



Florida Department of Environmental Protection

Bob Martinez Center
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Charlie Crist
Governor

Jeff Kottkamp
Lt. Governor

Michael W. Sole
Secretary

Meeting Minutes

Subject:	PharmTAG Meeting #6
Date:	July 14, 2009
Time:	9:00 AM
Location:	BMC Room 176, Tallahassee; Room 501A, Pensacola; Room 213A, Jacksonville; Room F Orlando; Room 111, Temple Terrace; Room (No #), West Palm Beach
Meeting Manager:	Mike Redig, FDEP Environmental Manager
Attendees:	Agusta Posner, Yvonne Peters, Claire Arnold, Steve Berman, John Bosek, Pamela Bulloch, Brian Clemente, Dan Clemente, Barry Fernandez, Rich Galka, Ed Golding, Mohsen Habib, Mollie Hayes, Gregg Jones, Ismael Jusino, Jim Kendig, Beth Knauss, Janine Kraemer, Sharlene Lau, Paul Leiser, Mike McGann, Ron McGrier, Stephanie Meyer, Kathy Mihalek, Lori Palin, Dan Skalecki, Barry Stewart, Laurie Tenace, Stephen Utt, Tim Vinson, Kathy Winston

Meeting Discussion:

- ☞ Mike opened with introductions of all present and via teleconference.
- ☞ As promised in the last meeting, Denise Roach-Rodney submitted an education tool she utilizes as training material. Mike presented it to the group in Denise's absence.
 - Mike noted the current corporate fines indicated in the presentation needed to be updated to \$32,500 per violation per day and Kathy Winston concurred.
 - Stephen Utt from DEA has had several requests from various medical facilities requesting permission to flush unused controlled substances. Mike stated there is no current wastewater prohibition of flushing controlled substances.
 - Gregg Jones asked if there was any agriculture or aquaculture data on environmental impact where antibiotics, hormones, medicated feeds, etc are concerned. Laurie Tenace mentioned that is regulated by DOAC, but that the claims are that they are not utilizing prophylactic antibiotics.

- Tim Vinson noted that the slide which contained “Regular Landfill vs Lined Landfill” needs some clarification as all landfills are lined. The concern is more with the leachate.
- ☞ Mike presented the draft RCRA Overview which incorporated several presentations from past meetings (a .pdf copy can be located on the website).
 - Mike stated prior to presenting that it is a draft and was open to everyone’s suggestions for what may be added, deleted or updated.
 - Gregg Jones asked what was meant by “ship unsorted and unused pharmaceuticals to a permitted and qualified reverse distributor” (slide 6). Mike stated it refers to they are not sorted as to whether or not they are hazardous waste. Mike said the slide should be qualified to state “...solid and hazardous waste pharmaceuticals....”
 - Barry Fernandez had a question regarding the first reverse distributor scenario where the medical facility segregates and inventories the waste. It was pointed out this is a scenario and not meant to contradict the UPW rule.
 - There was some discussion as to whether or not ethyl alcohol is considered a pharmaceutical. It was inventoried by and located in the pharmacy at the facility Mike Redig and Yvonne Peters visited. So the question arose of what would happen to this if it became outdated. Not all pharmacies may inventory or store alcohol. Dan Skalecki mentioned it is also utilized for cleaning hoods. He also mentioned there are several acne medications such as Clindamycin that would contain > 24% alcohol.
 - Dan Skalecki mentioned the tinctures (Benzoin, Tin-Ben, Podocon-25) used in the presentation may not still be used very much anymore.
 - Mike asked if anyone had an example of a reactive. Beth suggested looking into some of the more concentrated sodium azides to see if any of them qualify. Mike will check with Tiffany Holmes from Watson Labs about a potential reactive she mentioned in a previous meeting.
 - Mike asked if anyone knew if Silvadene cream had ever been tested for TCLP and Beth said it has and it failed.
 - Mike asked if anyone knew if baralyme is still utilized at any hospitals. Jim Hendig stated with the new Joint Commission standards with medication safety and security and materials that may have been handled by general stores are all now handled by the pharmacy, barium included (contrasting solution). Mike stated there should be a third bullet on this slide that it is not UPW (it is hazardous waste), but it is managed through the pharmacy.

- Barry Fernandez requested Mike expand on the wrappers and containers for Coumadin (sodium Warfarin) 3% or above and potentially P-listed for “empty-container” residues. Mike mentioned the guidance on the website which addresses bulk containers for coumadin tablets are considered as a solid waste not a hazardous waste because < 0.3% coumadin trace residues have been found via testing.
 - Laurie Tenace stated she will be creating a presentation which will focus on prevention.
 - Barry Stewart asked the proper disposal method for choral hydrate. Stephen Utt stated there is no clear DEA guideline for this at this time but that the DEA defers to state guidelines. Gregg Jones stated in Florida it would have to go a reverse distributor which is registered with DEA or to a destruction facility. If the generating facility were to destroy it, there would have to be witnesses to verify the destruction and DEA destruction form 41 would have to be completed. Although some facilities may dump unused medication down the drain, this is not a good idea and should not be done as it may not break down.
 - One facility had Norepinephrine bitartrate in a RCRA black container although it was exempted from RCRA as per the October 15, 2007 EPA memo. During an inspection this will fall under RCRA rules, not UPW rules. The container will therefore become a satellite container, a 90-day container or a 180-day container.
 - John Bosek had a question for Gregg Jones regarding inventory requirement for a waste containers such as this with partially filled drug dosage bottles or vials in the container. Gregg noted there will probably need to be some updates to the DOH pharmaceutical rules to address this.
 - The question of how to handle partially-used medications arose. Some examples of what may be occurring are injection into the carpet, injection into the red sharps containers and utilizing sinks or drains. While this should not be considered best management practices, the DOH does not have a clear-cut answer to this question as of yet.
 - Mike was asked what the acronym PHMSA (Pipeline and Hazardous Materials Safety Administration) stood for.
 - Augusta Posner stated “manufacture of pharmaceuticals” does not pertain to formularies.
 - Michigan and Florida are currently the only two states where UPW rules apply to waste pharmaceuticals.
- ☞ Mike requested a break. When the group reconvened he asked those who newly joined us to please introduce themselves.

- ☞ Mike continued with the RCRA Overview
 - Augusta mentioned that “Transporting more than 5,000 kg or 1 kg of p-listed waste must meet financial responsibility requirements of 62-730.170(2) F.A.C.” (slide 58) is when one is transporting that much *at any one time*.
- ☞ Mike asked for feedback on the presentation. The request was made to include more of DOH and DOT requirements.
- ☞ A question arose regarding the possibility of a “walk-through” without repercussions or fines. Mike mentioned DEP does conduct compliance assistance visits with anyone who wishes an inspector to visit, offer suggestions and help a facility reach compliance.
- ☞ Mohsen Habib offered a suggestion regarding bladder cancer drugs that would need to be evacuated by the patient into the toilet by pouring bleach into the toilet and let it sit for treatment within the unit prior to flushing.
- ☞ The Pharm TAG list serve was brought up as a forum for questions and suggestions.
- ☞ Dan Skalecki suggested incorporating reasons *why* UPW needs to be handled properly (even if it’s not officially regulated) because of the drug’s potential chemical composition which may make it highly toxic if ingested (for example).
- ☞ Gregg Jones asked for specific situations which may not be specifically addressed in the presentation. There may be situations where the current practices of the industry may not be addressed in the rule.
- ☞ Mike asked that the members of the Pharm TAG review the draft RCRA Overview and provide feedback directly to him no later than Friday, August 14 [please provide slide number(s) if applicable]. Barry Fernandez suggested also having a discussion on this via the list serve.
- ☞ The group decided to reconvene in September with a tentative date of September 15th set.
 - Barry Fernandez requested another face-to-face meeting.
- ☞ Mike adjourned the meeting.

Follow-up:

- ☞ Next PharmTAG meeting is scheduled tentatively for September 15th 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.
- ☞ Mike will check with PHMSA regarding their conference in August.
- ☞ Laurie will check on the settings of the PharmTAG list serve to try to determine why a member may be required to sign on each time and change that if possible.
- ☞ Yvonne will get the training modules mock-up on the pharmTAG website.

☞ Mike will check on the feasibility of a face-to-face meeting.

PLEASE NOTE: We were unable to reserve the conference rooms for September 15th, therefore, the updated meeting date is September 9th.