



# Florida Department of Environmental Protection

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## Meeting Minutes

Subject:	PharmTAG Meeting #4
Date:	March 11, 2009
Time:	9:00 AM
Location:	BMC Room 609, Tallahassee
Meeting Manager:	Mike Redig, FDEP Environmental Manager
Attendees:	Augusta Posner, Yvonne Peters, Rich Galka, Glen Perrigan, Christina Bailey, Michelle Chambers, Dr Lisa Conti (teleconference), Barry Fernandez, Ismael Jusino, Janine Kraemer (teleconference), Michelle Leavis (teleconference), Robert Losurdo, Phil McAtee, Mike McQuone, Charles Mendez, Kathy Mihalek, Bob Miller, Stuart Pheil, Mark Razny, Denise Roach-Rodney (teleconference), Mike Snapp, Dawn Spencer, Barry Stewart, Simon Tanner, Gina Vallone-Hood, Tim Vinson, Offad Vallejo, Melissa Vorhees, Jack Whitley, Mera Youssef

### Meeting Discussion:

- ☞ Mike opened with introductions of all present and via teleconference.
- ☞ Mike referred to the "butcher paper" chart created at the last meeting and asked for the first group (Controlled Substance) to give their presentation to the group. However, no one from this group was present in person or via teleconference. Therefore, this presentation was tabled for the next meeting.
- ☞ Mike then requested the second group ("Known" RCRA) give their presentation. Denise Roach-Rodney was present via teleconference and Jack Whitley was present in person. Denise created and provided an outline of the process for this group which she presented. Several questions and comments arose from this discussion:
  - Waste for this facility is shipped out-of-state to an incinerator in OH. She referred certain questions to Barry of Clean Fuels, her facility's transporter.
  - The question arose of whether or not a facility's trace chemo waste needs to be manifested. Gina, Kathy and Mark all agreed that it does. Mark stated that even if the waste is just going across the street, it should be manifested.

- o Comes down to the education at the healthcare profession level of the person administering material has to know how to separate the units of used chemo therapy sets or hazardous pharmaceuticals so they know what is infectious, what can go to trace and what has to go to bulk. This will be a continuous process.
- o There are waste streams: bulk, trace and, within both of these, there is potential for biohazardous. On the trace end if there are no sharps or blood, waste can be managed as solid waste (incinerator not required). At the point that it is no longer regulated through RCRA program, and is strictly through the FDOH infectious waste program then any appropriately permitted facility under FDOH's medical waste program can manage the material. Under FDOH the definition is anything that is saturated with bodily fluids. If there is no visible contamination, it is solid waste. If facility wants to manage it as regulated medical waste they still have to have permits, all required paperwork, etc.
- o Education has to come down to separate bulk from trace materials and then also decide if trace material contains sharps because you could technically have 3 potential waste streams; bulk that needs to go hazardous waste incineration, trace which you would prefer to go a medical incinerator or appropriately treated for sharps and then stuff with no sharps could simply be landfilled and save on disposal costs, but an overriding factor may be what a risk loss manager requires of a healthcare facility to avoid future liabilities from current disposal practices. ESH knows technical parts of law but risk loss people are coming in from the perspective of insurance for the hospital may say no you will manage your trace without sharps along with sharps and send to medical treatment facility. At that point insurance requirements trumps the regulatory requirements from the perspective of the hospital to say no infectious waste went untreated.
- o Mixed infectious and hazardous waste becomes hazardous waste per the FDOH rule for dual waste. Incinerators must be notified per OSHA requirements of infectious material content. Per OSHA regulations a facility cannot open infectious waste containers (it goes straight to the kiln), but hazardous waste can be opened and is periodically tested. If container is opened and infectious material is discovered and if they are not a permitted facility they must send it back to the generator or to an appropriately permitted facility as a dual waste and notify the recipient that the waste is infectious and RCRA hazardous. If it is mislabeled, the fault could be placed on the generator, the transporter or both. It may depend on the contract a facility has with its transporter (comes down to who is the one labeling the containers?). Potentially everyone involved in the shipment could be held responsible.
- o Michelle Leavis, Mike McQuone and Jack Whitley were present for the group "Unknown" Prescription (in-house packaging). The question

arose concerning the proper procedure for disposal of one pill that might fall on the floor and that may later be unidentifiable since the rule states everything has to be labeled. One suggestion was to have it tested. Another suggestion was to check with a pharmacist either in the facility or at a local pharmacy. Another suggestion was to place it in a plastic bag and put it into the pharmaceutical waste container for incineration so that the lab pack rule applies. Issues in the past with pills were that usually pills were shipped out as a commodity not as waste and would go to reverse distributor and they would receive everything combined and then the role of reverse distributor would be to sift through and determine what was creditable and was isn't. Mike Redig passed out a flyer containing guidance for people with individual prescriptions which tells them to trash not flush.

- A question arose on a manifest how does the facility indicate it has dual waste material (e.g. bulk chemo as well as infectious)? Mark, USDOT, said to classify it as to what the most serious risk is and include this in the description section on the manifest (e.g. primary as flammable, secondary as toxic and infectious as well for incineration as hazardous waste).
- ☞ Stamping or prelabeling containers "for incineration" or "not for incineration" during production may not be helpful if a facility is out of one or the other.
- ☞ A question arose whether or not trace chemo waste may be autoclaved. For trace if it's RCRA empty it's considered solid waste; if it's infectious it's dealt with as infectious.
- ☞ Robert asked if the person separating has to make sure there is absolutely no bulk in trace at all? What it comes down to is if you can no longer pump or aspirate material or no more than .3% remains. The situation comes down to if you have a system you can take apart as a set and you have the intubation part inserted into the IV hooked to the patient that comes from a pump or other mechanism and pushes the drug through system or a simple drip IV. The preparation that's hung in the bag (16oz, liter, pint, etc) would be where the .3% would apply, not the stuff in the tubing since there's no other practical way to get it out if it didn't come out with gravity it's "RCRA empty" at that point. P-listed drugs are up to a pharmacist to determine if they can go out separately or together.
- ☞ Bob had a question regarding sorting. He was instructed years ago that everything in a container must be deemed hazardous if there is any leakage of a hazardous waste. He was wondering how someone could be allowed to then go through and sort waste. When waste is comingled and has been cross contaminated it has to be dealt with as hazardous waste (it is no longer universal waste) and cannot be separated. If dual waste is determined at the point of generation to be cross contaminated and is, therefore, hazardous waste, transporter has to have biomedical transporter license and should be notified by the generator that there is biomedical waste mixed in (not only for

their own safety but to comply with OSHA requirements). Does transporter have to be registered with DEP as hazardous waste transporter with appropriate insurance as well as registered as a medical waste transporter with FDOH? Gina doesn't think so although it may not be clear in the current rule. Driver would be required by DOT to have medical waste training in addition to hazardous waste training.

- ☞ If there is blood drawback into tubing connected to the IV, and the tubing cannot be separated from the IV, it is considered biomedical waste and should go into a red bag.
- ☞ Mixing non-hazardous and hazardous pharmaceuticals is ok (as long as there aren't any adverse reactions by doing so). They can also be managed in the same manner (sent to the same facility) and is encouraged by EPA. The shipping aspect of it still has to follow DOT requirements.
- ☞ Mike requested the group take a break.
- ☞ Mike then requested the third group ("Unknown" Prescription – manufacturing packaging) give their presentation. However, no one from this group was present in person or via teleconference. Therefore, this presentation was tabled for the next meeting.
- ☞ Michelle continued her earlier presentation ("Unknown" Prescription - in house packaging). Should all unknown prescription in house medications be handled as hazardous? Jack suggested to err on the side of safety. It would be better to label something that is non-toxic as toxic than not labeling something that is toxic as such.
- ☞ Mike then requested the fifth group (Chemicals – in house compounding) give their presentation. Tim, Gina and Mike R. were all present from this group. This does not meet the definition for universal pharmaceutical waste. Formulary compounding materials not produced as pharmaceuticals, yet (alcohols, acetones, etc) when sitting there on the shelf and have been cross contaminated or expired they are considered RCRA hazardous waste. If they are formulated into a pharmaceutical then at that point they would qualify as universal pharmaceutical waste and can be characterized by what's in it (flammable, corrosive, etc).
- ☞ Denise had a question concerning the classification of Dakins solution, a very diluted mixture of bleach and saline. The pH was unknown. Mike McQuone conveyed the percent of bleach might be around .125% or .25%. Its use is for wound care, astringent and irrigation. A suggestion was to consult the MSDS. Mike R. suggested having the pH verified as the pH may push it into a corrosive.
- ☞ Denise requested a blog on the website. Mike R. reminded everyone of the list serve ability. Mark reminded everyone of the USDOT PHMSA website and informed the group USDOT is now on Twitter (ID=HMSAT).
- ☞ Michelle had a question regarding mobile trailers for storage. She was concerned that a transporter wouldn't be able to remove universal

waste prior to a hurricane (for example). Dawn stated she was aware of others who are not located in “hurricane country” using trailers. They still have to meet requirements on communications, spill kits, etc in that building to meet standards for central accumulation area which can sometimes be a challenge.

- ☞ The group tossed around the next meeting date. Kathy suggested not having it in the middle of the week for those flying in from out of state. Mike Snapp mentioned there will be an FHA conference May 13-15. Group agreed to May 12<sup>th</sup>. Simon asked if the 12<sup>th</sup> didn’t work, possibly the 19<sup>th</sup>?
- ☞ Denise asked USDOT to repeat contact information. Jack repeated his phone number and email address. Mike R. reminded everyone this information is also on the website <http://pharmtag.org>. Mark stated on August 18-19 in Tampa (exact location TBA) there will be a regional multimode conference. Some of the agencies who will be there: USCG, motor carrier, federal rail, FAA, legal, FDOT, etc. The 2-day conference will have 4-5 breakout sessions which are all free of charge. This will not satisfy USDOT training requirements.
- ☞ Barry F. asked about the proposed EPA Amendment to the Universal Waste Rule: Addition of Pharmaceuticals. Augusta stated that assuming the regulation gets passed on the federal level FDEP will look at it at that point and decide if anything needs to be changed about FDEP’s rule to make it more in component with EPA’s but that it probably will not be the case that FDEP just wholesale adopts EPA’s rule. One thing FDEP might do is change the definition of Pharmaceutical if their definition is a little bit more comprehensive so FDEP might tweak the rule based on that. Mike R. reminded everyone the rule is an optional rule and adoption is discretionary. Only two states have their own pharmaceutical waste rule: Michigan and Florida.
- ☞ Melissa raised a question regarding antimicrobial silver coated devices (dressings, catheters, etc) and how they are addressed or categorized. Mike R. and Augusta suggested pressing the manufacturer for TCLP (Toxicity Characteristic Leaching Procedure) information. This might be a good topic for the list serve.
- ☞ Mike adjourned the meeting.

### **Follow-up:**

- ☞ Next PharmTAG meeting is scheduled for May 12<sup>th</sup> at 9:00 am. Yvonne will reserve our Tallahassee video conference room as well as our 6 district video conference rooms to help alleviate travel concerns for everyone involved.