

Summary of Proposed Revisions

Regulation 61-105

Infectious Waste Management

September 2016

Please note, this summary of the proposed revisions is provided for convenience. The complete text of revisions and exact regulatory language are detailed in the Notice of Proposed Regulations published in the State Register on September 23, 2016. Each item is followed by the corresponding regulatory citation(s).

DEFINITIONS: ADDED, DELETED, OR REVISED:

- New definitions include: “Alternate treatment technology”, “Demonstration of need”, “Director”, “Donate”, “Planning radius”, “Trust agreement”, “U.S. DOT”, and “USPS”. [D.1]
- The following definitions are revised: “Certification”, “Closure”, “Contingency Plan”, “Dispose”, “EPA”, “Expand”, “Generator facility”, “Generator Registration Status”, “Hazardous waste”, “Infectious waste”, “Intermediate handling facility”, “Manifest”, “Offsite”, “Products of conception”, “Pump event”, “Radioactive material”, “Release”, “Site”, “Solid waste”, “State”, “Supersaturated”, “Transfer Facility”, “Transporter”, “Transport vehicle”, “Treatment facility”, and “Universal biohazard symbol”. [D.1]
- The following definitions are deleted: “CFR”, “Commissioner”, “Containment”, “Destination facility”, “EPA identification number”, “Existing facility”, “Final closure”, “Free liquids”, “Onsite”, “Secured area”, and “Transport”. [D.1]

- The definition of regulated infectious waste will include waste generated by body piercing and tattoo facilities to be consistent with existing requirements found in R. 61-109 (body piercing) and R. 61-111 (tattoo). **[E.1]**
- The definition of 'Isolation Waste' is updated and clarified to include only dangerous and/or exotic agents that pose a high risk of life-threatening disease, may be transmitted by the aerosol route, and for which there is no vaccine or therapy. Many generators isolate patients for reasons other than these agents. The waste generated in the care for those patients may not meet the definition of regulated waste. **[E.1.f]**

GENERAL REQUIREMENTS

- An exemption is created to allow a person treating infectious waste to not label individual bags or containers with the word "treated" if they have a written agreement with the landfill accepting the treatment residue. **[J.7.c]**
- Sharps containers that do not meet US DOT requirements must be packaged further before storage and transport. Note that sharps containers that are approved for transport by US DOT without further packaging (i.e., placed in a bag to assure leak resistance) typically have a gasket or a certification from the manufacturer. **[K.1.d]**
- Biohazard signs must be in good condition and large enough to effectively convey the warning that there is a hazard present and replaced as necessary. **[K.4]**
- Approvals for variances and the use of an alternative treatment technology will have expiration dates set by the Department with an option for renewal. **[T.3]**

- With Department approval and on a case-by case basis, a facility may be allowed up to 5 days after a physical inspection to submit records such as protocols, manifests and weight records. **[AA.2]**

GENERATOR REQUIREMENTS

- An email address (if available) and an EIN will be required during the registration and permitting processes. **[F.1.i; F.1.j]**
- The generator's protocol will be required to include at a minimum: packaging, storage, labeling and manifesting. **[F.5]**
- Small quantity generators will be able to transport waste without marking their vehicle or generating a manifest. **[G.2]**
- Generators must include in written policy if they choose to dispose of solid waste as infectious waste. **[E.1.g; H.1; H.2; H.3]**
- Requirements are clarified so that any bag that contains regulated infectious waste must be red, not just those inside a container. **[I.6]**
- Language is revised to clarify that container markings for infectious waste can meet the requirements of either OSHA or US DOT. **[J.2]**
- If there are special handling requirements for waste, those requirements must be communicated on the waste package and the manifest. **[J.2.f; M.2.I]**
- The manifest does not have to include the date the treatment facility accepted the waste. **[M.2.I]**
- Facilities that treat waste onsite and then send it offsite for further treatment (and receive a complete record of treatment) are allowed 14 additional days to store the "pre-treated" waste onsite and are not considered to be operating under Permit-By-Rule. **[K.5.b; X.1]**

- Generators that treat waste under Permit-By-Rule will have to inform the Department of the method of treatment at the time of their notification. **[X.2.d.v]**

TRANSPORTER REQUIREMENTS

- Cargo-carrying bodies must be disinfected once each day, rented cargo-carrying bodies must be disinfected immediately prior to return to the owner, and a record must be kept of the disinfection. **[L.1.b; L.1.d; Q.1.b]**
- Sharps mail-back programs will not be subject to manifesting requirements. **[M.6]**
- Government employees transporting waste in government vehicles will not have to register as transporters or be subject to manifesting requirements. **[N.12]**
- An email address (if available) and an EIN will be required during the registration and permitting processes. **[O.1.i; O.1.k]**

TREATMENT AND INTERMEDIATE HANDLING FACILITY REQUIREMENTS

- The requirement to submit training documentation to the Department is deleted but continues to be required to be maintained. **[U.9; V.8]**
- Treatment facilities using steam sterilization will have to record the pressure in addition to the temperature, and pressure gauges will be required to be calibrated annually. **[U.15.b]**
- Treatment facilities using steam sterilization have the flexibility to use manufacturer's specifications (for time, temperature and pressure) or other specifications that meet efficacy testing requirements. **[U.15.d]**
- The demonstration of need process for a new or expanding treatment facility or an intermediate handling facility will have standards added that are similar to those for solid waste facilities. **[W.1; W.7]**

- A facility's closure plan must include procedures outlining actions required to properly close the facility. **[W.6.m.i]**
- Closure cost estimates must be based on permitted storage amounts and current industry prices. **[W.6.m.ii]**
- An email address (if available) and an EIN will be required during the registration and permitting processes. **[W.6.n; W.6.o]**
- Financial responsibility coverage must be demonstrated before the Department will issue a final permit for a treatment facility or intermediate handling facility. **[W.13]**
- Treatment and Intermediate Handling Facility applicants and permittees must establish a trust agreement as part of the demonstration of financial responsibility coverage. **[W.13]**
- A clarification will be added requiring permitted treatment facilities to submit a report including the amount of waste treated from each state. **[Z.2.a]**

PRODUCTS OF CONCEPTION

- Any material that results from the termination of a pregnancy, including bodily fluid(s), is considered pathological waste. **[E.1.d]**
- The responsibility to properly manage products of conception is primarily that of the generator and includes the responsibility to convey to the transporter and treatment facility that products of conception waste must be incinerated. **[F.6.k]**
- Generators of products of conception that choose to donate them must complete a record of the donation that includes: the weight of the material, the date of the donation and assurances that no payment exceeds reasonable compensation for costs. **[F.10]**