



Florida Department of Environmental Protection

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Meeting Minutes

Subject:	PharmTAG Meeting #7
Date:	September 9, 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:	Tim Bahr, Julie Rainey, Yvonne Peters, Claire Arnold, Steve Berman, John Bosek, Ralph Ciano, Stephen Cruz, Lori Davis, Karina Davison (intern), Barry Fernandez, Michael Jackson, Ismael Jusino, Jim Kendig, Beth Knauss, Janine Kraemer, Sharlene Lau, Michelle Leavis, Mark Matthews, Chuck McClellan, Ron McGrier, Kathy Mihalek, John Pcolka, Glen Perrigan, Denise Roach-Rodney, Linda Simon, Dan Skalecki, Dawn Spencer, Barry Stewart, Laurie Tenace, Kathy Winston

Meeting Discussion:

- ☞ Mike opened with introductions of all present and via teleconference.
- ☞ Mike went over some of the comments he received regarding the RCRA Overview he presented at the meeting in July. He was hoping a representative from DOH biomedical waste program would be present, but no one was able to attend this meeting.
 - He mentioned the acronym RMH (regulated medical waste) was suggested to be added.
 - Also a photo of a proper UPW container label was requested.
 - Mike asked Jim Kendig to email a photo of a properly labeled UPW container.
 - Barry Stewart and Jim Kendig had UPW label samples they both held up to the camera for all to see.
 - Some facilities may label UPW waste as RCRA hazardous. UPW waste that needs to leave Florida for proper disposal has to be labeled RCRA hazardous.

- Barry Stewart mentioned the black containers come with the RCRA labels on them which can also cause confusion.
- Clarification on the record keeping process for drugs disposed as hazardous waste or UPW was also suggested. Is a detailed list of drugs required for DOH/DEA or DOT? Mike and Gregg Jones spoke via emails concerning this and the understanding is that if you are getting rid of pharmaceuticals (not trace) DOH didn't have a good answer about the partials, but expired are still in inventory and have to be accounted for. Mike suggested possibly keeping a list of partially-used substances on the container, but Jim Kendig and Ron McGrier stated a partial controlled substance has to be wasted and the destruction witnessed. Mike mentioned chemo drugs that aren't considered controlled substances and posed the question to the group if they would have to be inventoried. Jim stated his staff returns partials to the pharmacy and it is disposed of there under their current rule set. Certainly any waste that has been mixed should not be segregated. Expired drugs can be reverse distributed. Mike said we need clarity from DOH or DEA.
- Another question was about including the general shipping requirements for pharmaceuticals. No one from USDOT or FDOT was present at this meeting. Janine reminded the group that the ultimate responsibility lies with the generator.
- The next question concerned proper disposal of biohazardous and infectious drugs such as vaccines. Mike has been working via email with Gina Vallone and Ed Golding to get a more definitive answer. The one thing that comes to mind is if it's an empty vial it should go via biomedical waste disposal. The partials and outdates are a little more troublesome, especially if it has a Thimerisol preservative. Some hospitals buy them when they need them and they come as single doses to help eliminate waste. Live viruses would have to be disposed of as biomedical waste according to the DOH. Dead viruses could be disposed of as solid waste. Mike reminded everyone that if something is considered RCRA hazardous and biomedical that RCRA "trumps" biomedical so that it would have to be disposed of as RCRA hazardous, so any vaccines preserved by Thimerisol would have to be disposed of as RCRA hazardous waste. In the end, there are three ways to dispose of vaccines.
- Another question was regarding UPW to clarify management vs disposal in Florida. Mike asked the group for suggestions on how to make is less confusion.
- The next question was to clarify the best management practices for controlled substances. Mike will have to get with DEA on this one. No one from DEA was able to attend this meeting. Mike asked the group for suggestions since it requires witnessed disposal. Some facilities may be expelling into the carpet or down the drain which is certainly not a suggested practice and should not be done. A suggestion of

mixing it with kitty litter arose, but then the facility would have amounts of kitty litter to also dispose of.

- The next question was to provide a best management practice for non-hazardous pharmaceuticals. In the proposed EPA regulation that came out last December they advocated mixing hazardous and non-hazardous. Segregating is cheaper. Some facilities are expelling partial non-hazardous liquid drugs down the drain and non-liquid non-hazardous wastes are disposed of as solid waste. Unfortunately there isn't a definitive directive on proper disposal of non-hazardous materials. However, although there is no specific regulation for disposing of them down the drain or in the trash, it is not recommended as the drugs may end up back in the drinking water. The question was asked if there would be a way to get something in writing stating non-hazardous drugs should not be put in the trash or down the drain. Mike said he would ask upper management about that and reminded the group about the current "flyer" for homeowners on how to properly dispose of their medications (a copy is on the pharmTAG website as well as on the DEP website). Proposed legislation concerning this didn't make it through this year, but it may return next year.
 - Barry Fernandez mentioned some hospitals are questioning the effectiveness of trying to identify every item. There are a couple of things associated with this such as environmental stewardship. Just because it may not be regulated under RCRA does not mean it's not harmful to the environment. Encourage but don't require language could go a long way. Denise mentioned when she spoke to her nurses and they asked for one area and only one container to dispose of waste. Jim mentioned color coding in the pharmacy to help nurses properly segregate later. John Bosek reminded the group transporters have to know RCRA codes for containers being shipped.
 - Another comment made was regarding a list of facts and Mike said he would try to address that by having a list of facts as they arise posted to the pharmTAG website.
 - Another comment was referring to the lack of guidance from DOH and Mike has been working with Gregg Jones on this.
 - Another question was concerning prisons with UPW. This could be handled as one pill being dropped on the floor since an inmate wouldn't be in possession of an entire prescription. Barry Stewart mentioned many hospitals no longer accept dispensed drugs from prisons/jails due to problems in the past.
- ☞ Mike asked for any further comments or questions regarding the RCRA Overview presentation from last week. Ron McGrier stated he researched Baralyme and discovered it isn't used much anymore in the CO2 absorbers; another product is used (Amsorb Plus). Barium is still used as an oral contrast agent, but is diluted (less than 5mg per liter mixed in a flavor

drink). Mike asked Ron for an MSDS for Amsorb Plus. Mike asked Beth Knauss about a test performed at local hospitals in the southwest district on barium solutions. She was unable to locate a copy of the test. Mike will strike Baralyme from the presentation and look at Amsorb Plus.

- ☞ Mike requested a break. When the group reconvened he asked those who newly joined us to please introduce themselves.
- ☞ Mike said he would add all the suggestions and comments to the RCRA Overview and put out again for review.
- ☞ Mike continued with the training modules by profession. Mike suggested sticking to 3 modules such as pharmacy, nursing, and EHS and asked for suggestions of any others to tackle first. Jim Kendig stated some facilities have long-term care/hospice care/home healthcare so this may need to fall under the hospitals also not just stand alone. Jim and Laurie agreed the stand alone clinics and those hospitals that may incorporate some type of long-term care are drastically different, so it will still need to also be a separate category for those not associated with a hospital. Mike asked how to divide this up with people with expertise to help develop these areas. Jim Kendig offered to share training developed by Ron Grier with the group as a draft framework. He said their program would be e-learning. Michael Jackson asked if there would be a fee for this. The question also arose as to whether or not CEUs or CMEs would be possible for the training. We are hoping to make that possible to make the training and compliance more appealing. Mike asked if anyone else would be willing to share any training modules and Michelle Leavis stated she is creating an interactive one that she would share a prototype with the group in November. Michael Jackson also volunteered to share previously-presented Florida Pharmacy Association training presentations with the group in November. It was suggested that all these presentations get sent to Mike and Yvonne to be placed on the pharmTAG website for the group to peruse and offer suggestions/comments for the meeting in November to help hone them.
- ☞ Mike mentioned the CEU/CME possibility for this training. He has been in contact with UF's College of Pharmacy. Michael Jackson asked whether there are any rules or statutes which have an education requirement that this program may help toward. Mike said in 62-730.186 there is an education requirement for staff for managing waste materials (safety-oriented). Documentation of this training is required under this rule. Mike wasn't sure about DOH's biomedical rules. Michelle asked if there is a required time (such as the 40-hr OSHA HAZWOPR training) for the training under the rule. Mike stated there is not a required training program length in the rule, but that there is a staff training requirement for operations and safety.
- ☞ Janine asked about facilities who choose not to handle UPW as UPW, but handle it all as RCRA hazardous waste. Mike stated he and Janine will work on a couple of slides to cover the requirements for facilities that choose this route.

- ☞ Denise asked if inspectors issue fines when they find facilities are not compliant to UPW. Several DEP personnel responded, "yes." Michael Jackson asked what the fines have been. A few case studies were mentioned where fines ranged from \$30,000-\$99,000.
- ☞ The question arose again 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. Beth, Kathy and Mike all mentioned that if there is significant non-compliance, the Department may not have a choice but to enforce the non-compliance and assess a penalty based on the MOA with EPA. However, if violations or potential violations which are not significant non-compliant issues, the facility would have 90-120 days to bring itself back into compliance before possible enforcement or fines would be assessed.
 - Michael Jackson suggested a facility having a copy of the checklists in hand prior to the compliance assistance visit to perform a self-check and get into compliance, if necessary, prior to the site visit. Mike said we could post those checklists to the pharmTAG website. Barry Fernandez asked about inspector discretion and Mike iterated that not everything is a "slam dunk." Glen Perrigan will create a universal pharmaceutical waste checklist.
- ☞ The group decided to reconvene in November with a tentative date of November 18th set.
 - Dan Skalecki requested another face-to-face meeting.
- ☞ Mike adjourned the meeting.

Follow-up:

- ☞ Next Pharm TAG meeting is scheduled tentatively for November 18th 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.
- ☞ Michael Jackson will get past FPA presentations to Mike and Yvonne and will present them at the next pharmTAG meeting in November.
- ☞ Jim Kendig and Ron McGrier will get recent training presentations to Mike and Yvonne and will present them at the next meeting in November.
- ☞ Michelle Leavis will complete and get training presentations to Mike and Yvonne and will present them at the next meeting in November.
- ☞ Glen will create the universal pharmaceutical waste checklist and Yvonne will get it on the website.
- ☞ Mike will check on the feasibility of a face-to-face meeting.