and chemotherapeutic waste in several respects. The amendments allow generators, transporters and those involved in storage, processing and disposal of regulated medical and chemotherapeutic waste to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations instead of the currently prescribed, but outdated, paper manifest. The amendments allow for the manifest requirement to be satisfied with a shipping paper, log or electronic tracking system that provides the required information, allowing the generator to track its waste in accordance with current industry practices. This provision will allow the generators and haulers to choose which tracking option is best to satisfy their compliance needs.

Additionally, the regulatory amendments allow authorized waste haulers, under certain conditions, to transport containerized regulated medical and chemotherapeutic wastes along with other wastes in the same vehicle. This will reduce the number of trips needed to transport waste from generators that have both regulated medical and chemotherapeutic waste and other wastes, increasing fuel efficiency and reducing the hauling costs borne by the generators.

These amendments also allow the shipment of regulated medical waste through the USPS, in accordance

with its program and requirements. Currently, sharps from small quantity generators may be sent through the mail. The proposed revisions will broaden this authorization to include other types of regulated medical waste, providing facilities more options for transporting their regulated medical waste to a processing or disposal site.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

The Department is not aware of any provisions in the proposed rulemaking that are more stringent than federal requirements.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

The amendments reflect a global change in terminology from "infectious waste" to "regulated medical waste," which is consistent with most other states and the federal government to identify this waste stream. By making the terminology consistent with federal requirements and the requirements of other states, containers used for collection, storage and transportation could be used, processed and reused without the need for any additional marking or labeling requirements. Additionally, the changes in the manifesting system should allow easier transport between states and decrease the amount of paperwork generators and transporters would need to complete in order to comply with Pennsylvania's regulations. Rather than continuing to use a dedicated Department form and require that copies of that form accompany the waste shipment, the manifesting requirements can now be met with a generic shipping paper, log or electronic tracking system accompanying the waste stream, provided it includes all the required information.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The proposed regulations are not expected to affect any other regulations of the Department.

The Department of Corrections and health centers operated by the Department of Health are currently required to comply with the Department's existing regulations for the management of infectious and chemotherapeutic waste and will continue to be regulated under these proposed regulations. The benefits of the proposed amendments will be realized by these facilities in the same manner that they will be realized by all generators, processors and transporters of regulated medical and chemotherapeutic waste (see numbers 15, 17 & 18).

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

In April of 2008, the Department conducted a Regulatory Review Meeting and representatives of the following groups attended: Stericycle, Inc., the nation's largest medical waste transportation and disposal company serving hospitals, dentist offices, long-term care facilities, medical laboratories, and physician's offices, including those that qualify as a small business; American Red Cross; Thomas Jefferson

University Hospital/Greater Philadelphia ASHES; Children's Hospital of Philadelphia; University of Penn Health System; University of Pennsylvania; Pugliese Associates; and Johnson & Johnson PRD.

In September of 2011, the Department's Solid Waste Advisory Committee (SWAC) considered the proposed amendments to these regulations and urged the Department to present them to the Environmental Quality Board for action.

In November of 2012, the Department presented this proposed rulemaking to the Department's Small Business Compliance Advisory Committee (SBCAC). The SBCAC is comprised of nine small business owners and other representatives from around the state, including the Department's Small Business Ombudsman. The committee voiced support for this rulemaking and wrote a letter of support to Secretary Krancer, stating that these regulations will benefit small and rural health facilities by helping them to comply with regulatory requirements for management of regulated medical and chemotherapeutic waste.

The Department also contacted the Pennsylvania Medical Society, the Pennsylvania Dental Association, and the Pennsylvania Veterinary Medical Association regarding the proposed amendments. All were provided copies of the draft proposed revisions approved by the SWAC in 2011, as well as a summary of the proposed changes. The Department met with a representative of the Pennsylvania Medical Society on January 29, 2013, to discuss the regulatory changes proposed and additional opportunities for outreach to small businesses through the organization. The Department has agreed to make a presentation to the Society's Executive Board at its next meeting. In addition, the Department will continue to work with these organizations to provide outreach and support to doctors, dentists and veterinarians that will be subject to the proposed revisions.

Furthermore, the Department reached out randomly to a number of private medical facilities in an attempt to calculate the cost savings analysis for this regulation. These facilities include: Summit Health Chambersburg Hospital, Pinnacle Health Camp Hill Family Care, Phoenix Wellness Center, Mechanicsburg Family Dentistry, Cameron County Health Center, Cameron County Dental Center, Johnsonburg Dental Center, and Mountaintop Area Medical Center. All facilities expressed that the changes the Department is proposing regarding the management of regulated medical and chemotherapeutic waste could benefit their operations. None of the facilities surveyed indicated that it would impact their regulated medical and chemotherapeutic waste disposal procedures negatively (see number 19).

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Types of facilities affected:
All generators, processors and transporters of regulated medical or chemotherapeutic waste currently regulated by the Department would be required to comply with these proposed regulations. Generators and processors include providers of medical care, such as hospitals, physician offices, veterinary offices, home health care, nursing facilities, dentist offices, blood collection agencies, laboratories, and research facilities.

The Department assumes a portion of these affected facilities are small businesses, as defined in Section

3 of the Regulatory Review Act. This Act defines a small business in the medical industry based on the dollar amount of gross annual receipts generated by the business. This dollar amount is different for each type of facility. A facility that shows gross annual receipts less than the figures shown below is defined as a "small business" under the Regulatory Review Act.

- Hospital <$34.5 million gross annual receipts
- Waste Collection <$12.5 million
- Doctor's Office <$10 million
- Dentist Office <$7 million
- Veterinary Office <$7 million
- Nursing Home <$13.5 million
- Medical Lab <$13.5 million

Number of facilities affected:
The Department estimates there are approximately 16,063 facilities across Pennsylvania that may be generators of infectious and chemotherapeutic waste. This estimation is based on the following data obtained from DEP's Bureau of Radiation Protection, the Pennsylvania Department of Health, and the Pennsylvania Department of Corrections. In parenthesis is the accompanying 2012 NAICS code, along with the amount of gross annual receipts to indicate the threshold for small business consideration, as provided in the Regulatory Review Act.

Generators
According to the Department of Health, currently in Pennsylvania there are:

- 190 hospitals (622110; less than $34.5 m);
- 6,000 doctor's offices with in-house laboratories (621111; less than $10 m);
- 11 outpatient rehabilitation facilities (621498; less than $19 m);
- 95 outpatient physical therapy facilities (621498; less than $19 m);
- 64 rural health clinics (621111; less than $10 m);
- 13 birth centers (621410; less than $10 m);
- 5 pediatric extended care centers;
- 613 nursing home facilities (623110; less than $25.5 m);
- 272 renal dialysis centers (621492; less than $35.5 m);
- 188 intermediate care facilities;
- 106 psychiatric residential treatment facilities (622210; less than $35.5 m); and
- 340 independent laboratories (621511; less than $30 m).

The Department used data from the Bureau of Radiation Protection's licensing of X-Ray machines to obtain information on the number of the following businesses currently operating in Pennsylvania:

- 5,715 dentist offices (621210; less than $7 m);
- 556 podiatrist facilities (621391; less than $7 m);
- 918 chiropractor offices (621310; less than $7 m); and
- 867 veterinarian offices (541940; less than $7 m).

According to the Department of Corrections, in Pennsylvania there are:

- 26 state correctional institutions;

- 14 community corrections centers; and
- 70 county prisons.

Transporters
Currently, there are 42 transporters of infectious and chemotherapeutic waste licensed by the Department. For solid waste collection, NAICS: 562111, the maximum gross annual receipts allowable by definition for a small business is $35.5 million.

Small Businesses:
Because the definition of a small business is based on the gross annual receipts of the individual company, an exact number of small businesses affected by this regulation cannot be identified by the Department with any certainty. However, some assumptions and estimates can be made. The Department assumes that all 64 rural health facilities and most of the transporters qualify as small businesses. Of the other facilities, the Department assumes that a portion of each would qualify as a small business. Regardless of the amount shown in gross receipts each year, each facility will have more options for storage, transportation and disposal of their regulated medical and chemotherapeutic waste from this proposed rulemaking; thereby providing the regulated community with additional efficiencies not achievable under the current regulations.

How they will be affected:
Terminology
By changing the terminology from "infectious waste" to "regulated medical waste", generators and transporters will no longer be required to have two labels on each waste container nor two signs on each truck in order to be compliant with both federal requirements and Pennsylvania requirements. This change in terminology will align Pennsylvania's regulations with federal requirements and the requirements of other states, and reduce costs for this regulated community, particularly when waste is disposed of out-of-state.

Disposal and On-site Storage
Currently, generators of infectious waste are required to seal and dispose of containers within 30 days of first placing waste in the container. Many generators have cited difficulty in keeping track of the date when waste was first placed in the container and have expressed frustration that they are required to dispose of and transport partially full bags and containers. This proposed rulemaking will allow generators to seal containers of regulated medical waste when they are full and allow them to store the waste on-site for an additional 30 days after the container is full or sealed, whichever occurs first. This provision will reduce the costs borne by generators, by eliminating the disposal of partially full containers.

Manifesting
The ability to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations will provide benefits to both generators and transporters of regulated medical and chemotherapeutic waste. Currently, an outdated paper manifest is required to accompany the waste shipment to ensure that the waste is being disposed of in the manner intended by the generator. This regulation will allow the generator and the transporter to utilize whichever system (shipping paper, log or electronic tracking) is best for their compliance needs.

Fuel Efficiency
Additionally, both generators and transporters of regulated medical and chemotherapeutic waste will benefit from the fuel efficiency achieved by being able to transport containerized regulated medical and chemotherapeutic waste along with other waste generated from the site. Current regulations require infectious and chemotherapeutic waste to be transported in separate vehicles from municipal waste. This change will reduce the number of trips needed to transport waste from generators that have regulated medical and chemotherapeutic waste and other types of waste that require disposal, thus further reducing fuel costs.

Additional Options - Shipping
Currently, sharps from small quantity generators may be sent through the USPS's Medical Waste Program. This proposed regulation will allow generators to ship other types of regulated medical waste in any amount or volume through the USPS's Medical Waste Program, provided that certain conditions are satisfied, including mailing standards and other relevant USPS regulations. This provision is consistent with federal regulations and regulations of other states and will allow generators more options for disposing of their regulated medical waste.

Permits-by-rule for Processing Facilities
These proposed regulatory amendments will provide 7 permits-by-rule for qualifying processing facilities. Autoclaves, incinerators, and steam superheated water disinfection operators may qualify for permits-by-rule instead of having to obtain individual permits for processing. These permits-by-rule will allow these facilities to operate under standard requirements contained in the regulations and will eliminate the need for these facilities to submit individual permit applications to the Department.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

See the "number of facilities affected" section in number (15) for a breakdown of the estimated 16,063 entities that will be affected by this regulatory amendment. All generators of regulated medical and chemotherapeutic waste will be required to comply with this regulation. These facilities are currently required to comply with the Department's regulations on infectious and chemotherapeutic waste. The proposed regulation does not increase the number of entities that would currently have to comply with the Department's regulations.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The Department expects the proposed regulatory revisions to reduce the costs borne by all generators, processors and transporters of regulated medical or chemotherapeutic waste by allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers prior to sending them for disposal. The revisions encourage labor and fuel efficiency and reduce costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations.

The Department expects the largest financial and economic benefit of the proposed revisions to be realized by small medical facilities located in rural areas. Currently, these businesses must pay for the

transportation of regulated medical and chemotherapeutic wastes and municipal wastes separately, meaning that two trips are necessary to regularly haul the facilities' wastes. In addition, small facilities must remove and dispose of containers of regulated medical waste within 30 days of wastes first being placed into the containers, resulting in many partially full containers being shipped for disposal. The proposed amendments alleviate both the requirement for wastes to be collected in two separate vehicles and allow businesses to completely fill containers of regulated medical waste before they must be shipped off-site for disposal.

The proposed amendments allow generators, transporters and those involved in storage and processing of regulated medical and chemotherapeutic waste to use standard business documentation, including electronic tracking, to demonstrate compliance with the regulations instead of the currently prescribed and outdated paper manifest. The proposed revisions also provide an alternative transportation and disposal option for all medical facilities by allowing these facilities to ship waste through the mail where authorized by the USPS. The USPS allows small facilities to ship regulated medical waste based on need rather than on a prescribed regulatory frequency or schedule.

The proposed revisions allow businesses to manage regulated medical and chemotherapeutic wastes more efficiently, while maintaining the equivalent level of protection to public safety and the environment that is currently realized under the existing regulations.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

No adverse effects are expected from the proposed regulation, while the benefits are numerous.

The benefits of this regulation involve the increased flexibility for generators, processors and transporters of regulated medical and chemotherapeutic waste. These proposed regulations create consistency with the US Department of Transportation requirements and with other states by changing the term "infectious waste" to "regulated medical waste". The shift in terminology will simplify the labeling and signage requirements and reduce costs, in addition to ensuring consistency.

Generators will benefit from managing their medical waste as needed instead of a prescribed disposal schedule. They will also be able to utilize shipping options through the USPS.

The amendments encourage labor and fuel efficiency by allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle. Transporters will also benefit by eliminating unnecessary trips to rural parts of the state. The proposed amendments will allow waste to be disposed on an as-needed basis.

This proposed regulation will allow generators, transporters, and those involved in storage and processing of medical waste to use standard business documentation, including electronic tracking, to demonstrate compliance with regulations instead of the currently prescribed and outdated paper manifest.

Qualifying processors will be able to utilize permits-by-rule instead of individual permits for their facilities.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain

how the dollar estimates were derived.

Generators

The realized savings for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates.

The Department reached out to different types of facilities to gauge the cost savings that each could expect from the changes this regulation proposes.

- *Medium-sized hospital:* In conversations with Summit Health Chambersburg Hospital, a medium-sized hospital, it indicated to the Department that infectious and chemotherapeutic waste is picked up four times a week. Stericycle, Inc. (the waste hauler used) charges $35 per box, whether it is full or not. Due to the volume of medical waste generated, a medium-sized hospital, such as Summit Health Chambersburg Hospital, does not expect to see savings from the provisions included in the proposed rulemaking.

- *Medium-sized physician's office:* Pinnacle Health Camp Hill Family Care indicated to the Department that, on average, two full boxes of infectious waste are transported for disposal every other week. Since its hauler charges a flat fee per box, and the facility generates enough waste that it does not dispose of partially full boxes, a medium-sized physician's office, such as Pinnacle Health Camp Hill Family Care, does not expect to see savings due to the provisions included in the rulemaking.

- *Small physician's office:* The Department spoke with Phoenix Wellness Center, a small physician's office, regarding management of its medical waste. This office has its transporter pick up infectious waste once a month, whether the box is full or not. Under the proposed amendments, it would be able to develop a schedule based on when its container is full, stretching out its pickup times and ensuring that all loads are full. If one box costs $35 a month and they stretch the pickup to every 2 months, they could save $210 a year ($35 x 6 months of eliminated half full pickups).

- *Dentist's office:* Most dentist offices do not generate as much infectious waste as doctor's offices, but are still required to comply with the regulations regarding this waste stream. According to Mechanicsburg Family Dentistry, who serves a large clientele, it has infectious waste picked up every four weeks. Sometimes the boxes are not completely full. Smaller generators, like dentists, will benefit from the amendments which allow generators to wait until the container is full before being required to seal and dispose of it. They will also have another option to mail it through the USPS Medical Waste Program as needed, instead of having a dedicated pickup schedule.

- *Rural Dentist Facility:* Cameron County Dental Center and Johnsonburg Dental Center, small dentist offices in rural areas, indicated to the Department that they have their infectious waste picked up every two months and pay $86.53 per pickup. These offices each spend $519.18 per year ($86.53 x 6 pickups) for infectious waste disposal. Under the proposed amendments, each office could possibly reduce its pickup schedule to every 6 months or longer, resulting in a savings of at least $346.12 each year. Both offices also expressed interest in utilizing the USPS Medical Waste Program for transportation to a processing or disposal site on an as-needed basis.

- *Rural Health Facility:* The Mountaintop Area Medical Center and Cameron County Health Center both spoke with the Department regarding the management of their infectious waste. Both stated that infectious waste is picked up every two months, regardless of whether the box is full. Pickup is offered once per month; however, the facilities do not generate enough infectious waste for a monthly schedule. The facilities each spend $86.53 per box, significantly more than other urban or suburban facilities. Rural facilities are expected to be some of the biggest beneficiaries of this change in regulation, based on their size (less regulated medical waste generated) and location (farther to drive for pickups). Through this change, they will have the additional option of shipping regulated medical waste through the USPS Medical Waste Program as needed, instead of having a dedicated pickup schedule.

Cost savings analysis per generator type:

- *Large and medium-sized hospital:* No additional costs, but no savings.

- *Medium-sized physician's offices:* No additional costs, but no savings.

- *Small physician's offices:* According to the above, a small physician's office will potentially save $210 per year. Based on estimates of the number of health facilities affected by the proposed regulations (see number 15 for a breakdown of affected facilities), for this cost-savings analysis, the Department assumed that a total of 3,841 facilities would generate a similar amount of waste as the small physician's office identified above, and therefore, these facilities would realize similar cost-savings DEP conservatively estimated that one-quarter of all physician's offices would be considered small. (1,500 of the 6,000 doctor's offices with in-house laboratories (1/4 of all doctor's offices); all 556 podiatrist facilities; all 918 chiropractic facilities; and all 867 veterinary facilities).

  Using the above assumptions, small physician's offices would collectively save ($210) x (3,841 facilities) = $806,610 per year.

- *Dentist's offices:* According to the outreach conducted and described above, the Department conservatively estimated that 75% of all dentists' offices would generate a similar amount of waste as the small physicians' offices. Therefore, of the 5,715 dentists' offices currently operating in Pennsylvania (given in number 15), 4,286 offices are assumed to generate a quantity of medical waste similar to that generated by a small physicians' office for the purpose of this cost analysis.

  Using the above assumptions, these dentists' offices would collectively save ($210) x (4,286 facilities) = $900,060 per year.

- *Rural Dentist's offices:* The Department conservatively estimated that 25% of all dentists' offices are rural dentist facilities. Therefore, of the 5,715 dentist offices currently operating in Pennsylvania (given in number 15), 1,429 offices are assumed to generate a quantity of medical waste similar to that generated by a rural dentist facility for the purpose of this cost analysis.

  Using the above assumptions, these dentists' offices would collectively save

($346.12) x (1,429 facilities) = $494,605.48 per year.

- *Rural Health Facilities:* According to the above, a rural health facility will potentially save $346.12 per year. Based on estimates of the number of rural health clinics affected by the proposed regulations (see number 15 for a breakdown of affected facilities), for this cost-savings analysis, the Department assumed that all 64 rural health clinics would realize the cost savings identified above for rural health facilities.

  Using the above assumptions, rural health facilities would collectively save ($346.12) x (64 facilities) = $22,151.68 per year.

Therefore, the total estimated annual savings for generators is approximately ($806,610) + ($900,060) + ($494,605.48) + ($22,151.68) = $2,223,427.16.

Transporters

Currently, a generator must have a separate pick up of their infectious waste at least every 30 days. Most transporters charge a flat fee based on number of boxes or weight of infectious and chemotherapeutic waste, not based on the number of times they visit a facility. Transporters will benefit from being able to make fewer trips, by picking up more waste on each trip. They will also benefit from being able to transport regulated medical and chemotherapeutic waste on the same truck as other wastes generated from the same facility.

According to Stericycle, Inc., increases in generator storage time will save an average of two unnecessary trips per transporter per week. That is approximately 100 trips per transporter per year.

(100 trips) x (42 transporters) = 4,200 unnecessary trips eliminated.

According to information obtained from transporters, a typical trip consists of 50 miles.

The average total transport cost (including labor) is approximately $80 per hour to operate a standard box truck. An average speed of 35 mph is used, resulting in a cost of approximately $2.30/mile.

The average total transport cost (including labor) for tractor/trailer shipments is $95.00 per hour. An average speed of 55 mph is used, resulting in a cost of approximately $1.75/mile.

Therefore, the average transportation cost is approximately $2 per mile.

Using the above assumptions, transporters would save ($2) x (50 miles) x (4200 trips) = $420,000 per year.

When added to the estimated annual savings for generators, the total estimated annual savings for generators and transporters is ($420,000) + ($2,223,427.16) = $2,643,427.16

Signs on transportation vehicles would need to be replaced within one year of the regulation taking effect. Most transporters have adequate signage already, as it is required in most of the surrounding states. Assuming half of the transporters will need the signage update, and the cost is $500 to replace or add required signs, the regulated community will spend:

(1/2) x (42 transporters) x ($500) = $10,500.

See number (23) for a breakdown of projected yearly savings versus costs of the proposed regulations.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Local government facilities, such as health centers and county prisons, are generators of medical waste, and therefore, said facilities will be subject to the proposed revisions. The savings realized for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates (see number 19).

These facilities will no longer need to use labels that satisfy differing state and federal regulations. Allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers and vehicles before it must be placed into service will reduce the overall costs of transportation and disposal. The revisions encourage aggregation and consolidation of waste; encourage labor and fuel efficiency; reduce costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations; and allow the utilization of standard business documentation, such as electronic tracking, to show compliance with the regulations, instead of the outdated paper manifests.

The proposed rulemaking is not expected to impose any additional regulatory costs on local governments.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

State government facilities, such as state-supported hospitals, local Department of Health facilities, and the Department of Correction's state correctional facilities are generators of medical waste, and therefore, those facilities will be subject to the proposed revisions. The savings realized for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates (see number 19).

These facilities will no longer need to use labels that satisfy differing state and federal regulations. Allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers and vehicles before it must be placed into service, will reduce the overall costs of transportation and disposal. The revisions encourage aggregation and consolidation of waste; encourage labor and fuel efficiency; reduce costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations; and allow the utilization of standard business documentation, such as electronic tracking, to show compliance with the regulations, instead of the outdated paper manifests.

The proposed rulemaking is not expected to impose any additional direct regulatory costs on state governments, except those nominal costs the Commonwealth will incur to provide training, outreach and technical assistance to the regulated community. It is not anticipated that any new staffing resources will be necessary.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

No additional legal, accounting or consulting procedures, nor additional reporting, recordkeeping or other paperwork are required for implementation of the regulation for the regulated community.

The proposed revisions allow generators and businesses involved in the transportation, storage and processing of regulated medical and chemotherapeutic waste to use standard business documentation, including electronic tracking, to demonstrate compliance with the regulations instead of the currently prescribed and outdated paper manifest. The use of alternative documentation provides the Department with the same information contained in a paper manifest, while reducing the amount of paperwork required of regulated entities.

Paperwork will be reduced by the creation of permits-by-rule for qualifying facilities in the proposed regulation. The permits-by-rule will eliminate the need to issue individual permits to those facilities, reducing reporting, record keeping and paperwork submissions to the Department for those qualifying facilities, while reducing the amount of paperwork managed by the Department in authorizing the operation of facilities permitted-by-rule.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

The dollar amounts below are taken from number (19) above, rounded to whole dollar amounts. See number (19) above for a breakdown of the estimated costs and annual savings associated with the proposed rulemaking.

	Current FY Year	**FY +1 Year**	**FY +2 Year**	**FY +3 Year**	**FY +4 Year**	**FY +5 Year**
SAVINGS:	**$ 2.6 mil**	**$ 2.6 mil**	**$ 2.6 mil**	**$ 2.6 mil**	**$ 2.6 mil**	**$ 2.6 mil**
Regulated Community	$ 2.6 mil	$ 2.6 mil	$ 2.6 mil	$ 2.6 mil	$ 2.6 mil	$ 2.6 mil
Local Government						
State Government						
Total Savings	$ 2.6 mil	$ 2.6 mil	$ 2.6 mil	$ 2.6 mil	$ 2.6 mil	$ 2.6 mil
COSTS:						
Regulated Community	$ 10,500	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	$ 10,500	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community						

Local Government						
State Government						
Total Revenue Losses						

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Environmental Program Management (#161-10382)	$31,1001000	$28,881,000	$25,787,000	$24,965,000
Environmental Protection Operations (#160-10381)	$84,218,000	$78,021,000	$88,879,000	$74,547,000

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

The Department does not believe that this proposed rulemaking will have any adverse impact on small businesses.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

There are no special provisions in the proposed rulemaking for any specific social or economic sectors. The largest financial and economic benefit of the proposed revisions is expected to be realized by the small medical facilities located in rural areas. Currently, these businesses must pay for the collection and transportation of regulated medical/chemotherapeutic wastes and municipal wastes separately, meaning that two trips are necessary to regularly haul the facilities' wastes. In addition, small facilities must remove and dispose of containers of regulated medical waste within 30 days of wastes first being placed into the containers, resulting in many partially full containers being shipped for disposal. The proposed amendments allow businesses to completely fill containers of regulated medical and chemotherapeutic

waste before they must be shipped off-site for disposal and alleviate the requirement for wastes to be collected in two separate vehicles. As a result, the proposed regulations will make compliance easier for these small facilities without reducing the level of protection to public health and the environment. All regulated facilities will be able to use the USPS program to ship regulated medical waste for disposal. That program provides an on-demand or as-needed approach for shipping regulated medical and chemotherapeutic waste rather than a prescribed schedule.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No program alternatives were considered.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;

The target of these regulatory amendments is all generators and transporters, including small businesses. These changes will allow all generators to store regulated medical and chemotherapeutic waste on site for longer periods of time. They will be able to ship regulated medical and chemotherapeutic waste when their containers are full, instead of in accordance with a prescribed schedule. This will result in less pickups of partially full containers. Generators and transporters will also be able to utilize standard business documentation, including electronic tracking or shipping logs, to demonstrate compliance with the regulations, instead of the currently prescribed, but outdated, paper manifest.

b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

There are no schedules or deadlines for compliance or reporting requirements except all regulated facilities will be required to comply with the new regulations, if approved.

c) The consolidation or simplification of compliance or reporting requirements for small businesses;

Compliance and reporting requirements were simplified for businesses that qualify for permits-by-rule including those considered small businesses. The proposed revisions allow these facilities to operate under a standard set of regulatory requirements that eliminate the need of a facility to apply for an individual permit. Regulatory compliance was further simplified in the proposed rulemaking by allowing generators and transporters to utilize standard business documentation, including electronic tracking or shipping logs, to track their waste disposal, instead of the currently prescribed, but outdated, paper manifest.

d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and

The proposed revisions provide permits-by-rule for qualifying facilities, which allow these facilities to operate under a standard set of requirements without reducing the level of protection for public health or

the environment.

e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Small businesses are not exempted from any of the requirements of this regulation. All businesses are given additional options for the transportation to a processing or disposal site of regulated medical and chemotherapeutic waste, such as utilizing the USPS Medical Waste Program where applicable.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

The following article recommends the renaming of Bacillus stearothermophilus to Geobacillus stearothermophilus:

International Journal of Systematic and Evolutionary Microbiology, Vol 51, 433-446, Copyright © 2001

- A copy of the article is attached to this form. (Attachment 1)

The following article recommends the reclassification of bioindicator strains Bacillus subtilis DSM 675 and Bacillus subtilis DSM 2277 as Bacillus atrophaeus:

International Journal of Systematic and Evolutionary Microbiology *January 2001 51:35-7*

- A copy of the article is attached to this form. (Attachment 2)

The following link will redirect you to a publication by the United Nations, regarding health care waste, which recommends using mycobacteria only as an indicator of disinfection. According to the publication, Mycobacteria is the toughest to neutralize and therefore the best indicator:

http://gefmedwaste.org/downloads/Guidance%20on%20Microbiological%20Challenge%20Testing%20for%20Medical%20Waste%20Autoclaves-%20November%202010.pdf

- A copy of the publication is attached to this form. (Attachment 3)

The following link will redirect you to a fact sheet regarding steam autoclaves, written by the EPA. The fact sheet provides guidelines for bacterial reductions and temperature requirements:

http://www.epa.gov/osw/nonhaz/industrial/medical/mwpdfs/alt/autoclav.pdf

- A copy of the fact sheet is attached to this form. (Attachment 4)

(29) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: Summer 2013

B. The date or dates on which public meetings or hearings will be held:	N/A
C. The expected date of promulgation of the proposed regulation as a final-form regulation:	Spring 2014
D. The expected effective date of the final-form regulation:	Spring 2014
E. The date by which compliance with the final-form regulation will be required:	Spring 2014
F. The date by which required permits, licenses or other approvals must be obtained:	N/A

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.

International Journal of Systematic and Evolutionary Microbiology (2001), 51, 433–446 Printed in Great Britain

Taxonomic study of aerobic thermophilic bacilli: descriptions of *Geobacillus subterraneus* gen. nov., sp. nov. and *Geobacillus uzenensis* sp. nov. from petroleum reservoirs and transfer of *Bacillus stearothermophilus, Bacillus thermocatenulatus, Bacillus thermoleovorans, Bacillus kaustophilus, Bacillus thermoglucosidasius* and *Bacillus thermodenitrificans* to *Geobacillus* as the new combinations *G. stearothermophilus, G. thermocatenulatus, G. thermoleovorans, G. kaustophilus, G. thermoglucosidasius* and *G. thermodenitrificans*

T. N. Nazina,[1] T. P. Tourova,[1] A. B. Poltaraus,[2] E. V. Novikova,[1] A. A. Grigoryan,[1] A. E. Ivanova,[1] A. M. Lysenko,[1] V. V. Petrunyaka,[1] G. A. Osipov,[3] S. S. Belyaev[1] and M. V. Ivanov[1]

Author for correspondence: T. N. Nazina. Tel: +7 095 1351021. Fax: +7 095 1356530. e-mail: nazina@inmi.host.ru

[1] Department of Microbial Biogeochemistry and Biotechnology, Institute of Microbiology, Russian Academy of Sciences, pr. 60-letiya Oktyabrya 7/2, Moscow, 117811 Russia

[2] Engelhardt Institute of Molecular Biology, Russian Academy of Sciences, ul. Vavilova 32, Moscow, 117984 Russia

[3] Research group of Academician Yu. Isakov, Russian Academy of Medical Sciences, Sadovaya-Kudrinskaya 15, Moscow, 103001 Russia

Five hydrocarbon-oxidizing strains were isolated from formation waters of oilfields in Russia, Kazakhstan and China. These strains were moderately thermophilic, neutrophilic, motile, spore-forming rods, aerobic or facultatively anaerobic. The G+C content of their DNA ranged from 49·7 to 52·3 mol%. The major isoprenoid quinone was menaquinone-7; cellular fatty acid profiles consisted of significant amounts of iso-15:0, iso-16:0 and iso-17:0 fatty acids (61·7–86·8% of the total). Based on data from 16S rDNA analysis and DNA–DNA hybridization, the subsurface isolates could be divided into two groups, one of which consisted of strains U^T and X and the other of which consisted of strains K, Sam and 34^T. The new strains exhibited a close phylogenetic relationship to thermophilic bacilli of 'Group 5' of Ash *et al.* [Ash, C., Farrow, J. A. E., Wallbanks, S. & Collins, M. D. (1991). *Lett Appl Microbiol* 13, 202–206] and a set of corresponding signature positions of 16S rRNA. Comparative analysis of the 16S rDNA sequences and fatty acid compositions of the novel isolates and established species of thermophilic bacilli indicated that the subsurface strains represent two new species within a new genus, for which the names *Geobacillus subterraneus* gen. nov., sp. nov., and *Geobacillus uzenensis* sp. nov. are proposed. It is also proposed that *Bacillus stearothermophilus, Bacillus thermoleovorans, Bacillus thermocatenulatus, Bacillus kaustophilus, Bacillus thermoglucosidasius* and *Bacillus thermodenitrificans* be transferred to this new genus, with *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*) as the type species.

Keywords: thermophilic *Bacillus* group 5, *Geobacillus subterraneus*, *Geobacillus uzenensis*, 16S rDNA analysis, fatty acids

The GenBank accession numbers for the 16S rDNA sequences of strains U^T, X, 34^T, K and Sam are AF276304–AF276308.

INTRODUCTION

The genus *Bacillus* is a large and diverse collection of aerobic and facultatively anaerobic, rod-shaped, Gram-positive (to Gram-variable), endospore-forming bacteria (Claus & Berkeley, 1986). The genus includes thermophilic and psychrophilic, acidophilic and alkalophilic, freshwater and halophilic bacteria that utilize a wide range of carbon sources for heterotrophic growth or grow autotrophically. 16S rRNA gene sequence analysis has revealed high phylogenetic heterogeneity in the genus *Bacillus* (Ash *et al.*, 1991; Rainey *et al.*, 1994). Seven phylogenetic groups have been reclassified as the new genera *Alicyclobacillus* (Wisotzkey *et al.*, 1992), *Paenibacillus* (Ash *et al.*, 1993; Heyndrickx *et al.*, 1996), *Brevibacillus* (Shida *et al.*, 1996), *Aneurinibacillus* (Shida *et al.*, 1996; Heyndrickx *et al.*, 1997), *Virgibacillus* (Heyndrickx *et al.*, 1998), *Salibacillus* and *Gracilibacillus* (Wainø *et al.*, 1999).

Currently, thermophilic aerobic spore-forming bacteria having growth optima in the temperature range 45 to > 70 °C are classified into the genera *Bacillus*, *Alicyclobacillus*, *Brevibacillus*, *Aneurinibacillus*, *Sulfobacillus*, *Thermoactinomyces* and *Thermobacillus* (Sneath, 1986; Wisotzkey *et al.*, 1992; Dufresne *et al.*, 1996; Heyndrickx *et al.*, 1997; Touzel *et al.*, 2000). The majority of the thermophilic species described belong to the genus *Bacillus* genetic groups 1 and 5, as judged from their 16S rRNA sequences (Ash *et al.*, 1991; Rainey *et al.*, 1994). The thermophilic species *Bacillus smithii* and *Bacillus coagulans* fall into group 1, along with the type species of the genus, *Bacillus subtilis*, and other mesophilic species. *Bacillus tusciae* is related to the genus *Alicyclobacillus* according to RDP grouping and *Bacillus thermocloaceae* and *Bacillus thermosphaericus* represent distinct lineages (Rainey *et al.*, 1994; Andersson *et al.*, 1995).

Group 5 is a phenotypically and phylogenetically coherent group of thermophilic bacilli displaying very high similarity among their 16S rRNA sequences (98·5–99·2%). This group comprises established species of thermophilic bacilli (*Bacillus stearothermophilus*, *Bacillus thermocatenulatus*, *Bacillus thermoleovorans*, *Bacillus kaustophilus*, *Bacillus thermoglucosidasius* and *Bacillus thermodenitrificans*), species that have not been validly published ('*Bacillus caldolyticus*', '*Bacillus caldotenax*', '*Bacillus caldovelox*' and '*Bacillus thermoantarcticus*') and the asporogenous species *Saccharococcus thermophilus*, representing a separate line of descent (Ash *et al.*, 1991; Rainey *et al.*, 1994; Sunna *et al.*, 1997; Nicolaus *et al.*, 1996; Manachini *et al.*, 2000). Phylogenetic analysis has revealed that the genus *Bacillus* and its thermophilic members require extensive taxonomic revision (Stackebrandt *et al.*, 1987; Ash *et al.*, 1991; Rainey *et al.*, 1994).

We have studied high-temperature oilfields from different geographical areas (Nazina *et al.*, 1992, 1995, 2000). An active and diverse microbial community, including hydrocarbon-oxidizing bacteria, was found in these deep subsurface ecosystems. Several pure cultures of dominant aerobic, thermophilic, hydrocarbon-oxidizing bacteria were isolated. A preliminary characterization of these bacteria based on phenotypic features indicated that they belong to the genus *Bacillus* (Nazina *et al.*, 1993). Comparative 16S rDNA analysis revealed that five isolates clustered with group 5 of the genus *Bacillus* and might represent two novel species (Nazina *et al.*, 2000).

In order to examine the taxonomic position of the five strains U^T, X, K, Sam and 34^T within the family *Bacillaceae*, we determined virtually complete sequences of their 16S rRNA genes and compared these sequences with those available for other members of the *Bacillaceae*. These isolates were characterized further by electron microscopy methods, including thin sectioning, by studying cultural and physiological features and by determination of fatty acid composition and DNA–DNA similarity to other thermophilic *Bacillus* species. In this paper, we describe these strains as members of two new species, *Geobacillus subterraneus* (strains 34^T, K, Sam) and *Geobacillus uzenensis* (strains U^T, X), of the new genus *Geobacillus*, which comprises group 5 of the genus *Bacillus* and contains the transferred species *Geobacillus stearothermophilus* comb. nov., *Geobacillus thermoleovorans* comb. nov., *Geobacillus thermocatenulatus* comb. nov., *Geobacillus kaustophilus* comb. nov., *Geobacillus thermoglucosidasius* comb. nov. and *Geobacillus thermodenitrificans* comb. nov.

METHODS

Source of bacterial strains and maintenance of cultures. The isolation of subsurface bacterial strains was carried out using tenfold serial dilutions of thermophilic hydrocarbon-oxidizing enrichments from different oilfields. The dilutions were inoculated on agar medium (Zarilla & Perry, 1987) containing *n*-hexadecane. Incubation was carried at 55–60 °C. Strain Sam was isolated after inoculation in agar medium (Adkins *et al.*, 1992) containing nitrate and acetate. Colonies were formed after a few days and were then transferred into liquid medium of the same composition. The purity of isolates was checked microscopically. The designation and origin of the isolates as well as those of the reference strains used are compiled in Table 1. The temperature of the oilfields investigated was 50–80 °C and the formation water had total salinity in the range of 3·5–18·0 g l^{-1} and pH 6·2–7·8 (Nazina *et al.*, 1992, 1995, 2000). Strains were cultured on nutrient agar (Difco), potato agar or mineral medium (Adkins *et al.*, 1992) with *n*-hexadecane (0·1%, v/v) as the substrate.

Light and electron microscopy. Cell morphology was examined under a Zetopan phase-contrast microscope. Bacterial size was determined in living cell preparations from cultures grown on medium with sucrose (0·2%, w/v) and mannitol (0·2%, w/v) (Adkins *et al.*, 1992) for 12–18 h. Gram staining was performed using a Merck kit. Negative staining of cells was achieved with 1% phosphotungstic acid and cells were examined under a transmission electron microscope. The fine structure of cells was studied after fixation of cells with a 1% (w/v) solution of OsO_4 in

Table 1 Strains isolated from oilfields and reference strains used in this study

Taxon	Origin/source
Strain U^T	New isolate from Uzen oilfield, Kazakhstan
Strain X	New isolate from Mykhpaiskoe oilfield, Western Siberia, Russia
Strain 34^T	New isolate from Liaohe oilfield, People's Republic of China
Strain Sam	New isolate from Samotlor oilfield, Western Siberia, Russia
Strain K	New isolate from Uzen oilfield, Kazakhstan
B. stearothermophilus 22^T	C. Jeanthon* (DSM 22^T)
B. thermoleovorans 5366^T	C. Jeanthon (DSM 5366^T)
B. thermodenitrificans 466	C. Jeanthon (DSM 466)
B. thermocatenulatus B-1259^T	All-Russian Collection of Microorganisms B-1259^T (= DSM 730^T)
B. subtilis B-4520	All-Russian Collection of Microorganisms B-4520 (= ATCC 15841)
B. subtilis B-4537	All-Russian Collection of Microorganisms B-4537 (= ATCC 6633)

*Isolates obtained from Christian Jeanthon, Laboratory of Marine Microbiology, Station Biologique, CNRS UPR9042, Roscoff, France.

acetate/veronal buffer (pH 6·2) by the method of Ryter & Kellenberger (1958). The cells were placed into agar, dehydrated with ethanol of increasing concentration (30, 50, 70, 80, 96 and 100%) and then with acetone and embedded in Epon 812 (Fluka). Ultrathin sections were obtained on an LKB-4800 ultramicrotome and contrasted with a 3% (w/v) aqueous solution of uranyl acetate with subsequent treatment with lead citrate (Reynolds, 1963). A JEM-100C electron microscope was used at magnifications of ×10000–30000.

Physiological characterization. Bacterial growth was monitored by measuring the OD_{600} (Spekol 11) in liquid media or by determination of protein content with a Merck kit. The effect of salinity (at 55 °C) or temperature on the growth of strains was tested in nutrient broth. The effect of pH on growth was determined in media adjusted to the appropriate pH with HCl or NaOH and recorded after 3 d at 55 °C.

Anaerobic growth was tested by incubation of the cultures in 100-ml rubber-sealed screw-cap bottles containing anoxic medium (Adkins *et al.*, 1992) with 2 g acetate, peptone or glucose l^{-1} as potential substrates and 0·85 g KNO_3 l^{-1} or in acetate/ferric citrate medium (Lovley & Phillips, 1988). Pure argon was used as the gas phase. Occurrence of denitrification was confirmed using a GC equipped with a Porapak Super Q column and a flame-ionization detector. Iron reduction was monitored visually: positive cultures change their colour from green to clear during growth.

Gelatin liquefaction, starch hydrolysis, casein and tyrosine decomposition, phenylalanine deamination, the Voges–Proskauer reaction, nitrate and nitrite reduction, H_2S and indole production, catalase reaction, acid production from carbohydrates, citrate and propionate utilization were all examined by the methods described by Logan & Berkeley (1984). The organic acid utilization tests were performed in a basal medium (Adkins *et al.*, 1992) supplemented with a separately sterilized solution of one of the substrates. Carbohydrates were added at 5 g l^{-1}, sodium salts of organic acids at 2·5 g l^{-1} and hydrocarbons at 5 ml l^{-1}. Strains were incubated at 55 °C. All assays were performed in duplicate and repeated in at least three consecutive culture transfers. Readings were made at days 1, 2 and 7.

DNA analysis. Bacterial DNA was prepared according to Marmur (1961). The G+C content of DNA was determined by the thermal denaturation method using the DNA of *Escherichia coli* K-12 as a standard (Owen *et al.*, 1969). DNA–DNA hybridization was carried out as described by De Ley *et al.* (1970).

Sequencing of the 16S rRNA gene. The sets of primers used to amplify and sequence 16S rDNA were as described by Brosius *et al.* (1978) and Edwards *et al.* (1989). Amplification was performed in a Perkin-Elmer temperature controller. Fifty microlitres of the reaction buffer [170 mM $(NH_4)_2SO_4$, 60 mM Tris/HCl, 20 mM $MgCl_2$, pH 8·8] was supplemented with 50–100 ng genomic DNA as the template, 5 pmol of each primer and 5 U of *Taq* polymerase (BioMaster). Amplification involved 30 cycles of DNA denaturation at 94 °C for 1 min, primer annealing at 40 °C for 1 min and elongation at 72 °C for 2 min. The amplified fragment of the 16S rRNA gene was purified on agarose gel and sequenced on an ABI 373A automated DNA sequencer using a Ready Reaction Dye Terminator Sequencing kit with Amplitaq DNA polymerase FS (Applied Biosystems).

Phylogenetic analysis. The nucleotide sequences of the 16S rRNA genes from thermophilic bacilli were aligned manually against representatives of the genus *Bacillus* and related taxa available from the latest versions of the Ribosomal Database Project (Larsen *et al.*, 1993) and GenBank databases. Sequence positions for which not all nucleotides had been determined were excluded from the analysis and a total of 1217 nucleotides were compared. Pairwise evolutionary distances (expressed as estimated changes per 100 nucleotides) were computed by use of the correction of Jukes & Cantor (1969). A phylogenetic tree was constructed by the neighbour-joining method (Saitou & Nei, 1987) with the bootstrap analysis of 100 trees by the TREECON software package (Van de Peer & De Wachter, 1994).

Analyses of cellular fatty acids and quinones. Whole-cell fatty acids and the main type of isoprenoid quinones were determined using biomass grown on nutrient agar at 55 °C for 18–24 h. Fatty acids were extracted from lyophilized cells. To 30 mg of dry biomass, 200 µl of a 5·4 M solution of anhydrous HCl in methanol was added and the mixture was heated at 70 °C for 2 h. The methyl esters of fatty acids and aldehyde derivatives obtained were extracted twice with 100 µl hexane. The extract was dried and silylated in 20 µl *N,O*-bis(trimethylsilyl)trifluoroacetamide for 15 min at

Table 2 Characteristics that differentiate the thermophilic bacilli from oilfields from thermophiles of *Bacillus* group 5

Taxa are indicated as: 1, *G. uzenensis* strain U^T; 2, *G. uzenensis* strain X; 3, *G. subterraneus* strain Sam; 4, *G. subterraneus* strain K; 5, *G. subterraneus* strain 34^T; 6, *B. stearothermophilus*; 7, *B. thermoglucosidasius*; 8, *B. thermocatenulatus*; 9, *B. thermoleovorans*; 10, *B. kaustophilus*; 11, *B. thermodenitrificans*. Characteristics are scored as: +, 90% or more of strains are positive; D, 11–89% of strains are positive; −, 90% or more of strains are negative. ND, Not determined. Data were obtained from the present study (*G. uzenensis*, *G. subterraneus*) or from Suzuki *et al.* (1983), White *et al.* (1993) and Priest *et al.* (1988) (*B. thermoglucosidasius*), Claus & Berkeley (1986) (*B. stearothermophilus*), Golovacheva *et al.* (1975) (*B. thermocatenulatus*), Zarilla & Perry (1987) (*B. thermoleovorans*), White *et al.* (1993) (*B. kaustophilus*) and Manachini *et al.* (2000) (*B. thermodenitrificans*) unless otherwise indicated.

Characteristic	1	2	3	4	5	6	7	8	9	10	11
Cell width (μm)	0·9–1·3	1·0–1·7	0·8–1·5	1·0–1·5	0·8–1·2	0·6–1	< 3	0·5–1·2	0·9	1·5	0·5–1·0
Cell length (μm)	4·7–8·0	5·5–8·5	5·5–8·0	4·7–7·0	4·6–6·6	2–3·5	< 0·9	3–7	6–8	3·5	1·5–2·5
Motility	+	+	+	+	+	+	ND	+	+	−	ND
Production of acid from:											
Adonitol	−	−	−	−	−	ND	+	−	ND	ND	ND
L-Arabinose	+	+	−	−	−	D	−	−	−	D	+
Cellobiose	+	+	+	+	+	−	+	+	+	+	+
Galactose	+	+	+	+	+	−	D	−	+	+	+
Ribose	+	+	+	+	+	ND	−	ND	ND	+	+
Glycerol	+	+	+	+	+	+	−	+	+	D	+
Inositol	−	−	−	−	−	−	+	−	−*	−*	ND
Lactose	−	−	−	−	−	−	−	−	−	−	+
Rhamnose	−	−	−	−	−	−	−	+	−	−	−
Sorbitol	−	−	−	−	−	−	−	+	ND	−	ND
D-Xylose	−	−	−	−	−	D	+	+	−	D	+
Hydrolysis of:											
Gelatin	+	+	−	−	−	D	+	−	−	ND	ND
Casein	−	−	−	−	−	D	+	+	ND	+	−
Starch	+	+	+	+	+	+	+	+	−	D	+
Aesculin	+	+	+	+	+	ND	−	+	ND	ND	ND
Utilization of:											
n-Alkanes	+	+	+	+	+	+*	ND	ND	+*	+	ND
Formate	−	−	+	+	+	−	D	ND	ND	ND	ND
Acetate	+	+	+	+	+	+	−	ND	ND	+	ND
Lactate	+	+	+	+	+	−	−	ND	ND	ND	ND
Citrate (Simmons)	−	−	−	−	−	D	+	D	+	ND	ND
Fermentation of glucose	−	−	−	−	−	D	−	−	+	−	ND
Denitrification	−	−	+	+	+	−	ND	−	+	ND	+
Methyl red test	−	−	+	+	+	D	−	D	ND	ND	ND
NaCl range (% w/v)	0–4	0–4	0–5	0–5	0–3	0–5	0–< 5	0–1·5	0–4	ND	0–3
pH range	6·2–7·8	6·2–7·8	6·0–7·8	6·2–7·6	6·2–7·6	6·0–8·0	6·0–8·0	6·5–8·5	6·2–7·8	6·2–7·5	6–8
Temperature range (°C)	45–65	45–65	45–70	48–70	45–65	37–65	37–68	42–69	35–78	40–75	45–70
DNA G+C content (mol%) (T_m)	50·4	51·5	52·3	49·7	52·3	51·9†	53·9	45–46	55·2*	52–58	48·2–52·3

*Data obtained in the present study.

†Data obtained from Fahmy *et al.* (1985).

65 °C. Aliquots of 1 μl of the reaction mixture were analysed with a model HP-5985B GC/MS system (Hewlett Packard) equipped with a fused-quartz capillary column (25 m × 0·25 mm) containing an Ultra-1 non-polar methyl-silicone phase. The temperature program was run from 150 °C (2-min isotherm) to 250 °C at 5 °C min^{-1} and then from 250 to 300 °C at 10 °C min^{-1}. Data processing was carried out with an HP-1000 computer by using the standard programs of the GC/MS system (Hewlett Packard). A dendrogram based on principal-component analysis of whole fatty acid composition of the organisms was generated by treating the Euclidian distances of the fatty acids with the unweighted pair group method with arithmetic averages (UPGMA) algorithm.

Isoprenoid quinones were extracted by treating 100 mg lyophilized cells with chloroform–methanol (2:1, v/v) for 2 h, using a reciprocal shaker (120 strokes per min) at room temperature (Collins, 1985). The extracted solution was concentrated using a rotary vacuum evaporator and transferred by redissolving in acetone. The resulting solution was evaporated and separated by TLC using *n*-hexane–dimethyl ether (85:15, v/v) as the solvent. Quinones were detected at 269 nm, recovered from the TLC plate and dissolved in methanol. Quinones were analysed with a Finnigan Mat 8430 GC/MS system.

Nucleotide sequence accession numbers. The accession numbers of the reference strains used in the phylogenetic analyses are as follows: *B. stearothermophilus*, X60640; *B. thermocatenulatus*, Z26926; *B. thermodenitrificans*, Z26928; *B. thermoleovorans*, M77488; *B. kaustophilus*, X70430; '*B. caldolyticus*', M77484; '*B. caldotenax*', X62180; '*B. caldovelox*', M77485; *B. thermoglucosidasius*, X60641; '*Bacillus caldoxylolyticus*', AF067651; '*Bacillus thermoalkalophilus*', Z26931; *Bacillus pallidus*, Z26930; '*Bacillus flavothermus*', AF001960; *B. smithii*, Z26935; *Bacillus thermoamylovorans*, L27478; *Bacillus thermoaerophilus*, Z26934; *Bacillus licheniformis*, X60623; *B. coagulans*, X60614; *Bacillus infernus*, U20385; *B. subtilis*, X60646; *B. thermosphaericus*, X90640; *Bacillus schlegelii*, Z26934; *B. thermocloaceae*, Z26939; *B. tusciae*, Z26933; *Aneurinibacillus thermoaerophilus*, X94196; *Brevibacillus thermoruber*, Z26921; *Alicyclobacillus acidocaldarius*, X60742; *Saccharococcus thermophilus*, L09227;

Sulfobacillus thermosulfidooxidans, X91080; and *Thermobacillus xylanilyticus*, AJ005795.

RESULTS

As a result of microbiological analysis of the formation waters of high-temperature oilfields located in different geographical areas, five pure cultures (strains U^T, X, 34^T, K and Sam) of thermophilic, aerobic, hydrocarbon-oxidizing, spore-forming bacteria were obtained (Nazina *et al.*, 1993, 1995, 2000).

Colony and cell morphology

On the surface of nutrient agar, all strains formed round, mucous, small, colourless colonies with a diameter of about 1 mm (strains U^T, X, 34^T and K) or about 5 mm (strain Sam). The vegetative cells of all strains were motile (in the exponential phase) peritrichous rods with rounded ends, sometimes occurring in chains (strain X). Many sporulating cells and separately lying refractive spores could be observed in old cultures. Endospores were terminal or subterminal (strain Sam) and ellipse-shaped and did not distend the mother cell or distended it slightly (strain U^T). Morphological and cultural characteristics are presented in Table 2.

Electron-microscopic examination showed a typical Gram-positive cell envelope profile (Fig. 1), which was confirmed by Gram staining. Only strain X stained Gram-negative. Terminally swollen (strain U^T) or non-swollen sporangia liberated ellipsoidal spores. No parasporal bodies were found. A multilayered cell

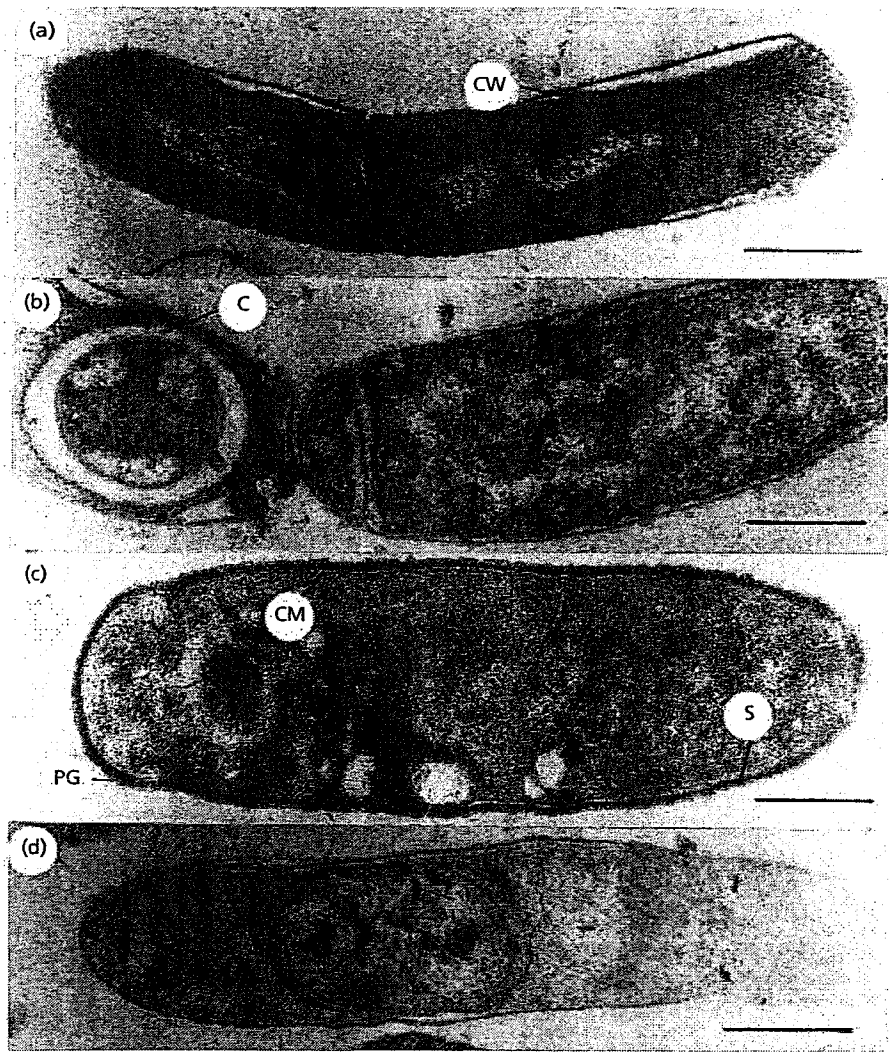


Fig. 1. Thin sections of 2-d-old vegetative and sporulating cells of strains U^T (a), X (b), K (c) and Sam (d), showing round to ovoid spores located terminally (b) or subterminally (d) within the sporangium. The cell envelope shows multiple layers, where the outermost layer exhibits the regularly arranged structure of the S layer. CW, Cell wall; CM, cytoplasmic membrane; PG, peptidoglycan; S, S layer; C, cortex. Bars, 0·5 μm.

Table 3 DNA G+C content and DNA–DNA homology (%) among the thermophilic isolates from oilfields and reference strains of the genus *Bacillus*

Taxon	DNA G+C content (mol%)		Reassociation (%) with DNA from:										
	Genome	16S rDNA	1	2	3	4	5	6	7	8	9	10	11
1. *B. stearothermophilus* 22^T	52·2	52·4	100										
2. *B. thermodenitrificans* 466	49·6	59·0	32	100									
3. *B. thermoleovorans* 5366^T	53·7	59·0	51	31	100								
4. *B. thermocatenulatus* B-1259^T	55·2	60·0	37	47	51	100							
5. Strain U^T	50·4	56·0	38	45	45	54	100						
6. Strain X	51·5	57·5	33	43	48	51	80	100					
7. Strain K	49·7	58·3	39	44	41	44	32	37	100				
8. Strain Sam	52·3	ND	37	47	45	48	42	44	93	100			
9. Strain 34^T	52·3	56·4	53	45	48	50	49		96	91	100		
10. *B. subtilis* B-4520	44·8	ND	3	5	7	4	7	9	4	5	5	100	
11. *B. subtilis* B-4537	44·1	ND	3	4	6	3	9	10	3	2	5	84	100
12. *E. coli* K-12	51·7	ND											

ND, Not determined.

envelope is seen in Fig. 1. The cytoplasmic membrane was surrounded by a thin peptidoglycan layer; an overlaid surface layer was separated from peptidoglycan by a zone of low contrast. Cell division was frequently asymmetric. In micrographs of immature spores within sporangia, the following structures were observed: mother cell wall, mother cell membrane, mother cell cytoplasm, spore coats and cortex (Fig. 1).

Nutritional requirements and physiology

The subsurface isolates were moderately thermophilic organisms able to utilize aerobically a large variety of sugars, carboxylic acids, alcohols, hydrocarbons and petroleum (Table 2). Strains 34^T, K and Sam could grow anaerobically, reducing nitrate to N_2; strains U^T and X reduced nitrate only to nitrite. Bacteria developed on synthetic media and did not require growth factors, vitamins, NaCl or KCl. Good growth was observed on potato agar and nutrient agar. Growth in liquid media with hydrocarbons was characterized by low biomass yields (300–500 mg of wet cells l^{-1}) compared with the yield of other thermophilic, hydrocarbon-oxidizing bacteria (Zarilla & Perry, 1987). Significant visible turbidity was observed in media with glucose or fructose as substrates, with a cell yield of 3–6 g l^{-1} (wet weight) and a doubling time (t_d) of 2–3 h.

All five strains produced acid but no gas from cellobiose, galactose, glucose, fructose, glycerol, maltose, mannose, ribose, sucrose and trehalose. No acid was formed from adonitol, inositol, lactose, raffinose, rhamnose, sorbitol or xylose. The substrates used by all strains as energy and carbon sources included hydrocarbons (C_{10}–C_{16}), methane–naphthenic and naphthenic–aromatic oils, peptone, tryptone, nutrient broth, yeast extract, acetate, butyrate, pyruvate, benzoate, lactate, fumarate, succinate, ethanol, phenol and phenylacetate. All five strains failed to grow autotrophically on H_2+CO_2 or to ferment glucose, were catalase-positive, hydrolysed starch and aesculin and produced NH_3 from peptone. Phenylalanine was not deaminated, Fe^{3+} was not reduced, casein was not hydrolysed and urea and tyrosine were not decomposed. H_2S, indole and dihydroxyacetone were not produced and the egg yolk lecithinase reaction and Voges–Proskauer reaction were negative.

Strains K, Sam and 34^T differed from strains U^T and X in their ability to grow on formate, to produce nitrogen from nitrate and to give a positive reaction in the methyl red test and by their failure to hydrolyse gelatin and to produce acid from arabinose.

The strains grew optimally at pH 6·8–7·0, 55–60 °C and with 0·5–1 % (w/v) NaCl in the medium. Thus, as a result of phenotypic investigation, the subsurface isolates could be divided into two groups: the first included strains U^T and X and the second included strains K, Sam and 34^T.

G+C content and DNA–DNA homologies

For DNA analysis, we used the subsurface isolates and reference strains of the thermophilic species *B. stearothermophilus* 22^T, *B. thermoleovorans* 5366^T, *B. thermocatenulatus* B-1259^T and *B. thermodenitrificans* 466, which grow at 50–60 °C and have G+C contents of 50 mol% or above (Fahmy *et al.*, 1985; Claus & Berkeley, 1986). Our data on base composition calculated from the thermal melting points (T_m) (Table 3) differed from published data by less than 0·6 mol% for *B. stearothermophilus* 22^T and *B. thermodenitrificans* 466 (Fahmy *et al.*, 1985; Claus & Berkeley, 1986). A greater difference of 4·3 mol% was observed for *B.*

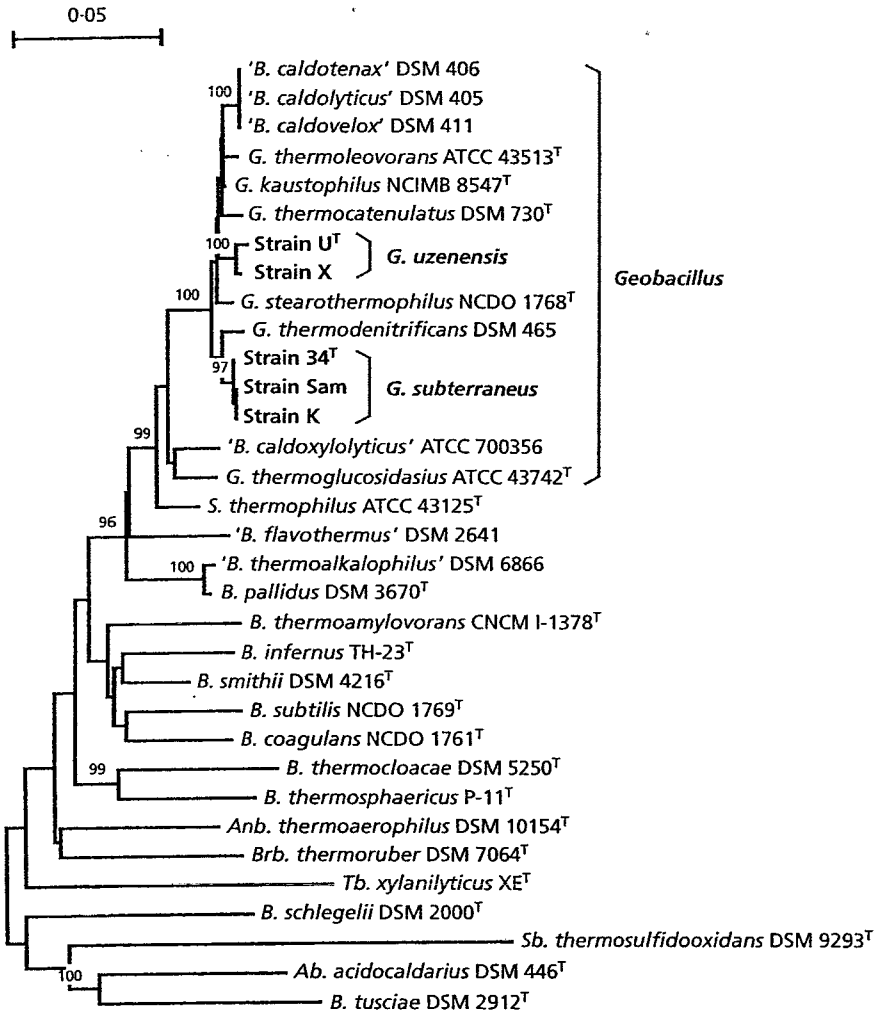


Fig. 2. Phylogenetic positions of the subsurface isolates (strains U^T, K, X, 34^T and Sam) among other thermophilic members of family *Bacillaceae*. Bootstrap values (expressed as percentages of 100 replications) are shown at branch points; values greater than 85% were considered significant. The bar indicates the Jukes–Cantor distance. Abbreviations: *G., Geobacillus; B., Bacillus; Anb., Aneurinibacillus; Brb., Brevibacillus; Sb., Sulfobacillus; Ab., Alicyclobacillus; Tb., Thermobacillus.*

thermoleovorans 5366^T (Zarilla & Perry, 1987). The G+C content of DNA of *B. thermocatenulatus* B-1259^T was determined to be 55·2 mol%, which was lower than the value reported previously for this strain (69 mol%; Golovacheva *et al.*, 1975). The five strains from oilfields had DNA G+C contents in the range 49·7–52·3 mol%, similar to those of other thermophiles of *Bacillus* rRNA group 5.

The level of DNA–DNA homology between strains U^T and X was 80%, and that between strains K, Sam and 34^T was 91–96%. The levels of homology between the two groups of strains were significantly lower (32–49%) and corresponded to those observed between the known thermophilic species of group 5 bacilli (31–51%). The levels of DNA homology between all nine thermophilic strains and two mesophilic strains, *B. subtilis* B-4520 and B-4537, were 10%.

16S rDNA sequence analysis

Almost complete 16S rDNA sequences of strains U^T, X, K and 34^T (more than 1500 nucleotides) and a partial sequence of strain Sam (430 nucleotides between positions 84 and 502 of the *Escherichia coli* nomenclature) were determined. These strains had G+C contents of 16S rDNA in the range 55·8–58·3 mol%. 16S rDNA sequence analysis showed that the new strains fall within group 5 of the genus *Bacillus* of the Gram-positive subdivision of the *Bacteria* (Ash *et al.*, 1991; Rainey *et al.*, 1994; Nazina *et al.*, 2000).

Table 4 Cellular fatty acid composition (% w/w) of the thermophilic isolates from oilfields and the recognized species of thermophilic bacilli

Taxa are identified as: 1, strain U^T; 2, strain X; 3, strain Sam; 4, strain K; 5, strain 34^T; 6, *B. thermodenitrificans* 466; 7, *B. thermoleovorans* 15366^T; 8, *B. thermocatenulatus* B-1259^T; 9, *B. stearothermophilus*; 10, '*B. caldotenax*' DSM 406; 11, '*B. caldovelox*' DSM 411; 12, '*B. caldolyticus*' DSM 405; 13, *B. thermoglucosidasius*; 14, *B. licheniformis*; 15, *B. smithii* DSM 459^T; 16, *B. thermosphaericus* $P11^T$; 17, *Aneurinibacillus thermoaerophilus* DSM 10154^T. Fatty acid abbreviations: 10:0, decanoic acid; 12:0, dodecanoic acid; a13:0, 10-methyl dodecanoic acid; i14:0, 12-methyl tridecanoic acid; 14:0, tetradecanoic acid; i15:0, 13-methyl tetradecanoic acid; a15:0, 12-methyl tetradecanoic acid; 15:0, pentadecanoic acid; i16:0, 14-methyl pentadecanoic acid; 16:0, hexadecanoic acid; i17:0, 15-methyl hexadecanoic acid; a17:0, 14-methyl hexadecanoic acid; 17:0, heptadecanoic acid; i18:0, 16-methyl heptadecanoic acid; 18:0, octadecanoic acid. Data were taken from this study (columns 1–8), Kämpfer (1994) (9, 13 and 14), Andersson *et al.* (1995) (10–12 and 15–16) and Meier-Stauffer *et al.* (1996) (17). Major components are shown in bold.

Fatty acid	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
10:0							2·7										
a13:0									5·1								
i14:0		2·3	3·3	5·2	2·9	0·4	1·0	1·3	0·1					0·5			0·2
14:0		1·1	0·3	0·5		1·8	1·4	0·6	1·5				0·6				0·2
i15:0	**20·7**	**14·5**	**39·1**	**26·3**	**37·8**	**33·6**	**22·6**	**25·5**	**39·8**	**29·0**	**27·0**	**22·0**	**22·0**	**38·0**	**19·0**	**13·0**	**54·3**
a15:0	2·0	1·7	2·2	2·1	2·3	1·8	1·3	0·6	6·4	2·0	1·0	1·0	1·6	30·4	12·0		0·6
15:0	0·4	4·1	1·6	1·3	1·4	2·3	2·1	1·3	0·5	3·0	2·0	1·0				3·0	0·6
i16:0	**16·6**	**38·9**	**27·4**	**41·7**	**29·2**	**9·5**	**21·0**	**31·8**	**6·2**	**31·0**	**26·0**	**37·0**	**10·4**	**2·0**	**6·0**	**61·0**	**2·3**
16:0	3·7	10·5	2·0	3·4	1·7	11·0	11·2	8·3	9·2	3·0	3·0	5·0	11·6	2·0	8·0	6·0	3·5
i17:0	**36·7**	7·3	**18·2**	**12·1**	**18·5**	**26·6**	**18·5**	**21·0**	**17·1**	**21·0**	**27·0**	**22·0**	**30·3**	**10·0**	**13·0**	**11·0**	**32·8**
a17:0	18·7	8·4	4·9	4·9	5·8	7·3	4·6	3·1	13·3	7·0	11·0	8·0	16·6	10·2	42·0	1·0	0·8
17:0	0·4	6·1	0·5	0·5	0·4	2·9	1·3	2·3		2·0	1·0	1·0	0·8			1·0	0·2
i18:0	0·6	0·8	0·3	1·4		0·2	0·9	1·3		1·0		2·0				1·0	
18:1		0·4		0·1		1·3	1·2	0·7									
18:0		1·4	0·2	0·5		1·3	3·4	2·2					0·5				0·3
Unsaturated C16		2·5					6·6							1·7		3·0	
Other	0·2						0·2		0·8	1·0	2·0	1·0	5·6	5·2			4·2
Total	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

The sequences of 16S rDNA of strains 34^T, K and Sam were identical; the 16S rDNAs of strains U^T and X were similar (99·4% sequence similarity). The new isolates formed a very compact phylogenetic cluster with the species of group 5: *B. thermoleovorans*, *B. kaustophilus*, *B. thermocatenulatus*, *B. stearothermophilus*, *B. thermodenitrificans*, '*B. caldolyticus*', '*B. caldotenax*' and '*B. caldovelox*' (97·3–99·5% sequence similarity). More distant relatedness was found between the new isolates and two other representatives of group 5, *B. thermoglucosidasius* and *Saccharococcus thermophilus* (96·9–97·9% sequence similarity). The unrooted phylogenetic tree in Fig. 2 shows the relationship of the subsurface strains to each other and to other organisms listed in Methods.

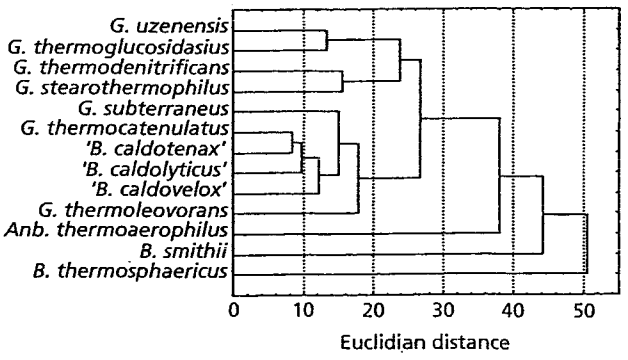


Fig. 3. Dendrogram of fatty acid similarities (Euclidian distance) based on data for strains shown in Table 4. See legend to Fig. 2 for abbreviations for genera.

Fatty acids and quinones

The fatty acid compositions of the subsurface isolates and thermophiles of group 5 (*B. thermodenitrificans* 466, *B. thermoleovorans* 5366^T and *B. thermocatenulatus* B-1259^T) were determined. The major fatty acids present in all strains were iso-fatty acids. Among them, iso-15:0, iso-16:0 and iso-17:0 accounted for about 61·7–86·8% of the total fatty acids (Table 4). All strains exhibited anteiso-15:0 and anteiso-17:0 as minor components (3·7–20·7% of total). However, a difference could be seen in the content of anteiso-17:0: it was present in smaller amounts in strains K, Sam and 34^T than in strains U^T and X.

The dendrogram in Fig. 3 summarizes the relatedness of the whole-cell fatty acid compositions of two subsurface isolates and the 11 thermophilic strains. The subsurface isolates and bacilli of group 5 formed one cluster, at a Euclidean distance of about 30. Other thermophilic bacilli did not cluster tightly with the subsurface isolates and strains of group 5, indicating that members of the latter may not belong to the same genus.

The major menaquinone detected in strains 34^T and U^T was menaquinone-7. Both strains revealed a

maximum band with an m/z value of 225, characteristic of the naphthoquinone fragment of menaquinones, and an intense band at m/z 648, corresponding to menaquinone-7, having the composition $C_{46}H_{64}O_2$.

Physiological characteristics of reference strains

We studied the utilization of saturated hydrocarbons by reference strains of group 5. Cultures were incubated without shaking at 55 °C for 4 d. *B. stearothermophilus* 22^T grew on C_{10} and C_{11} hydrocarbons (OD 0·14) and *B. thermodenitrificans* 466 and *B. thermocatenulatus* B-1259^T grew on C_{10}–C_{16} hydrocarbons (OD 0·13–0·22). Thus, the ability to utilize hydrocarbons is a widely distributed property in this group. *B. thermocatenulatus* B-1259^T and *B. thermoleovorans* 5366^T produced acid but no gas from mannose and maltose; no acid was formed from inositol. The Voges–Proskauer reaction was negative.

DISCUSSION

Geothermally heated oil reservoirs with a temperature of 50–60 °C or higher, in which liquid hydrocarbons are the prevailing organic matter, are a unique ecological niche for thermophilic, hydrocarbon-oxidizing bacteria. We have studied the microbiological characteristics of a range of high-temperature oilfields in Russia, Kazakhstan and China and isolated five strains that have a number of ecologically beneficial features that demonstrate their adaptation to the habitat (Nazina *et al.*, 1992, 1993, 1995). All five isolates were moderately thermophilic, neutrophilic, aerobic or facultatively anaerobic, motile, spore-forming rods that utilize a range of hydrocarbons, oil, aromatic compounds, lower alcohols, organic acids and carbohydrates.

Phylogenetic position

According to both DNA–DNA reassociation studies and 16S rDNA sequence analysis, the subsurface strains formed two related groups. Within each of these groups, the strains had almost identical 16S rRNA sequences (99·4–100%) and exhibited high DNA homology (80–96%). These results suggest an interspecies level of relatedness (Stackebrandt & Goebel, 1994; Wayne *et al.*, 1987) between the groups.

Examination of the 16S rDNA sequences of the subsurface isolates showed that these organisms are members of the phyletic group 5 of the genus *Bacillus*, exhibiting 96·5–99·2% sequence similarity to other members of this group. The 16S rDNA sequence similarity of this coherent cluster to the type species of the genus *Bacillus*, *B. subtilis*, was less than 91%; the sequence similarity to other thermophilic members of *Bacillus* ranged from 80·3 to 94·7% and to thermophiles of the genera *Aneurinibacillus*, *Brevibacillus*, *Alicyclobacillus*, *Thermobacillus* and *Sulfobacillus* it was 81·4–91·3%. These values indicate that the subsurface isolates and bacilli of group 5 are less closely related to the six genera above and represent the core of a new genus. The levels of 16S rDNA sequence similarity of strains U^T, X, 34^T, K and Sam to bacilli of group 5 (98·2–99·1%) were approximately the same as those between established species of this group (97·9–99·5%).

Strains Sam, K and 34^T were clearly distinct from strains U^T and X and from the type strains of the group 5 bacilli by levels of DNA homology, which were greater than 30% but less than 70%. This means that new strains and all of the group 5 bacilli examined in this work belong to one genus. The subsurface isolates exhibited low DNA homology to strains of the type species of the genus *Bacillus*, *B. subtilis* (10%). The low level of relatedness (less than 20% DNA homology for *B. stearothermophilus* and *B. thermoleovorans* to other mesophilic and thermophilic members of the genus *Bacillus*, *Bacillus amyloliquefaciens*, *Bacillus cereus*, *B. licheniformis*, *Bacillus megaterium*, *B. subtilis*, *Bacillus thuringiensis* and *B. smithii*) was demonstrated previously (Sharp *et al.*, 1980; Priest, 1981; Zarilla & Perry, 1987; Nakamura *et al.*, 1988).

Morphology and physiology

The affiliation of the subsurface isolates to two new species is supported by a number of morphological and physiological characters. The new strains were motile, spore-forming, thermophilic rods. Strains K, Sam and 34^T differed from strains U^T and X by the ability to utilize arabinose and formate and to grow anaerobically as denitrifiers, by the reaction in the methyl red test and by gelatin hydrolysis. The subsurface isolates could be distinguished from bacilli of group 5 by a number of morphological and biochemical features, nutritional traits (utilization of arabinose, cellobiose, galactose, lactose, rhamnose and xylose), production of gas from nitrate and temperature and NaCl growth ranges (Table 2).

Chemotaxonomy

On the basis of 16S rDNA sequence analysis and DNA–DNA hybridization data, chemotaxonomic studies were undertaken with the new strains and reference species of the group 5 bacilli in order to test the hypothesis that they belonged within the same higher taxon.

The presence of MK-7 in strains U^T and 34^T does not allow them to be distinguished from thermophilic bacilli of the genera *Bacillus*, *Alicyclobacillus*, *Paenibacillus*, *Brevibacillus*, *Aneurinibacillus*, *Salibacillus*, *Gracilibacillus* and *Thermobacillus*, in which MK-7 is the major menaquinone.

The genus *Bacillus* has been extensively studied with respect to fatty acid profiles and *B. stearothermophilus* was assigned to a separate group in all studies (Kaneda, 1977, 1991; Vaisanen & Salkinoja-Salonen, 1989; Kämpfer, 1994). According to our data and data

Table 5 Salient characters of genera containing thermophilic, aerobic, endospore-forming rods

Data were taken from Claus & Berkeley (1986), Golovacheva *et al.* (1975), Suzuki *et al.* (1983), Zarilla & Perry (1987), White *et al.* (1993) and Manachini *et al.* (2000) (*Geobacillus* and *Bacillus*); this study (*Geobacillus*); Shida *et al.* (1996, 1997) (*Brevibacillus*); Wisotzkey *et al.* (1992) (*Alicyclobacillus*); Heyndrickx *et al.* (1997) (*Aneurinibacillus*); Golovacheva & Karavaiko (1978), Dufresne *et al.* (1996) and Norris *et al.* (1996) (*Sulfobacillus*); and Touzel *et al.* (2000) (*Thermobacillus*). Abbreviations: MK-7, menaquinone 7; +, positive reaction; V, variable reaction; −, negative reaction; NT, not tested; ND, no data available; NA, not applicable.

Character	*Geobacillus*	*Bacillus*	*Brevibacillus*	*Aneurinibacillus*	*Alicyclobacillus*	*Sulfobacillus*	*Thermobacillus*
No. of species	8	> 60	10	3	3	3	1
Spore shape*	E, C	E, C, S, B	E	E	E	O, S	E
Sporangia swollen	+/−	+/−	+	+	+/−	+	+
Anaerobic growth	+/−	+/−	+/−	−	+/−	−	−
Catalase	+	+	+	+	+	ND	+
Optimum growth conditions:							
Temperature (°C)	55–65	V (15–55)	30–48	37–55	65	35–50	55
pH	6·5–7·0	V (7·0–9·5)	7·0	7·0	3·0	1·5–2·5	7·8
Main isoprenoid quinone	MK-7	MK-7	MK-7	MK-7	MK-7	ND	MK-7
Major cellular fatty acids	Iso-C15:0, iso-C16:0, iso-C17:0	V	Anteiso-C15:0 and iso-C15:0 or iso-C15:0	Iso-15:0, C16:0, iso-C16:0	ω-Alicyclic acids	ω-Alicyclic acids	Iso-C16:0, C16:0, anteiso-C17:0
Intragenic similarity (%) of 16S rRNA gene sequences	> 96·5	NT	> 93·2	98·6?	> 92·7	95·2	NA
DNA G+C content (mol %)	49–58	32–69	43–57	41–43	52–60	46–57	57·5

*E, Ellipsoid; S, spherical; O, oval; C, cylindrical; B, banana-shaped.

available in the literature, the subsurface isolates and all other representatives of group 5, *B. stearothermophilus*, *B. thermoglucosidasius*, *B. thermoleovorans*, *B. thermocatenulatus*, *B. thermodenitrificans*, '*B. caldolyticus*', '*B. caldotenax*' and '*B. caldovelox*', contain iso-branched saturated acids, iso-15:0, iso-16:0 and iso-17:0, as the main fatty acids (61·7–86·8% of total; Table 4) (Kämpfer, 1994; Andersson *et al.*, 1995). Thus, the fatty acid profile is a useful characteristic that distinguishes this group of bacilli clearly from other mesophiles and thermophiles of the genera *Bacillus*, *Alicyclobacillus*, *Brevibacillus*, *Aneurinibacillus*, *Sulfobacillus* and *Thermobacillus* (Fig. 3; Tables 4 and 5).

The subsurface isolates and thermophiles of group 5 differ essentially from thermoacidophilic *Alicyclobacillus* species and acidophilic *Sulfobacillus* species, which contain the rarely encountered ω-alicyclic fatty acid as the major membranous lipid component (Wisotzkey *et al.*, 1992; Norris *et al.*, 1996). They differ from *Aneurinibacillus thermoaerophilus*, which also contains iso-15:0 and iso-17:0 as dominant fatty acids, by a higher level of iso-16:0 (6·2–42 versus 2·6%) (Andersson *et al.*, 1995). They differ from the thermophilic *B. smithii* and thermotolerant *B. licheniformis* by a lower level of anteiso-15:0 plus anteiso-17:0 fatty acids (3·7–20·7% versus > 40%) and from *B. thermosphaericus*, which has an unusually high content of iso-16:0 (61%) (Andersson *et al.*, 1995; Kämpfer, 1994).

All these data show that the subsurface isolates are biochemically and genetically unique and support the proposal that they should be classified as two new species of a new genus.

Taxonomy

On the basis of physiological characteristics, the results of fatty acid analysis, DNA–DNA hybridization studies and 16S rRNA gene sequence analysis, we propose to create a new genus, *Geobacillus* gen. nov., containing the subsurface isolates as two new species, *Geobacillus subterraneus* sp. nov. (strains K, Sam and 34^T) and *Geobacillus uzenensis* sp. nov. (strains X and U^T). We propose the transfer of the validly described species of group 5, *B. stearothermophilus*, *B. thermoleovorans*, *B. thermocatenulatus*, *B. kaustophilus*, *B. thermoglucosidasius* and *B. thermodenitrificans*, to this new genus, with *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus* DSM 22^T) as the type species.

The taxonomic position of '*B. caldotenax*', '*B. caldovelox*', '*B. caldolyticus*', '*B. caldoxylolyticus*', '*B. thermoantarcticus*' and *Saccharococcus thermophilus*, included in group 5, should be investigated (Sharp *et al.*, 1980; Claus & Berkeley, 1986; Rainey *et al.*, 1994; Nicolaus *et al.*, 1996).

Description of *Geobacillus* Nazina *et al.* gen. nov.

Geobacillus (Ge.o.ba.cil'lus. Gr. n. *Ge* the Earth; L. dim. n. *bacillus* small rod; M.L. masc. n. *Geobacillus* earth or soil bacillus).

The description below is based on our observations, as well as on previous descriptions of obligately thermophilic species of the group 5 bacilli (Claus & Berkeley, 1986; Fahmy *et al.*, 1985; Suzuki *et al.*, 1983; Zarilla & Perry, 1987; Priest *et al.*, 1988; Golovacheva *et al.*, 1975, White *et al.*, 1993; Manachini *et al.*, 2000).

Vegetative cells are rod-shaped and produce one endospore per cell. Cells occur either singly or in short chains and are motile by means of peritrichous flagella or non-motile. The cell wall structure is Gram-positive, but the Gram-stain reaction may vary between positive and negative. Ellipsoidal or cylindrical endospores are located terminally or subterminally in slightly swollen or non-swollen sporangia. Colony morphology and size are variable; pigments may be produced on certain media. Chemo-organotrophs. Aerobic or facultatively anaerobic. Oxygen is the terminal electron acceptor, replaceable in some species by nitrate. Obligately thermophilic. The temperature range for growth is 37 to 75 °C, with an optimum at 55–65 °C. Neutrophilic. Growth occurs in a pH range of 6·0 to 8·5, with an optimum at pH 6·2–7·5. Growth factors, vitamins, NaCl and KCl are not required by most species. Acid but no gas is produced from glucose, fructose, maltose, mannose and sucrose. Most species do not produce acid from lactose. Most species form catalase. Phenylalanine is not deaminated, tyrosine is not degraded, indole is not produced, the Voges–Proskauer reaction is negative. Oxidase-positive or negative. The major cellular fatty acids are iso-15:0, iso-16:0 and iso-17:0, which make up more than 60 % of the total. The main menaquinone type is MK-7. The G+C content of DNA is 48·2–58 mol% (thermal denaturation method). The levels of 16S rRNA gene sequence similarity are higher than 96·5% for the members of this genus. Most species are widely distributed in nature.

The type species is *Geobacillus stearothermophilus* (basonym *Bacillus stearothermophilus* Donk 1920); the type strain of this species is strain DSM 22^T.

Description of *Geobacillus subterraneus* sp. nov.

Geobacillus subterraneus (sub.ter.ra'ne.us. L. adj. *subterraneus* subterranean, below the Earth's surface).

In addition to the description given above for the genus, the following features are characteristic for *G. subterraneus*. Cells are rod-shaped, motile by means of peritrichous flagella and produce subterminally or terminally located ellipsoidal spores in non-swollen sporangia. Gram staining is positive. Colonies are round, mucous and colourless. Acid but no gas is produced from cellobiose, galactose, glycerol, mannose and ribose. No acid is produced from adonitol, arabinose, inositol, raffinose, rhamnose, sorbitol or xylose. Utilizes as carbon and energy sources hydrocarbons (C_{10}–C_{16}), methane–naphthenic and naphthenic–aromatic oil, phenylacetate, formate, acetate, butyrate, pyruvate, benzoate, fumarate, succinate, peptone, tryptone, nutrient broth, potato agar, yeast extract, phenol, ethanol, butanol and lactate. Nitrate is reduced to dinitrogen. Does not grow autotrophically on H_2+CO_2. Gelatin is not hydrolysed. Starch and aesculin are degraded. Phenylalanine is not deaminated, Fe^{3+} is not reduced, casein is not hydrolysed, urea and tyrosine are not decomposed and H_2S, indole and dihydroxyacetone are not produced. The egg-yolk lecithinase reaction and Voges–Proskauer reaction are negative. The methyl red test is positive. Growth occurs both in the absence of NaCl and at 5% (w/v) NaCl. The G+C content of DNA is 49·7–52·3 mol%.

Isolated from formation waters of high-temperature oilfields. The type strain is 34^T, which has been deposited in the Russian Collection of Microorganisms as VKM B-2226^T, in the DSMZ as DSM 13552^T and at the China General Microbiological Culture Collection Centre as AS 12673^T, and reference strains are K (= VKM B-2225) and Sam (= VKM B-2227).

Description of *Geobacillus uzenensis* sp. nov.

Geobacillus uzenensis (u.ze.nen'sis. N.L. adj. *uzenensis* of Uzen, referring to the Uzen oilfield, Kazakhstan, from where the type strain was isolated).

In addition to the characteristics given above for the genus, the following features are characteristic for *G. uzenensis*. Cells are rod-shaped, motile by means of peritrichous flagella and produce terminally located ellipsoidal spores in swollen or non-swollen sporangia. Gram staining is positive or negative. Colonies are round, mucous, small and colourless. Acid but no gas is produced from arabinose, cellobiose, galactose, glycerol, maltose, mannitol, mannose, ribose and trehalose. No acid is produced from adonitol, inositol, raffinose, rhamnose, sorbitol or xylose. Utilizes as carbon and energy sources hydrocarbons (C_{10}–C_{16}), methane–naphthenic and naphthenic–aromatic oil, acetate, propionate, butyrate, pyruvate, benzoate, phenylacetate, phenol, ethanol, butanol, malate, lactate, fumarate, succinate, peptone, tryptone, nutrient broth, potato agar and yeast extract. Nitrate is reduced to nitrite. Does not grow autotrophically on H_2+CO_2. Gelatin, starch and aesculin are hydrolysed. Phenylalanine is not deaminated, Fe^{3+} is not reduced, casein is not hydrolysed and urea and tyrosine are not decomposed. H_2S, indole and dihydroxyacetone are not produced. The egg-yolk lecithinase reaction and Voges–Proskauer reaction are negative. The methyl red test is negative. Growth occurs both in the absence of NaCl and at 4% (w/v) NaCl. The G+C content of DNA is 50·4–51·5 mol%.

Isolated from formation waters of high-temperature oilfields. The type strain is U^T (= VKM B-2229^T = DSM 13551^T = AS 12674^T) and strain X (= VKM B-2228) is a reference strain.

Description of *Geobacillus stearothermophilus* Nazina *et al.* comb. nov. [basonym *Bacillus stearothermophilus* Donk 1920 (Approved Lists 1980, 27)]

In addition to the characteristics given for the new genus and those given for this species by Claus & Berkeley (1986), the following feature is characteristic

for *G. stearothermophilus*: it utilizes maltose and hydrocarbons (C_{10},C_{11}) as carbon and energy sources. An additional character found by Kämpfer (1994) is that the sum of iso-15:0, iso-16:0 and iso-17:0 fatty acids makes up more than 60% of the total fatty acids. The type strain of this species is strain DSM 22^T.

Description of *Geobacillus thermoleovorans* Nazina *et al.* comb. nov. [basonym *Bacillus thermoleovorans* Zarilla and Perry 1987 (Validation List no. 25, 1988)]

The description of *Geobacillus thermoleovorans* comb. nov. is identical to the description given by Zarilla & Perry (1987). Additional characters found in this study are as follows: utilizes mannose; no acid is formed from inositol; Voges–Proskauer reaction is negative; the major cellular fatty acids are iso-15:0, iso-16:0 and iso-17:0, making up more than 60% of the total fatty acids. The type strain is strain DSM 5366^T.

Description of *Geobacillus thermocatenulatus* Nazina *et al.* comb. nov. [basonym *Bacillus thermocatenulatus* Golovacheva *et al.* 1975 (Validation List no. 36, 1991)]

The original description of this species was given by Golovacheva *et al.* (1975). In addition to the characteristics given for the new genus and for this species, the following features are characteristic for *G. thermocatenulatus*: it utilizes maltose, mannose and a number of hydrocarbons (C_{10}–C_{16}) as carbon and energy sources; no acid is formed from inositol; Voges–Proskauer reaction is negative; the major cellular fatty acids are iso-15:0, iso-16:0 and iso-17:0, making up more than 60% of the total fatty acids. The revised value for the G+C content of DNA is 55·2 mol%. The type strain is strain DSM 730^T (= VKM B-1259^T).

Description of *Geobacillus kaustophilus* Nazina *et al.* comb. nov. [basonym *Bacillus kaustophilus* nom. rev. Priest *et al.* 1988 (Validation List no. 28, 1989)]

The description of *Geobacillus kaustophilus* comb. nov. is identical to that given for the new genus and to the description given by White *et al.* (1993). The type strain is strain ATCC 8005^T.

Description of *Geobacillus thermoglucosidasius* Nazina *et al.* comb. nov. [basonym *Bacillus thermoglucosidasius* Suzuki *et al.* 1983 (Validation List no. 14, 1984)]

The description of *Geobacillus thermoglucosidasius* comb. nov. is identical to that given for the new genus and to the description given by Suzuki *et al.* (1983). An additional character found by Kämpfer (1994) is that the main cellular fatty acids are iso-15:0, iso-16:0 and iso-17:0, making up more than 60% of the total fatty acids. The type strain is strain DSM 2542^T.

Description of *Geobacillus thermodenitrificans* Nazina *et al.* comb. nov. (basonym *Bacillus thermodenitrificans* nom. rev. Manachini *et al.* 2000)

The description of *Geobacillus thermodenitrificans* comb. nov. is identical to that given for the new genus and to the description given by Manachini *et al.* (2000). The type strain is strain DSM 465^T.

ACKNOWLEDGEMENTS

We are grateful to Professor H. Trüper, University of Bonn, Germany, for correction of the nomenclature of the new species, to Christian Jeanthon from the Laboratory of Marine Microbiology, CNRS UPR9042, Roscoff, France, for providing type strains of bacilli, to V. Adanin, Institute of Biochemistry and Physiology of Microorganisms, Russian Academy of Sciences, for quinone analysis and to L. L. Mityushina from INMI RAS for assistance. This work was supported by grants from the Russian Foundation for Basic Research (project number 98-04-48682), from the Russian Ministry of Science and Technology (Russian–Chinese project) and from INTAS (project number 96-1341).

REFERENCES

Adkins, J. P., Cornell, L. A. & Tanner, R. S. (1992). Microbial composition of carbonate petroleum reservoir fluids. *Geomicrobiol J* **10**, 87–97.

Andersson, M., Laukkanen, M., Nurmiaho-Lassila, E.-L., Rainey, F. A., Niemelä, S. I. & Salkinoja-Salonen, M. (1995). *Bacillus thermosphaericus* sp. nov., a new thermophilic ureolytic bacillus isolated from air. *Syst Appl Microbiol* **18**, 203–220.

Ash, C., Farrow, J. A. E., Wallbanks, S. & Collins, M. D. (1991). Phylogenetic heterogeneity of the genus *Bacillus* revealed by comparative analysis of small-subunit-ribosomal RNA sequences. *Lett Appl Microbiol* **13**, 202–206.

Ash, C., Priest, F. G. & Collins, M. D. (1993). Molecular identification of rRNA group 3 bacilli (Ash, Farrow, Wallbanks and Collins) using a PCR probe test. Proposal for the creation of a new genus *Paenibacillus*. *Antonie Leeuwenhoek* **64**, 253–260.

Brosius, J., Palmer, M. L., Kennedy, P. J. & Noller, H. F. (1978). Complete nucleotide sequence of a 16S ribosomal RNA gene from *Escherichia coli*. *Proc Natl Acad Sci USA* **75**, 4801–4805.

Claus, D. & Berkeley, R. C. W. (1986). Genus *Bacillus* Cohn 1872. In *Bergey's Manual of Systematic Bacteriology*, vol. 2, pp. 1105–1139. Edited by P. H. A. Sneath, N. S. Mair, M. E. Sharpe & J. G. Holt. Baltimore: Williams & Wilkins.

Collins, M. D. (1985). Analysis of isoprenoid quinones. *Methods Microbiol* **18**, 329–363.

De Ley, J., Cattoir, H. & Reynaerts, A. (1970). The quantitative measurement of DNA hybridization from renaturation rates. *Eur J Biochem* **12**, 133–142.

Dufresne, S., Bousquet, J., Boissinot, M. & Guay, R. (1996). *Sulfobacillus disulfidooxidans* sp. nov., a new acidophilic, disulfide-oxidizing, Gram-positive, spore-forming bacterium. *Int J Syst Bacteriol* **46**, 1056–1064.

Edwards, U., Rogall, T., Blöcker, H., Emde, M. D. & Böttger, E. C. (1989). Isolation and direct complete nucleotide determination of entire genes. Characterization of a gene coding for 16S ribosomal RNA. *Nucleic Acids Res* **17**, 7843–7853.

Fahmy, F., Flossdorf, J. & Claus, D. (1985). The DNA base composition of the type strains of the genus *Bacillus*. *Syst Appl Microbiol* **6**, 60–65.

Golovacheva, R. S. & Karavaiko, G. I. (1978). A new genus of thermophilic spore-forming bacteria, *Sulfobacillus*. *Microbiology* (English translation of *Mikrobiologiya*) **47**, 658–665.

Golovacheva, R. S., Loginova, L. G., Salikhov, T. A., Kolesnikov, A. A. & Zaitseva, G. N. (1975). A new thermophilic species *Bacillus thermocatenulatus* nov. sp. *Microbiology* (English translation of *Mikrobiologiya*) **44**, 230–233.

Heyndrickx, M., Vandemeulebroecke, K., Scheldeman, P., Kersters, K., De Vos, P., Logan, N. A., Aziz, A. M., Ali, N. & Berkeley, R. C. W. (1996). A polyphasic reassessment of the genus *Paenibacillus*, reclassification of *Bacillus lautus* (Nakamura 1984) as *Paenibacillus lautus* comb. nov. and of *Bacillus peoriae* (Montefusco *et al.* 1993) as *Paenibacillus peoriae* comb. nov., and emended descriptions of *P. lautus* and of *P. peoriae*. *Int J Syst Bacteriol* **46**, 988–1003.

Heyndrickx, M., Lebbe, L., Vancanneyt, M. & 7 other authors (1997). A polyphasic reassessment of the genus *Aneurinibacillus*, reclassification of *Bacillus thermoaerophilus* (Meier-Stauffer et al. 1996) as *Aneurinibacillus thermoaerophilus* comb. nov., and emended descriptions of *A. aneurinilyticus* corrig., *A. migulans*, and *A. thermoaerophilus*. *Int J Syst Bacteriol* **47**, 808–817.

Heyndrickx, M., Lebbe, L., Kersters, K., De Vos, P., Forsyth, G. & Logan, N. A. (1998). *Virgibacillus*: a new genus to accommodate *Bacillus pantothenticus* (Proom and Knight 1950). Emended description of *Virgibacillus pantothenticus*. *Int J Syst Bacteriol* **48**, 99–106.

Jukes, T. H. & Cantor, C. R. (1969). Evolution of protein molecules. In *Mammalian Protein Metabolism*, vol. 3, pp. 21–132. Edited by H. N. Munro. New York: Academic Press.

Kämpfer, P. (1994). Limits and possibilities of total fatty acid analysis for classification and identification of *Bacillus* species. *Syst Appl Microbiol* **17**, 86–98.

Kaneda, T. (1977). Fatty acids of the genus *Bacillus*: an example of branched-chain preference. *Bacteriol Rev* **41**, 391–418.

Kaneda, T. (1991). Iso- and anteiso-fatty acids in bacteria: biosynthesis, function, and taxonomic significance. *Microbiol Rev* **55**, 288–302.

Larsen, N., Olsen, G. J., Maidak, B. L., McCaughey, M. J., Overbeek, R., Macke, T. J., Marsh, T. L. & Woese, C. R. (1993). The Ribosomal Database Project. *Nucleic Acids Res* **21**, 3021–3023.

Logan, N. A. & Berkeley, R. C. W. (1984). Identification of *Bacillus* strains using the API system. *J Gen Microbiol* **130**, 1871–1882.

Lovley, D. R. & Phillips, E. J. P. (1988). Novel mode of microbial energy metabolism: organic carbon oxidation coupled to dissimilatory reduction of iron or manganese. *Appl Environ Microbiol* **54**, 1472–1480.

Manachini, P. L., Mora, D., Nicastro, G., Parini, C., Stackebrandt, E., Pukall, R. & Fortina, M. G. (2000). *Bacillus thermodenitrificans* sp. nov., nom. rev. *Int J Syst Evol Microbiol* **50**, 1331–1337.

Marmur, J. (1961). A procedure for the isolation of deoxyribonucleic acid from micro-organisms. *J Mol Biol* **3**, 208–218.

Meier-Stauffer, K., Busse, H.-J., Rainey, F. A. & 7 other authors (1996). Description of *Bacillus thermoaerophilus* sp. nov., to include sugar beet isolates and *Bacillus brevis* ATCC 12990. *Int J Syst Bacteriol* **46**, 532–541.

Nakamura, L. K., Blumenstock, I. & Claus, D. (1988). Taxonomic study of *Bacillus coagulans* Hammer 1915 with a proposal for *Bacillus smithii* sp. nov. *Int J Syst Bacteriol* **38**, 63–73.

Nazina, T. N., Ivanova, A. E. & Blagov, A. V. (1992). Microbiological characteristics of oil fields of Mangyshlak peninsula. *Microbiology* (English translation of *Mikrobiologiya*) **61**, 216–221.

Nazina, T. N., Ivanova, A. E., Mityushina, L. L. & Belyaev, S. S. (1993). Thermophilic hydrocarbon-oxidizing bacteria from oil strata. *Microbiology* (English translation of *Mikrobiologiya*) **62**, 359–365.

Nazina, T. N., Ivanova, A. E., Borzenkov, I. A., Belyaev, S. S. & Ivanov, M. V. (1995). Occurrence and geochemical activity of microorganisms in high-temperature water-flooded oil fields of Kazakhstan and Western Siberia. *Geomicrobiol J* **13**, 181–192.

Nazina, T. N., Tourova, T. P., Poltaraus, A. B., Novikova, E. V., Ivanova, A. E., Grigoryan, A. A., Lysenko, A. M. & Belyaev, S. S. (2000). Physiological and phylogenetic diversity of thermophilic spore-forming hydrocarbon-oxidizing bacteria from oil fields. *Microbiology* (English translation of *Mikrobiologiya*) **69**, 96–102.

Nicolaus, B., Lama, L., Esposito, E., Manca, M. C., di Prisco, G. & Gambacorta, A. (1996). '*Bacillus thermoantarcticus*' sp. nov., from Mount Melbourne, Antarctica: a novel thermophilic species. *Polar Biol* **16**, 101–104.

Norris, P. R., Clark, D. A., Owen, J. P. & Waterhouse, S. (1996). Characteristics of *Sulfobacillus acidophilus* sp. nov. and other moderately thermophilic mineral-sulphide-oxidizing bacteria. *Microbiology* **142**, 775–783.

Owen, R. J., Hill, L. R. & Lapage, S. P. (1969). Determination of DNA base compositions from melting profiles in dilute buffers. *Biopolymers* **7**, 503–516.

Priest, F. G. (1981). DNA homology in the genus *Bacillus*. In *The Aerobic Endospore-forming Bacteria: Classification and Identification*, pp. 33–57. Edited by R. C. W. Berkeley & M. Goodfellow. London: Academic Press.

Priest, F. G., Goodfellow, M. & Todd, C. (1988). A numerical classification of the genus *Bacillus*. *J Gen Microbiol* **134**, 1847–1882.

Rainey, F. A., Fritze, D. & Stackebrandt, E. (1994). The phylogenetic diversity of thermophilic members of the genus *Bacillus* as revealed by 16S rDNA analysis. *FEMS Microbiol Lett* **115**, 205–211.

Reynolds, E. S. (1963). The use of lead citrate at high pH as an electron-opaque stain in electron microscopy. *J Cell Biol* **17**, 208–212.

Ryter, A. & Kellenberger, E. (1958). Etude au microscope electronique de plasmas contenant de l'acide desoxyribonucleique. *Z Naturforsch* **13b**, 597–605.

Saitou, N. & Nei, M. (1987). The neighbor-joining method: a new method for reconstructing phylogenetic trees. *Mol Biol Evol* **4**, 406–425.

Sharp, R. J., Bown, K. J. & Atkinson, A. (1980). Phenotypic and genotypic characterization of some thermophilic species of *Bacillus*. *J Gen Microbiol* **117**, 201–210.

Shida, O., Takagi, H., Kadowaki, K. & Komagata, K. (1996). Proposal for two new genera, *Brevibacillus* gen. nov. and *Aneurinibacillus* gen. nov. *Int J Syst Bacteriol* **46**, 939–946.

Shida, O., Takagi, H., Kadowaki, K., Nakamura, L. K. & Komagata, K. (1997). Transfer of *Bacillus alginolyticus*, *Bacillus chondroitinus*, *Bacillus curdlanolyticus*, *Bacillus glucanolyticus*, *Bacillus kobensis*, and *Bacillus thiaminolyticus* to the genus *Paenibacillus* and emended description of the genus *Paenibacillus*. *Int J Syst Bacteriol* **47**, 289–298.

Sneath, P. H. A. (1986). Endospore-forming Gram-positive rods and cocci. In *Bergey's Manual of Systematic Bacteriology*, vol.

2, pp. 1104–1207. Edited by P. H. A. Sneath, N. S. Mair, M. E. Sharpe & J. G. Holt. Baltimore: William & Wilkins.

Stackebrandt, E. & Goebel, B. M. (1994). Taxonomic note: a place for DNA-DNA reassociation and 16S rRNA sequence analysis in the present species definition in bacteriology. *Int J Syst Bacteriol* **44**, 846–849.

Stackebrandt, E., Ludwig, W., Weizenegger, M., Dorn, S., McGill, T. J., Fox, G. E., Woese, C. R., Schubert, W. & Schleifer, K.-H. (1987). Comparative 16S rRNA oligonucleotide analyses and murein types of round-spore-forming bacilli and non-spore-forming relatives. *J Gen Microbiol* **133**, 2523–2529.

Sunna, A., Tokajian, S., Burghardt, J., Rainey, F., Antranikian, G. & Hashwa, F. (1997). Identification of *Bacillus kaustophilus*, *Bacillus thermocatenulatus* and *Bacillus* strain HSP as members of *Bacillus thermoleovorans*. *Syst Appl Microbiol* **20**, 232–237.

Suzuki, Y., Kishigami, T., Inoue, K., Mizoguchi, Y., Eto, N., Takagi, M. & Abe, S. (1983). *Bacillus thermoglucosidasius* sp. nov., a new species of obligately thermophilic bacilli. *Syst Appl Microbiol* **4**, 487–495.

Touzel, J. P., O'Donohue, M., Debeire, P., Samain, E. & Breton, C. (2000). *Thermobacillus xylanilyticus* gen. nov., sp. nov., a new aerobic thermophilic xylan-degrading bacterium isolated from farm soil. *Int J Syst Evol Microbiol* **50**, 315–320.

Vaisanen, O. & Salkinoja-Salonen, M. (1989). Use of phage typing and fatty acid analysis for the identification of bacilli from food packaging paper and board machines. *Syst Appl Microbiol* **12**, 103–111.

Van de Peer, Y. & De Wachter, R. (1994). TREECON for Windows: a software package for the construction and drawing of evolutionary trees for the Microsoft Windows environment. *Comput Appl Biosci* **10**, 569–570.

Wainø, M., Tindall, B. J., Schumann, P. & Ingvorsen, K. (1999). *Gracilibacillus* gen. nov., with description of *Gracilibacillus halotolerans* gen. nov., sp. nov.; transfer of *Bacillus dipsosauri* to *Gracilibacillus dipsosauri* comb. nov., and *Bacillus salexigens* to the genus *Salibacillus* gen. nov., as *Salibacillus salexigens* comb. nov. *Int J Syst Bacteriol* **49**, 821–831.

Wayne, L. G., Brenner, D. J., Colwell, R. R. and 9 other authors (1987). Report of the ad hoc committee on reconciliation of approaches to bacterial systematics. *Int J Syst Bacteriol* **37**, 463–464.

White, D., Sharp, R. J. & Priest, F. G. (1993). A polyphasic taxonomic study of thermophilic bacilli from a wide geographical area. *Antonie Leeuwenhoek* **64**, 357–386.

Wisotzkey, J. D., Jurtshuk, P., Jr, Fox, G. E., Deinhard, G. & Poralla, K. (1992). Comparative sequence analyses on the 16S rRNA (rDNA) of *Bacillus acidocaldarius*, *Bacillus acidoterrestris*, and *Bacillus cycloheptanicus* and proposal for creation of a new genus, *Alicyclobacillus* gen. nov. *Int J Syst Bacteriol* **42**, 263–269.

Zarilla, K. A. & Perry, J. J. (1987). *Bacillus thermoleovorans*, sp. nov., a species of obligately thermophilic hydrocarbon utilizing endospore-forming bacteria. *Syst Appl Microbiol* **9**, 258–264.

International Journal of Systematic and Evolutionary Microbiology (2001), 51, 35–37 Printed in Great Britain

NOTE

Reclassification of bioindicator strains *Bacillus subtilis* DSM 675 and *Bacillus subtilis* DSM 2277 as *Bacillus atrophaeus*

Dagmar Fritze and Rüdiger Pukall

Author for correspondence: Dagmar Fritze. Tel: +49 531 2616 254. Fax: +49 531 2616 418. e-mail: dfr@dsmz.de

DSMZ–Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, Mascheroder Weg 1b, D-38124 Braunschweig, Germany

On the basis of high DNA–DNA reassociation values and confirmatory automated RiboPrint analysis, two aerobic spore-forming strains hitherto allocated to *Bacillus subtilis* and used as bioindicators (DSM 675, hot-air sterilization control; DSM 2277, ethylene oxide sterilization control) are reclassified as *Bacillus atrophaeus*.

Keywords: sterilization control, '*Bacillus globigii*', red strain, '*Bacillus subtilis* var. *niger*', *Bacillus atrophaeus*

Strains of the species *Bacillus subtilis* are used in a variety of applications, an important one being sterilization control. Strains of this species produce spores of specific resistance to, for example, dry heat or ethylene oxide and are thus proposed for testing the effectiveness of such methods for sterilization (Kelsey, 1967; Russell *et al.*, 1992; US Pharmacopeia, 1995; CEN–European Committee for Standardization, 1997a, b). *B. subtilis* DSM 675, originally designated as the 'red strain', was especially suited for routine use because of its distinctly coloured colonies.

Modern taxonomic methods have led to numerous reclassifications and rearrangements of strains, species and genera. This has been particularly true for the genus *Bacillus*, which has undergone a wide range of taxonomic developments in recent years. Most of these investigations are usually based on type strains; only rarely are additional strains of the species in question included. Thus, strains of practical importance, e.g. test and control strains, are often not taken into account.

The long history of strain DSM 675, the 'red strain'

In 1900, Migula described the species '*Bacillus globigii*'. When Smith *et al.* (1952) re-examined a number of strains received under this name, they had to allocate all of them to other more established species. Strains with traits corresponding to the original description were transferred to *Bacillus licheniformis*, because the original description of '*B. globigii*' by Migula was judged to be synonymous with that for *B. licheniformis*. Those strains not corresponding to the original description were allocated to *Bacillus circulans*, *Bacillus pumilus* and '*B. subtilis* var. *niger*'. Two strains from the Bacon Laboratories (the 'red strain' and the 'brown strain') were allocated to the latter species and were designated as NRS-1221A and NRS-1221B, respectively. In the same work, the authors concurrently reduced '*Bacillus niger*' from species to variety because they had found no discriminatory property, other than pigmentation, between *B. subtilis*, '*Bacillus aterrimus*' and '*B. niger*'. This property was shown to be susceptible to culture conditions (e.g. cultivation on media containing glucose or cultivation at a high incubation temperature). Clarifying the situation, Smith *et al.* (1952) stated (p. 83) that "the characterization of *B. subtilis* serves for '*B. subtilis* var. *niger*' by adding the words substrate blackened to the description of the growth on mediums containing tyrosine".

Later, Gordon *et al.* (1973) found 'varieties' unsatisfactory and subsumed them under *B. subtilis* knowing that this was a 'lumped' group; this group, with the arrival of better tests and methods, could then be taken apart again and 'good' species described. Indeed, since then, a number of new species have been separated from the species *B. subtilis sensu stricto* and validly published (Priest *et al.*, 1987; Nakamura, 1989; Roberts *et al.*, 1994, 1996; Nakamura *et al.*, 1999).

Nakamura (1989) re-examined the black-pigment-producing strains of *B. subtilis* and, on the basis of pigment production (on two different media) and DNA hybridization studies, he was able to discriminate between three groups of strains. Group 3 did not produce any pigment on either medium and included the type strain of *B. subtilis*. Group 2 was a pigment-forming variant but still belonged to *B. subtilis sensu*

Table 1. *Bacillus* strains investigated in this study

ATCC, American Type Culture Collection; BMTU, Boehringer Mannheim Tutzing; CCM, Czech Collection of Microorganisms; CIP, Collection de l'Institut Pasteur; DSM, DSMZ–Deutsche Sammlung von Mikroorganismen und Zellkulturen; IFO, Institute for Fermentation, Osaka; NCDO, National Collection of Dairy Organisms; NCIB, National Collection of Industrial Bacteria; NCTC, National Collection of Type Cultures; NRRL, Northern Regional Research Laboratory; NRS, Nathan R. Smith.

DSM no.	History	Other collection nos
B. subtilis DSM 675	←BMTU←ATCC←N. R. Smith (1221A, '*B. subtilis* var. *niger*')←Frederick S. Bacon Laboratories, Watertown, Massachusetts, 1947 ('*Bacillus globigii*', 'red strain')←C. R. Phillips, Fort Detrick, USA ←Elisabeth McCoy	ATCC 9372, NCIB 8058, CIP 77.18 NRS 1221A, IFO 13721, NCDO 738
B. subtilis DSM 2277	←NCTC←J. C. Kelsey, London←C. R. Phillips, Fort Detrick, USA ('*B. globigii*')	NCTC 10073, NCIB 8649, CIP 103406
B. atrophaeus DSM 7264^T	←NRRL←NRS-213 ('*B. subtilis* var. *niger*')	NRRL–NRS 213^T, ATCC 49337^T
B. subtilis DSM 10^T	←ATCC←H. J. Conn, strain Marburg	NRS 744^T, ATCC 6051^T, CCM 2216^T, NCIB 3610^T, NCTC 3610^T, IFO 12210^T

Table 2. Percentage DNA–DNA similarity

The DNA–DNA similarity values are the means of at least two determinations.

Strain	DSM 2277	DSM 675	DSM 7264^T	DSM 10^T
DSM 2277	–	87	98	30
DSM 675		–	88	32
B. atrophaeus DSM 7264^T			–	ND
B. subtilis DSM 10^T				–

ND, Not determined.

stricto according to the high DNA–DNA similarity values between groups 2 and 3. Both groups (2 and 3) represent the species *B. subtilis*. Group 1, which produced a brownish-black pigment on one medium and a brown pigment on the other, showed low levels of DNA hybridization with groups 2 and 3. Thus, group 1 was described as the new species *Bacillus atrophaeus*. Twenty-one of the 25 strains in this group had previously been designated as '*B. subtilis* var. *niger*'.

Unfortunately, neither '*B. subtilis* var. *niger*' DSM 675 (or any of its equivalents in other collections) nor '*B. subtilis* var. *niger*' DSM 2277 was included in this study. To reveal the taxonomic position of these important sterilization control strains, spectroscopic DNA–DNA hybridizations (Huß *et al.*, 1983) and automated RiboPrint (Qualicon) analyses (Bruce, 1996) were performed on all relevant strains (Table 1, Table 2, Fig. 1).

The present study reveals high DNA–DNA homology values between the two strains and the type strain of *B. atrophaeus* (DSM 7264^T) and low hybridization values with *B. subtilis* DSM 10^T. In addition, RiboPrint patterns for all of the strains involved were generated and compared with each other and with other *Bacillus* type strains. Strains DSM 675 and DSM 2277 showed a close association with *B. atrophaeus*, and a separation from *B. subtilis* was confirmed (the similarity coefficients of the RiboPrint patterns were approximately 0·92 and 0·94, respectively; see Fig. 1).

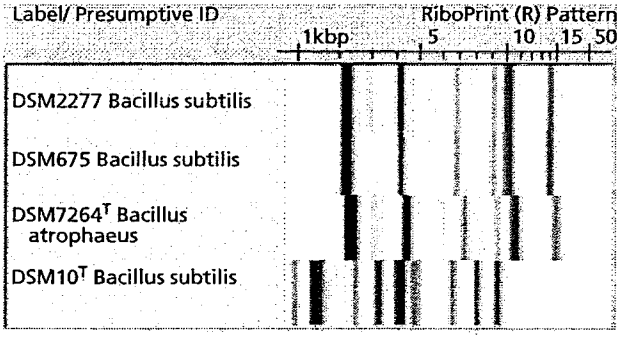


Fig. 1. Normalized RiboPrint pattern found within '*Bacillus subtilis*' strains DSM 675 and DSM 2277, related to the type strain of *Bacillus atrophaeus*, compared with the ribotype pattern of the type strain of *B. subtilis*.

Thus, both sterilization control strains DSM 675 and DSM 2277, previously named '*B. globigii*', '*B. niger*', '*B. subtilis* var. *niger*' and, finally, *B. subtilis*, have to be reclassified as members of the species *B. atrophaeus*. Species descriptions of *B. subtilis* and *B. atrophaeus* are not affected by this reclassification, as Smith *et al.* (1952) had classified the 'red strain' as '*B. subtilis* var. *niger*' after its substrate blackening of media containing tyrosine. Nakamura (1989) described the soluble pigment as 'brownish black' or 'dark brown' and stated that 'except for the colour of the soluble pigment, all of the strains were indistinguishable by the standard characterization method; i.e. they exhibited the traits typical of *B. subtilis*'.

Acknowledgements

The excellent technical assistance of Claudia Wahrenburg and Ulrike Steiner is gratefully acknowledged.

References

Bruce, J. (1996). Automated system rapidly identifies and characterizes microorganisms in food. *Food Technol* **50**, 77–81.

CEN–European Committee for Standardization (1997a). Biological systems for testing sterilizers and sterilization processes – Part 2: particular systems for use in ethylene oxide sterilizers. European Norm EN 866-2.

CEN–European Committee for Standardization (1997b). Biological systems for testing sterilizers and sterilization processes – Part 6: systems for use in hot air sterilizers. European Norm prEN 866-6.

Gordon, R. E., Haynes, W. C. & Pang, C. H.-N. (1973). *The Genus Bacillus. Agriculture Handbook No. 427.* Washington, DC: United States Department of Agriculture.

Huß, V. A. R., Festl, H. & Schleifer, K. H. (1983). Studies on the spectrophotometric determination of DNA hybridization from renaturation rates. *Syst Appl Microbiol* **4**, 184–192.

Kelsey, J. C. (1967). Use of gaseous antimicrobial agents with special reference to ethylene oxide. *J Appl Bacteriol* **30**, 92–100.

Migula, W. (1900). *System der Bakterien*, vol. 2. Jena: Gustav Fischer.

Nakamura, L. K. (1989). Taxonomic relationship of black-pigmented *Bacillus subtilis* strains and a proposal for *Bacillus atrophaeus* sp. nov. *Int J Syst Bacteriol* **39**, 295–300.

Nakamura, L. K., Roberts, M. S. & Cohan, F. M. (1999). Relationship of *Bacillus subtilis* clades associated with strains 168 and W23: a proposal for *Bacillus subtilis* subsp. *subtilis* subsp. nov. and *Bacillus subtilis* subsp. *spizizenii* subsp. nov. *Int J Syst Bacteriol* **49**, 1211–1215.

Priest, F. G., Goodfellow, M., Shute, L. A. & Berkeley, R. C. W. (1987). *Bacillus amyloliquefaciens* sp. nov., nom. rev. *Int J Syst Bacteriol* **37**, 69–71.

Roberts, M. S., Nakamura, L. K. & Cohan, F. M. (1994). *Bacillus mojavensis* sp. nov., distinguishable from *Bacillus subtilis* by sexual isolation, divergence in DNA sequence, and differences in fatty acid composition. *Int J Syst Bacteriol* **44**, 256–264.

Roberts, M. S., Nakamura, L. K. & Cohan, F. M. (1996). *Bacillus vallismortis* sp. nov., a close relative of *Bacillus subtilis*, isolated from soil in Death Valley, California. *Int J Syst Bacteriol* **46**, 470–475.

Russell, A. D., Hugo, W. B. & Ayliffe, G. A. J. (1992). Disinfection, preservation and sterilization. Oxford: Blackwell Scientific Publications.

Smith, N. R., Gordon, R. E. & Clark, F. E. (1952). *Aerobic Spore-forming Bacteria. Agriculture Mongraph No. 16.* Washington, DC: United States Department of Agriculture.

US Pharmacopeia (1995). *Twenty-third Revision*, pp. 200–204. Rockville, MD: US Pharmacopeial Convention.

GUIDANCE ON THE MICROBIOLOGICAL CHALLENGE TESTING OF HEALTHCARE WASTE TREATMENT AUTOCLAVES

INTRODUCTION

Two components of the UNDP GEF Project on Global Healthcare Waste involve the demonstration of non-incineration healthcare waste treatment technologies, the most common of which is the autoclave. This document provides a microbiological challenge test protocol for validation testing of gravity-displacement or vacuum autoclaves used for the treatment of medical waste.

OBJECTIVE OF THE TEST PROTOCOL

The objective of the test protocol is to demonstrate the ability of an autoclave to effectively treat medical waste according to accepted treatment standards.

BASIC PRINCIPLES AND GENERAL APPROACH

Treatment efficacy refers to the capability of an autoclave to alter waste such that its potential for transmitting disease is eliminated or substantially decreased. The terms disinfection and sterilization are often used when discussing treatment efficacy. Disinfection can be defined as the reduction or removal of disease-causing microorganisms (pathogens) in order to minimize the potential for disease transmission. Sterilization is defined as the destruction of all microbial life. Since the complete destruction of all microorganisms is difficult to establish, sterilization of medical and surgical instruments is generally expressed as a 6 $\log_{10}$ reduction of a specified microorganism, corresponding to a one millionth (0.000001) survival probability of the microbial population.

The STAATT classification system, in lieu of the terms disinfection or sterilization, denotes levels of "microbial inactivation" specifically for healthcare waste treatment. It was established to define measures of performance of healthcare waste treatment technologies. The international microbial inactivation standard for healthcare waste treatment based on the STAATT criteria is Level III:

> Level III Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of *G. stearothermophilus* spores and *B. atrophaeus* spores at a 4 Log_{10} reduction or greater

The representative microbiological indicators generally used to test compliance with this standard are: *Mycobacterium phlei* or *Mycobacterium bovis* (BCG) at a 6 Log_{10} reduction or greater; and heat-

resistant spores *Geobacillus stearothermophilus* or *Bacillus atrophaeus* at a 4 Log_{10} reduction or greater.

Spores of *Geobacillus stearothermophilus*, formerly called *Bacillus stearothermophilus*, are dormant nonpathogenic endospores that are able to withstand the high temperatures of steam treatment as well as dry heat. Spores of *Bacillus atrophaeus*, formerly *Bacillus subtillis var. niger*, are also resistant to moist and dry heat as well as chemical inactivation. Table 1 lists the major types of microorganisms excluding prions according to their resistance to chemical disinfection; the same pattern is found with heat disinfection. Due to the high resistance of the bacterial spores, validation testing with the "gold standard" (spores of *Geobacillus stearothermophilus* or *Bacillus atrophaeus*) is generally all that is required for waste treatment autoclaves.

Table 1. Microorganisms listed in order of *decreasing* resistance to chemical disinfection

MICROORGANISMS	EXAMPLES
BACTERIAL SPORES *[MOST RESISTANT]*	*GEOBACILLUS STEAROTHERMOPHILUS, BACILLUS ATROPHAEUS, CLOSTRIDIUM SPOROGENES*
CYST FORMS OF PARASITES	*CRYPTOSPORIDIUM* CYSTS
MYCOBACTERIA	*MYCOBACTERIUM TUBERCULOSIS VAR. BOVIS*, NON-TUBERCULOUS MYCOBACTERIA
NONLIPID OR SMALL VIRUSES	POLIOVIRUS, COXSACKIE VIRUS, RHINOVIRUS
FUNGI	*TRICHOPHYTON* SPP., *CRYPTOCOCCUS* SPP., *CANDIDA* SPP.
NON-CYST FORMS OF PARASITES	
VEGETATIVE BACTERIA	*PSEUDOMONAS AERUGINOSA, STAPHYLOCOCCUS AUREAUS, SALMONELLA CHLOERAESUIS*, ENTEROCOCCI
LIPID OR MEDIUM-SIZE VIRUSES *[LEAST RESISTANT]*	HERPES SIMPLEX VIRUS, CYTOMEGALOVIRUS, RESPIRATORY SYNCYTIAL VIRUS (RSV), HEPATITIS B VIRUS, HEPATITIS C VIRUS, HUMAN IMMUNODEFICIENCY VIRUS (HIV)

Source: *Sterilization, Part 1: Sterilization in Health Care Facilities*, Arlington: Association for the Advancement of Medical Instrumentation (2006)

The traditional method for testing wet thermal systems such as autoclaves uses endospores placed on dry paper strips protected by glassine envelopes. After processing, the strip is retrieved, carefully removed from the glassine envelope and transferred to a vial of sterile medium. Within 24 hours, the test strip is aseptically inoculated in 5.0ml soybean–casein digest broth medium. This process has to be done carefully to prevent the introduction of environmental bacteria into the medium. The strip with the growth medium is then incubated for at least 48 hours, at 30°C for *Bacillus atrophaeus* and at 55 °C for *Geobacillus stearothermophilus* to allow any surviving spores to grow and replicate. Failure of the autoclave treatment is indicated by a cloudy medium.

An easier method is used today and is recommended in this guidance document. It entails the use of a self-contained biological indicator (SCBI) comprised of a spore strip in a vial with growth medium inside a sealed inner ampoule; a cap with holes coupled with a hydrophobic filter is used as a bacterial barrier. The vial is placed inside a test load and recovered after treatment. The vial is then squeezed to break the ampoule and allow the growth medium to mix with the processed spore

strip. The vial is incubated for 24 or 48 hours at a specified temperature. The self-contained biological indicator for waste treatment autoclaves contains a pre-determined amount of spores (10^4 concentration) such that a negative test result corresponds to a 4 Log_{10} reduction. SCBIs containing a pH indicator show a change of color to indicate surviving spores and a positive result (failure). Another method uses a hermetically sealed glass ampoule with a growth medium and a pH indicator. Each ampoule, containing a known population of endospores, is kept refrigerated until use and requires a 48-hour incubation period. Growth is evident by either turbidity and/or a color change. Another biological indicator system detects the activity of an enzyme found on the bacterial spore. The enzyme's response has been shown to be equivalent to the spore's ability to multiply. This method detects the fluorescence produced by a positive indicator. Due to its high sensitivity, the method provides results in one to three hours, which has been correlated with a seven-day incubation period.

For initial validation tests of a new autoclave, the process cycle should be adjusted until at least three consecutive tests pass the requisite log reduction criteria. The operating parameters corresponding to those successful tests (exposure time, temperature or pressure) should be documented. Operating conditions for all future loads should replicate those parameters and should be recorded.

The approached used in this protocol is a microbiological challenge test using self-contained biological indicators of *Geobacillus stearothermophilus* placed into carriers that are then placed inside the waste bag to demonstrate a $\geq$ 4 log reduction of the bacterial spores.

TEST PROTOCOL

General

The following are general guidelines for the test protocol:

- The autoclave should be run at normal operating conditions.
- Tests should be conducted using waste typical for the particular healthcare facility. Special attention should be given to sharps and lab culture wastes. Test should be conducted using the same containers or bags used by the healthcare facility and sealed in the manner commonly done at the facility.
- The placement of the sample waste bag in the treatment system should reflect typical placement and stacking arrangements used. If multiple bags are treated, the biological indicators should be placed in the waste bags where treatment is most difficult.

Personnel

The test should be conducted by personnel specifically trained for this purpose. The test could be done by an autoclave operator if he or she is properly trained and supervised by a facility manager.

PPE

Occupational safety procedures should be followed when testing infectious waste. The following PPE should be used when opening medical waste bags, placing carriers into the bags, closing bags, and

placing bags into the autoclave: heavy duty gloves, face mask, goggles (or face shield), hard sole shoes (or boots), and apron (or protective gown) over regular clothes. The following PPE should be used when retrieving the carriers: heavy duty gloves, hard sole shoes (or boots), apron (or protective gown) over regular clothes, and face shield to protect from steam as needed. PPE should be cleaned after use.

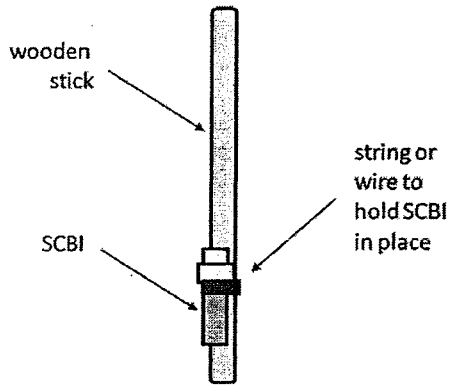
Materials

The self-contained biological indicators (SCBIs) should have the following specifications (see Appendix A for examples):

- Biological indicator: *Geobacillus stearothermophilus* spores
- Concentration: $\geq 1 \times 10^4$ cfu/ml
- D-value: greater than 1.5 minutes at 121°C (D-value > 2 min is suggested if available)

If the autoclave treats multiple bags or containers per load, three SCBIs and one control should be used for a challenge test. Each SCBI should be marked to distinguish the test indicators and the control. The three SCBIs should be placed in three separate bags, one of which should be at the center bottom of the stack. If only one bag is treated per load, one SCBI and one control should be used for a challenge test.

Carriers should be prepared as shown in the drawing below.



SCBI CARRIER
(not drawn to scale)
To be placed inside a sealed medical waste bag

Procedure

The following procedure for placement, retrieval and incubation should be followed:

A) Three individual bags typical of the average size of healthcare waste bags in the load are randomly selected. The bags are opened carefully and a carrier placed inside. The wooden stick is positioned such that the SCBI is in the middle of the bag. If inner bags are found inside the medical waste bag, the carrier is placed inside an inner bag. The bags are then fastened in the manner in which they were originally found.

B) The three bags are placed in the center bottom, middle, and top of the batch of waste in the autoclave. The control is set aside and kept at room temperature.

C) After the autoclave is filled in the usual manner, the treatment process is started.

D) The following data should be recorded: name of person conducting the test, date, operating parameters including start and finish times, general description of the waste, and weight of the bag.

E) At the end of the treatment process as the waste bags are removed, the three bags with the carriers are separated.

F) The SCBIs are retrieved from the carriers and observations made to determine if any damage to the SCBIs has occurred.

G) Once observations have been recorded, the three SCBIs and the control are incubated following the instructions provided by the SCBI vendor (typically 24 hours at 55-60°C). The incubator should be able to maintain the temperature within ±2°C during the incubation period.

H) After incubation, the SCBI ampoules or vials shall be examined for Growth or No Growth following the instructions provided by the SCBI vendor. The results shall be recorded (see sample form provided in Appendix B).

Frequency Except for the initial validation test of a new autoclave, the normal frequency of microbiological challenge testing is once a week.

If all test indicators show No Growth for four consecutive tests (one month), the frequency of testing can be decreased to once every two weeks.

Failures SCBIs that show any damage that may affect the determination of microbial inactivation (such as cracked vials and exposure of spore strips, leaking glass ampoules containing the growth medium, broken caps) should be noted in the report but not included in the determination. There should be three undamaged SCBIs for a test to be valid, otherwise the test should be repeated.

The process is considered successful if all SCBIs show No Growth. If one or more SCBIs indicate Growth, troubleshooting should be conducted to determine the source of the problem, such as the need for equipment maintenance or adjustment of operating parameters (increasing exposure time, temperature, or the number or depth of the vacuum cycles if a vacuum autoclave is used). The test should be repeated for every run until all SCBIs show No Growth. The test should be continued until three consecutive tests show No Growth for all SCBIs. Subsequently, the tests should be conducted weekly until four consecutive tests show No Growth, after which the frequency of testing can be decreased to once every two weeks.

Records The records of the results of microbiological challenge testing should be made available to regulatory authorities upon request or submitted periodically to regulatory authorities according to existing rules. The records should be kept by the facility for at least three years.

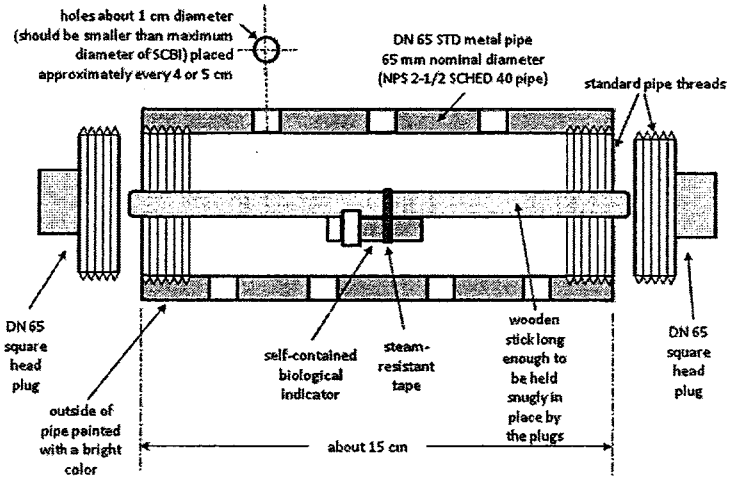
MODIFICATIONS FOR OTHER TREATMENT SYSTEMS

This protocol can be modified to apply to microwave units and steam-based hybrid systems that incorporate internal shredding or mixing such that waste bags are ruptured and the contents released inside the autoclave or microwave chamber.

To prevent the SCBIs from being destroyed by internal shredders, the biological indicators would have to be introduced into the unit in a way that would bypass the shredding section. For units that use a mixing arm or paddle or for autoclaves that rotate, a carrier should be design with the following characteristics:

- Relatively small
- Easy to open and to secure
- Robust enough to protect the SCBI and to be used repeatedly
- Designed to allow steam to penetrate easily
- Easily seen (e.g., painted with bright colors) for retrieval.

Examples of simple carrier designs are tennis balls with holes drilled through them, Teflon® tubes with holes and wooden plugs held in place by heavy gauge wire on both ends, and short metal pipes with holes and threaded caps on both ends as shown in the drawing below. Shredded waste should be placed inside the carrier along with the SCBI.



SCBI CARRIER
(not drawn to scale)
To be placed inside a sealed medical waste bag

Jorge Emmanuel, PhD and Ed Krisiunas, MT(ASCP), MPH
4 November 2010

APPENDIX A

Examples of Testing Supplies

Note 1: Mention of the products below does not constitute an endorsement or recommendation by the UNDP GEF Project. The products are presented only as examples. Other products meet the requirements in this guidance.

Note 2: These examples use 1.0×10^5 concentrations of the bacterial spores. For waste treatment autoclaves, STAATT only requires concentrations of 1.0×10^4 of bacterial spores. A 10^5 concentration is a more stringent requirement but may be easier to obtain commercially.

Raven ProSpore Ampoules or ProSpore 2 Self-Contained Biological Indicators
Geobacillus stearothermophilus ATCC 7953, minimum concentration 1.0×10^5 cfu/ml
ProSpore or ProSpore 2 dry bath incubator, 12 wells, 240 Volts, 35 or 55 °C
Raven Labs, P.O. Box 27261, Omaha, NE 68127 USA; TEL: +1-402-593-0781
http://www.mesalabs.com/products-services/raven-labs.html

3M™ Attest™ Self-Contained Biological Indicators
Geobacillus stearothermophilus (derived from ATCC 7953) in a flexible polypropylene vial, minimum population of 1×10^5 spores per strip, includes a Tryptic Soy broth growth medium with a pH-sensitive indicator dye (bromocresol purple)
Attest incubator, 220/240 Volts, 14 vial capacity, 56 ± 2°C
3M Center, St. Paul, MN 55144 USA
http://solutions.3m.com/wps/portal/3M/en_US/IP/infectionprevention/solutions/sterilization-assurance/load-control/

SporView® Self-Contained Biological Indicators
Geobacillus stearothermophilus, population 2.2×10^5, results in 24 hours
Medical Engineering Technologies Ltd., Yew Tree Studios, Stone Street, Stanford North, Ashford, Kent TN25 6DH, UK; TEL: +44 (0)8454 588924
http://www.met.uk.com/6a-medical-sterilisation-indicators.php#self-contained-biologigal

Bionova Terragene Self-Contained Biological Indicators
Geobacillus stearothermophilus bacterial spores on filter-paper packaged within a plastic tubewith a sealed-glass ampoule of culture medium and a color indicator
MedNet GmbH, Borkstraße 10, 48163 Münster, Germany; TEL: +49 (0) 251 32266-0
http://www.medneteurope.com/Sterilisation-Monitori.14.0.html?&L=2

APPENDIX B

Biological Indicator Test Log

Challenge Test

Name: _____ Date of Test: _____

Address: _____

Biological Indicator Brand: _____ Concentration: _____

Product #/Lot - _____ Expiration Date: _____

Autoclave/Model Number: _____

Autoclave Operating Parameters: _____

Cycle Start Time: _____

Cycle End Time: _____

Description of waste bags selected for the SCBIs

Sample #	Weight (kg)	Description of waste	Location in the autoclave
# 1			
# 2			
# 3			

Test results

Neg. Control	
Sample #	Results
# 1	
# 2	
# 3	
Positive Control	

Negative control is an unprocessed BI
Record results as "+" for Growth (failure)
and "NG" for No Growth

Comments / Upset conditions during testing if any:

_____

_____

_____

DRAFT

"The attached draft information is provided as a tool for organizations developing their own means for evaluating medical waste treatment technologies. This information is provided only as a framework and is not for distribution and should not in any way be interpreted or represented as an official EPA document or test protocol."

STEAM AUTOCLAVE

DESCRIPTION: Steam autoclave treatment combines moisture, heat, and pressure to inactivate microorganisms. All steam autoclaves are constructed with a metal chamber to withstand the increased pressure/temperature. Autoclaves come in two basic varieties, gravity displacement and prevacuum autoclaves. The size of the devices may vary from benchtop models to large commercial models which can treat more than a ton of waste per cycle.

OPERATING PARAMETERS: The factors that affect the efficacy of steam autoclave treatment of medical waste are those affecting the internal waste load temperature, steam penetration of the waste, and the duration of treatment. These factors include:

- temperature and pressure achieved by the autoclave
- size of the waste load
- composition of the waste load
- steam penetration of the waste
- packaging of the waste for treatment
- orientation of the waste load within the autoclave

Steam autoclaves operate most effectively when the temperature measured at the center of the waste load approaches 121 °C and there is adequate steam penetration of the waste load under pressure.

WASTES SUITABLE FOR TREATMENT BY STEAM AUTOCLAVING: All wastes with the exceptions of body parts and contaminated animal carcasses which are excluded from treatment by steam autoclaving because the density of the waste items prevents adequate steam penetration. Radioactive, hazardous, and cytotoxic wastes are also inappropriate for treatment by steam autoclaving.

INDICATOR ORGANISMS: Thermally resistant indicator organisms are selected to provide a maximum challenge. *Bacillus subtilis* (globigii) ATCC 9372 (10^4) may be used to demonstrate a 4 $\log_{10}$ reduction of viable spores.

Bacillus stearothermophilus ATCC 12980 (10^6) may be used to demonstrate a 6 $\log_{10}$ reduction of viable spores.

TEST PROCEDURE: Dried test spores are placed in a thermally resistant and steam permeable container near the center of the waste load. The autoclave is operated under normal conditions. At the conclusion of the cycle the test organisms are removed from the load and recovered within 24 hours. To recover the test organism the test discs or strips should be aseptically inoculated into 5.0 mL soybean-casein digest broth medium (or equivalent) and incubated for at least 48 hours (30 °C for *B. subtilis* or 55 °C for *B. stearothermophilus*). At the end of the incubation period the media should be examined for turbidity as a sign of bacterial growth. Any growth should be subcultured onto appropriate media to confirm the identity of the organism as the indicator organism or an environmental contaminant.

CDL-1

FACE SHEET FOR FILING DOCUMENTS WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED
IRRC

2013 AUG -5 AM 11: 12

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality.
Attorney General

By: Amy M. Elliott
(Deputy Attorney General)

JUL 23 2013
DATE OF APPROVAL

☐ Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 7-480

DATE OF ADOPTION APRIL 16, 2013

BY E. Christopher Abruzzo

TITLE E. CHRISTOPHER ABRUZZO
ACTING CHAIRMAN

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality
~~Executive~~ or Independent Agencies

BY Shawn E. Smith

APR 26 2013
DATE OF APPROVAL

(Deputy General Counsel)
~~(Chief Counsel - Independent Agency)~~
(Strike inapplicable title)

☐ Check if applicable. No Attorney General Approval or objection within 30 days after submission.

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Regulated Medical and Chemotherapeutic Waste

25 *Pa. Code*, Chapters 271-273, 284-285, 287-288 and 299

Preamble

Regulated Medical and Chemotherapeutic Waste
[25 *Pa. Code* Chs. 271, 272, 273, 284, 285, 287, 288, and 299]

The Environmental Quality Board (Board) proposes to amend 25 *Pa Code* Chapters 271, 272, 273, 284, 285, 287, 288 and 299 (relating to Municipal Waste Management – General Provisions; Municipal Waste Planning; Municipal Waste Landfills; Infectious and Chemotherapeutic Waste; Storage, Collection and Transportation of Municipal Waste; Residual Waste Management – General Provisions; Residual Waste Landfills; and Storage and Transportation of Residual Waste) to read as set forth in Annex A. The proposed rulemaking would amend Chapter 271 to add and clarify terms and definitions in § 271.1 (relating to definitions) and Chapter 284 to provide permits-by-rule for certain processors of regulated medical waste using autoclave, incineration, steam or superheated water, and chemical treatment techniques; generators of regulated medical waste processing small quantities of waste; transfer facilities; and organizations that generate regulated medical waste at multiple locations. The proposed amendments to Chapter 284 would also simplify testing requirements for autoclaves, provide flexibility in both the storage and transportation of regulated medical waste and chemotherapeutic waste, update practices for manifesting, recordkeeping, signage and disinfectant requirements, and delete provisions that are under the jurisdiction of the U.S. Occupational Safety and Health Administration (OSHA) to eliminate any potential inconsistencies. The amendments to Chapter 284 would also provide language that incorporates by reference the U.S. Postal Service's program for shipping regulated medical waste through the U.S. Postal Service. The amendments proposed to Chapters 285 and 299 would revise signage requirements for transportation vehicles to be consistent with the recommended changes to Chapter 284. Finally, the amendments to Chapters 272, 273, 287, and 288 would replace all references to "infectious" waste to be consistent with the recommended changes to Chapters 271 and 284.

This proposed rulemaking was adopted by the Board at its meeting on April 16, 2013.

A. Effective Date

This proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin.*

B. Contact Persons

For further information, contact Ali Tarquino Morris, Program Development and Support Section, P.O. Box 69170, Rachel Carson State Office Building, Harrisburg, PA 17106-9170, (717) 783-2388, or Susan Seighman, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Information regarding submitting comments on this proposal appears in Section J of this preamble. Persons with a disability may use the AT&T Relay Service by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users). This proposal is available electronically

through the Department of Environmental Protection's (Department) website at www.depweb.state.pa.us (select Public Participation).

C. Statutory Authority

This proposed rulemaking is being made under the authority of the following:

The Solid Waste Management Act (SWMA) (35 P.S. §§ 6018.101 - 6018.1003), which in section 105(a) (35 P.S. § 6018.105(a)) grants the Board the power and the duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the SWMA. Sections 102(4) and 104(6) of SWMA (35 P.S. §§ 6018.102 and 104), which provide the Department with the power and duty to regulate the storage, collection, transportation, processing, treatment and disposal of solid waste to protect the public health, safety and welfare.

The Infectious and Chemotherapeutic Waste Disposal Law (35 P.S. §§ 6019.1 - 6019.6), which at section 6019.4(b), (35 P.S. § 6019.4(b)) grants the Board the power and duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the law.

The Administrative Code of 1929 (71 P.S. §§ 510-1 - 510-27), which at section 1917-A (71 P.S. § 510-17) authorizes and requires the Department to protect the people of this Commonwealth from unsanitary conditions and other nuisances, including any condition that is declared to be a nuisance by any law administered by the Department. Section 1920-A (71 P.S. § 510-20), which grants the Board the power and duty to formulate, adopt, and promulgate such rules and regulations as may be determined by the Board for the proper performance of the work of the Department.

D. Background and Purpose

The proposed amendments represent a comprehensive revision of the Commonwealth's existing infectious and chemotherapeutic waste regulations, which is necessary for several reasons.

First, since solid waste is not always generated, processed and disposed of within the Commonwealth, the revisions allow persons generating and managing infectious and chemotherapeutic waste to do so in a manner that complies with Pennsylvania law and is consistent with federal requirements and the requirements of other states. Other states and the federal government identify infectious waste as "regulated medical waste." These amendments include revisions that would identify "infectious waste" as "regulated medical waste," making the terminology consistent with federal and other states' requirements. This change in terminology will simplify the labeling requirements on containers that are used to collect, transport, process, and dispose of the waste. Persons managing regulated medical waste will no longer need to ensure that Pennsylvania containers and labels are used and kept separate from those employed in other states. This uniform practice should reduce the costs borne by generators and other persons managing regulated medical waste because the same containers and labels could be used to satisfy Pennsylvania requirements, federal requirements and the requirements imposed by other states.

Second, these amendments streamline the transportation and shipment requirements for regulated medical waste in several respects. The amendments allow generators, transporters and those involved in storage, processing and disposal of regulated medical waste to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations instead of prescriptive and outdated paper manifests. A manifest is a document that accompanies a waste shipment and ensures that the waste being shipped is processed or disposed of in the manner intended by the generator. The Infectious and Chemotherapeutic Waste Law requires that any person who generates, transports, stores, processes, or disposes regulated medical waste use a manifest to track waste through the shipping process to the disposal facility. The amendments allow for the manifest requirement to be satisfied with a shipping paper, log or electronic tracking system that provides the required information, allowing the generator to track its waste in accordance with current industry practices. The flexibility added to this process should prove to be more efficient for all persons managing this waste stream.

In addition, the amendments authorize the transportation of regulated medical waste through the U.S. Postal Service pursuant to the U.S. Postal Service's program and requirements for shipping medical waste. The existing regulations specifically provide that sharps from small quantity generators may be sent through the mail. However, the amendments broaden this authorization to include other types of regulated medical waste in any amount or volume provided that certain conditions are satisfied, including the mailing standards and other relevant regulations of the U.S. Postal Service. This should provide generators, especially those generating small quantities of medical waste, with an alternative transportation and disposal option.

The amendments also encourage labor and fuel efficiency by removing certain storage and transportation restrictions. The existing regulations limit storage of regulated medical waste at the generation site for a maximum of 30 days from the date that waste was first placed into the container. This provision governing the duration of storage has required small generators to transport partial loads offsite, and thereby incur additional costs. The amendments allow for generators to store regulated medical waste for up to 30 days from the date that the container is full or the date the generator seals the container, whichever occurs earlier. These revisions provide the generator with more control over the length of time the waste may be stored onsite and promote more efficient business practices by reducing the need to transport partial loads, which will result in a cost savings for the generator.

Additionally, the revisions allow haulers to transport containerized regulated medical waste and chemotherapeutic waste along with other wastes in the same vehicle. This will reduce the number of trips needed to transport waste from generators that have both regulated medical waste and other waste streams which require disposal, provided that the transportation can be done in a manner that does not adversely affect the public health and safety or the environment.

These amendments also eliminate provisions that relate to areas governed by OSHA. This removes the possibility that provisions may be inconsistent or duplicative of OSHA requirements but in no way affects the applicability of OSHA requirements to persons within the Commonwealth.

E. Summary of Regulatory Requirements

The following discussion outlines the regulatory requirements that have been affected by the proposed regulations and describes the basis for the amendments.

There has been one global change to the regulations. "Regulated medical waste" has been added as a new term and is defined in § 271.1 as "infectious waste." Aside from the definition of "infectious waste" in § 271.1, all other references to "infectious waste" have been removed throughout Chapters 271, 272, 273, 284, 285, 287, 288, and 299 and replaced with "regulated medical waste." There is no substantive change in the definitions, other than minor amendments set forth in the following discussion on § 271.1. This shift in terminology will result in Pennsylvania's labeling requirements being consistent with federal and other states' requirements.

Section 271.1 – Definitions

The Board is proposing to amend certain terms and to add additional terms that assist in the identification of materials that are considered regulated medical or chemotherapeutic waste. The terms used to identify these classifications of waste include the following: "autoclave," "body fluids," "commercial regulated medical or chemotherapeutic waste facility," "disinfection," "general composting facility," "incineration," "infectious waste," "mobile regulated medical waste processing facility," "regulated medical waste," "regulated medical waste aggregation facility," "sharps," "special handling waste," "thermal processing," and "unrecognizable regulated medical waste." Of these terms, "autoclave," "disinfection," "general composting facility," "special handling waste," "thermal processing," and "unrecognizable regulated medical waste" include a reference to "infectious waste" within their definitions. That reference has been replaced with "regulated medical waste."

The term "body fluids" has been revised to include saliva because saliva is a fluid that is capable of containing visible blood.

The definition for "commercial regulated medical or chemotherapeutic waste facility" has been amended to eliminate redundancies and is rewritten for clarity.

The definition for "environmental protection acts" has been revised by citing the relevant sections so that the formatting is consistent with the other citations.

The term "incineration" has been added and is defined as the act of reducing to ashes by combustion. "Incineration" has been added to the list of definitions to clarify its meaning throughout Chapter 271.

As indicated previously, the term "regulated medical waste" is being defined in the amendments as "infectious waste," thereby incorporating the existing definition of "infectious waste." However, some changes have been made to the definition of "infectious waste" as described below:

- Pathological wastes will not include tissues that have been preserved in formaldehyde or any other approved preserving agents, because preserved tissues do not exhibit the pathological characteristics of unpreserved tissues. Therefore, preserved tissues have been explicitly excluded from pathological wastes.
- Components of human blood and body fluid waste have been added. Soft plastic pipettes and plastic blood vials that have been used for blood transfusions will be considered human blood and body fluid waste. Also, tubing that is used to connect the intravenous bag to the patient has been added.
- Under the category for animal wastes, all animal waste known to have been exposed to zoonotic infectious agents or nonzoonotic human pathogens is now defined as infectious waste in the proposed regulation. The requirement that exposure to said pathogens must have occurred during research in order for the animal wastes to fall subject to regulation has been removed.
- Used sharps are no longer limited to those generated at medical, research or industrial laboratories.
- Tissues and specimens that are being transported to or stored at a laboratory prior to laboratory testing will be excluded from infectious waste.
- Because regulated medical waste incineration is no longer covered under Chapter 283 (relating to resource recovery and other processing facilities), ash residue from the incineration of regulated medical waste will be regulated under § 284.321, which relates to regulated medical waste monitoring requirements. Therefore, the regulatory reference in subsection (iii)(F) under the definition of infectious waste has been corrected and now references § 284.321.

The term "mobile infectious waste processing facility" has been changed to "mobile regulated medical waste processing facility."

The term "regulated medical waste aggregation facility" has been added and is defined as a facility that accepts, aggregates or stores regulated medical waste.

The definition for "sharps" has been amended to clarify an existing ambiguity. Broken glass no longer has to have been in contact with pathogenic organisms to be considered sharps, as are syringes to which a needle is or can be attached. The phrase "with or without the attached needle, suture needles," is redundant and has been removed. Razors are no longer required to be "disposable" to qualify as sharps.

Subchapter A. General Provisions

Section 284.1 – Scope

References to Chapter 283 (relating to resource recovery and other processing facilities) and Chapter 285 (relating to storage, collection and transportation of municipal waste) have been added.

Section 284.2 – Permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements.

The amendments to § 284.2 provide 6 permits-by-rule for qualifying processing facilities, which implement autoclaves, incinerators, steam and superheated water disinfection, onsite processing of blood and body fluids, short duration storage facilities, and small quantity generators that process their own waste.

In order for autoclaves, incinerators, and steam superheated water disinfection operators to qualify for a permit-by-rule under paragraphs (a)(1)-(3), the facility must process at least 50% of its own regulated medical and chemotherapeutic waste, and is limited to accepting not more than 50% of regulated medical waste for processing from small quantity generators. Facilities that process waste must ensure that the processed waste is disposed or processed in a landfill or incinerator authorized to accept the waste. The operator of the facility must also provide the Department with the following: a notice of intention to operate under permit-by-rule, the name and address of the facility, a description of the processing activity, and the names and telephone numbers of the individuals responsible for operation of the processing facility.

More specifically under paragraphs (a)(1) and (3), autoclave facilities and facilities with steam and superheated water disinfection may not process pathological or chemotherapeutic waste. However, these facilities may process regulated medical waste to render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing, or breaking. Existing regulations required the waste to be vaporized, but the amendments have revised the language to "render the waste unrecognizable" since, by definition, autoclaves do not vaporize all liquid. Under paragraph (a)(2) a processing facility with an incinerator may process other municipal waste generated onsite if the resulting ash is managed as regulated medical or chemotherapeutic waste.

The permit-by-rule available under paragraph (a)(4) is for onsite processing of liquid blood and body fluids using chemical treatment techniques that encapsulate or convert liquid blood or body fluids into solids or gels such that no free liquids remain. The proposed regulations provide the Department with the authority to approve the use of other disinfectant-based products under this paragraph if their effectiveness can be demonstrated. The processed regulated medical waste may be disposed at a municipal waste landfill provided that no free liquids remain in the processed waste, and the landfill has received written approval from the Department authorizing the disposal of this type of processed medical waste.

The permit-by-rule at paragraph (a)(5) covers transfer facilities that temporarily store regulated medical or chemotherapeutic waste for up to 72 hours, provided that the stored waste remains in its original packaging and is not putrescent.

The permit-by-rule at § 284.2(b) applies to generators that process and disinfect less than 220 pounds per month of regulated medical waste onsite, but do not render the waste unrecognizable. The generator shall dispose of the processed waste in a landfill or have the waste incinerated in a facility that has written approval from the Department to accept this type of waste. In addition, the generator must comply with the manifest requirements as set forth in § 284.701(b)(5) (relating to scope).

Subsection (c) specifies the operating requirements for the permit-by-rule facilities identified in subsections (a)(1) - (4) and (b). Paragraph (c)(1) incorporates the amended citations that require

the facility to comply with the requirements in Chapter 284, Subchapters E and F (relating to segregation and storage; and collection and transportation) and Chapter 285 (relating to storage, collection and transportation of municipal waste).

For facilities operating under subsection (a), in addition to the current requirements, amendments to (c)(3)(i) require the written plan used to manage regulated medical waste generated at the facility to also contain the frequency of equipment calibration.

Under paragraph (c)(8), for onsite autoclave facilities, "treated or processed regulated medical waste" is substituted for "processing residue" in the proposed regulation because "treated or processed regulated medical waste" more clearly describes waste that has not been rendered unrecognizable.

Paragraphs (c)(10) and (11) have been removed because these compliance criteria have been included in paragraphs (1)-(3) of proposed subsection (a).

Section 284.3 – Regulated medical waste aggregation facilities

This section has been added to establish a permit-by-rule for regulated medical waste aggregation facilities. The regulated medical waste aggregation facilities must comply with the generator standards in Subchapter E (relating to segregation and storage) and only accept waste generated onsite or offsite by the operator of the aggregation facility, or waste generated in the same building or complex of buildings by physicians in their private practices or other medical personnel. The Department retains the ability to require an operator to obtain an individual permit, or take other appropriate action, if the generator is not in compliance or harms or presents a threat of harm to the health, safety or welfare of the people or the environment.

Subchapter B. General Permits

Section 284.102 – Nature of a general permit; substitution for individual applications and permits

Regulatory references that no longer exist have been removed from § 284.102, and a clause has been added clarifying that the Department can require a person or municipality authorized by a general permit to obtain an individual permit if a general permit is not available to conduct the specified activity.

Section 284.111 – Application for general permit

A typographical error has been corrected: "employes" has been changed to "employees."

Section 284.112 – Completeness Review

The Department previously required that potential users of certain general permits obtain a determination of applicability from the Department prior to conducting the activity authorized by the general permit. The Department has since determined that a registration process for the issuance of general permits will be used, as opposed to a determination of applicability.

Therefore, the language regarding the determination of applicability has been removed from subsection (a).

Section 284.115 – Department-initiated general permits

"Departmental" has been replaced with "Department" in paragraph (c)(5) for clarity.

Section 284.116 – General permit renewal

Section 284.116 has been added to provide a procedure for renewing general permits. The section is based on the existing practices of the Department and has been added for clarity.

Section 284.121 – Contents of general permits

The Department believes that a registration process will increase efficiency in the processing of general permits for both the applicant and the Department. Under the proposed regulation, the Department has eliminated determinations of applicability from the process of general permit issuance. Therefore, language regarding determination of applicability has been removed from paragraph (3) of § 284.121.

The requirement in paragraph (11) that processing residue be disposed of in a landfill has been removed and replaced with a requirement for processing residue to be managed in accordance with the Solid Waste Management Act to avoid potential conflicts.

In addition, a typographical error has been corrected in paragraphs (12) and (13): "employes" has been changed to "employees" or "employee" where grammatically correct.

Finally, in paragraph (18), the prohibition of processing pathological waste or chemotherapeutic waste in an autoclave has been rewritten for clarity.

Section 284.122 – Modification of certain requirements

In § 284.122 of the proposed regulation, the term "waiver" has been deleted from the section heading. The Department retains the ability to waive certain requirements where those requirements are inappropriate or otherwise not applicable to the applicant's proposed operation under a general permit. However, in such a situation, the Department would modify the applicant's permit conditions to account for requirements that may not apply to the applicant's operation.

Provisions that limit the Department's flexibility to provide applicants with an effective permit have been removed from subsection (b). These mandatory provisions relate to the Department's legal right to enter the permitted area, the identification of interested parties, compliance information, verification of the application, and the administration of civil penalties and enforcement actions. Removal of these mandatory provisions will allow the Department to use its discretion in issuing and modifying permits to provide the applicant with a permit that makes sense within the context of the applicant's proposed operation, while complying with the regulations that are in the best interest of the Commonwealth.

Section 284.131 – Authorization for persons or municipalities to be included in a general permit

The Department is using a registration process, instead of a determination of applicability, to authorize an applicant's operation under a general permit. Therefore, language relating to determinations of applicability has been removed from § 284.131.

Section 284.132 – Determination of applicability

The Department has determined that a registration process will be used for the issuance of general permits, instead of a determination of applicability. Therefore, § 284.132 is no longer necessary and has been removed from the proposed regulations.

Subchapter C. Transfer Facilities

Section 284.210 – Application requirements

A typographical error has been corrected in this section: The reference to sections "279.101 – 279.111 (relating to general requirements)" has been changed to "279.101 – 279.111 (relating to application requirements for transfer facilities)" to accurately reflect the name of the referenced sections.

Section 284.220 – Operating requirements

Section 284.220 has been revised to reference the sections in Chapter 279 that are applicable to operating requirements for transfer facilities.

Subchapter D. Processing Facilities

Section 284.320 – Operating requirements

Section 284.320 has been revised to reference the sections in Chapter 283 that are related to operating requirements for processing facilities.

Section 284.321 – Regulated waste monitoring requirements

Throughout the section, abbreviations of spore names have been spelled out for clarity, and the nomenclature of "Bacillus stearothermophilus" has been updated to "Geobacillus stearothermophilus" to reflect its taxonomy in a new genus.

The current regulations require that microbiological analysis of a composite sample of the processing or ash residue be submitted to the Department quarterly. In proposed subsection (b), the requirement to submit these microbiological analyses is reduced to annual submissions to be consistent with the schedule for submission of chemical analyses contained in subsection (c).

Subsection (f) regarding disinfection has been revised to require that sterility indicators, analyzed to verify the effectiveness in the disinfection process, must be placed within the load where disinfection is most difficult to achieve.

Subsection (m) has been revised to state that an autoclave facility must comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapeutic waste.

Also, autoclave testing requirements have been added in subsection (n) to ensure that disinfection occurs under the proper operating conditions, with reference to § 284.322 (relating to autoclave validation testing requirements).

Section 284.322 – Autoclave validation testing requirements

Section 284.322 has been added to define the proper protocols and testing conditions that processors must use to test their autoclaves. The requirements of the section ensure that proper performance criteria have been met and adequate disinfection is achieved. Generally, each autoclave must be tested individually to establish its operating parameters prior to its first use and regularly thereafter. If a facility uses multiple autoclaves that are identical, an initial validation test may be performed on one of the autoclaves, and the results used to establish the operating parameters of all identical autoclaves at the facility.

Subchapter E. Segregation and Storage

Subchapter E has been reorganized to mirror the steps taken by generators and processors when managing waste, starting with the segregation of waste through its storage. Since segregation by waste type is the first step taken by the generator in managing regulated medical and chemotherapeutic waste, the Department has relocated the section regarding segregation, so that it is the first section in Subchapter E following a description of the subchapter's scope. The order of management continues by next addressing basic storage requirements, followed by storage containers, marking of containers, duration of storage, reuse of containers, storage of ash residue and storage of processing residue. Table 1 below summarizes the reorganization of sections in Subchapter E:

Table 1

Subject of Section	Location in Current Regulation	Location in Proposed Regulation
Segregation	**§ 284.412**	**§ 284.411**
Basic storage requirements	**§ 284.411**	**§ 284.412**
Storage containers	**§ 284.415**	**§ 284.413**
Marking of containers	**§ 284.416**	**§ 284.414**
Duration of storage of waste for generators	**§ 284.413**	**§ 284.415**
Duration of storage of waste for processors	**§ 284.414**	**§ 284.416**
Reuse of containers	**§ 284.417**	**§ 284.417**
Storage of ash residue	**§ 284.418**	**§ 284.418**
Storage of processing residue	**§ 284.419**	**§ 284.419**

Section 284.401 – Scope

The description of the reference to § 285.121 has been revised from "types of storage" to "containers" to correspond with the correct name of § 285.121.

Section 284.411 – Segregation

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors. The name of proposed § 284.411 has been changed from "Sorting," currently located in § 284.412, to "Segregation."

In addition, the section has been changed to state that regulated medical and chemotherapeutic waste be separated into the following three categories at the point of origin in the generating facility: (1) regulated medical waste, excluding pathological waste; (2) pathological waste; and (3) chemotherapeutic waste. Sharps that qualify as regulated medical waste may be placed in a chemotherapeutic waste sharps container under the proposed regulations. This section also

contains requirements for bags used to store waste, which is discussed in § 284.413 (relating to storage containers).

Section 284.412 – Basic storage requirements

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors. Basic storage is the next logical step considered by generators and processors after the waste has been segregated.

Subsection (a) was revised to ensure segregation occurs first, and the temperature for refrigeration has been added in degrees Fahrenheit in paragraph (a)(4) for clarification.

Section 284.413 – Storage containers

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors.

Subsection (f), regarding protective clothing for persons packaging regulated medical or chemotherapeutic waste, has been removed in order to eliminate any possible conflicts with OSHA regulations or other workplace safety procedures.

Section 284.414 – Marking of containers

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors. Throughout proposed § 284.414, "infectious waste" has been replaced with "regulated medical waste" with regards to marking containers, and the labeling requirements have been revised so that compliance is more convenient, while maintaining the intention of the regulations.

The proposed amendments provide a one-year transition period after the effective date of the regulations for persons to comply with the new labeling requirements.

Also, containers will no longer be labeled with the date the waste was generated; instead, labels must include the date the container was full or the date the generator sealed the container. The exception to this rule is that roll-off containers need not be marked with the date, but a record of the date on which the roll-off was full or sealed must be maintained at the generating facility for at least one year.

In the proposed regulation, labeling requirements only apply when waste is transported offsite. For onsite transportation of waste within the same geographical property or facility, such as within a hospital campus, it is no longer necessary for generator and transporter information to be labeled on the containers.

Prescriptive size requirements for container labels have been replaced with performance-based requirements that ensure labeling is clearly legible.

Section 284.415 – Duration of storage of regulated medical waste for generators

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors.

Throughout § 284.415, language referring to "the date that waste was first placed in a container" has been changed to "to the date that the container was full or sealed" in order to be consistent with other sections of the proposed regulations. Therefore, under proposed § 284.415, generators are required to mark the container with the date on which the container was full or the date that the container was sealed, as required in § 284.414 (relating to marking of containers), and generators may store regulated medical waste onsite for up to 30 days from the date the container was full or sealed. Language relative to freezing as a method to lengthen the duration of storage has been removed from § 284.413 because the time periods for storage were difficult to interpret. Temperature standards for storage are now located in § 284.412. The requirement that putrescent waste be moved offsite within 24 hours has been changed to within 3 business days. The Department believes that the new amendments are more easily understood and provide generators sufficient storage times under typical operations, while maintaining the intent of the regulations.

Section 284.416 – Duration of storage of regulated medical waste for processors

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors. Storage temperatures in proposed § 284.416 were modified slightly to correct errors in the existing text.

Section 284.417 – Reuse of containers

Current § 284.417 provides separate subsections addressing the reuse of nonfiberboard containers housing regulated medical waste versus chemotherapeutic waste. Proposed § 284.417 allows the same standards to apply for the reuse of nonfiberboard containers regardless of whether the container houses chemotherapeutic waste or regulated medical waste. Therefore, subsection (d), regarding the reuse of containers housing chemotherapeutic waste, has been removed, and subsection (c) has been modified to include chemotherapeutic waste.

Section 284.418 – Storage and containment of ash residue from regulated medical or chemotherapeutic waste incineration

Paragraph (a)(2) has been clarified to indicate that ash residue must be stored on a pad to contain a spill or release of ash and facilitate clean-up.

Subchapter F. Collection and Transportation

Section 284.511 – Transportation of ash residue from regulated medical or chemotherapeutic waste incineration

Subsection (c) has been rewritten to more clearly state that ash from separate generators must be kept separate. Subsection (d) has been rewritten to more clearly state that municipal waste may

be commingled with ash residue from regulated medical or chemotherapeutic waste incineration for transportation, provided that both come from the same generator.

Section 284.512 – Transportation of regulated medical and chemotherapeutic waste; general provisions

In paragraph (b)(4), a Fahrenheit equivalent has been added to clarify the temperature required to maintain waste in a non-putrescent state.

The prescriptive strength and weight limits for a corrugated fiberboard container in subparagraph (c)(1)(iv) have been removed and replaced with performance-based requirements that require containers to be of sufficient strength to prevent puncturing, tearing and bursting during transportation. Subparagraph (c)(1)(v) has been added to reference § 284.414, relating to marking of containers to ensure that the containers are marked properly for transportation.

Subsection (d) has been deleted because infectious waste, now labeled as regulated medical waste, and chemotherapeutic waste are required to be segregated into separate containers at the point of generation. Since these wastes are containerized and not commingled, the Department proposes to allow these containerized waste streams to be transported in the same vehicle and has removed the existing prohibition.

Subsection (e) has been added to clarify that, although regulated medical or chemotherapeutic waste may be transported in the same vehicle as municipal waste, it may not be commingled with municipal waste or transported in the same vehicle with residual waste.

In subsection (g) the transport time for regulated medical waste in an unrefrigerated vehicle has been increased from 48 to 72 hours provided the waste is not putrescent. This allows transporters to more easily comply with the regulations, provided the waste is not putrescent.

Section 284.513 – Transportation of regulated medical and chemotherapeutic waste; additional provisions

The reference to OSHA regulations in paragraph (b)(2) has been corrected to accurately cite the applicable OSHA regulation relating to bloodborne pathogens and the standards for biohazard signage.

Paragraph (c) has been revised to state that portable disinfectants must be EPA-approved.

Subsection (e) has been deleted from proposed § 284.513 to remove potential conflicts with OSHA regulations or workplace safety procedures.

Section 284.514 – Transportation of processing residue from a regulated medical or chemotherapeutic waste facility

Subsection (b) has been rewritten to more clearly state the requirement that processing residue from chemotherapeutic or regulated medical waste from separate generators must be transported separately.

Subchapter G. Transporter Licensing for Regulated Medical and Chemotherapeutic Waste

Section 284.602 – License requirement

A grammatical error, "onside" instead of "onsite," has been corrected, and a minor clarification has been made to paragraph (b)(3).

Section 284.623 – Conditions of licenses

A grammatical error, "employes" instead of "employees," has been corrected.

Section 284.641 – Bond requirement

All subsections of § 284.641 in the current regulation are given a heading, except for subsection (f). Therefore, for consistency, "*Review of bonds*" has been added as the heading for subsection (f).

Subchapter H. Manifesting for Regulated Medical and Chemotherapeutic Waste

Section 284.701 – Scope

In the proposed regulations, logs or shipping papers, including electronic tracking systems, are recognized acceptable ways of tracking waste for manifesting purposes. Paragraph (b)(4) incorporates by reference the U.S. Postal Service's program for shipping regulated medical waste. Additional minor clarifications have been made throughout the section.

Section 284.702 – Transfer facilities

The subsections of § 284.702 have been renumbered for clarity. Language in former subsection (a) regarding the existing paper manifest tracking system has been removed because shipping papers or logs, including electronic tracking systems, have become acceptable standard business practices for tracking the transportation and delivery of regulated medical and chemotherapeutic wastes. Subsection (b) has been renumbered and rewritten for clarity, and a provision has been added to proposed paragraph (1), which requires the transfer facility to be permitted by the Department.

Section 284.703 – Recordkeeping

In proposed § 284.703, the subsection numbering has been removed. The record retention requirement in former subsection (a) has been reduced from 5 years to 2 years. Section 284.703 has been revised to clarify that the record is to be retained for 2 years from the date the record was prepared, and records shall be submitted to the Department upon request. Subsection (b) regarding manifests is obsolete and has been removed.

Section 284.711 – Use of manifest

Language regarding manifests has been removed because logs or shipping papers, including electronically based tracking systems, are acceptable standard business practices and are acceptable for compliance with the proposed regulation.

Section 284.712 – Preparation of manifest

Generators shall be required to create a log or shipping paper, which will qualify as a manifest, allowing the use of standard shipping procedures to track regulated medical waste during shipment through to its disposal.

Paragraph (a)(10) has been removed from the proposed regulation because, in accordance with proposed § 284.722(f) (relating to preparation and use of manifest), the generator will receive the shipping log back from the transporter after the waste has been delivered to the designated facility. Therefore, the designated facility no longer needs to be included in the original shipping log prepared by the generator.

Section 284.713 – Reserved

This section has been removed because the record or shipping log is not required to be distributed to the various parties as previously required.

Section 284.714 – Exception reporting

In subsection (a), a log or shipping paper is to be received by the generator rather than a copy of a manifest since logs or shipping papers will satisfy the manifesting requirement under the proposed regulations and the Infectious and Chemotherapeutic Waste Disposal Law. The time limit for the paperwork to be completed and transmitted to the proper entity has been extended from 20 days to 30 days based on the amount of time needed for industry practices.

Subsection (b) has been reworded for clarity.

Section 284.721 – Reserved

This section is now reserved because the provisions to satisfy the manifest requirements have been amended.

Section 284.722 – Preparation and use of manifest

The provisions regarding manifest copies have been removed because logs or shipping papers, including electronic tracking systems, now qualify as a manifest under these proposed regulations. The transporter shall ensure that processing facilities and generators have been provided with the relevant logs or shipping papers that are required.

Section 284.723 – Reserved

This section is now reserved because the provisions to satisfy the manifest requirements have been amended.

Section 284.724 – Transportation limitations

Regulatory citations have been changed to maintain accuracy with the proposed reorganization of Subchapter E. Information regarding copies of the manifests has been removed since this requirement will be satisfied by logs or shipping papers.

Section 284.731 – Scope

Section 284.733 has been reserved in the proposed regulation. Therefore, the reference to § 284.733 has been removed from § 284.731. Also, in proposed § 284.731, language regarding "owners" of waste processing facilities has been deleted since the owner of the facility may or may not be involved with the daily operations of the facility.

Section 284.732 – Use of manifest

Language regarding "owners" of waste processing facilities has been deleted since the owner of the facility may or may not be involved with the daily operations of the facility. A log or shipping paper has been substituted for manifests to simplify documentation procedures.

Section 284.733 – Reserved

This section is now reserved because the provisions to satisfy the manifest requirements have been amended.

Section 284.734 – Significant discrepancies

In paragraph (a)(2), a significant discrepancy is defined as less than 1% variation in piece count for batch waste and 5% weight discrepancy for bulk waste. The time limits in subsection (b) have been changed from days to business days, allowing more flexibility for a resolution to be reached in the case of a dispute.

Section 285.218 – Signs on vehicles

"Infectious or chemotherapeutic waste" has been replaced with "regulated medical or chemotherapeutic waste" throughout the proposed regulation. Therefore, required signage on transportation vehicles must also change. Signs on vehicles transporting regulated medical or chemotherapeutic waste must now read "Regulated Medical/Chemotherapeutic Waste" under the proposed regulations.

F. Benefits, Costs and Compliance

Benefits

The proposed amendments simplify the labeling requirements to reduce costs and ensure consistency with the requirements of other states and the federal government. The new regulations would allow generators, transporters and those involved in storage and processing to use standard business documentation to demonstrate compliance with the regulations instead of the currently prescribed, outdated paper manifest. The amendments also encourage labor and fuel efficiency by allowing haulers to transport regulated medical waste along with other wastes in the same vehicle and by allowing facilities more time to completely fill a vehicle before the vehicle must be placed into service. In order to avoid conflicts with OSHA requirements, duplicative requirements are eliminated by the amendment. The amendments will also provide another convenient shipping option by removing barriers to shipping waste through the mail where authorized by the U.S. Postal Service.

Compliance Costs

The proposed rulemaking provides a cost savings to the regulated community through:

- Providing consistency with the US Department of Transportation and other states.
- Reduced transportation cost for generators and transporters due to consolidation of waste in trucks.
- Longer storage times for generators, meaning fewer waste pickups.
- Reducing transportation costs for collection and processing.

Compliance Assistance Plan

The Department will assist the regulated community by developing fact sheets and continue to work with industry during program implementation. The Department's field staff will provide compliance assistance during routine facility permitting activities and inspections.

Paperwork Requirements

The proposed amendments should result in a reduction of paperwork requirements through the revised provisions for satisfying manifest requirements; the change in terminology from "infectious" to "regulated medical" waste ensures Pennsylvania signage and labeling requirements align with the requirements of the U.S. Department of Transportation and the requirements of other states; and the creation of permits-by-rule for qualifying facilities will eliminate the need to issue general or individual permits to those facilities.

G. Pollution Prevention

The Federal Pollution Prevention Act of 1990 established a national policy that promotes pollution prevention as the preferred means for achieving state environmental protection goals. DEP encourages pollution prevention, which is the reduction or elimination of pollution at its source, through the substitution of environmentally friendly materials, more efficient use of raw

materials, or the incorporation of energy efficiency strategies. Pollution prevention practices can provide greater environmental protection with greater efficiency because they can result in significant cost savings to facilities that permanently achieve or move beyond compliance.

This proposed rulemaking will continue to assure that the citizens and the environment of this Commonwealth experience the advantages of a regulated medical waste regulatory program that is protective of public health and the environment. The rulemaking encourages consolidation of waste for transportation, reducing the number of trips needed to transport waste, and thereby reducing air emissions from transportation vehicles.

H. Sunset Review

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

I. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on August 5, 2013, the Department submitted a copy of the proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees. A copy of this material is available to the public upon request.

Under Section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days after the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

J. Public Comments

Written Comments - Interested persons are invited to submit comments, suggestions or objections regarding the proposed rulemaking to the Environmental Quality Board, P.O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 16th Floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions, or objections must be received by the Board by September 16, 2013. Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by September 16, 2013. The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final regulation will be considered.

Electronic Comments - Comments may be submitted electronically to the Board at RegComments@pa.gov and must also be received by the Board by September 16, 2013. A subject heading of the proposed rulemaking and a return name and address must be included in

each transmission. If an acknowledgement of electronic comments is not received by the sender within two working days, the comments should be retransmitted to the Board to ensure receipt.

E. CHRISTOPHER ABRUZZO
Acting Chairman
Environmental Quality Board

ANNEX A

TITLE 25. ENVIRONMENTAL PROTECTION
PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION
Subpart D. ENVIRONMENTAL HEALTH AND SAFETY
ARTICLE VIII. MUNICIPAL WASTE

CHAPTER 271. MUNICIPAL WASTE MANAGEMENT — GENERAL PROVISIONS
Subchapter A. General

§ 271.1. Definitions.

The following words and terms, when used in this article, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Autoclave—A pressure vessel in which [infectious] **regulated medical** waste is disinfected using high temperature steam, directly or indirectly, to maintain specified temperatures for retention times consistent with the waste being processed.

* * * * *

Body fluids—Liquids emanating or derived from humans and limited to the following: blood; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; semen and vaginal secretions; and amniotic fluid. The term also includes the following fluids if they contain visible blood: feces, sputum, **saliva,** urine and vomitus.

* * * * *

*Commercial **[infectious]** **regulated medical** or chemotherapeutic waste facility*—A facility that processes **[infectious]** **regulated medical** or chemotherapeutic waste **under either of the following conditions:**
[not generated primarily onsite. The term includes facilities where one of the following exist:

(i) Of the waste processed, less than 50% on a monthly average was generated onsite.

(ii) Greater than 50% of the waste processed on a monthly average is not generated from entities that are wholly-owned by the owner of the waste processing facility.]

(i) The facility does not generate any of the regulated medical or chemotherapeutic waste that it processes.

(ii) If the facility generates the regulated medical or chemotherapeutic waste that it processes, the amount of waste on a monthly average that is generated onsite and offsite by wholly-owned

generators of the facility is less than 50% of the waste that it processes.

* * * * *

Disinfection—The treatment or processing of **[infectious]** **regulated medical** waste so that it poses no risk of infection or other health risk to individuals handling or otherwise coming into contact with the waste. The term includes autoclaving; dry heat, gas or chemical disinfection; radiation and irradiation; and incineration.

* * * * *

Environmental protection acts—The act, The Clean Streams Law (35 P. S. §§ 691.1—691.1001), the Municipal Waste Planning, Recycling and Waste Reduction Act (53 P. S. §§ 4001.101—4001.1904), the Hazardous Sites Cleanup Act (35 P. S. §§ 6020.101—6020.1305), the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.906), **[the act of July 13, 1988 (35 P. S. §§ 6019.1—6019.6), known as]** the Infectious and Chemotherapeutic Waste Disposal Law (**35 P. S. §§ 6019.1—6019.6)**, the Air Pollution Control Act (35 P. S. §§ 4001—4015), the Surface Mining Conservation and Reclamation Act (52 P. S. §§ 1396.1—1396.31), the Noncoal Surface Mining Conservation and Reclamation Act (35 P. S. §§ 3301—3326), the Dam Safety and Encroachments Act (32 P. S. §§ 693.1—693.27), and other State or Federal statutes relating to environmental protection or the protection of public health, including statutes adopted or amended after April 9, 1988.

* * * * *

General composting facility—A composting facility other than an individual backyard composting facility or yard waste composting facility operating under § 271.103(h) (relating to permit-by-rule for municipal waste processing facilities other than for **[infectious]** **regulated medical** or chemotherapeutic waste; qualifying facilities; general requirements).

* * * * *

***Incineration* – The act of reducing to ashes by combustion.**

* * * * *

Infectious waste—

(i) *General.* Municipal and residual waste which is generated in the diagnosis, treatment, immunization or autopsy of human beings or animals, in research pertaining thereto, in the preparation of human or animal remains for interment or cremation, or in the production or testing of biologicals, and which falls under one or more of the following categories:

(A) *Cultures and stocks.* Cultures and stocks of infectious agents and associated biologicals, including the following: 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 except for residue in emptied containers; and culture dishes, assemblies and devices used to conduct diagnostic tests or to transfer, innoculate and mix cultures.

(B) *Pathological wastes.* Human pathological wastes, including tissues, organs and body parts and body fluids that are removed during surgery, autopsy, other medical procedures or laboratory procedures. The term does not include hair, nails or extracted teeth **or tissues that have been preserved with formaldehyde or other approved preserving agents**.

(C) *Human blood and body fluid waste.*

(I) Liquid waste human blood.

(II) Blood products.

(III) Items saturated or dripping with human blood.

(IV) Items that were saturated or dripping with human blood that are now caked with dried human blood, including serum, plasma and other blood components, which were used or intended for use in patient care, specimen testing or the development of pharmaceuticals.

(V) Intravenous bags that have been used for blood transfusions**, including soft plastic pipettes and plastic blood vials**.

(VI) Items, including dialysate, that have been in contact with the blood of patients undergoing hemodialysis at hospitals or independent treatment centers.

(VII) Items saturated or dripping with body fluids or caked with dried body fluids from persons during surgery, autopsy, other medical procedures or laboratory procedures.

(VIII) Specimens of blood products or body fluids, and their containers.

(D) *Animal wastes.* Contaminated animal carcasses, body parts, blood, blood products, secretions, excretions and bedding of animals that were known to have been exposed to zoonotic infectious agents or nonzoonotic human pathogens **[during research (including research in veterinary schools and hospitals)]**, production of biologicals or testing of pharmaceuticals.

(E) *Isolation wastes.* Biological wastes and waste contaminated with blood, excretion, exudates or secretions from:

(I) Humans who are isolated to protect others from highly virulent diseases.

(II) Isolated animals known or suspected to be infected with highly virulent diseases.

(F) *Used sharps.* Sharps that have been in contact with infectious agents or that have been used in animal or human patient care or treatment**[, at medical, research or industrial laboratories]**.

(ii) *Mixtures.*

(A) The term also includes materials identified under subparagraph (i) that are mixed with municipal and residual waste, including disposable containers.

(B) The term also includes mixtures of materials identified in subparagraph (i) with quantities of radioactive waste not subject to regulation.

(iii) *Exceptions.* The term does not include the following:

(A) Wastes generated as a result of home self-care.

(B) Human corpses, remains and anatomical parts that are intended for interment or cremation, or are donated and used for scientific or medical education, research or treatment.

(C) Etiologic agents being transported for purposes other than waste processing or disposal pursuant to the requirements of the United States Department of Transportation (49 CFR 171.1—190), the Department of Transportation (67 Pa. Code Part I) and other applicable shipping requirements.

(D) Samples of **[infectious]** **regulated medical** waste transported offsite by Commonwealth or United States government enforcement personnel during an enforcement proceeding.

(E) Body fluids**, tissues, specimens** or biologicals **[which]** **that** are being transported to or stored at a laboratory prior to laboratory testing.

(F) Ash residue from the incineration of materials identified in subparagraphs (i) and (ii) if the incineration was conducted in accordance with **[§ 283.402]** **§ 284.321** (relating to **[infectious]** **regulated medical** waste monitoring requirements). The ash residue shall be managed as special handling municipal waste.

(G) Reusable or recyclable containers or other nondisposable materials, if they are cleaned and disinfected, or if there has been no direct contact between the surface of the container and materials identified in subparagraph (i). Laundry or medical equipment shall be cleaned and disinfected in accordance with the United States Occupational Safety and Health Administration Requirements in 29 CFR 1910.1030 (relating to bloodborne pathogens).

(H) Soiled diapers **[which]** **that** do not contain materials identified in subparagraph (i).

(I) Mixtures of hazardous waste subject to Article VII (relating to hazardous waste management) and materials identified in subparagraph (i) shall be managed as hazardous waste and not **[infectious]** **regulated medical** waste.

(J) Mixtures of materials identified in subparagraph (i) and regulated radioactive waste shall be managed as radioactive waste in accordance with applicable Commonwealth and Federal statutes and regulations, including**[, but not limited to,]** § 236.521 (relating to minimum requirements for classes of waste).

(K) Mixtures of materials identified in subparagraph (i) and chemotherapeutic waste shall be managed as chemotherapeutic waste in accordance with this article.

* * * * *

Mobile ***[infectious]*** ***regulated medical*** *waste processing facility*—**[An infectious]** **A regulated medical** waste processing unit **[which]** **that** is moved from one waste generation site to another for the purpose of onsite processing of a generator's **[infectious]** **regulated medical** waste. The term refers to any processing activity designed to disinfect **[infectious]** waste in accordance with § 284.321 (relating to **[infectious]** **regulated medical** waste monitoring requirements) to render the waste noninfectious. The term does not include any permanently placed waste processing units.

* * * * *

Regulated medical waste **- infectious waste.**

***Regulated medical waste aggregation facility*—A facility that accepts, aggregates or stores regulated medical waste.**

* * * * *

Sharps—Broken glass **[that has been in contact with pathogenic organisms]**, hypodermic needles**,** **[and]** syringes to which a needle **is or** can be attached, **[with or without the attached needle, suture needles, disposable]** razors, pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, culture dishes, suture needles, slides, cover slips and other broken or unbroken glass or plasticware.

* * * * *

Special handling waste—Solid waste that requires the application of special storage, collection, transportation, processing or disposal techniques due to the quantity of material generated or its unique physical, chemical or biological characteristics. The term includes dredged material, sewage sludge, **[infectious waste]** **regulated medical waste**, chemotherapeutic waste, ash residue from a solid waste incineration facility, friable asbestos-containing waste, PCB-containing waste, waste oil that is not hazardous waste and fuel contaminated soil.

* * * * *

Thermal processing—A method, technique or process, excluding incineration and autoclaving, designed to disinfect **[infectious]** **regulated medical** waste by means of exposure to high thermal temperatures through methods such as ionizing radiation or electric or plasma arc technologies.

* * * * *

*Unrecognizable **[infectious]** **regulated medical** waste* —All components of the waste have been processed to produce indistinguishable and unusable pieces smaller than 3/4 of an inch, except that all sharps must be smaller than 1/2 inch. The term does not mean compaction or encapsulation except through:

(i) Processes such as thermal treatment or melting, during which disinfection and destruction occur.

(ii) Processes such as shredding, grinding, tearing or breaking, during or after disinfection occurs.

(iii) Processes that melt plastics and fully encapsulate metallic or other sharps and seals waste completely in a container that will not be penetrated by untreated sharps.

* * * * *

§ 271.2. Scope.

* * * * *

(b) Management of the following types of residual waste is subject to this article instead of Article IX (relating to residual waste management), and shall be regulated as if the waste is municipal waste, regardless of whether the waste is a municipal waste or residual waste.

* * * * *

(2) **[Infectious]** **Regulated medical** and chemotherapeutic waste.

§ 271.101. Permit requirement.

* * * * *

(b) A person or municipality is not required to obtain a permit:

* * * * *

[(4) For temporary storage, which facilitates the transportation or transfer of [infectious] regulated medical or chemotherapeutic waste, that does not exceed 24 hours. The stored waste shall remain in its original packaging, as received for storage.]

* * * * *

§ 271.103. Permit-by-rule for municipal waste processing facilities other than for [infectious] regulated medical or chemotherapeutic waste; qualifying facilities; general requirements.

* * * * *

§ 271.114. Transition period.

A person or municipality possessing a permit for a municipal waste disposal or processing facility which was issued by the Department prior to December 23, 2000, shall file with the Department an application for permit modification to bring the facility operation into compliance with the following requirements for radioactive material monitoring and detection that became effective on December 23, 2000, according to the following schedule, unless the Department imposes in writing an earlier date in a specific situation for reasons of public health, safety or environmental protection:

* * * * *

(5) *Resource recovery and other processing facilities.* Including **[infectious] regulated medical** and chemotherapeutic waste processing facilities, an application for a permit modification addressing the requirements of § § 283.103(20) and 283.113 (relating to maps and related information; and radiation protection action plan) shall be filed by September 23, 2001.

§ 271.421. Administrative inspections.

* * * * *

(c) The Department, its **[employes] employees** and agents intend to conduct inspections under the act of:

* * * * *

(2) Municipal waste processing facilities other than resource recovery facilities, which process or incinerate **[infectious] regulated medical** or chemotherapeutic waste, at least 2 times per year.

(3) Municipal waste processing facilities other than resource recovery facilities, which do not process or incinerate **[infectious] regulated medical** or chemotherapeutic waste, at least once per year.

(4) Hospitals where **[infectious] regulated medical** or chemotherapeutic waste is generated, at least 2 times per year.

(5) Locations other than hospitals where **[infectious] regulated medical** or chemotherapeutic waste is generated, at least once per year.

* * * * *

(7) Facilities and beneficial use areas subject to permit-by-rule under § 271.103 (relating to permit-by-rule for municipal waste processing facilities other than for **[infectious]** **regulated medical** or chemotherapeutic waste; qualifying facilities; general requirements), a general permit for beneficial use or processing, or both, under Subchapter I (relating to beneficial use), or a permit for the land application of sewage sludge under Subchapter J (relating to beneficial use of sewage sludge by land application), at least once per year.

* * * * *

§ 271.601. Scope.

* * * * *

(c) The Department may require analyses under this subchapter for special handling waste other than sewage sludge, **[infectious]** **regulated medical** waste, chemotherapeutic waste and ash residue from a resource recovery facility.

§ 271.611. Chemical analysis of waste.

* * * * *

(f) *Waiver.* The Department may, in writing, waive the requirements of this section for special handling waste, waive or modify the requirements of this section for general permits issued under Subchapter I and waive or modify the chemical analysis requirements under § 271.103 (relating to permit-by-rule for municipal waste processing facilities other than for **[infectious]** **regulated medical** or chemotherapeutic waste; qualifying facilities; general requirements).

§ 271.801. Scope.

(a) This subchapter sets forth requirements for general permits for the processing and beneficial use of municipal waste, except as follows:

(1) This subchapter does not set forth requirements for general permits for the processing or beneficial use of **[infectious]** **regulated medical** or chemotherapeutic waste.

* * * * *

§ 271.811. Authorization for general permit.

* * * * *

(g) The Department will not issue a general permit under this subchapter for the following:

* * * * *

(3) The processing or beneficial use of **[infectious]** **regulated medical** or chemotherapeutic waste.

CHAPTER 272. MUNICIPAL WASTE PLANNING, RECYCLING AND WASTE REDUCTION

Subchapter C. MUNICIPAL WASTE PLANNING

PLAN CONTENT

§ 272.223. Description of waste.

(a) The plan shall describe and explain the origin, content and weight or volume of municipal waste currently generated within the county's boundaries, and the origin, content and weight or volume of municipal waste that will be generated within the county's boundaries during the next 10 years. The plan shall also include a statement of the county or other geographical area for which the plan is prepared.

(b) In describing the content of waste, the plan shall specifically address sewage sludge (including septage), **[infectious]** **regulated medical** and chemotherapeutic waste, ash from resource recovery facilities, construction/demolition waste other than waste from demolition of an industrial site and other municipal waste.

(c) In describing the origin of waste, the plan shall provide:

(1) An estimate of the number of residential, commercial, municipal and institutional establishments, and community activities within the county, for municipal waste other than the special handling wastes specifically addressed in this subsection.

(2) An inventory of public and private sewage treatment plants, including mobile homes, restaurants and hotels, and an inventory of septage haulers serving the county, for sewage sludge (including septage).

(3) An inventory of hospitals in the county, and a representative sampling of different medical specialists, such as clinics, doctors, dentists, funeral directors and veterinarians, for **[infectious]** **regulated medical** and chemotherapeutic waste.

(4) An inventory of the facilities serving the county, for ash from resource recovery facilities.

(5) An estimate of the amount of construction/demolition waste currently generated within the county's boundaries and that will be generated within the county's boundaries during the next 10 years; and an estimate of the amount of construction/demolition waste that is currently recycled and that could be recycled during the next 10 years.

(d) In describing the weight or volume of waste, the plan shall provide:

(1) A total waste generation estimate for the planning area derived from best available National studies, sampling data from similar counties or other reliable information, for municipal waste other than special handling waste described in subsection (c).

(2) Sampling or survey data for the planning area, or other reliable information, for the special handling waste described in subsection (c).

(3) A detailed analysis, for each type of waste, of the extent to which recycling currently reduces the weight or volume of waste that requires processing or disposal, and the extent to which waste reduction or recycling will reduce the weight or volume of waste that will require processing or disposal within the next 10 years. If less than 35% of the weight or volume of waste will be recycled or reduced, the plan shall contain a detailed justification.

(e) The plan may also, at the discretion of the county, specifically address one or more of the following:

(1) Waste tires.

(2) Household hazardous waste.

(3) Leaf waste, yard waste and other waste suitable for composting.

(4) Bulk items from community cleanup days.

(5) Other components of municipal waste not described in this section.

Subchapter F. HOUSEHOLD HAZARDOUS WASTE COLLECTION, TRANSPORTATION AND MANAGEMENT

OPERATION OF PROGRAMS

§ 272.531. Basic operational requirements.

(a) A program for the collection and management of household hazardous waste shall be operated in accordance with the following:

(1) The approved registration, including any conditions the Department attaches to approval.

(2) The Small Business and Household Pollution Prevention Program Act.

(3) The requirements of Article VII (relating to hazardous waste management) as made applicable by this subchapter.

(b) Only eligible entities may deposit waste at a household hazardous waste collection event.

(c) Waste exchanges may be conducted as part of the collection event in a manner approved by the Department.

§ 272.532. Limitations on acceptable waste.

(a) The following wastes may not be accepted at a collection event:

(1) Radioactive material.

(2) **[Infectious waste]** **regulated medical,** except sharps.

(3) Explosives.

(b) An eligible entity may not deposit more than 1,000 kilograms (2,200 lbs.) of waste at an individual collection event. The collection contractor shall weigh waste received at a collection event to ensure that no entity deposits more than 1,000 kilograms of waste at an individual collection event. A sponsor may lower the maximum amount of waste that may be deposited by an eligible entity.

CHAPTER 273. MUNICIPAL WASTE LANDFILLS

Subchapter D. ADDITIONAL APPLICATION REQUIREMENTS FOR SPECIAL HANDLING AND RESIDUAL WASTES

SPECIFIC WASTES

§ 273.411. Processed [infectious] regulated medical or chemotherapeutic waste disposal.

(a) An application for the disposal of processed **[infectious]** **regulated medical** or chemotherapeutic waste shall contain necessary plans and specifications showing how the applicant will comply with § 273.511 or § 273.512 (relating to processed **[infectious]** **regulated medical** waste disposal; and chemotherapeutic waste) or both, whichever is applicable.

(b) The application, on a form provided by the Department, shall contain the following information:

(1) The name and location of the generator of the waste.

(2) A description of the origin and content of the waste, its containerization and the expected volume and frequency of waste disposal at the facility.

(3) A description of the facility where the waste will be disinfected prior to disposal, including its name and location. For a permitted processing facility that is not operating under a permit by rule under Chapter 271, Subchapter B (relating to general requirements for permits and permit applications), the applicant shall provide the permit number.

(4) A description of the processing methods to be used for each type of waste, including, when necessary, schematic drawings.

(5) A description of the containers to be used for storage during collection and during movement within the facility, including the length of storage.

(6) A description of the alternatives to be used if the processing equipment is inoperable, and the procedures to be used for storage of the waste if it cannot be promptly processed.

(7) A description of handling and safety measures that will be employed for each type of waste, including personal protection and safety as well as modifications to the operational safety plan that are required.

(8) If disinfection will be employed, a description of the monitoring and quality assurance program to ensure proper disinfection.

(9) A description of modifications to an existing processing facility that is required to process the waste, including drawings.

(10) A certification indicating that the waste to be disposed is noninfectious. The certification shall include the method of processing, indicator test results and testing frequency.

Subchapter E. ADDITIONAL OPERATING REQUIREMENTS FOR SPECIAL HANDLING AND RESIDUAL WASTES

SPECIFIC WASTES

§ 273.511. Processed [infectious] regulated medical waste disposal.

(a) **[Infectious] regulated medical** waste may not be disposed at a municipal waste landfill unless:

(1) The waste has been disinfected in accordance with § 284.321 (relatingto **[infectious waste] regulated medical** monitoring requirements).

(2) Prior to initial disposal the landfill operator has obtained the necessary approval for disposal from the Department based on the application provided under § 273.411 (relating to processed **[infectious] regulated medical** and chemotherapeutic waste disposal).

(3) The waste being received has been disinfected by a permitted processing facility.

(b) Waste consisting of human anatomical remains, including human fetal remains, may not be disposed at municipal waste landfills unless the waste has first been incinerated at a permitted waste processing facility.

(c) Body fluids and animal body fluids may be disposed by discharge into a permitted sewage treatment system that provides a minimum of secondary treatment in accordance with local, Federal and State requirements, including The Clean Stream Law (35 P. S. §§ 691.1—691.1001).

(d) Sharps shall be rendered unusable prior to disposal.

CHAPTER 284. [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

Subchapter A. GENERAL PROVISIONS

GENERAL PROVISIONS

GENERAL PROVISIONS

§ 284.1. Scope.

This chapter sets forth application and operating requirements for a person or municipality that operates **[an infectious]** **a regulated medical** or chemotherapeutic waste facility. The requirements in this chapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management -- general provisions)**, Chapter 283 (relating to resource recovery and other processing facilities) and Chapter 285 (relating to storage, collection and transportation of municipal waste)**.

§ 284.2. Permits-by-rule for [infectious] regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements.

(a) **[If the requirements of this section are met, the]** **The** following **[onsite]** processing facilities for **[infectious]** **regulated medical** and chemotherapeutic waste shall be deemed to have a municipal waste processing permit under this article **if the following requirements in this subsection and subsection (c) are met**:
(1) **[An onsite autoclave]** **A processing** facility **with an autoclave if the following requirements are met: [, including one which renders waste unrecognizable, which processes at least 50% of**

its own infectious waste generated onsite and accepts offsite waste for disinfection only from small quantity generators that generate less than 220 pounds per month of infectious waste if the following conditions are met:]

(i) **The facility processes at least 50% of its own regulated medical waste. The facility may accept no more than 50% of regulated medical waste for disinfection from small quantity generators that generate less than 220 pounds per month.**

(ii) **[Processing of pathological waste is prohibited.]** **The facility does not process pathological waste or chemotherapeutic waste.**

(iii) **[The retention time for processing bulk fluids (greater than 500 ml) allows for the complete vaporization of fluids.]** **The facility may additionally process regulated medical waste to render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking.**

(iv) The processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste.

(v) The operator of the facility provides notice to the Department that includes the following:

(A) An intention to operate under permit-by-rule.

(B) The name and address of the facility.

(C) A description of the processing activity.

(D) The names and telephone numbers of the individuals responsible for operation of the processing facility.

(2) **[An onsite incineration]** **A processing** facility **with an incinerator if the following requirements are met: [that burns at least 50% of its own infectious or chemotherapeutic waste generated onsite and accepts offsite infectious or chemotherapeutic waste for incineration only from small quantity generators that generate less than 220 pounds per month of infectious or chemotherapeutic waste. This onsite incineration facility may process municipal waste generated onsite as long as the resulting ash is managed as processed infectious and chemotherapeutic waste.]**

(i) The facility processes at least 50% of its own regulated medical or chemotherapeutic waste. The facility may accept no more than 50% of regulated medical or chemotherapeutic waste for disinfection from small quantity generators that generate less than 220 pound per month.

(ii) The facility may process other municipal waste generated onsite if the resulting ash is managed as processed regulated medical or chemotherapeutic waste.
(iii) The processed waste is disposed of or processed in a landfill or incinerator authorized to

accept the waste.

(iv) The operator of the facility provides notice to the Department that includes the following:

(A) An intention to operate under permit-by-rule.

(B) The name and address of the facility.

(C) A description of the processing activity.

(D) The names and telephone numbers of the individuals responsible for operation of the processing facility.

(3) [An onsite steam and superheated water disinfection] A processing facility with steam and superheated water disinfection if the following requirements are met: [which processes infectious waste, including one which renders waste unrecognizable, which processes at least 50% of its own infectious waste generated onsite and accepts offsite waste for disinfection only from small quantity generators that generate less than 220 pounds per month of infectious waste. Processing of pathological waste is prohibited.]

(i) The facility processes at least 50% of its own regulated medical waste. The facility may accept no more than 50% of regulated medical waste for disinfection from small quantity generators that generate less than 220 pounds per month.

(ii) The facility does not process pathological waste or chemotherapeutic waste.

(iii) The facility may additionally process regulated medical waste to render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking.

(iv) The processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste.

(v) The operator of the facility provides notice to the Department that includes the following:

(A) An intention to operate under permit-by-rule.

(B) The name and address of the facility.

(C) A description of the processing activity.

(D) The names and telephone numbers of the individuals responsible for operation of the processing facility.

(4) Onsite processing of liquid blood and body fluids using a glutaraldehyde-based or hypochlorite-based product that encapsulates or converts liquid blood or body fluids into solids or gels such that no free liquids remain. The Department may approve the use of other disinfectant-based products under these provisions if their efficacy can be demonstrated. The processed infectious waste may be disposed at a municipal waste landfill provided:

(i) No free liquids remain in the processed waste.

(ii) The landfill has received written approval from the Department authorizing disposal of the processed medical waste.

(5) Transfer facilities that temporarily store regulated medical or chemotherapeutic waste for a period that is less than 72 hours provided the stored waste remains in its original packaging and it is not putrescent.

(b) Generators that process and disinfect less than 220 pounds per month of **[infectious]** **regulated medical** waste onsite and render the waste unrecognizable will be deemed to have **a** municipal waste processing **[permits]** **permit** under this article if the requirements under **[subsections (c) -- (g)]** **subsection (c)** are met. Generators that process and disinfect less than 220 pounds per month of **[infectious]** **regulated medical** waste onsite without rendering the waste unrecognizable will be deemed to have **a** municipal waste processing **[permits]** **permit** under this article if the **[requirements under subsections (c) -- (g)]** **following requirements under this subsection and subsection (c)** are met **[and if the following requirements are met]**:

(1) The generator **[may]** **shall** dispose of the processed waste in a landfill or have the waste incinerated in a facility that has **[obtained]** written approval from the Department to accept **[the]** **this type of** waste.

(2) The generator shall comply with the manifest requirements in § 284.701(b)(5) (relating to scope).

(c) The following requirements shall be met by facilities identified in subsections (a)**(1)-(4)** and (b) to operate under a permit-by-rule:

(1) The facility complies with **the requirements of Subchapters E and F (relating to segregation and storage; and collection and transportation) and** Chapter 285 **(relating to storage, collection and transportation of municipal waste). [and Subchapters E and F (relating to storage, collection and transportation of municipal waste; storage, collection and transportation).]**

(2) The facility has necessary permits under the environmental protection acts, and is operating in accordance with the environmental protection acts and the regulations promulgated thereunder, the terms and conditions of permits and orders of the Department.

(3) The operator maintains at the facility in a readily accessible place the following information:

(i) For a processing facility identified in subsection (a), a written plan for managing **[infectious]** **regulated medical** waste generated at the facility, including waste handling, equipment operation and maintenance, processing method, disinfection monitoring procedures including quality assurance procedures, **frequency of calibration** and a description of how noninfectious waste is managed to prevent commingling.

(ii) For processing facilities subject to a permit-by-rule, daily records of the weight or volume of the waste that is processed, the method and location of disposal facilities for wastes from the processing facility, and waste handling problems and emergencies.

(4) Processing does not have an adverse effect on public health, safety, welfare or the environment.

(5) The waste is disinfected in accordance with § 284.321 (relating to **[infectious]** **regulated medical** waste monitoring requirements).

(6) Disinfection occurs before or during processing of the waste.

(7) A log is maintained for each disinfection unit and is made available to the Department upon request. The log shall record the following:

(i) The date, time and operator for each use.

(ii) The dates and results of calibration.

(iii) The postdisinfection color reading of temperature sensitive tape and the results of biological indicator spore testing, in accordance with § 284.321 for steam disinfection facilities.

(iv) Results of ash testing which utilizes a methodology approved by the Department, for incineration facilities.

(8) Remaining waste is managed in accordance with the act and the regulations promulgated thereunder. For onsite autoclave facilities **[which]** **that** do not render the waste unrecognizable, the **[processing residue shall]** **treated or processed regulated medical waste shall** be manifested in accordance with Subchapter H (relating to manifesting for **[infectious]** **regulated medical** and chemotherapeutic waste).

(9) For incineration facilities, an air quality permit shall be obtained **as required** under the Air Pollution Control Act (35 P. S. §§ 4001 -- 4015).

[(10) For facilities identified in subsection (a), notice is provided to the Department by the operator of a facility which indicates an intention to operate under permit-by-rule and which includes the following information:

(i) The name and address of the facility.

(ii) A description of the processing activity.

(iii) The names and telephone numbers of the individuals responsible for operation of the processing facility.

(11) For facilities identified in subsection (a), the processed waste is disposed of in a landfill or processed in an incinerator that has obtained written approval from the Department to dispose or process the waste.]

(d) Chapter 271, Subchapter E (relating to civil penalties and enforcement) is applicable to facilities subject to permit-by-rule.

(e) Notwithstanding a provision in this section to the contrary, a facility will not be deemed to have a permit-by-rule if it causes or allows violations of the environmental protection acts, the regulations promulgated thereunder, the terms or conditions of a permit issued by the Department, or an order issued by the Department, or causes a public nuisance. A facility that is subject to permit-by-rule is not required to apply for a permit under this article, if that facility operates in accordance with this section.

(f) **[Generators who qualify for a permit-by-rule may render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking.**

(g)] The requirements under Chapter 271, Subchapter D (relating to financial assurances requirements) **[which]** **that** relate to bonding and insurance are waived for facilities **[which]** **that** are deemed to have a permit under this section.

§ 284.3. Regulated medical waste aggregation facilities.

(a) *Applicability.* This section applies to operators of regulated medical waste aggregation facilities.

(b) *Permit-by-rule for regulated medical waste aggregation facilities.* The operator of an aggregation facility may operate under a permit-by-rule. For the operation of a regulated medical waste aggregation facility to be authorized by a permit-by-rule, the owner or operator shall:

(1) Comply with the generator standards in Subchapter E (relating to segregation and storage).

(2) Only accept the following regulated medical waste:

(i) Generated onsite or offsite by the operator of the aggregation facility.

(ii) Generated by physicians in their independent practices or other medical personnel within

the same building or complex of buildings.

(c) *Noncompliance.* The Department may require the operator of an aggregation facility operated under permit-by-rule to apply for and obtain a permit, or take other appropriate action, when the generator is not in compliance with the requirements for the permit-by-rule or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment.

Subchapter B. GENERAL PERMITS

GENERAL

§ 284.101. Authorization for general permits.

(a) In accordance with this subchapter, the Department may issue general permits on a regional or Statewide basis for a category of mobile or stationary **[infectious]** **regulated medical** waste processing facilities or stationary chemotherapeutic waste processing facilities if the Department determines the following:

(1) The processing facilities and the waste to be processed in the category are substantially similar.

(2) The processing facilities in the category can be adequately regulated utilizing standard conditions without harming or presenting a threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.

(3) The processing facilities in the category will comply with the requirements established in the permit and with the standards and requirements for design, construction, operation, maintenance and monitoring in Chapter 283 (relating to resource recovery and other processing facilities) and Subchapter D (relating to processing facilities).

(b) The Department may issue a general permit upon its own motion under § 284.115 (relating to Department-initiated general permits) or upon an application from a person or municipality under §§ 284.111 -- 284.114.

(c) The Department may issue a general permit for the mixing of disinfection products with **[infectious]** **regulated medical** waste to perform processing.

(d) The Department may issue a general permit for the processing of mixtures of the same types of waste that are **[infectious]** **regulated medical** or residual wastes.

(e) The Department may modify, suspend, revoke or reissue general permits under this subchapter as it deems necessary to prevent harm or the threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.

(f) The Department will not issue a general permit for a commercial **[infectious]** **regulated medical** or chemotherapeutic waste processing facility, including commercial incinerators.

§ 284.102. Nature of a general permit; substitution for individual applications and permits.

(a) When the Department issues a general permit for **[an infectious]** **a regulated medical** or chemotherapeutic waste processing facility on either a regional or Statewide basis, persons or municipalities who intend to process **[infectious]** **regulated medical** or chemotherapeutic waste in accordance with the terms and conditions of the general permit may do so without filing an individual application for, and first obtaining, an individual permit.

(b) The use of an applicable general permit shall satisfy the requirement to obtain a permit in § 271.101 (relating to permit requirement) if the following are met:

(1) The processing activities are conducted in accordance with the terms and conditions of the applicable general permit.

(2) The person or municipality conducting the processing activities is authorized to operate under the general permit at the time that the Department issued the general permit or under the applicable general permit in accordance with **[§ 284.132 or]** § 284.133 (relating to **[determination of applicability; and]** registration).

(c) Notwithstanding subsections (a) and (b), the Department may require a person or municipality authorized by a general permit to apply for, and obtain, an individual permit **if a general permit is not available to conduct an activity,** when the person or municipality is not in compliance with the conditions of **[the]** **a** general permit or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment of this Commonwealth.

ISSUANCE OF A GENERAL PERMIT

§ 284.111. Application for general permit.

(a) A person or municipality may apply to the Department for the issuance of a general permit for a specific category of processing of **[infectious]** **regulated medical** or chemotherapeutic waste.

(b) An application for the issuance of a general permit for processing **[infectious]** **regulated medical** or chemotherapeutic waste shall be submitted on a form prepared by the Department and shall contain the following:

(1) A description of the waste.

(2) A characterization of the waste as either **[infectious]** **regulated medical** or chemotherapeutic.
(3) An operation plan which contains the following:

(i) A description of the proposed processing activity and equipment.

(ii) A description of the method proposed to receive **[infectious]** **regulated medical** or chemotherapeutic waste which ensures the waste is handled separately from other solid waste until processing and disposal, and that prevents unauthorized persons from having access to or contact with the waste.

(iii) A description of the procedure for managing containers which arrive in a leaking condition, which includes whether the waste is processed immediately, repacked or rejected.

(iv) A description of the method proposed to unload and process **[infectious]** **regulated medical** or chemotherapeutic waste, limiting the number of persons handling the waste and minimizing the possibility of exposure of that waste to **[employes]** **employees** and the public using or visiting the facility.

(v) A description of the method proposed for disinfecting emptied, reusable **[infectious]** **regulated medical** waste containers, transport vehicles and facility equipment which are known or suspected to be contaminated with **[infectious]** **regulated medical** waste.

(vi) A description of the method proposed for handling and disposal of **[infectious]** **regulated medical** or chemotherapeutic waste containers which cannot be reused.

(vii) A description of reuse of containers if the surfaces of the containers have been protected from direct contact with chemotherapeutic waste.

(viii) A description of the means by which provisions will be made to require the use of clean gloves and clean uniforms along with other protective clothing to provide protection of **[employes]** **employees** against exposure to infectious or chemotherapeutic waste.

(ix) A description of the means by which provisions will be made to require decontamination of a person having had bodily contact with **[infectious]** **regulated medical** or chemotherapeutic waste while handling that waste at the facility.

(x) A description of the method proposed to quantify, on a weight basis, the maximum amount of **[infectious]** **regulated medical** or chemotherapeutic waste to be stored and processed each month.

(xi) A schedule of the operating hours of the facility.

(xii) A description of the method proposed to assure that infectious or chemotherapeutic waste received at the facility is consistent with § 283.201 (relating to basic limitations).

(xiii) A description of periodic testing using biological indicators which demonstrate effective disinfection of the waste, in accordance with § 284.321 (relating to **[infectious]** **regulated medical** waste monitoring requirements).

(xiv) A description of closure activities which are proposed to be carried out upon cessation of

operations, in accordance with § 283.272 (relating to cessation of operations).

(xv) A description of how the processing residue will be managed.

(xvi) A description of how aerosols will be minimized and controlled during processing activities.

(4) A contingency plan which provides procedures to be used for emergency situations including, at a minimum, spills of **[infectious] regulated medical** or chemotherapeutic waste and ruptures of containers containing the waste. The plan shall include procedures for cleanup and disinfection of spill area, protection of personnel, disposal of spill residue and repackaging of the waste. The plan shall also include a description of an alternative waste handling system during periods when the proposed facility is not in operation, including procedures to be followed in the case of equipment breakdown. Alternate waste handling procedures may include use of standby equipment, extension of operating hours and contractual agreements for diversion of **[infectious] regulated medical** or chemotherapeutic waste to other facilities.

(5) A personnel training plan which describes the hiring of equipment operators and the training of personnel involved in the handling and processing of **[infectious] regulated medical** or chemotherapeutic waste. The plan shall include a detailed explanation of the operation and contingency plans.

(c) A nonrefundable fee in the form of a check payable to the "Commonwealth of Pennsylvania" for $ 1,000 shall accompany the application.

(d) The application requirements in subsection (b) may be waived or modified for the mixing of disinfection products with **[infectious] regulated medical** waste to perform processing.

§ 284.112. Completeness review.

(a) After receipt of an application for the issuance of a general permit**[, or an application for a determination of applicability under § 284.132 (relating to determination of applicability)]**, the Department will determine whether the application is administratively complete. For purposes of this subchapter, an application is administratively complete if it contains the necessary analyses, fees, documents and information, regardless of whether the analyses, fees, documents and information would be sufficient for the issuance of the permit **[or the determination of applicability]**.

(b) If the application is not administratively complete, the Department will return it to the applicant, within 60 days of receipt of the application. A written statement of the specific analyses, fees, documents or information that are required to make the application administratively complete will accompany an application which is returned.

(c) The Department will deny the application if the applicant fails to provide the analyses, fees, documents and information within 90 days of receipt of the notice in subsection (b).

§ 284.113. Public notice and review period.

(a) The Department will publish notice of receipt of an application for a general permit in the *Pennsylvania Bulletin* when the Department determines that the application is administratively complete.

(b) The notice shall include:

(1) A brief description of the waste and the category of processing of **[infectious]** **regulated medical** or chemotherapeutic waste that is identified in the application as a candidate for a general permit.

(2) The Department's address and telephone number at which interested persons or municipalities may obtain further information and review a copy of the application for the general permit.

(3) A brief description of the procedures for public comment on the general permit application.

(4) A statement that interested persons or municipalities may submit comments to the Department within 60 days of the publication of the notice, and may recommend conditions upon, revisions to, approval or disapproval of the general permit application.

(c) The Department may hold a public meeting or public hearing on the application for a general permit.

(d) Upon issuance of a general permit, the Department will place a notice in the *Pennsylvania Bulletin* of the availability of the general permit. If a county has made recommendations to the Department concerning conditions, revisions or disapproval of the permit during the 60-day comment period, and the Department has overriden the recommendations, the Department will publish its justification for overriding the recommendations in the *Pennsylvania Bulletin.*

(e) Each applicant for coverage under the general permit shall provide written notice to each municipality in which the applicant intends to operate under a general permit.

§ 284.114. Approval or denial of an application.

The Department may not issue a general permit for a category of processing of **[infectious]** **regulated medical** or chemotherapeutic waste unless the applicant has affirmatively demonstrated the following:

(1) The application for the general permit is accurate and complete.

(2) The applicant has complied with the requirements of §§ 284.101, 284.102 and 284.111 -- 284.113.

(3) The proposed processing activities will be conducted in a manner that will not harm or present a

threat of harm to the health, safety or welfare of the people or environment of this Commonwealth through exposure to constituents of the waste during the processing activities and afterwards.

§ 284.115. Department-initiated general permits.

(a) The Department may issue or modify a general permit for a category of processing of **[infectious]** **regulated medical** or chemotherapeutic waste upon its own motion in accordance with this section.

(b) At least 60 days prior to the issuance or modification of a general permit under this section, the Department will publish a notice in the *Pennsylvania Bulletin* of intent to issue or modify a general permit under this section.

(c) The notice required by subsection (b) shall include the following:

(1) A clear and specific description of the category of processing of **[infectious]** **regulated medical** or chemotherapeutic waste eligible for coverage under the proposed general permit.

(2) The standards in § 284.101(a) (relating to authorization for general permits), and a brief description of the reasons for the Department's determination that the category of processing is eligible for coverage under a general permit in accordance with these standards.

(3) A brief description of the terms and conditions of the proposed general permit.

(4) A brief description of the procedures for public comment on the general permit in accordance with this subchapter.

(5) The **[Departmental]** **Department** address and telephone number at which interested persons or municipalities may obtain further information and review a copy of the proposed general permit.

(6) A statement that interested persons or municipalities may submit comments to the Department within 60 days of the publication of the notice and may recommend conditions upon, revisions to, and approval or disapproval of the proposed general permit.

(d) The Department may hold a public meeting or public hearing on the proposed general permit or proposed modification to the general permit.

(e) Upon issuance or modification of a general permit, the Department will place a notice in the *Pennsylvania Bulletin* of the availability of the new or modified general permit.

§ 284.116. General permit renewal.

(a) A person or municipality that plans to process regulated medical or chemotherapeutic waste after the expiration of the term in the general permit shall file notice to the Department of intent to continue operating under the permit at least 180 days before the expiration date of

the permit. The notice must include updated registration information on forms provided by the Department, a check payable to the "Commonwealth of Pennsylvania" for $250, and any suggested changes to the terms or conditions of the permit.

(b) A permit renewal may include all persons or municipalities that have applied for renewal within the time period provided in subsection (a). A person or municipality that does not meet the time period provided in subsection (a) shall be required to register under a renewed general permit.

(c) At least 120 days prior to the permit expiration, the Department will provide public notice of the permit renewal along with an update of the terms or conditions in accordance with the public notice requirements of §284.115 (relating to Department-initiated general permits.)

(d) General permits will be renewed for a maximum term of 10 years.

(e) If the Department is unable to reissue the general permit prior to its expiration date, the Department may extend the term of a general permit for a period not to exceed 1 year for any permittee that is operating in compliance with the terms and conditions of the general permit and the environmental statutes and regulations of the Commonwealth.

CONTENT OF GENERAL PERMITS AND MODIFICATIONS

§ 284.121. Contents of general permits.

Each general permit issued by the Department will include, at a minimum:

(1) A clear and specific description of the category of processing of **[infectious]** **regulated medical** or chemotherapeutic waste eligible for coverage under the general permit.

(2) The standards in § 284.101(a) (relating to authorization for general permits) and a brief explanation of the reasons for the Department's determination that the category of processing is eligible for coverage under the general permit in accordance with the standards in § 284.101(a).

(3) A specification of registration **[or determination of applicability]** requirements established in accordance with § 284.131 (relating to authorization for persons or municipalities to be included in a general permit) and the fee imposed on registrants **[or applicants]** for coverage under the general permit.

(4) An effective date, and a fixed permit term, which may not exceed 10 years from the effective date. If the Department renews a general permit, the term may not exceed the term of the original permit.

(5) A set of terms and conditions governing the construction, operation, maintenance, inspection and monitoring of the processing activities covered by the general permit as are necessary to assure compliance with this act, this article and the environmental protection acts.

(6) A requirement that persons or municipalities who conduct activities authorized by the general permit shall allow authorized representatives of the Commonwealth, without advance notice or a search warrant, upon the presentation of appropriate credentials, and without delay, to have access to areas in which the activities covered by the general permit will be, are being or have been conducted to ensure compliance with the act and the act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1 -- 6019.6), known as the Infectious and Chemotherapeutic Waste Law, regulations promulgated thereunder and a permit, license or order issued by the Department under the act.

(7) A requirement that the activities authorized by the general permit will not harm or present a threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.

(8) A requirement that waste be accompanied by a properly completed manifest, in accordance with Subchapter H (relating to manifesting for **[infectious]** **regulated medical** and chemotherapeutic waste)**[, when appropriate]**.

(9) A requirement that waste be delivered by a licensed transporter in accordance with Subchapter G (relating to transporter licensing for **[infectious]** **regulated medical** and chemotherapeutic waste), when appropriate.

(10) A requirement that the processing facility operate in accordance with local, State and Federal requirements.

(11) A requirement that the processing residue be **[disposed of in a landfill that has obtained written approval by the Department to dispose of the waste]** **managed in accordance with the Solid Waste Management Act (35 P. S. § § 6018.101—6018.1003) and the regulations promulgated thereunder**.

(12) A requirement that an up-to-date list of names, addresses and telephone numbers of **[employes]** **employees** that have been designated by the permittee to respond to emergencies at the processing facility be maintained at the facility.

(13) A requirement that individual **[employes]** **employee** training records be maintained at the processing facility.

(14) A requirement for use of additional indicators selected by the Department to monitor the disinfection process.

(15) A requirement that daily records of the weight or volume of the waste processed, the method and location of disposal facilities for wastes from the processing facility and waste handling problems and emergencies be maintained for 3 years.

(16) A requirement that a log be maintained for each disinfection unit for 3 years that records the following:

(i) The date, time and operator for each use.

(ii) The dates and results of calibration.

(iii) The results of biological indicator spore testing.

(iv) Other information that the Department may require relating to the disinfection process.

(17) Requirements for closure.

(18) **[A requirement that autoclaves meet the following:**

(i) Processing of pathological waste is prohibited.

(ii) The retention time for processing bulk fluids (greater than 500 ml) allows for the complete vaporization of fluids.] **A prohibition against processing pathological waste or chemotherapeutic waste in an autoclave.**

§ 284.122. [Waiver or modification] Modification of certain requirements.

(a) An operation that is approved under this subchapter does not require an individual processing or disposal permit under this article.

(b) For an operation that is approved under this subchapter, the Department may **[waive or]** modify any application and operating requirements in this article**[, except the Department may not waive § 271.123 and may not waive or modify Chapter 271, Subchapter A, §§ 271.124, 271.125, 271.129 and Chapter 271, Subchapter E]**.

REGISTRATION [AND DETERMINATION OF APPLICABILITY]

§ 284.131. Authorization for persons or municipalities to be included in a general permit.

(a) A person or municipality is authorized to operate under a general permit if **[one of the following occurs:**

(1) If the applicable general permit requires persons or municipalities to register with the Department prior to operating under the general permit,] the person or municipality has registered in accordance with the terms of the general permit and the requirements of this subchapter.

[(2) If the applicable general permit requires persons or municipalities to apply for and obtain a determination of applicability from the Department prior to operating under the general permit, and the Department has made this determination.]

(b) Registration **[or application]** requirements and time limits, if any, shall be set forth in the

general permit governing each category of processing **[infectious]** **regulated medical** or chemotherapeutic waste. The general permit shall also set forth the area or region within which each category of processing is allowed.

(c) At a minimum, the registration **[or application for determination of applicability]** shall include:

(1) The name, address and location of the person or municipality conducting the activity covered under the general permit.

(2) A description of the waste, including a characterization of the waste as either **[infectious]** **regulated medical** or chemotherapeutic, that will be processed in accordance with the general permit.

(3) A description of the proposed method of processing of the waste.

(4) The name or number of the general permit being utilized for the activity.

(5) A demonstration that the activities which the person or municipality intends to conduct are authorized by the general permit.

(6) A signed and notarized statement by the person or municipality conducting the activity authorized by the general permit, on a form prepared by the Department, which states that the person or municipality agrees to accept the conditions imposed by the general permit for processing of **[infectious]** **regulated medical** or chemotherapeutic waste under the general permit.

(d) A person or municipality that registers for coverage under a general permit **[or applies to the Department for a determination of applicability of a general permit]** shall submit a copy of the registration **[or application]** to each municipality in which the processing activity will be located. The submission shall occur at the same time that the person or municipality files the registration **[or application]** with the Department.

§ 284.132. [Determination of applicability.] **Reserved.**

[If a general permit specifies that potential users of the permit shall obtain a determination of applicability from the Department prior to conducting the activity authorized by the general permit, the procedures in this section shall be followed in addition to those stated in § 284.131 (relating to authorization for persons or municipalities to be included in a general permit):

(1) An application for a determination of applicability shall be accompanied by a nonrefundable fee in the form of a check payable to the "Commonwealth of Pennsylvania" for $ 500.

(2) The Department will provide notice in the *Pennsylvania Bulletin* of each application for a

determination of applicability for a general permit which the Department has determined to be administratively complete. The Department may indicate in the notice that interested persons or municipalities may submit comments to the Department within a 60-day period. If a comment period is provided, counties may recommend to the Department conditions, revisions or disapproval of the application. The Department may hold a public meeting or public hearing on an application for determination of applicability for a general permit.

(3) The Department will make a determination that a general permit is or is not applicable to an activity for which an application for determination of applicability is filed within 60 days from the publication of the notice under paragraph (2) or, if a comment period is provided, within 120 days after publication of the notice. The time period does not include periods beginning with the date the Department has requested in writing that the applicant make substantive corrections or changes to the application and ending with the date that the applicant submits corrections or changes to the Department's satisfaction. Failure by the Department to comply with this timetable will not be construed or understood to constitute grounds for a determination that the general permit applies to the proposed activity.

(4) The Department will determine that the general permit does not apply to the proposed processing activity and deny coverage under the general permit if the applicant fails to demonstrate the following to the Department's satisfaction:

(i) That the proposed activity is consistent with the terms and conditions of the general permit.

(ii) That the activity does not have the potential to harm or present a threat of harm to the health, safety or welfare of the people or the environment of this Commonwealth.

(5) The Department will publish notice of its decision regarding each determination of applicability in the *Pennsylvania Bulletin*. If a county has made recommendations to the Department concerning conditions, revisions or disapproval of the permit during a 60-day comment period, and the Department has overriden the recommendations, the Department will publish its justification for overriding the recommendations in the *Pennsylvania Bulletin*. The applicant for a determination of applicability for coverage under a general permit shall provide written notice to each municipality in which the applicant intends to operate pursuant to the general permit.

(6) The Department may amend, suspend or revoke coverage under a general permit if the waste or the activity is not consistent with the terms and conditions of the general permit.]

Subchapter C. TRANSFER FACILITIES

§ 284.201. Scope.

This subchapter sets forth application and operating requirements for a person or municipality that operates a transfer facility for **[infectious]** **regulated medical** or chemotherapeutic waste. The

requirements in this subchapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management – general provisions).

§ 284.210. Application requirements.

An application to operate a transfer facility shall comply with §§ 279.101 -- 279.111 (relating to **[general]** **application** requirements **for transfer facilities**).

§ 284.220. Operating requirements.

A person or municipality that operates a transfer facility shall comply with **[§§ 279.201, 279.202, 279.211 -- 279.223, 279.231 -- 279.234, 279.241 -- 279.243, 279.251, 279.252, 279.261 and 279.262]** **Chapter 279, Subchapters A and C (relating to general provisions and operating requirements for transfer facilities)**.

Subchapter D. PROCESSING FACILITIES

§ 284.301. Scope.

This subchapter sets forth application and operating requirements for a person or municipality that operates a processing facility, other than a transfer or composting facility, for **[infectious]** **regulated medical** or chemotherapeutic waste. The requirements in this subchapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management -- general provisions).

§ 284.311. Plan for monitoring.

An application for a processing facility for **[infectious]** **regulated medical** waste shall contain a plan, including necessary designs, procedures and test protocols on forms provided by the Department, for meeting the requirements of § 284.321 (relating to **[infectious]** **regulated medical** waste monitoring requirements), including the following:

(1) The method by which disinfection will be accomplished.

(2) A description of the monitoring and quality assurance program to ensure disinfection.

§ 284.320. Operating requirements.

A person or municipality that operates a processing facility shall comply with **[§§ 283.201, 283.202, 283.211 -- 283.223, 283.231 -- 283.234, 283.241, 283.242, 283.251 -- 283.253, 283.261, 283.262, 283.271 and 283.272]** **Chapter 283, Subchapter C (relating to operating requirements).**

§ 284.321. [Infectious] Regulated medical waste monitoring requirements.

(a) A person or municipality that disinfects **[infectious]** **regulated medical** waste shall monitor the waste to ensure the following:

(1) For thermal processing or incineration, the absence of anaerobic or aerobic bacterial growth in a composite sample of processing residue or ash.

(2) For other disinfection processes, both of the following are met:

(i) The process shall be capable of inactivating **[vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and]** mycobacteria at a 6 log 10 reduction or greater.

(ii) The process shall be capable of inactivating **[B.]** **Geobacillus** stearothermophilus spores, **[B.]** **Bacillus** pumilus or **[B.]** **Bacillus atrophaeus** **[subtilis]** spores at a 4 log 10 reduction or greater.

(b) The operator of a facility that incinerates or thermally processes **[infectious]** **regulated medical** waste shall submit to the Department a microbiological analysis of a composite sample of the processing or ash residue on forms provided by the Department at a minimum, **[quarterly]** **annually** during the life of the facility.

(c) The operator of a facility that incinerates **[infectious]** **regulated medical** waste shall submit to the Department, at least annually during the life of the facility, a chemical analysis of composite samples of the ash residue on forms provided by the Department.

(d) If the facility disinfects **[infectious]** **regulated medical** waste by means other than incineration or thermal processing, the operator shall perform a microbiological analysis of indicators removed from the processed waste. The analysis shall be conducted at a minimum, every 40 hours during the operational life of the facility, unless otherwise provided in a permit. The analyses shall be made available to the Department upon request.

(e) Unless the Department approves another indicator or test in writing, the following indicators shall be used to establish and verify the following processes:

(1) For autoclaving, spores of **[Bacillus]** **Geobacillus** stearothermophilus.

(2) For dry heat, gas or chemical disinfection, spores of Bacillus **atrophaeus** **[subtilis]** variety niger (globigii). Ethylene oxide may not be used for gas disinfection.

(3) For ionizing radiation, spores of Bacillus pumilus.

(f) Indicators used for methods of disinfection other than incineration or thermal processing shall be located prior to disinfection at a point **within the load** where disinfection will be most difficult to achieve.

(g) **[Infectious]** **Regulated medical** waste will be considered to be infectious after disinfection, unless one of the following has occurred:

(1) For disinfection processes other than incineration or thermal processing, the indicator spores are

determined by microbiological analysis to have been destroyed in accordance with subsection (a).

(2) For incineration or thermal processing using a test other than an indicator spore, a microbiological analysis determines that disinfection has occurred in accordance with subsection (a).

(h) The operator of the disinfection facility shall so certify that the requirements of subsection (a) have been met on a form provided by the Department.

(i) Ash or other processing residue shall be stored in accordance with § 284.418 or § 284.419 (relating to storage and containment of ash residue from **[infectious]** **regulated medical waste** or chemotherapeutic waste incineration; and storage and containment of processing residue from **[an infectious]** **a regulated medical** or chemotherapeutic waste facility).

(j) Ash or other processing residue shall be transported in accordance with § 284.511 or § 284.514 (relating to transportation of ash residue from **[infectious]** **regulated medical waste** or chemotherapeutic waste incineration; and transportation of processing residue from **[an infectious]** **a regulated medical** or chemotherapeutic waste facility).

(k) Compactors, grinders or similar devices may not be used to reduce the volume of **[infectious]** **regulated medical** waste before the waste has been rendered noninfectious. If the volume reduction device is within a continuous, enclosed disinfection process and part of one processing system, then the reduction device may be used.

(l) The operator of **[an infectious]** **a regulated medical** waste processing facility shall dispose of ash or other processing residue from the facility in a landfill that has been approved by the Department to accept the waste, if the waste is disposed in this Commonwealth.

(m) **[In addition to other applicable requirements, an autoclave facility shall comply with the following:**

(1) The processing of pathological waste is prohibited.

(2) The facility shall maintain a retention time for processing bulk fluids (greater than 500 ml) which allows for the complete vaporization of fluids.] **An autoclave facility shall comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapeutic waste.**

(n) Unless otherwise approved in writing by the Department, an operator of an autoclave facility shall employ the procedure(s) outlined in § 284.322 (related to autoclave validation testing requirements) to validate the operating parameters and protocols of the processing equipment. These procedures must be employed in the following circumstances:

(1) When a new autoclave is installed.

(2) When an autoclave is modified with respect to hardware, software, controls, or ancillary

equipment.

(3) To validate existing systems within six months of the adoption of these regulations and at a frequency specified by the manufacturer, but not less than 1 year.

(4) When a significant change in the waste stream occurs or a problem is evident.

(o) The facility shall maintain a record of the autoclave validation testing protocols and procedures.

§ 284.322. Autoclave validation testing requirements.

Autoclave operating parameters must be established in accordance with the following:

(1) For facilities with one autoclave or multiple autoclaves that are not identical, each autoclave must have an initial validation test that establishes its operating parameters.

(2) For facilities with multiple autoclaves that are identical, one autoclave may have an initial validation test that establishes the operating parameters for all identical autoclaves at that facility.

(3) Autoclaves shall be tested using the manufacturer's recommended vacuum pulse plan, operating temperature, operating pressure and residence time at the maximum weight and with the most difficult heat transfer challenge anticipated with the indicators located where disinfection would be most difficult to achieve.

(4) If multiple vacuum pulse plans, residence times, temperatures and pressures are recommended, the autoclave shall be tested to validate its performance at each recommended vacuum pulse plan, residence time, temperature and pressure. If a test fails, more stringent operating parameters shall be used incrementally until a satisfactory test and set of operating parameters is determined.

(5) Autoclave operating parameters must be validated to achieve a minimum of 250 [deg] F or 121 [deg] C measured at a point where disinfection would be most difficult to achieve.

(6) The residence time required to achieve a 6 log 10 reduction of mycobacteria and a 4 log 10 reduction of Geobacillus stearothermophilus spores for the level of heat transfer challenge selected shall be the residence time set into that autoclave's controls.

(7) The vacuum pulse plan, residence time, operating temperature and operating pressure established in the validation test will form the permitted operating parameters for the autoclave tested.

Subchapter E. SEGREGATION AND STORAGE

§ 284.401. Scope.

This subchapter sets forth operating requirements for a person or municipality that stores **[infectious]** **regulated medical** or chemotherapeutic waste, ash residue from **[infectious]** **regulated medical** or chemotherapeutic waste incineration and processing residue from **[an infectious]** **a regulated medical** or chemotherapeutic waste processing facility. The requirements in this chapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management -- general provisions) and the requirements in §§ 285.111 -- 285.115 and 285.121 (relating to general requirements; and **[types of storage]** **containers**).

§ 284.411. [Basic storage requirements.] **Segregation.**

[(a) Infectious and chemotherapeutic waste shall be stored and contained in a manner that:

(1) Maintains the integrity of the containers, prevents the leakage or release of waste from the containers and provides protection from water, rain and wind.

(2) Prevents the spread of infectious or chemotherapeutic agents.

(3) Affords protection from animals and does not provide a breeding place or a food source for insects or rodents.

(4) Maintains the waste in a nonputrescent state, using refrigeration (<= 7 [deg] C) or freezing (<= -- 18 [deg] C) when necessary.

(5) Prevents odors from emanating from the container.

(6) Prevents unauthorized access to the waste. As part of this requirement, the following shall be met:

(i) Enclosures and containers used for storage of infectious or chemotherapeutic waste shall be secured to deny access to unauthorized persons.

(ii) Enclosures and containers shall also be marked with prominent warning signs indicating the storage of infectious or chemotherapeutic waste.

(b) Enclosures at a waste generating or processing facility that are used for the storage of infectious or chemotherapeutic waste shall be constructed of finish materials that are impermeable and capable of being readily maintained in a sanitary condition. Storage areas shall be ventilated to minimize human exposure to the exhaust air.

(c) Infectious and chemotherapeutic waste may not be commingled with other waste.

(d) The generator may store infectious and municipal waste that has been sorted and separately containerized on the same cart for movement to an onsite processing or disposal

facility. Chemotherapeutic waste may also be stored on the cart with municipal and infectious waste if it is sorted and separately containerized and if it is moved to an onsite incinerator.]

(a) Regulated medical waste and chemotherapeutic waste shall be segregated at the point of origin at the generating facility into the following three categories:

(1) Regulated medical waste, excluding pathological waste.

(2) Pathological waste.

(3) Chemotherapeutic waste.

(b) Each category of waste segregated under subsection (a) shall be placed in a separate container, except used sharps that qualify as regulated medical waste may be placed in a chemotherapeutic waste sharps container.

(c) If bags are used as containers to segregate the waste, the bags shall be fluorescent orange, orange-red or red in color for regulated medical waste and yellow in color for chemotherapeutic waste.

(d) If bags are used to segregate and store the waste, the requirements of §284.413 (relating to storage containers) must be satisfied.

§ 284.412. [Sorting.] Basic storage requirements.

[(a) Infectious and chemotherapeutic waste shall be placed in separate containers from other waste at the point of origin in the generating facility.

(b) Infectious and chemotherapeutic waste may be stored together in the same container if approved in writing by the Department.

(c) Used sharps, regardless of whether they are infectious or chemotherapeutic waste, may be stored in the same container if the requirements of §§ 284.413(a) and 284.415(a) and (b) (relating to duration of storage of infectious waste for generators; and storage containers) are met.

(d) Infectious waste and shall be sorted at the point of origin in the generating facility into the following three classes, and each class shall be placed in a separate container:
(1) Used sharps.

(2) Fluids -- quantities greater than 20 cubic centimeters.

(3) Other infectious waste.

(e) Chemotherapeutic waste shall be sorted at the point of origin in the generating facility into

the following three classes, and each class shall be placed in a separate container:

(1) Used sharps.

(2) Fluids.

(3) Other chemotherapeutic waste.

(f) Sorted and separately containerized regulated medical waste may be placed together into another container for onsite handling or offsite transportation.]

(a) After regulated medical and chemotherapeutic waste has been segregated and collected for transportation to an onsite or offsite processing facility, the waste shall be stored and contained in a manner that:

(1) Maintains the integrity of the containers, prevents the leakage or release of waste from the containers and provides protection from water, rain and wind.

(2) Prevents the spread of regulated medical waste or chemotherapeutic agents.

(3) Affords protection from animals and does not provide a breeding place or a food source for insects or rodents.

(4) Maintains the waste in a nonputrescent state, using refrigeration (<= 7 [deg] C or <= 45 [deg] F) or freezing (<= -- 18 [deg] C or <= --0 [deg] F) when necessary.

(5) Prevents odors from emanating from the container.

(6) Prevents unauthorized access to the waste. As part of this requirement, the following shall be met:

(i) Enclosures and containers used for storage of regulated medical or chemotherapeutic waste shall be secured to deny access to unauthorized persons.

(ii) Enclosures and containers shall also be marked with prominent warning signs indicating the storage of regulated medical or chemotherapeutic waste.

(b) Enclosures at a waste generating or processing facility that are used for the storage of regulated medical or chemotherapeutic waste shall be constructed of finish materials that are impermeable and capable of being readily maintained in a sanitary condition. Exhaust air from storage areas shall be ventilated to minimize human exposure.

(c) Regulated medical and chemotherapeutic waste may not be commingled with other waste.

(d) The generator may store regulated medical and municipal waste that has been sorted and

separately containerized on the same cart for movement to an onsite processing or disposal facility. Chemotherapeutic waste may also be stored on the cart with municipal and regulated medical waste if it is sorted and separately containerized and if it is moved to an onsite incinerator.

§ 284.413. [Duration of storage of infectious waste for generators.] Storage containers.

[(a) Generators that store infectious or chemotherapeutic waste onsite shall meet the following requirements:

(1) Infectious waste, excluding used sharps, may be stored at room temperature until the storage container is full, but for no longer than 30 days from the date waste was first placed in the container.

(2) A storage container filled with infectious waste may be stored in a refrigeration unit for up to 30 days from the date waste was first placed in the container.

(3) A storage container of infectious waste that has been filled within 30 days from the date waste was first placed in the container may be frozen immediately for up to 90 days from the date waste was first placed in the container.

(b) If the infectious waste becomes putrescent during the storage period identified in subsection (a), the waste shall be moved offsite within 24 hours for processing or disposal.

(c) Used sharps containers may be used until full as long as the storage is in accordance with § 284.411 (relating to basic storage requirements).]

(a) Regulated medical and chemotherapeutic waste shall be placed in containers that are:

(1) Leakproof.

(2) Impervious to moisture.

(3) Sufficient in strength to prevent puncturing, tearing or bursting during storage.

(b) In addition to the requirements of subsection (a), used sharps shall be placed in containers that are:

(1) Rigid.

(2) Tightly lidded.

(3) Puncture resistant.

(c) In addition to the requirements of subsection (a), regulated medical waste fluids in quantities greater than 20 cubic centimeters and chemotherapeutic waste fluids shall be placed in containers that are:

(1) Break resistant.

(2) Tightly lidded or tightly stoppered.

(d) When bags are used as the only container, double or multiple bagging shall be employed and the following requirements shall be met:

(1) Upon packaging, the bags shall be securely tied.

(2) The bag shall be constructed of material of sufficient single thickness strength to meet the following:

(i) The ASTM Standard D1709, *Test Method for Impact Resistance of Polyethylene Film by the Free Falling Dart Method*, with an impact resistance of 165 grams or greater (Method A).

(ii) The ASTM Standard D1922, *Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method*, with a tearing resistance, parallel and perpendicular to the length of the bag, of 480 grams.

(iii) If the standards in subparagraphs (i) and (ii) are modified by ASTM, the standard that is in effect on the date of manufacture of the bags shall be applied.

(3) Bags shall include one of the following certifications indicating that the ASTM standards have been met:

(i) Each bag shall contain a printed certification by the manufacturer.

(ii) The manufacturer may issue a certification letter to the regulated medical or chemotherapeutic waste generator and print a certification on each packaged lot of the bags.

(4) Bags shall have sufficient seam strength that is at least equal in resistance to tearing and equally impermeable as the other portions of the bag.

(5) Bags shall be fluorescent orange, orange-red or red in color for regulated medical waste and yellow in color for chemotherapeutic waste and shall contain colorants that are organic pigments with no heavy metal content.

§ 284.414. [Duration of storage of infectious waste for processors.] Marking of containers.

[If the waste processing facility is separate from the waste generating facility, infectious waste may not be stored at the waste processing facility for more than the following periods unless other periods are approved in a permit :

(1) Seventy-two hours at a temperature <= 28 [deg] C or <=82 [deg] F.

(2) Seven days in a refrigerator at <= 7 [deg] C or <= 45 [deg] F.

(3) Thirty days in a freezer at <= -- 18 [deg] C or <= 64 [deg] F.]

(a) For onsite or offsite transportation of regulated medical or chemotherapeutic waste, the following information shall be provided on the outermost container:

(1) The words "chemotherapeutic waste" if chemotherapeutic waste is containerized.

(2) Up to _____ (*Editor's Note*: The blank refers to one year after the effective date of adoption of the proposed rulemaking.), the words "infectious waste" or "regulated medical waste" if regulated medical waste is containerized.

(3) After _____ (*Editor's Note*: The blank refers to one year after the effective date of adoption of the proposed rulemaking.), the words "regulated medical waste" if regulated medical waste is containerized.

(4) The universal biohazard symbol that conforms to the design shown in regulations of the United States Occupational Safety and Health Administration at 29 CFR §1910.1030(g)(1)(B) (relating to bloodborne pathogens) and the word "BIOHAZARD."

(5) The date the container was full or the date that the generator sealed the container, whichever occurs earlier. If the container is a roll-off and the date is not recorded on the roll-off, a record of the date must be maintained at the generating facility and available for inspection by the transporter or Department for one year.

(b) For offsite transportation of regulated medical or chemotherapeutic waste, the following information shall be provided on the outermost container:

(1) The name, address and telephone number of the generator.

(2) The name of the transporter and, if applicable, Department-issued regulated medical and chemotherapeutic waste transporter license number.

(c) Non-wall mounted used sharps containers storing regulated medical waste shall have fluorescent orange, orange-red or red markings, and chemotherapeutic waste shall have yellow markings. The markings shall sufficiently identify the waste as regulated medical or chemotherapeutic waste.

(d) The information required in this section shall be clearly legible and produced with indelible ink in a color that contrasts with the color of the container, such as black. If a label is used to provide the information, the label shall be securely attached to the container.

§ 284.415. [Storage containers.] Duration of storage of regulated medical waste for generators.

[(a) Infectious and chemotherapeutic waste shall be placed in containers that are:

(1) Leakproof.

(2) Impervious to moisture.

(3) Sufficient in strength to prevent puncturing, tearing or bursting during storage.

(b) In addition to the requirements of subsection (a), used sharps shall be stored in containers that are:

(1) Rigid.

(2) Tightly lidded.

(3) Puncture resistant.

(c) In addition to the requirements of subsection (a), infectious waste fluids -- quantities greater than 20 cubic centimeters -- and chemotherapeutic waste fluids shall be stored in containers that are:

(1) Break resistant.

(2) Tightly lidded or tightly stoppered.

(d) When bags are used as the only storage container, double or multiple bagging shall be employed and the following requirements shall be met:

(1) Upon packaging, the bags shall be securely tied.

(2) The bag shall be constructed of material of sufficient single thickness strength to meet the following:

(i) The ASTM standard D1709-91, *Test Method for Impact Resistance of Polyethylene Film by the Free Falling Dart Method*, with an impact resistance of 165 grams or greater (Method A).

(ii) The ASTM standard D1922-89, *Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method* , with a tearing resistance, parallel and perpendicular to the length of the bag, of 480 grams.

(iii) If the standards in subparagraphs (i) and (ii) are modified by ASTM, the standard that is in effect on the date of manufacture of the bags shall be applied.

(3) Bags shall include one of the following certifications indicating that the ASTM standards have been met:

(i) Each bag shall contain a printed certification by the manufacturer.

(ii) The manufacturer may issue a certification letter to the infectious or chemotherapeutic waste generator and print a certification on each packaged lot of the bags.

(4) Bags used as containers shall have sufficient seam strength that is at least equal in resistance to tearing and equally impermeable as the other portions of the bag.

(5) Bags used as containers shall be yellow in color for each package of chemotherapeutic waste and fluorescent orange, orange-red or red in color for each package of infectious waste and shall be labeled in accordance with § 284.416(c) (relating to marking of containers).

(e) Fluorescent orange, orange-red or red or yellow containers shall contain colorants which are organic pigments with no heavy metal content.

(f) With the exception of persons who work at a small quantity generator's operation, where less than 220 pounds of infectious and chemotherapeutic waste is generated per month, persons packaging infectious or chemotherapeutic waste for offsite transportation shall wear:

(1) Protective overalls.

(2) Heavy gloves of neoprene or equivalent materials.]

(a) Generators that store regulated medical waste onsite shall record on the container the date that the container was full or the date that the generator sealed the container, whichever occurs earlier. If the container is a roll-off and the date is not recorded on the roll-off, a record of the date must be maintained at the generating facility for one year.

(b) Regulated medical waste may be stored for no longer than 30 days from the date that the storage container is full or sealed by the generator, whichever occurs earlier.

(c) If the regulated medical waste becomes putrescent during the storage period identified in subsection (b), the waste shall be moved offsite within 3 business days for processing or disposal.

§ 284.416. [Marking of containers.] Duration of storage of regulated medical waste for processors.

[(a) The outermost container for each package of infectious or chemotherapeutic waste for offsite transportation shall be labeled immediately after packing. The label shall be securely attached and shall be clearly legible. Indelible ink shall be used to complete the information on

the label. If handwritten, the label shall be at least 3 inches by 5 inches in dimension.

(b) The following information shall be included on the label:
(1) The name, address and telephone number of the generator.

(2) The date the waste was generated.

(3) The name of the transporter and, if applicable, Department-issued infectious and chemotherapeutic waste transporter license number.

(c) The following information shall be printed on the outermost container or bag for each package of infectious or chemotherapeutic waste for either onsite movement or offsite transportation:

(1) The words "infectious waste"or "chemotherapeutic waste," whichever is applicable.

(2) The universal biohazard symbol that conforms to the design shown in regulations of the United States Occupational Safety and Health Administration at 29 CFR 1910.145(f)(8)(ii) (relating to specifications for accident prevention signs and tags).

(d) The color coding scheme for infectious and chemotherapeutic waste bags and nonwall-mounted used sharps containers shall be fluorescent orange, orange-red or red in color, or predominately so, for infectious waste and yellow in color, or predominately so, for chemotherapeutic waste, with lettering and symbols in a contrasting color (for example, black).

(e) Stationary waste storage containers shall be lined with the appropriate colored bag for infectious or chemotherapeutic waste.]

If the waste processing facility is separate from the waste generating facility, regulated medical waste may not be stored at the waste processing facility for more than the following periods unless other periods are approved in a permit:

(1) Seventy-two hours at a temperature <= 25 C or <=77 F.

(2) Seven days in a refrigerator at <= 7 C or <= 45 F.

(3) Thirty days in a freezer at <= -- 18 C or <= 0 F.

§ 284.417. Reuse of containers.

(a) Nonrigid containers shall be managed as either **[infectious]** **regulated medical** or chemotherapeutic waste, based upon the contents of the container. These containers may not be reused.

(b) Corrugated fiberboard containers used for storage of **[infectious]** **regulated medical** or chemotherapeutic waste may be reused if the surface of the container has been protected from direct contact with the waste.

(c) A rigid, nonfiberboard container used for the storage of **[infectious]** **regulated medical** waste **or chemotherapeutic waste** may be reused if one of the following applies:

(1) The container has been decontaminated utilizing a Department-approved decontamination procedure.

(2) The surface of the container has been protected from direct contact with **[infectious]** **regulated medical and chemotherapeutic** waste**, as applicable**.

[(d) A rigid container used for the storage of chemotherapeutic waste may be reused if the surface of the container has been protected from direct contact with chemotherapeutic waste.]

§ 284.418. Storage and containment of ash residue from [infectious] regulated medical or chemotherapeutic waste incineration.

(a) Ash residue from **[infectious]** **regulated medical** or chemotherapeutic waste incineration shall be stored in accordance with the following:

(1) In an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building.

(2) On a pad **for collecting a spill or release of ash** that is no more permeable than 1 x 10 <-- 7 >cm./sec.

(3) **In a manner to** **[To]** prevent the release, dispersal or discharge of ash residue into the air, water or onto land.

(b) Ash residue may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with subsection (a).

§ 284.419. Storage and containment of processing residue from [an infectious] a regulated medical or chemotherapeutic waste processing facility.

(a) Processing residue from **[infectious]** **regulated medical** or chemotherapeutic waste processing facilities shall be stored in an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building, in order to:

(1) Prevent the release, dispersal or discharge of processing residue into the air, water or onto land.

(2) Afford protection from animals, rain and wind.

(3) Prevent the development of a breeding place or food source for insects or rodents.

(4) Prevent the leakage of waste from the storage container.

(b) Processing residue from **[an infectious]** **a regulated medical** or chemotherapeutic waste processing facility may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with subsection (a).

Subchapter F. COLLECTION AND TRANSPORTATION

GENERAL

§ 284.501. Scope.

This subchapter sets forth the requirements for a person or municipality that collects and transports **[infectious]** **regulated medical** or chemotherapeutic waste, ash residue from **[infectious]** **regulated medical** or chemotherapeutic waste incineration and processing residue from **[an infectious]** **a regulated medical** or chemotherapeutic waste processing facility. The requirements in this chapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management -- general provisions) and the requirements in §§ 285.211 -- 285.219 (relating to general provisions).

§ 284.511. Transportation of ash residue from [infectious] regulated medical or chemotherapeutic waste incineration.

(a) Ash residue from **[infectious]** **regulated medical** or chemotherapeutic waste incineration shall be wetted immediately prior to loading, and shall remain wetted during transportation and unloading at a municipal waste landfill, to prevent the dispersal of ash residue.

(b) Ash residue from **[infectious]** **regulated medical** or chemotherapeutic waste incineration shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.

(c) **[A transporter shall transport separately each generator's ash residue from infectious or chemotherapeutic waste.]** **A generator's ash residue from regulated medical or chemotherapeutic waste incineration shall be transported separately from the ash residue of other generators.**

(d) **[A transporter may transport ash residue from an infectious or chemotherapeutic waste incinerator that is commingled with other municipal waste if the commingled waste is from one generator and the waste is transported separately from another generator's waste.]** **Municipal waste from a generator may be commingled and transported with the generator's ash residue from regulated medical and chemotherapeutic waste incineration if the municipal waste and ash residue is being transported separately from the waste of other generators.**

§ 284.512. Transportation of [infectious] regulated medical and chemotherapeutic waste; general provisions.

(a) *General.* This section sets forth general requirements for a person or municipality that transports **[infectious]** **regulated medical** or chemotherapeutic waste. Section 284.513 (relating to transportation of **[infectious]** **regulated medical** and chemotherapeutic waste; additional provisions) sets forth additional provisions relating to the transportation of the waste.

(b) *Manner of transportation.* **[Infectious]** **Regulated medical** and chemotherapeutic waste shall be transported in a manner that:

(1) Maintains the integrity of the containers, prevents the leakage or release of waste from the containers and provides protection from water, rain and wind.

(2) Prevents the spread of infectious or chemotherapeutic agents.

(3) Affords protection from animals and does not provide a breeding place or a food source for insects or rodents.

(4) Maintains the waste in a nonputrescent state, using refrigeration (<= 7 [deg] C **or <= 45 [deg] F**) or freezing (<= -- 18 [deg] C **or <= 0 [deg] F**) when necessary.

(5) Prevents odors from emanating from the container.

(6) Prevents unauthorized access to the waste.

(c) *Containers.*

(1) **[Infectious]** **Regulated medical** and chemotherapeutic waste shall be transported in containers that are:

(i) Rigid.

(ii) Leakproof.

(iii) Impervious to moisture.

(iv) Sufficient in strength to prevent puncturing, tearing or bursting during transportation. **[A single-walled, corrugated fiberboard container shall be of a classified strength of at least 200 pounds per square inch, with a gross weight limit of at least 65 pounds at the time the container is manufactured. Compliance with these requirements shall be certified on the container by the manufacturer.]**

(v) Labeled in accordance with the requirements in §284.414 (relating to marking of containers).

(2) In addition to the requirements of paragraph (1), used sharps shall be transported in containers that are tightly lidded.

(3) In addition to the requirements of paragraph (1), **[infectious]** **regulated medical** waste fluids -- quantities greater than 20 cubic centimeters -- and chemotherapeutic waste fluids shall be transported in containers that are:

(i) Break resistant.

(ii) Tightly lidded or tightly stoppered.

(4) Bags meeting the requirements of **[§ 284.415] § 284.413** (relating to storage containers) may be used to meet the requirements of this subsection that containers be leakproof and impervious to moisture.

[(d) Infectious and chemotherapeutic waste may not be transported in the same containers, unless approved in writing by the Department. Infectious and chemotherapeutic waste shall be transported in separate vehicles from those used for other waste.]

[(e)] **(d)** Vehicles for transporting **[infectious]** **regulated medical** or chemotherapeutic waste shall be noncompaction type vehicles.

(e) Regulated medical or chemotherapeutic waste must not be commingled with municipal waste or transported in the same vehicle as residual waste.

(f) Load compartments of vehicles holding **[infectious]** **regulated medical** or chemotherapeutic waste for transportation shall be constructed of materials that are impermeable and easily cleaned. Surfaces of vehicles that have been in direct physical contact with **[infectious]** **regulated medical** or chemotherapeutic waste, because of a leak in the bag or container or because of another reason, shall be decontaminated as soon as possible after unloading.

(g) **[Infectious]** **Regulated medical** waste may **[not]** be kept in an unrefrigerated transport vehicle for **[more than 48]** **up to 72** hours **provided the waste is not putrescent**. If the vehicle is refrigerated (<= 7 [deg] C **or <= 45 [deg] F**) or maintained at freezing temperatures (<= -- 18 [deg] C **or <= 0 [deg] F**), the in-transit storage period may not exceed 5 days.

(h) Chutes may not be used by generators, processors or transporters to transfer **[infectious]** **regulated medical** or chemotherapeutic waste at onsite or offsite locations.

§ 284.513. Transportation of [infectious] regulated medical and chemotherapeutic waste; additional provisions.

(a) This section sets forth additional requirements for the transportation of **[infectious]** **regulated medical** and chemotherapeutic waste. This section does not apply to vehicles used by a generator of less than 220 pounds of **[infectious]** **regulated medical** and chemotherapeutic waste per month for

transporting **the generator's own** waste **[that he generated].**

(b) Vehicles for transporting **[infectious] regulated medical** or chemotherapeutic waste shall be identified on the two sides and back of the cargo compartment with the following:

(1) The transporter's Department-issued **[infectious] regulated medical** and chemotherapeutic waste license number, if applicable.

(2) A placard or decal containing the phrase "**[infectious] regulated medical** waste" or "chemotherapeutic waste," or both, **as applicable** and the universal biohazard symbol that conforms to the design shown in the United States Occupational Safety and Health Administration's regulations at 29 CFR **§1910.1030(g)(1)(B) (relating to bloodborne pathogens) [1910.145(f)(8)(ii) (relating to specifications for accident prevention signs and tags). The placard or decal shall be capable of being read at a distance of 25 feet.]**

(c) A vehicle used for transporting **[infectious] regulated medical** or chemotherapeutic waste shall contain, in a readily accessible place, a portable decontamination and spill containment unit, including at a minimum the following:

(1) An adequate amount of absorbent material.

(2) One gallon of **[hospital grade] EPA-approved** disinfectant in an appropriate applicator.

(3) Fifty fluorescent orange, orange-red or red or yellow, or both, plastic bags that meet the requirements of § **[284.415] 284.413** (relating to storage containers). The bags shall be accompanied by seals and appropriate labels, and shall be large enough to overpack any container normally transported in the vehicle.

(4) Two sets of protective overalls, gloves, boots, caps, goggles and masks. The protective garments shall be oversized or fitted for the vehicle operators.

(5) A first aid kit, boundary marking tape and other appropriate safety equipment.

(d) The surface of vehicles that have not been in direct physical contact with **[infectious] regulated medical** or chemotherapeutic waste shall be cleaned weekly. Drainage from the cleaning shall be discharged directly or through a holding tank to a sanitary sewer system or treatment facility.

[(e) Individuals loading or unloading containers of infectious or chemotherapeutic waste onto or off transportation vehicles shall wear protective overalls and heavy gloves of neoprene or equivalent materials. Gloves and coveralls shall be decontaminated after each loading or unloading operation if the gloves and coveralls have been contaminated or are suspected of having been contaminated. If no contamination occurs or none is suspected, decontamination shall be completed at the end of the working day or work shift.]

§ 284.514. Transportation of processing residue from [an infectious] a regulated medical or chemotherapeutic waste facility.

(a) Processing residue from **[an infectious]** **a regulated medical** or chemotherapeutic waste facility shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.

(b) A transporter shall transport **[separately each generator's]** processing residue from **[infectious]** **regulated medical** or chemotherapeutic waste **for each generator separately from other generators**.

(c) A transporter may transport processing residue from **[infectious]** **regulated medical** or chemotherapeutic waste that is commingled with other municipal waste if the commingled waste is from one generator and the waste is transported separately from another generator's waste.

Subchapter G. TRANSPORTER LICENSING FOR [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

§ 284.601. Scope.

This subchapter sets forth the Department's requirements for licensing of persons and municipalities that transport **[infectious]** **regulated medical** or chemotherapeutic waste.

§ 284.602. License requirement.

(a) Except as provided in subsection (b), a person or municipality may not transport **[infectious]** **regulated medical** or chemotherapeutic waste unless the person has first obtained a license from the Department in accordance with this subchapter.

(b) This subchapter does not apply to the following:

(1) Onsite movement of **[infectious]** **regulated medical** or chemotherapeutic waste by generators.

(2) **[Onside]** **Onsite** movement of **[infectious]** **regulated medical** or chemotherapeutic waste by **[owners or]** operators of permitted **[infectious]** **regulated medical** or chemotherapeutic waste management facilities.

(3) Transportation by a generator of less than 220 pounds per month of **[infectious]** **regulated medical** or chemotherapeutic waste when transporting only **the generator's own** **[the infectious]** **regulated medical** or chemotherapeutic waste **[he generated]** if the manifesting requirements under § 284.701(b)(3) (relating to scope) are met.

(4) The transportation of **[infectious]** **regulated medical** or chemotherapeutic waste generated outside this Commonwealth destined for processing or disposal outside this Commonwealth.

§ 284.603. Identification number.

A person or municipality subject to this chapter may not transport **[infectious]** **regulated medical** or chemotherapeutic waste without first receiving an identification number. The number shall be one of the following:

(1) An EPA identification number obtained under section 3010 of the Resource Conservation and Recovery Act of 1976 (42 U.S.C.A. § 6930).

(2) An identification number obtained from the Department, if the identification number under paragraph (1) is not available.

LICENSE APPLICATION REQUIREMENTS

§ 284.611. General application requirements.

(a) An application for a license to transport **[infectious]** **regulated medical** or chemotherapeutic waste shall be submitted to the Department, in writing, on forms provided by the Department. An application for a license shall be accompanied by information, specifications and other data required by the Department to determine compliance with this subchapter.

(b) The application shall contain the following:

(1) The applicant's identification number, as required by § 284.603 (relating to identification number).

(2) The name, mailing address, place of business, business telephone number and 24-hour emergency telephone number of the applicant.

(3) The average yearly total tonnage of **[infectious]** **regulated medical** and chemotherapeutic waste picked up or delivered in this Commonwealth.

(4) A nonrefundable application fee in the form of a check payable to the "Commonwealth of Pennsylvania" for $500.

(5) Information concerning terminal locations that will store **[infectious]** **regulated medical** and chemotherapeutic waste in-transit.

(6) An identification of interests and compliance history, as provided in §§ 271.124 and 271.125 (relating to identification of interests; and compliance information).

(7) Collateral bond, as required by § 284.641 (relating to bond requirement).

(8) Certificate of insurance, as required by § 284.612 (relating to vehicular liability insurance).

(9) A contingency plan consistent with § 284.632 (relating to **[infectious]** **regulated medical** or chemotherapeutic waste discharges or spills).
(c) An application for a license shall be certified by a responsible official of the applicant with a statement that the information contained in the application is true and correct to the best of the official's information and belief.

§ 284.612. Vehicular liability insurance.

(a) The application shall include a certificate of insurance issued by an insurance company authorized to do business in this Commonwealth, certifying that the applicant has comprehensive vehicular liability insurance in force covering the operation of vehicles and associated **[infectious]** **regulated medical** and chemotherapeutic waste transportation activities.

(b) The certificate of insurance shall expressly document coverage for property damage and bodily injury to third parties. The insurance coverage shall include coverage for the cost of cleaning up **[an infectious]** **a regulated medical** or chemotherapeutic waste spill, and damages arising from the spill. Minimum insurance coverage shall be $500,000 annual aggregate, exclusive of claims administration and legal defense costs.

(c) Insurance coverage provided under this section shall comply with the following:

(1) The insurance policy shall follow the standard commercial or comprehensive vehicular liability policy forms approved by the Insurance Department, and shall include coverage as specified in subsections (a) and (b).

(2) The insurance policy shall be issued by an insurer having a certificate of authority and a licensed agent authorized to transact the business of insurance in this Commonwealth by the Insurance Department. Insurance may be provided by an excess or surplus lines insurer approved by the Insurance Department.

(3) The full policy amount shall be applicable to each driver and vehicle authorized to operate under the license. There may be no proration of the policy amount of coverage among vehicles.

(4) The insurance policy shall provide that the insurer shall notify the Department by certified mail within 30 days whenever a substantive change is made in the policy,
including policy amounts, scope of coverage, tail period, claims procedures, definitions of occurrences or claims or other provisions related to the requirements of this subchapter.

(d) The licensee shall maintain the insurance required by this section in full force and effect during the term of the license and renewals thereof.

(e) An applicant for a transporter license to transport **[infectious]** **regulated medical** or chemotherapeutic waste which is a department or an agency of the United States or of the Commonwealth may fulfill the requirements under this section by means of one or more of the following:

(1) Commercial insurance as specified in this section.
(2) Self-insurance allowed by Federal or State law.

(3) Additional means approved by the Department.

(f) The amount of liability coverage for departments or agencies of the Commonwealth may not exceed the liability limits of 42 Pa.C.S. Chapter 85 (relating to matters affecting government units).

LICENSE APPLICATION REVIEW

§ 284.623. Conditions of licenses.

(a) The Department may place terms and conditions upon a license it deems necessary to protect public health, public safety and the environment, and to ensure compliance with the act, the environmental protection acts and this title.

(b) Except to the extent that the license states otherwise, the licensee shall conduct transportation activities as described in the approved application.

(c) A license to transport **[infectious]** **regulated medical** and chemotherapeutic waste is nontransferable and nonassignable. A license applies to the licensee and its **[employes]** **employees**. Leased or subcontracted drivers, and drivers who provide equipment, have no authority to operate under the licensee's license without prior written approval from the Department.

§ 284.624. License renewal.

A licensee that plans to transport **[infectious]** **regulated medical** or chemotherapeutic waste after expiration of the current license term under § 284.622 (relating to term of license) shall file a complete application for license renewal on forms provided by the Department at least 90 days before the expiration date of the license. The application shall include a nonrefundable application fee in the form of a check payable to the "Commonwealth of Pennsylvania" for $500. The license renewal application will be reviewed by the Department in the same manner as a new application for a license under this subchapter.

OPERATIONAL REQUIREMENTS

§ 284.631. Basic limitations.

(a) A person or municipality subject to this subchapter that transports **[infectious]** **regulated medical** or chemotherapeutic waste shall comply with the following:

(1) The act, this article and other applicable regulations promulgated under the act, including Subchapter F (relating to collection and transportation).

(2) The terms and conditions of the license, the environmental protection acts, this title and orders issued by the Department.
(b) A transporter shall allow authorized representatives of the Commonwealth, without advance notice or a search warrant, upon presentation of appropriate credentials, and without delay, to have access to areas in which operations will be, are being or have been conducted.

§ 284.632. [Infectious] Regulated medical or chemotherapeutic waste discharges or spills.

(a) A copy of the most recently approved Transporter Contingency Plan (TCP) shall be carried on each transport vehicle at all times. Information in the TCP shall be kept current.

(b) In the event of a discharge or spill of **[infectious] regulated medical** or chemotherapeutic waste during transportation, the transporter shall take appropriate immediate action to protect the health and safety of the public and the environment, in accordance with its approved TCP. The transporter shall also immediately telephone the Department and the affected municipality, and provide the following information:

(1) The name of the person reporting the spill or discharge.

(2) The transporter's name, address, the Department-issued **[infectious] regulated medical** and chemotherapeutic waste transporter license number and identification number.

(3) The telephone number where the person reporting the spill or discharge can be reached.

(4) The date, time and location of the spill or discharge.

(5) The mode of transportation and type of transport vehicle.

(6) A brief description of the accident.

(7) For each waste involved in the spill:

(i) The name and identification number of the generators of the waste.

(ii) The estimated quantity of the waste spilled.

(c) If a discharge or spill of **[infectious] regulated medical** or chemotherapeutic waste occurs during transportation, and if the immediate removal of the waste is necessary to protect public health and safety or the environment, the Department may authorize the
removal of the waste to a selected receiving facility by transporters who do not have identification numbers, licenses or manifests under this subchapter.

(d) A transporter shall:

(1) Clean up **[an infectious]** **a regulated medical** or chemotherapeutic waste discharge or spill that occurs during transportation or take action that may be required or approved by the Department so that the discharge or spill no longer presents a hazard to public health, public safety or the environment.

(2) File a complete report in writing concerning the incident with the Department's central office. The report shall include, at a minimum, a detailed description of the clean-up operation and the disposition of the waste, and the information required by subsection (a).

§ 284.633. Safety.

A transporter of **[infectious]** **regulated medical** or chemotherapeutic waste shall provide adequate personnel training to ensure transport activities are conducted safely, in compliance with applicable laws and regulations, and according to the contingency plan approved under § 284.632 (relating to **[infectious]** **regulated medical** or chemotherapeutic waste discharges or spills).

§ 284.634. Annual report.

(a) A transporter shall submit to the Department's Central Office an annual report. The report shall be submitted by the end of March of each calendar year. The report shall be submitted on forms supplied by the Department.

(b) The annual report shall be based on the shipments of **[infectious]** **regulated medical** or chemotherapeutic waste during the previous calendar year, and shall include the following:

(1) The name, location, telephone number and permit identification number of each processing or disposal facility to which the transporter delivered **[infectious]** **regulated medical** or chemotherapeutic waste.

(2) The weight or volume of each type of **[infectious]** **regulated medical** or chemotherapeutic waste transported.

(3) When more than one transporter is used to transport a single shipment of **[infectious]** **regulated medical** or chemotherapeutic waste from the generator to the processing or disposal facility, only the first transporter shall be required to submit information for that shipment on the annual report.

BOND

§ 284.641. Bond requirement.

(a) *General.* The applicant shall provide the Department a bond, secured by collateral as specified by this section and which bond is conditional upon compliance by the licensee with the requirements of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1 -- 6019.6), referred to as the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license and Department orders issued to the licensee. The bond shall be consistent with, and subject

to, the requirements of this section. The amount, duration, form, conditions and terms of the bond shall be specified by the Department. An additional bond amount will not be required of applicants that are also licensed hazardous waste transporters during the term of license or renewal thereof under this subchapter if the applicant or licensee submits a bond endorsement, including an increase in the amount of the bond of a minimum of $10,000, to the Department that includes liability for **[infectious]** **regulated medical** and chemotherapeutic waste transportation on the hazardous waste transporter bond.

(b) *Approval by Department.* A license to transport **[infectious]** **regulated medical** or chemotherapeutic waste will not be issued by the Department before the applicant for the license has filed a collateral bond payable to the Department on a form provided by the Department, and the bond has been approved by the Department.

(c) *Amount of bond.*

(1) The bond shall be in an amount sufficient to assure that the licensee faithfully performs the requirements of the act, the Infectious and Chemotherapeutic Waste Law and regulations thereunder, the terms and conditions of the license, and Department orders issued to the licensee. The minimum amount of the bond is $10,000.

(2) The Department may require additional bond amounts if the mode of transporting waste changes, or the Department determines additional bond amounts are necessary to meet the requirements described in paragraph (1).

(d) *Term of bond.* Liability under the bond shall contain at a minimum for the duration of the license, any renewals thereof and for 1 year after expiration, termination, revocation or surrender of the license. The 1-year extended period of liability includes, and shall be automatically extended for, an additional time period during which administrative or legal proceedings are pending involving a violation by the transporter of the act, the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license or Department orders issued to the licensee.

(e) *Collateral for transporter bonds.*

(1) The Department will accept the types of collateral for transporter bonds that are provided in § 271.322 (relating to general terms and conditions for collateral bonds).

(2) The terms and conditions for the bonds shall be as provided in §§ 271.322 -- 271.325.

(3) A department or agency of the United States or the Commonwealth applying for a transporter license to transport infectious or chemotherapeutic waste shall satisfy the requirements of this section by filing a bond with the Department under this section, or by another means of financial assurance approved by the Department which satisfies the terms and conditions for bonds under § 271.313(b) (relating to forms, terms and conditions of the bond or trust). The Department may accept a bond executed by a transporter who is not the licensee, in lieu of a bond executed by the licensee, if the liability on the bond meets the requirements of this subchapter. The transporter may

not accept waste or initiate operation prior to the approval by the Department of the financial assurances required by this section.

(f) ***Review of bonds.*** Bonds will be reviewed for legality and form according to established Department procedures.

§ 284.642. Release of bond.

(a) Except as provided in subsection (b), the Department will release a transporter bond 1 year after the expiration or termination of a license upon written request of the licensee.

(b) The Department will not release a bond if the transporter is in violation of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1 -- 6019.6), known as the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license or Department orders issued to the licensee, whether or not the violation results from **[infectious] regulated medical** or chemotherapeutic waste transportation.

(c) The release of a bond by the Department does not constitute a waiver or release of other liability provided in law, nor does it abridge or alter rights of action or remedies of a person or municipality presently or prospectively existing in equity or under criminal and civil common or statutory law.

§ 284.643. Bond forfeiture.

(a) The Department will declare a bond forfeit if the transporter is in violation of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1 -- 6019.6), known as the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the bond, the terms and conditions of the license or Department orders issued to the licensee, whether or not the violation results from **[infectious] regulated medical** or chemotherapeutic waste transportation.

(b) If the Department declares a bond forfeit, it will:

(1) Send written notification to the transporter of the Department's determination to declare the bond forfeit and the reasons for the forfeiture.

(2) Advise the transporter and surety of the right to appeal to the EHB under the Environmental Hearing Board Act (35 P. S. §§ 7511 -- 7514).

(3) Proceed to collect on the bond as provided by applicable laws for the collection of defaulted bonds or other debts.

(c) If the Department declares a transporter bond forfeited, it will pay, or direct the State Treasurer to pay, the collateral funds into the Solid Waste Abatement Fund. If upon proper demand and presentation, the banking institution or other person or municipality which issued the collateral refuses to pay the Department the proceeds of a collateral undertaking, the Department will take appropriate steps to collect the proceeds.

Subchapter H. MANIFESTING FOR [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

GENERAL

§ 284.701. Scope.

(a) Except as provided in **[subsections]** subsection (b) **[and (c)]**, this subchapter applies to a person or municipality that generates, transports, disposes or processes **[infectious]** **regulated medical** or chemotherapeutic waste or processed **[infectious]** **regulated medical** or chemotherapeutic waste that is recognizable.

(b) This subchapter does not apply to a person or municipality for the following activities:

(1) Onsite movement of **[infectious]** **regulated medical** or chemotherapeutic waste by generators.

(2) Onsite movement of **[infectious]** **regulated medical** or chemotherapeutic waste by **[owners or]** operators of permitted **[infectious]** **regulated medical** or chemotherapeutic waste management facilities.

(3) Transportation by a generator who generates less than 220 pounds per month of **[infectious]** **regulated medical** and chemotherapeutic waste if the following are met:

(i) The generator only transports its own waste.

(ii) The generator records on a log or shipping paper the following information for each shipment:

(A) The name, address and telephone number of the generator of the waste.

(B) The quantity of the waste transported and accepted by the processing or disposal facility.

(C) The date the waste is transported and accepted by the processing or disposal facility.

(iii) The generator carries and delivers a copy of this **[record]** **log or shipping paper** with the waste shipment to the offsite processing or disposal facility.

(4) The transportation of **[used sharps]** **regulated medical waste** **[from generators who generate less than 220 pounds per month of infectious and chemotherapeutic waste]** if the following are met:

(i) The package is sent to a permitted processing or disposal facility in this Commonwealth or to an out-of-State facility by certified mail, return receipt requested, indicating the name and address of the sender, the name of the addressee, the signature of the addressee, the date of delivery and the

address where delivered or by utilizing an alternate tracking system approved in writing by the Department if applicable.

(ii) **[The packaging meets the requirements of the United States Postal Service or other mail carriers.]** **The mailing standards of the United States Postal Service as set forth in 39 C.F.R. §211.2 (relating to regulations of the Postal Service) and incorporated by reference into this Chapter authorize the package to be mailed.**

(iii) The package is mailed in compliance with Postal Service regulations.

[(iii)] **(iv)** The generator maintains a log **or shipping paper** containing the following information:

(A) The weight of the waste transported.

(B) The date of shipment.

(C) The name and address of each processing or disposal facility to which the generator is shipping the waste by the United States Postal Service or other mail carrier.

(5) The transportation by a generator **[of]** who generates **and processes onsite** less than 220 pounds per month of **[infectious]** **regulated medical** or chemotherapeutic waste**, [that he generates and processes onsite, but]** which is recognizable waste, if the following are met:

(i) **The generator only transports its own waste.**

(ii) The generator records on a log or shipping paper the following information for each shipment:

(A) The name, address and telephone number of the generator of the waste.

(B) The quantity of the waste transported and accepted by the disposal facility.

(C) The name, address and telephone number of the transporter for each shipment of waste. If applicable, the log or shipping paper shall include the identification number of a licensed transporter.

(D) The date the waste is transported and accepted by the processing or disposal facility.

[(ii)] **(iii)** A copy of the log or **shipping paper** **[record]** shall be **[carried and delivered]** **provided** to the disposal facility by the transporter for each shipment of waste.

(6) The transportation through this Commonwealth of **[infectious]** **regulated medical** or chemotherapeutic waste generated outside this Commonwealth **[and which]** **that** is destined for processing or disposal outside this Commonwealth.

(7) The transportation of processed **[infectious]** **regulated medical** or chemotherapeutic waste to a disposal facility if the waste has been rendered unrecognizable.

[(c) This subchapter does not apply to a person or municipality which receives infectious or chemotherapeutic waste generated in this Commonwealth and which processes or disposes of the waste outside this Commonwealth in a state that provides a manifest or tracking form if the following are met:

(1) The state requires a manifest or tracking form for infectious or chemotherapeutic waste, regardless of whether the state requires a manifest or tracking form for infectious or chemotherapeutic waste as defined in this article.

(2) The generator obtains a manifest or tracking form for infectious or chemotherapeutic waste from that state.

(3) The generator, transporter and owner or operator of a processing or disposal facility comply with the requirements on the manifest or tracking form and applicable state or Federal law, managing the infectious or chemotherapeutic waste as if it were regulated waste under applicable law. For purposes of this subsection, applicable law includes the provisions of this subchapter that are expressly applicable to waste that will be transported outside this Commonwealth for processing or disposal.]

§ 284.702. Transfer facilities.

[(a) Infectious or] **Regulated medical waste,** chemotherapeutic waste or processed **[infectious]** **regulated medical** or chemotherapeutic waste that is recognizable may be transported to or from a transfer facility **[under this subchapter. The use of a transfer facility shall require two manifests, one for the transportation of waste to the facility, and one for the transportation of waste from the facility.]** **in accordance with the following:**

[(b)] **(1)** **The transfer facility is permitted by the Department.**

(2) If **[infectious** or **chemotherapeutic waste or processed waste which is recognizable is]** transported to a transfer facility, the transfer facility shall be considered the designated facility for purposes of this subchapter.

(3) **[When the waste is]** **If** transported from the transfer facility to a processing or disposal facility, the transfer facility shall be considered the generator and the processing or disposal facility shall be considered the **[new]** designated facility for purposes of this subchapter.

§ 284.703. Recordkeeping.

[(a)] The records required under this subchapter shall be retained for at least **[5]** **2** years from the date on which the **[report was required to be]** **record was** prepared. **Records shall be submitted to the Department upon request.** The retention period shall be extended automatically during the course of an enforcement action or as requested by the Department.

[(b) Manifest copies shall be retained for at least 5 years from the date of shipment of the waste. Manifest copies retained under this subchapter shall be furnished to the Department upon request. The retention period shall be extended automatically during the course of an enforcement action or as requested by the Department.]

GENERATOR RESPONSIBILITIES

§ 284.711. Use of manifest.

[(a)] A generator who transports, or offers for transportation, **[infectious]** **regulated medical** or chemotherapeutic waste for offsite processing or disposal shall ensure proper segregation of **[infectious]** **regulated medical** and chemotherapeutic waste from other types of waste and prepare a **[manifest according to the instructions supplied with the manifest]** **log or shipping paper as required in this subchapter**. A processor who transports, or offers for transportation, processed **[infectious]** **regulated medical** or chemotherapeutic waste that is recognizable for offsite disposal shall be considered a generator for purposes of **this subchapter.** **[manifesting. The manifest shall be in at least four parts.**

(b) If the waste is to be processed or disposed in this Commonwealth, the generator shall use one of the manifest formats prescribed by the Department.

(c) The manifest copies shall be distributed as follows:

(1) A four-part manifest shall be used by a generator who designates only one transporter.

(i) Copy 4 of the manifest is retained by the generator.

(ii) Copy 3 of the manifest is retained by the transporter.

(iii) Copy 2 of the manifest is retained by the owner or operator of the processing or disposal facility.

(iv) Copy 1 of the manifest is mailed to the generator by the owner or operator of the processing or disposal facility.

(2) A five-part manifest shall be used by a generator who designates two transporters.

(i) Copy 4 of the manifest is retained by the generator.

(ii) Copy 3A of the manifest is retained by the first transporter.

(iii) Copy 3 of the manifest is retained by the second transporter.

(iv) Copy 2 of the manifest is retained by the owner or operator of the processing or disposal facility.

(v) Copy 1 of the manifest is mailed to the generator by the owner or operator of the processing or disposal facility.

(3) A six-part manifest shall be used by a generator who designates three transporters.

(i) Copy 4 of the manifest is retained by the generator.

(ii) Copy 3B of the manifest is retained by the first transporter.

(iii) Copy 3A of the manifest is retained by the second transporter.

(iv) Copy 3 of the manifest is retained by the third transporter.

(v) Copy 2 of the manifest is retained by the owner or operator of the processing or disposal facility.

(vi) Copy 1 of the manifest is mailed to the generator by the owner or operator of the processing or disposal facility.

(d) If the waste is to be processed or disposed outside this Commonwealth, the generator shall obtain the manifest from the destination state. If the destination state does not supply the manifest, the generator shall use the manifest format required by the Department.]

§ 284.712. Preparation of manifest.

(a) The generator shall **[provide the following information on each manifest]** **create a log or shipping paper of the following information and provide it to the transporter** before the offsite transportation of the **[manifested]** waste occurs:
(1) The name, mailing address and telephone number of the generator.

(2) **[The total number of pages used to complete the manifest, counting the first page plus the number of continuation sheets, if any.**

(3)] Each transporter's company name, identification number, Pennsylvania **[infectious]** **regulated medical** and chemotherapeutic waste transporter license number and telephone number. **[If three transporters are designated by the generator, enter the third transporter's name, identification number, Pennsylvania infectious and chemotherapeutic waste transporter license number, telephone number and the words "Transporter 3 sign here," in the Special Handling Instruction Section.]**

[(4)] **(3)** The number of containers, types of containers and the total quantity of the waste by weight or volume.

[(5) The infectious or chemotherapeutic waste code number for each waste as indicated on the manifest instructions.]
[(6)] (4) The United States Department of Transportation proper shipping name, hazard class and identification number (UN or NA) for each waste identified by 49 CFR Subchapter C (relating to hazardous materials regulations), if applicable.

[(7)] (5) Special instructions and information necessary for proper handling of the waste during transportation, processing, storage or disposal, if any.

[(8)] (6) The printed or typed name and handwritten signature of the generator's authorized representative, and the date of shipment.

[(9)] (7) The printed or typed name and handwritten signature of the initial transporter's authorized representative, and the date of receipt.

[(10) The designated facility's name, site address, Pennsylvania State permit or identification number and phone number. One alternate facility's name, site address, Pennsylvania State permit or identification number and phone number may be designated on the manifest to receive the waste. A facility may only be designated if it has been approved by the Department to accept the generator's waste. A list of designated facilities identified by name, address and telephone number.]

(b) An authorized representative of the generator shall ensure that **[the manifest has been completed and shall read the certification statement on the manifest prior to signing the manifest.]** **a legible log or shipping paper has been completed.**

(c) **[The generator shall ensure before the waste is transported offsite that the required information on all parts of the manifest are capable of being read.**

(d) When the generator uses lab packs containing more than four different waste streams, the generator shall complete a continuation sheet (EPA Form 8700-22A).

(e) For a shipment containing more than four different waste streams, which is not a lab pack, the generator shall complete additional manifests as necessary for waste streams in excess of four, according to the instructions on the manifest.] **After the offsite transportation of the waste, the generator shall receive from the transporter and maintain as a record the log or shipping paper prepared by the transporter in accordance with §284.722(f) (relating to preparation and use of manifest).**

§ 284.713. [Generator's distribution of copies.] **Reserved.**

[(a) Except as provided in subsection (b), the generator shall detach and retain copy 4 of the manifest.

(b) A generator located in this Commonwealth and designating a facility in a state that supplies the manifest shall provide information and distribute copies as required by the manifest in accordance with instructions supplied with the manifest and retain one copy of the manifest.

(c) The generator shall give the transporter the remaining copies of the manifest before the transporter leaves the generator's property.]

§ 284.714. Exception reporting.

(a) A generator that does not receive a **[copy of the manifest with the handwritten signature of the owner or operator of the designated processing or disposal facility]** **log or shipping paper indicating the designated facility that received its waste** within **[20]** **30** days of the date the generator's waste was accepted by the initial transporter shall:

(1) Contact the transporter or the **[owner or]** operator of the designated facility, or both, to determine the status of the **[infectious or chemotherapeutic waste or processed recognizable waste]** shipment.

(2) Notify the Department's appropriate regional office by telephone within 1 business day of the status of the shipment.

(b) **[A generator shall notify by telephone the Department's appropriate regional office and submit an exception report to the Department's central office if]** **If** the generator has not received a **[copy of the manifest with the handwritten signature of the owner or]** **log or shipping paper indicating the designated facility that received its waste** from the **[operator of the designated processing or disposal facility]** **transporter** within 35 days of the date the generator's waste was accepted by the initial transporter**, the generator shall notify the Department's appropriate regional office by telephone and submit an exception report to the Department's central office**.

(c) The exception report shall include the following:

(1) **[A legible copy of the manifest]** **A record of the waste** for which the generator does not have confirmation of delivery.

(2) A cover letter signed by the generator or an authorized representative explaining the efforts taken to locate the waste shipment and the results of those efforts.

TRANSPORTER RESPONSIBILTIES

§ 284.721. [Basic requirements.] **Reserved.**

[Except as provided in § 284.701 (relating to scope), a transporter may not accept infectious or chemotherapeutic waste or processed infectious or chemotherapeutic waste that is

recognizable unless it is accompanied by a manifest which has been completed and signed by the generator or the generator's authorized agent under § 284.712 (relating to preparation of manifest).]

§ 284.722. Preparation and use of manifest.

(a) Before transporting **[infectious]** **regulated medical** or chemotherapeutic waste or processed **[infectious]** **regulated medical** or chemotherapeutic waste that is recognizable, the transporter shall **[print or type his name, sign and date the manifest, and, by the signature, acknowledge acceptance of the waste from the generator.]** **provide the generator with a dated, handwritten signature of an authorized representative of the transporter, acknowledging that the transporter has accepted the waste from the generator on the date of acceptance.**

(b) [Before leaving the generator's property, the transporter shall ensure that all copies of the manifest are properly completed and capable of being read, and shall return copy 4 of the manifest to the generator according to the instructions on the manifest.

(c)] The transporter shall ensure that the **[manifest]** **log or shipping paper required in subsections (c) and (d)** accompanies the waste shipment.

[(d) The transporter may not add additional information to the generator's or designated facility's portions of the manifest or alter the generator's information on a manifest as it existed when the generator signed the manifest.]

[(e)] **(c)** A transporter who delivers **[infectious]** **regulated medical** or chemotherapeutic waste or processed recognizable waste to the designated processing or disposal facility shall **create a log or shipping paper containing the following information**:

(1) **[Obtain on the manifest the date of delivery, the printed or typed name and handwritten signature of the owner or operator of the designated facility.]** **The date that each container of waste was delivered to a designated facility.**

(2) **[Retain copy 3 of the manifest according to the instructions supplied with the manifest.]** **The name and address of the designated facility for each container of waste.**

[(3) Give the remaining copies of the manifest to the owner or operator of the designated facility.]

[(f)] **(d)** The transporter who delivers **[infectious]** **regulated medical** or chemotherapeutic waste to another transporter shall **create a log or shipping paper containing the following information**:

[(1) Obtain the following information on the original manifest and on an additional copy of the manifest provided by the generator:]
[(i)] **(1)** The date **[of delivery]** **that each container of waste was delivered** to the subsequent transporter.

[(ii)] (2) The [printed or typed] name and address of the subsequent transporter that received each container of waste [and his handwritten signature].

[(2) Retain the additional copy signed by the subsequent transporter.

(3) Give the remaining additional copies of the manifest to the subsequent transporter.]

(e) At the time the waste is delivered to the designated facility, the transporter shall provide the operator of the designated facility with a log or shipping paper containing the following information:

(1) The name, mailing address and telephone number of the generator for each container of waste.

(2) The number of containers, types of containers and the total quantity of the waste by weight or volume for each generator.

(f) After the waste has been transported to the designated facility, the transporter shall provide the generator with a log or shipping paper containing the following information:

(1) The name, mailing address and telephone number of each designated facility that received each container of the generator's waste.

(2) The number of containers, types of containers and the total quantity of the waste by weight or volume received by each designated facility.

(3) The date that each designated facility received each container of the generator's waste.

(4) Acknowledgment from the designated facility that it accepted each container of the generator's waste.

§ 284.723. [Waste delivery.] Reserved.

[(a) The transporter shall deliver the entire quantity of infectious or chemotherapeutic waste or processed infectious or chemotherapeutic waste that is recognizable which he has accepted from a generator, a processor or a transporter to one of the following:

(1) The designated facility listed on the manifest by the generator.

(2) The next designated transporter listed on the manifest by the generator.

(b) If the waste cannot be delivered in accordance with subsection (a), the transporter shall do one of the following:

(1) Return the waste to the generator.
(2) Deliver the waste to the alternate facility designated by the generator on the original manifest.

(3) Receive from the generator another properly completed manifest designating an alternate facility from the originally designated facility before transporting the waste to the alternate facility.]

§ 284.724. Transportation limitations.

(a) A transporter may not accept or transport a shipment of **[infectious]** **regulated medical** or chemotherapeutic waste or processed **[infectious]** **regulated medical** or chemotherapeutic waste that is recognizable if:

(1) The waste is in containers or packaging which appear to be leaking, damaged or otherwise in violation of § **[284.415]** **284.413** or § 284.512 (relating to storage containers; and transportation of **[infectious]** **regulated medical** and chemotherapeutic waste; general provisions).

(2) The waste is not labeled or identified as required by § **[284.416]** **284.414** (relating to marking of containers).

(3) The number and type of containers and quantity of waste to be transported do not **appear to** correspond with the number and type of containers and quantity of waste stated **[on the manifest]** **in the generator's log or shipping paper at the time of acceptance by the transporter**.

[(4) Any copy of the manifest is not completed according to the manifest instructions or if information on copies of the manifest is not capable of being read.]

(b) A transporter shall ensure that the waste shipment complies with applicable United States Department of Transportation regulations and 67 Pa. Code Part I (relating to Department of Transportation).

FACILITY RESPONSIBILITIES

§ 284.731. Scope.

Sections 284.732 – **[and]** 284.734 (relating to use of manifest; **[distribution of copies;]** and significant discrepancies) apply to **[owners and]** operators of waste processing or disposal facilities that receive **[infectious]** **regulated medical** or chemotherapeutic waste or processed **[infectious]** **regulated medical** or chemotherapeutic waste that is recognizable from offsite sources.

§ 284.732. Use of manifest.

(a) Except for waste managed in accordance with § 284.701 (relating to scope), an **[owner or]** operator of a designated facility may not accept shipments of **[infectious]** **regulated medical** or chemotherapeutic waste or processed **[infectious]** **regulated medical** or chemotherapeutic waste

that is recognizable from offsite sources unless the shipment is accompanied by **[a Pennsylvania manifest in accordance with]** **a log or shipping paper as required by** this subchapter.

(b) The **[owner or]** operator of the designated facility shall:

(1) Examine the records of the transporter.

[Print or type his name, and sign and date each copy of the manifest to certify that the waste covered by the manifest was received.]

(2) Note significant discrepancies in the **[information on the manifest]** **log or shipping paper of the generator and transporter**, as defined in § 284.734 (relating to significant discrepancies).

(3) Provide the transporter with a dated, handwritten signature from an authorized representative of the facility, acknowledging that it has accepted the waste from the transporter on that date.

[(3) Note the rejection in the discrepancy indication space, and sign and date the manifest in accordance with paragraph (1) if either partially or totally rejecting the waste.

(c) The owner or operator of the designated facility may not alter or add to the information in the generator or transporter sections of the manifest form.

(d) The owner or operator of the designated facility shall ensure that information entered on the manifest is capable of being read on all copies of the manifest.]

§ 284.733. [Distribution of copies.] **Reserved.**

[The owner or operator of a designated facility or an authorized representative shall:

(1) Immediately upon signing the manifest to either partially or totally accept or reject the waste shipment, give the transporter copy 3 of the signed manifest.

(2) Retain copy 2 of the manifest for his records.

(3) Send copy 1 of the manifest to the generator within 14 days of the date of receipt of the waste.]

§ 284.734. Significant discrepancies.

(a) This section applies if there is a significant discrepancy in **[a manifest]** **the logs or shipping papers of the generator and transporter**. A discrepancy is a difference between the quantity or type of waste designated **[on the manifest]** **in the log or shipping paper**, and the quantity or type of waste a facility actually receives. A significant discrepancy occurs if one or more of the following apply:

(1) There is a variation greater than 5% in weight, for bulk waste.

(2) There is a variation in piece count, for batch waste**, excluding 1% variation for generator-loaded trailers**.

(3) There is a difference in waste type which can be discovered by inspection or waste analysis.

(b) If there is a significant discrepancy in **[a manifest]** **the logs or shipping papers**, the **[owner or]** operator shall attempt to reconcile the discrepancy before the waste is processed or disposed **of** at the facility or before the waste is accepted at a transfer facility. If the discrepancy is not resolved within 3 **business** days of receipt of the waste, the **[owner or]** operator shall immediately notify the appropriate regional office of the Department by telephone. Within 7 **business** days of receipt of the waste, the **[owner or]** operator shall also send a letter to the regional office describing the discrepancy and attempts to reconcile it**[and include a legible copy of the relevant manifest]**.

CHAPTER 285. STORAGE, COLLECTION AND TRANSPORATION OF WASTE

Subchapter A. STORAGE OF MUNICIPAL WASTE

ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF WASTE

§ 285.131. Storage and containment of ash residue from municipal waste incineration, including from [infectious] regulated medical or chemotherapeutic waste incineration.

(a) Ash residue from municipal waste incineration, including from **[infectious]** **regulated medical** or chemotherapeutic waste incineration, shall be stored in accordance with the following:

(1) In an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building.

(2) On a pad that is no more permeable than 1×10^{-7} cm./sec.

(3) To prevent the release, dispersal or discharge of ash residue into the air, water or onto land.

(b) Ash residue from an **[infectious]** **regulated medical** or chemotherapeutic waste incinerator may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with sub-section (a).

ADDITIONAL REQUIREMENTS FOR [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

§§ 285.141—285.145. [Reserved].

Subchapter B. COLLECTION AND TRANSPORATION OF MUNICIPAL WASTE

TYPES OF WASTE

GENERAL PROVISIONS

§ 285.218. Signs on vehicles.

A vehicle or conveyance that is ordinarily or primarily used for the transportation of solid waste shall bear a sign that meets the following:

(1) The sign shall include the name and business address of the person or municipality that owns the vehicle or conveyance.

(i) The name shall be the actually and commonly recognized name of the person or municipality. Abbreviations or acronyms are permissible if they do not obscure the meaning.

(ii) The address shall include the city, state and five digit zip code for the principal place of business for the person or municipality.

(2) The sign shall include the specific type of solid waste transported by the vehicle or conveyance.

(i) **[Infectious]** **Regulated medical** or chemotherapeutic waste shall be designated: **[Infectious]** **Regulated Medical**/Chemotherapeutic Waste.

(ii) Other municipal waste shall be designated: Municipal Waste.

(iii) Residual waste shall be designated: Residual Waste.

(iv) Mixed municipal and residual waste shall be designated: Municipal/Residual Waste.

(3) The sign shall have lettering that is 6 inches in height. The lettering shall be placed on the roll-off box or trailer. If available space for lettering on the trailer or roll-off box is so limited that all letters cannot be 6 inches in height, the lettering shall be as close to 6 inches as possible. The required information shall be clearly visible and easily readable.

(4) The sign may be permanent or detachable.

§ 285.221. Transportation of ash residue from municipal waste incineration and from [infectious] regulated medical or chemotherapeutic waste incineration.

(a) Ash residue from municipal waste incineration and from **[infectious] regulated medical** or chemotherapeutic waste incineration shall be wetted immediately prior to loading, and shall remain wetted during transportation and unloading at a municipal waste landfill, to prevent the dispersal of ash residue.

(b) Ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.

(c) A transporter shall transport separately each generator's ash residue from **[infectious] regulated medical** or chemotherapeutic waste.

(d) A transporter may transport ash residue from a**[n infectious] regulated medical** or chemotherapeutic waste incinerator that is commingled with other municipal waste if the commingled waste is from one generator and the waste is transported separately from another generator's waste.

ARTICLE IX. RESIDUAL WASTE

CHAPTER 287. RESIDUAL WASTE MANAGEMENT— GENERAL PROVISIONS

Subchapter A. GENERAL

§ 287.1. Definitions.

The following words and terms, when used in this article, have the following meanings, unless the context clearly indicates otherwise:

Special handling waste—Solid waste that requires the application of special storage, collection, transportation, processing or disposal techniques due to the quantity of material generated or its unique physical, chemical or biological characteristics. The term includes dredged material, sewage sludge, **[infectious] regulated medical** waste, chemotherapeutic waste, ash residue from a solid waste incineration facility, friable asbestos-containing waste, PCB-containing waste, waste oil that is not hazardous waste, fuel contaminated soil, waste tires and water supply treatment plant sludges.

§ 287.2. Scope.

(a) This chapter specifies general procedures and rules for persons or municipalities who generate, manage or handle residual waste. This article specifies the Department's requirements for residual waste processing, disposal, transportation, collection and storage.

(b) Management of the following types of residual waste is subject to Article VIII (relating to municipal waste) instead of this article, and shall be regulated as if the waste is municipal waste regardless of whether the waste is a municipal waste or residual waste:

(1) Construction/demolition waste, as defined in § 271.1 (relating to definitions).

(2) **[Infectious]** **Regulated medical** and chemotherapeutic waste. The terms shall have the same meaning for residual waste as set forth in § 271.1.

(3) Leaf waste and grass clippings.

(4) Waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material.

(c) Management of the following types of waste is subject to this article instead of Article VIII, and shall be regulated as if the waste is residual waste, regardless of whether the waste is municipal waste or residual waste:

(1) Water supply treatment plant sludges.

(2) Waste oil that is not hazardous waste.

(3) Waste tires and autofluff.

(4) Contaminated soil.

(5) Used asphalt.

(6) Dredged material.

(d) The disposal, processing, storage and transportation at a municipal waste management facility of the following types of special handling waste is subject to the applicable additional requirements for the disposal, processing, storage and transportation of these wastes in this article, and shall be regulated as if the waste is residual waste regardless of whether the waste is municipal waste or residual waste:

(1) Friable asbestos-containing waste.

(2) PCB-containing waste.

CHAPTER 288. RESIDUAL WASTE LANDFILLS

Subchapter D. ADDITIONAL REQUIREMENTS FOR CLASS I RESIDUAL WASTE LANDFILLS

ADDITIONAL OPERATING REQUIREMENTS – GENERAL

§ 288.423. Minimum requirements for acceptable waste.

(a) A person or municipality may not dispose of residual waste at a Class I residual waste landfill unless the waste meets the following criteria:

(1) Neither the residual waste nor leachate from the waste will adversely affect the ability of the liner system to prevent groundwater degradation.

(2) Leachate generated from the residual waste will be treated by the facility's leachate treatment system under applicable laws and in a manner that will protect public health, safety and the environment.

(3) The residual waste will not react, combine or otherwise interact with other waste that is or will be disposed at the facility in a manner that will adversely affect the ability of the liner system to prevent groundwater degradation.

(4) Except to the extent that leachate recirculation is allowed in the permit, residual waste may not be bulk or non-containerized liquid waste. Containers holding free liquids may not be accepted unless the container is less than 1 gallon in size, except as otherwise provided in the permit.

(5) The residual waste may not be allowed to react, combine or otherwise interact with other waste or materials in a way that endangers public health, safety and welfare or the environment by generating extreme heat or pressure, fire or explosion, or toxic mists, fumes, dusts or vapors. The potential for inter- action shall be determined using the procedure in the EPA's "*A Method for Determining the Compatibility of Hazardous Wastes*" (EPA-600/2-80-076)— available through the Department or the National Technical Information Service (NTIS), United States Department of Commerce, Springfield, VA. 22161—or another equivalent method approved by the Department in the permit.

(6) The physical characteristics of this waste will not cause or contribute to structural instability or other operating problems at the site.

(b) A person or municipality may not dispose of municipal waste or special handling waste at a Class I residual waste landfill, except that the Department may, in the permit, approve the storage or disposal of the following types of waste generated by the operator:

(1) Industrial lunchroom or office waste.

(2) Special handling waste, other than sewage sludge, **[infectious]** **regulated medical** or chemotherapeutic waste, waste oil or ash residue from the incineration of municipal waste.

(3) Construction/demolition waste.

(c) A person or municipality may not dispose of hazardous waste at a Class I residual waste landfill unless all of the following are met:

(1) Disposal of the waste at a residual waste landfill is authorized by Article VII (relating to hazardous waste management).

(2) The Department approves of the disposal of the waste at the residual waste landfill in the permit.

(d) A person or municipality may not dispose of solid waste at a Class I residual waste landfill if the Toxic Substances Control Act (15 U.S.C.A. §§ 2601—2629) prohibits the disposal of the solid waste at the residual waste landfill.

CHAPTER 299. STORAGE AND TRANSPORTATION OF RESIDUAL WASTE

Subchapter B. STANDARDS FOR COLLECTING AND TRANSPORTING OF RESIDUAL WASTE

GENERAL PROVISIONS

§ 299.220. Signs on vehicles.

A vehicle or conveyance that is ordinarily or primarily used for the transportation of solid waste shall bear a sign that meets the following:

(1) The sign shall include the name and business address of the person or municipality that owns the vehicle or conveyance.

(i) The name shall be the actually and commonly recognized name of the person or municipality. Abbreviations or acronyms are permissible if they do not obscure the meaning.

(ii) The address shall include the city, state and five digit zip code for the principal place of business for the person or municipality.

(2) The sign shall include the specific type of solid waste transported by the vehicle or conveyance.

[(i) Infectious or chemotherapeutic waste shall be designated: Infectious/Chemotherapeutic waste.]

[(ii)] **(i)** Other municipal waste shall be designated: Municipal Waste.

[(iii)] **(ii)** Residual waste shall be designated: Residual Waste.

[(iv)] **(iii)** Mixed municipal and residual waste shall be designated: Municipal/ Residual Waste.

(3) The sign shall have lettering that is 6 inches in height. The lettering shall be placed on the roll-off box or trailer. If available space for lettering on the trailer or roll-off box is so limited that all letters cannot be 6 inches in height, the lettering shall be as close to 6 inches as possible. The required information shall be clearly visible and easily readable.

(4) The sign may be permanent or detachable.

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION
POLICY OFFICE

August 5, 2013

David Sumner
Executive Director
Independent Regulatory Review Commission
14th Floor
333 Market Street
Harrisburg, PA 17120

Re: Proposed Rulemaking: Regulated Medical and Chemotherapeutic Waste (#7-480)

Dear Mr. Sumner:

Pursuant to Section 5(a) of the Regulatory Review Act, please find enclosed a copy of a proposed regulation for review and comment by the Independent Regulatory Review Commission (Commission). This proposal is scheduled for publication as a proposed rulemaking in the *Pennsylvania Bulletin* on August 17, 2013, with a 30-day public comment period. The Environmental Quality Board (Board) adopted this proposal on April 16, 2013.

The enclosed rulemaking includes amendments that comprehensively revise the Commonwealth's existing infectious and chemotherapeutic waste regulations. Pennsylvania's current infectious and chemotherapeutic waste regulations are not aligned with nationwide practices and therefore place Pennsylvania at a disadvantage. The proposed rulemaking will make Pennsylvania's requirements for regulated medical and chemotherapeutic waste consistent with federal requirements and the requirements of other states. The proposed amendments also eliminate duplicative and other outdated requirements and streamline regulations, which will enhance compliance and support cost effective business practices among medical practitioners, medical facilities, transporters of and processors of regulated medical and chemotherapeutic waste in Pennsylvania.

The proposed amendments included in the rulemaking modify existing terminology so that medical waste is identified under Pennsylvania regulations in a manner consistent with federal requirements and the requirements of other states. With the revision in terminology, the proposed amendments also simplify the labeling requirements for medical waste to reduce costs and ensure consistency with the requirements of other states and the federal government. The proposed amendments also provide 7 new permits-by-rule for qualifying processors of medical waste and allow generators, transporters and those involved in storage and processing to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations in lieu of the currently prescribed, outdated paper manifest. The amendments also encourage labor and fuel efficiency by allowing haulers to transport regulated medical waste and chemotherapeutic waste with other wastes in the same vehicle and by allowing facilities more time to completely fill a vehicle before that vehicle must be placed

into service. Finally, the amendments provide another convenient shipping option by removing barriers to shipping waste through the mail where authorized by the U.S. Postal Service.

The Department of Environmental Protection (Department) conducted extensive outreach in the development of this rulemaking, including consulting with Stericycle, Inc., which is the nation's largest medical waste transportation and disposal company, the Pennsylvania Medical Society, the Pennsylvania Dental Association, the Pennsylvania Veterinary Medical Association, the American Red Cross, Johnson & Johnson PRD, and a representative selection of hospitals, dentist offices, long-term care facilities, medical laboratories and physician's offices in Pennsylvania. On September 15, 2011, the Department presented the proposed rulemaking to the Solid Waste Advisory Committee (SWAC) who approved the rulemaking and urged the Department to present it to the EQB for action. In November of 2012, the Department also presented the proposed rulemaking to the Department's Small Business Compliance Advisory Committee (SBCAC). The committee voiced support for the rulemaking, stating that it will benefit small and rural health facilities by helping them to comply with regulatory requirements for the management of regulated medical and chemotherapeutic waste.

The Department will provide the Commission with the assistance required to facilitate a thorough review of the enclosed proposal. Section 5(g) of the Regulatory Review Act provides that the Commission may, within 30 days of the close of the comment period, convey to the agency its comments, recommendations and objections to the proposed regulation. The Department will consider any comments, recommendation or suggestions submitted by the Commission, as well as the Committees and public commentators, prior to final adoption of the enclosed regulation.

Please contact me at 717.783.8727 or by e-mail at mtate@pa.gov if you have any questions or need additional information.

Sincerely,

Michele L. Tate

Michele L. Tate
Regulatory Coordinator

Enclosures

0120-FM-PY0011 8/2006

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
OFFICE OF POLICY

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7- 480

SUBJECT: Regulated medical and Chemotherapeutic Waste

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

- [X] Proposed Regulation
- [ ] Final Regulation
- [ ] Final Regulation with Notice of Proposed Rulemaking Omitted
- [ ] 120-day Emergency Certification of the Attorney General
- [ ] 120-day Emergency Certification of the Governor
- [ ] Delivery of Tolled Regulation
  a. [ ] With Revisions b. [ ] Without Revisions

RECEIVED
IRRC
2013 AUG -5 AM 11: 12

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
8-5-13	Dan McGinley	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Rep. Ron Miller
8-5-13	Jim Kell	Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Rep. Greg Vitali
8-5-13	Patti Cahoy	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Yaw
8-5-13	Megan Boadbek	Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Yudichak
8/5/13	K Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
8-5-13	Samantha Husen	LEGISLATIVE REFERENCE BUREAU (for Proposed only)