Managing Pharmaceutical Waste

A 10-Step Blueprint for Healthcare Facilities

Revised for California Healthcare Facilities

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By

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An Update

- The original 10-Step Blueprint was published in 2006
- Primary authors were Charlotte Smith of PharmEcology Associates and Eydie Pines of H2E
- Published by Hospitals for a Healthy Environment
- The Bay Area Pollution Prevention Group funded development of a California version
- In 2008, updates to the federal version were funded by EPA and incorporated into the Cal version

California is often a Leader in Environmental Laws

- California led the way for hazardous waste laws
- Federal government followed with RCRA law
- California and federal definitions differed
  - Result: "California *Only" hazardous wastes*
- During 1996 California Only hazardous pharmaceuticals removed from DTSC and placed under Medical Waste Management Act

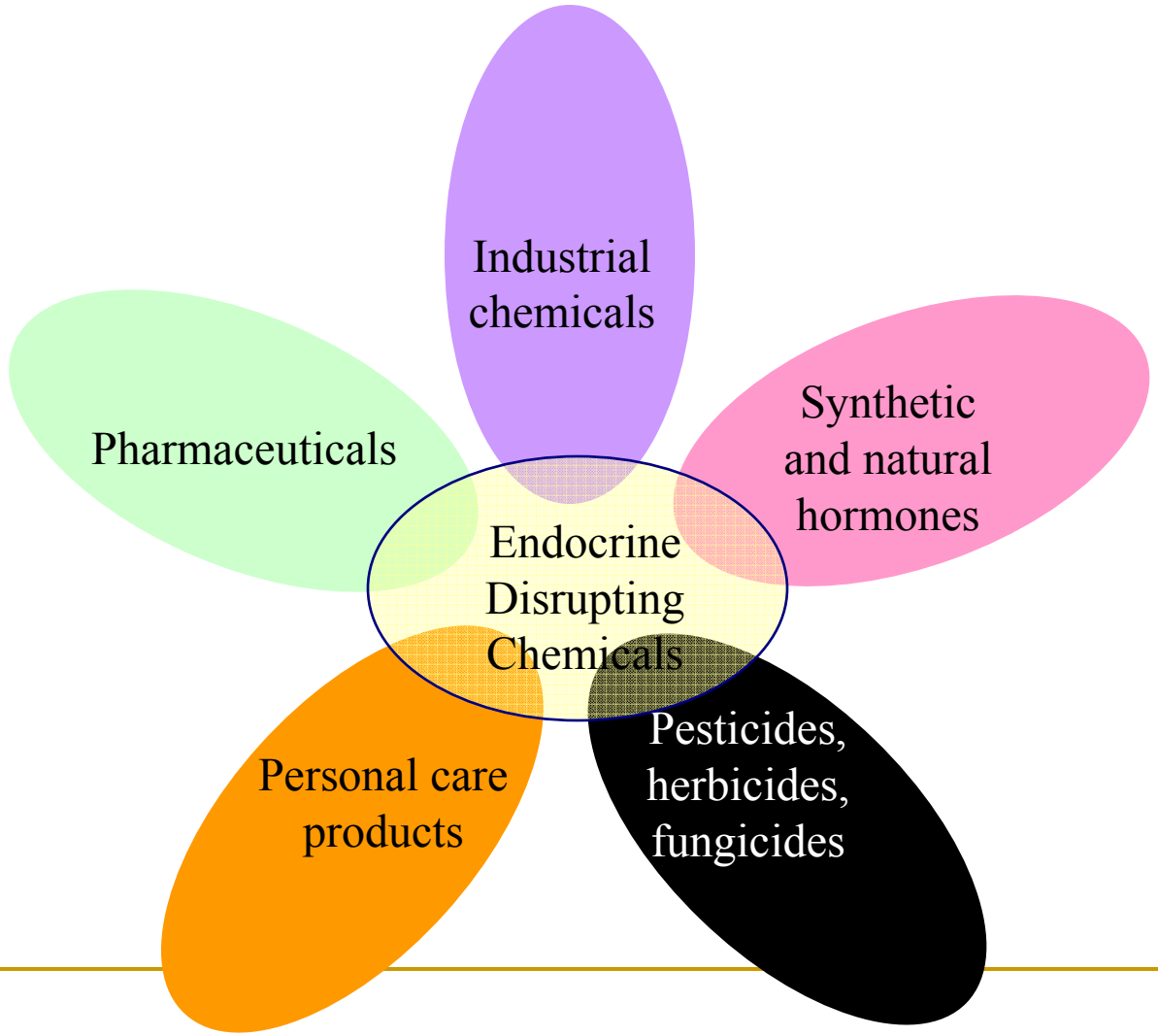
Why We Need a California Version

- Proper pharmaceutical waste management is a highly complex new frontier in environmental management in healthcare
- Hospital pharmacies typically stock between 2,000 and 4,000 different items
  - Pharmaceuticals handled as RCRA hazardous wastes – P and U listed wastes and characteristic waste (D-codes)
  - California Only pharmaceuticals handled under MWMA

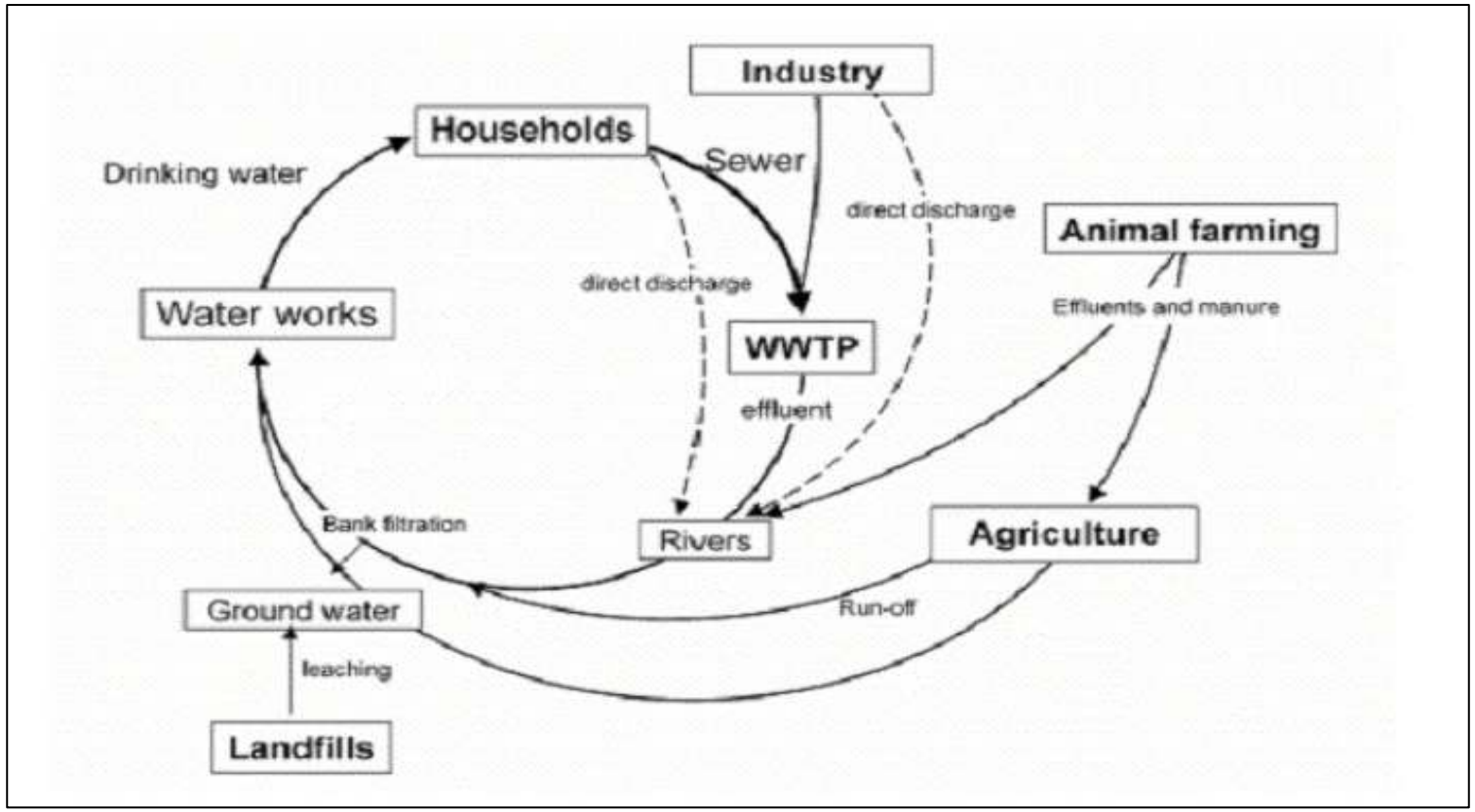
Concerns About Pharmaceutical Disposal

- Pharmaceuticals have been found in surface and ground sources of drinking water
- Minute concentrations of endocrine disruptors have been found in waste water treatment plant receiving waters
  - Having detrimental effects on aquatic species
  - May have an impact on human health

Endocrine Disrupting Chemicals (EDCs)



Sources of Pharmaceuticals in Waterways



Pharmaceuticals in the News

Medical facilities making uncontrolled releases of controlled drugs into water

By JEFF DONN | AP National Writer 12:36 PM EDT, September 14, 2008

MINNEAPOLIS (AP) _ In a frustrating quirk in government policy, the most tightly controlled drugs — like painkilling narcotics prone to abuse — are the ones that most often elude environmental regulation when they become waste.

The 10-Step Blueprint for California

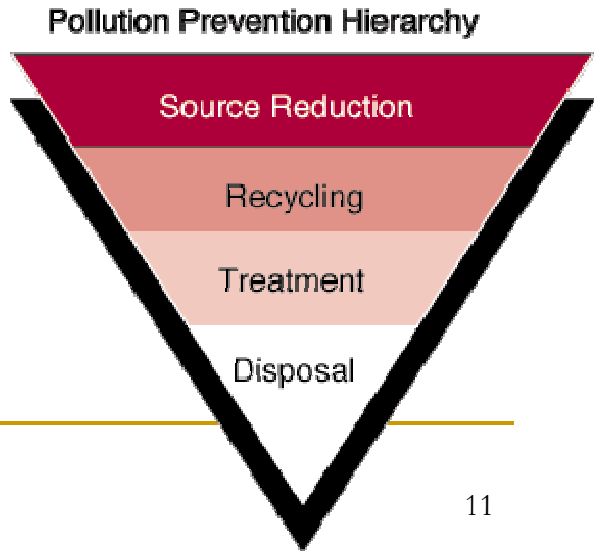
- Pharmaceutical waste is not a single waste stream
- California Blueprint focus:
  - Management of RCRA & California Only hazardous pharmaceutical wastes
  - Management of non-regulated hazardous pharmaceuticals
  - Minimization of pharmaceutical waste

California Pharmaceutical Waste

- Pharmaceutical waste is generated through a wide variety of activities
- Hospital pharmaceutical waste has been generally discarded into the sewer or landfill
- The different classification schemes for pharmaceutical wastes generated in California led to the California version of the 10-Step Blueprint

What can we do?

- Pollution Prevention
  - Control at source
  - Can implement & reduce loading in near term
- Product stewardship




OLIPHANT THE OREGONIAN © 2007 UFS
THE VIAGRA IN THE WATER MAKES ME WANT TO SWIM UPSTREAM, BUT THE PROZAC IS MAKING ME TOO TIRED...
Rx
WASTE

The 10-Step Process

- Step 1 Take immediate actions
- Step 2 Overview of laws governing pharmaceutical wastes
- Step 3 Guidance in handling non-regulated pharmaceutical wastes
- Step 4 Perform a drug inventory
- Step 5 Pharmaceutical waste minimization
- Step 6 Generator status and department reviews

The 10-Step Process

- Step 7 Communication and labeling
- Step 8 Management options
- Step 9 Implementation process
- Step 10 Launching the program

Step #1: *Take Immediate Action/Get Started*

- Establish a committee of stakeholders
  - Can use existing Committee (i.e.; EH&S)
  - Must include: Pharmacy, EVS, Nursing, Infection Control, Education,
  - Others to consider: Safety, Engineering, Administration, Laboratory, Purchasing/Materials Management
- Get support from Senior Management
- Keep Senior Management informed

Step #2: *Know the Laws Governing Pharmaceutical Waste Disposal*

- Federal RCRA Hazardous Waste
- DTSC definitions became "*California Only*" hazardous waste and pharmaceuticals under this definition must be handled as Medical Waste sent for incineration
- Non-RCRA and non-California only hazardous waste may still have sewer or landfill bans and ***best management practices: send it to medical waste incineration***

Key Issues

- Federal change in status of epinephrine salts being regulated as a P-listed RCRA waste (October 15, 2007)
- Expansion of the epinephrine syringe exclusion to other P and U-listed wastes (April 2008)
- EPA proposed amendment to Universal Waste Rules to include pharmaceuticals (March 4, 2009 comment period ended)

Epinephrine Salts Regulation Changes

- Epinephrine salts were RCRA P-listed 042 hazardous waste
- October 15, 2007 EPA memo:
  - EPA acknowledged that most if not all of the chemical used in hospitals was one of the several epinephrine salts
  - EPA determined that the scope of the P042 listing of epinephrine **does not** include epinephrine salts

Epinephrine Salts Regulation Changes

- Since this clarification epinephrine salts can be handled as a California Only hazardous waste eligible for treatment as medical waste in California
- ***Best Management Practice:*** Handle epinephrine salts as medical waste and send for treatment in a medical waste incinerator

Expansion of Epinephrine Syringe Exclusion

- December 1994 EPA Hotline interpretation:
  - Determined that excess and residue epinephrine in a syringe after the proper dose had been administered to a patient was the ***single pharmaceutical exemption*** to the phrase not used for its intended purpose
  - This allowed syringes that had contained epinephrine to be placed in a regular sharps container and **not sent as RCRA hazardous waste**

Expansion of Epinephrine Syringe Exclusion

- EPA published an interpretive letter on April 14, 2008:
  - Extended the exemption to other P and U-listed drugs administered by syringe
  - Did not include contents of unused syringes
  - Use did include both patient injection and transfer of product by syringe from a vial to an IV
  - Only covered syringe as a dispensing device

Trace Chemotherapy Waste

- Federal RCRA law does not address "*trace chemotherapy*" waste; but the California Medical Waste Act does.
- The Medical Waste Management Act requires that trace chemotherapy waste be sent for incineration at a medical waste incineration facility
- Bulk chemotherapy waste must be sent to a RCRA facility

Nitroglycerin Exclusion

- Nitroglycerin is listed as a RCRA waste solely based on its reactivity characteristic
- In 2001 a revision to the mixture and derived from rules excluded all P-and U-listed wastes listed solely for ignitability, reactivity, and corrosivity characteristics (including mixtures, derived-from and as generated wastes) once they no longer exhibit the characteristic
- This action removed nitroglycerin from the P-listed waste as it is weak and non-reactive

Step #3: *Best Management Practices for Non-Regulated Pharmaceuticals*

- Many drugs of concern to EPA & CDC are not currently regulated
  - Hormones
  - Antibiotics
  - Antidepresidents
  - Antihypertensives
- Some are regulated in California under Medical Waste Management Act
- Best Management Practice: **Send to Medical Waste Incinerator**

Incinerate as Medical Waste

- Formulations with a listed active ingredient that is not the sole active ingredient
- Non-chemotherapy drugs that meet NIOSH Hazardous Drug Criteria
- Therapeutic drugs meeting NIOSH Criteria
- Drugs listed in Appendix VI of OSHA Technical Manual
- Drugs with LD_{50} that are less than 50 mg/kg
- Vitamin/mineral preparations with heavy metals
- Endocrine disruptors

Best Management Practice

- Destruction by incineration of all discarded drugs is BMP at this time
- Eliminate drain disposal
- Eliminate landfilling

Step #4: *Perform a Drug Inventory*

- Most hospital pharmacies stock 2,000-4,000 drugs
  - 5% of the inventory are RCRA hazardous
  - Most chemotherapy drugs are not RCRA but should be managed as a hazardous waste as a best management practice
  - California's MWMA requires non-RCRA, "California-Only" hazardous waste to be sent to a medical waste incinerator for treatment
- RCRA places burden of hazardous waste determination on the generator

Drug Waste Determinations

- Gather drug specific data
  - Hospital's formulary
  - Drug purchasing for non-formulary drugs
    - Check the past 12 months purchasing records
  - National Drug Code
  - Brand name
  - Generic name
  - Manufacturer
  - Strength
  - Dosage form
  - Package size

Identify Ingredients and Waste Determination

- Determine all ingredients found in each drug
  - Include: preservatives, heavy metals and alcohol
- Consider all compounded items, re-formulations and IV admixtures
  - May change the hazardous waste characteristic and must be considered in your determination
- Make the waste determination
  - RCRA
  - Hazardous by BMP
  - California-Only medical waste

Other Points to Remember

- Document all your decisions to support you in an audit
- Keep the review current
- Services of other companies to do this work
- Subscription on-line web search engines can assist in the determination process

Step #5: *Minimizing Pharmaceutical Waste*

- Determine what pharmaceuticals are being wasted
- Determine why they are being wasted
- Explore strategies to reduce their wasting
- Source reduction can:
  - Minimize compliance issues
  - Lower costs
  - Reduce liability

Pharmaceutical Waste Minimization

- Consider lifecycle impacts in purchasing process
  - Don’t accept drugs with less than one year dating if you can
  - Select products with less packaging
  - Select drugs without mercury or m-cresol preservatives – use single dose if necessary
  - Work with your GPO to influence manufacturers

Pharmaceutical Waste Minimization

- Maximize the use of opened chemotherapy vials – look for ways to maximize usage of partial vials to minimize waste
- Implement a physician samples policy
  - Document the amount and cost of disposal of samples
  - Include staff time to review sample dating and waste characterization
  - Move to a tighter (or NO samples) policy; move to drug vouchers

Pharmaceutical Waste Minimization

- Labeling drugs for home use can reduce wastage of ointments/inhalers
  - Must have a discharge Rx
  - Must label for home use
  - Consider using pre-authorized discharge orders
  - Consider relabeling for home use
- Priming and flushing IV lines with saline
  - Flushing chemotherapy IV lines with saline allows bag and lines to go as trace chemotherapy waste

Pharmaceutical Waste Minimization

- Examine the size of the container relative to use
  - Survey of all drugs routinely wasted due to the prepared product being too large for complete administration
  - Changes to smaller doses can save money and reduce waste
  - If the product size you need isn't available, work with your GPO

Pharmaceutical Waste Minimization

- Replace prepackaged unit dose liquids with patient-specific oral syringes
  - Especially try this in the neonatal and pediatrics units
  - Review all Emergency Department multi-dose vials to determine the optimum dosage unit to stock based on usage and consider moving to single dose syringes to avoid possible mercury preservatives and partial use

Pharmaceutical Waste Minimization

- Monitor dating on emergency syringes
  - Move epinephrine and nitroglycerin syringes on crash carts by moving to emergency rooms for use prior to expiration on crash carts
- Create tight inventory controls to limit the amount of original manufacturers' containers and repacks that expire before use
- Staff time spent managing expired products is a cost that should be avoided

Step #6: Generator Status and Departmental Reviews

- Perform department reviews to gain information on waste generation and disposal practices for pharmaceuticals
  - Establishes a baseline to measure progress
  - Can use an informal interview process
    - Helps determine uniformity in handling pharmaceutical wastes
    - Identifies where policies and procedures have been established
    - Opportunity to obtain ideas from staff on waste minimization
  - Data can be gathered from dispensing cabinets

Generator Status and Departmental Reviews

- Conduct a frequency analysis
  - Which drugs are dispensed to each unit
  - Use dispensing software if available
  - Review with pharmacy staff if dispensing software not available to determine where 5% of RCRA drugs go
    - Provides information on which units have potential to generate hazardous waste
    - Targets where to start roll-out of improved handling practices to minimize wastes produced

Step #7: Communication and Labeling Challenge

- Must communicate the waste status of the pharmaceuticals handled at your facility
  - Segregate RCRA hazardous waste and bulk chemotherapy waste into hazardous waste containers and ship off as hazardous waste
  - Segregate the rest as California-Only pharmaceutical waste and ship off as medical waste
    - Label "INCINERATE ONLY"

Communication and Labeling Techniques

- Automating Disposition Data in the Labeling Process
  - Incorporating into dispensing hardware
    - Waste segregation data incorporated into patient label
    - Incorporate disposition practices into automated dispensing cabinet systems
  - Incorporate into bedside barcode system to notify nurses of disposition requirements
- Manually labeling disposition information in the pharmacy

Communication and Labeling Techniques

- Provide guidance on the Nursing Units
  - Clearly label hazardous pharmaceutical waste containers
  - Display guidance on posters near the containers
- Use a code name on the label
  - Should be easy for staff to remember, but doesn't alarm patients
  - Include discard location
  - Train on how the container is to be managed

Step #8: *Consider Management Options*

- Four models for managing pharmaceutical wastes
  - Automated bar-code driven sorting
  - Electronic labeling in nursing units
  - Manual labeling in nursing units
  - Managing all pharmaceutical wastes as RCRA hazardous wastes
- A fifth model included in the original Blueprint segregates at a central storage accumulation area. CDPH does NOT approve this method due to MWMA requirements that medical waste be contained separate from other wastes

Consider Management Options

- First three models segregate at the point of generation
  - Segregate RCRA as hazardous waste and label: "Hazardous Waste"
  - Segregate California-Only hazardous waste as medical waste labeled: "INCINERATE ONLY"
- Fourth model segregates all pharmaceutical wastes as RCRA hazardous waste
  - This is a costly approach to take

Step #9: *Getting Ready for Implementation*

- To maximize compliance, establish satellite accumulation sites as close as possible to where pharmaceutical wastes are generated
  - Pharmacies – locate hazardous and California Only hazardous pharmaceutical containers in clean room and main pharmacy
  - Nursing units – locate in soiled utility rooms, medication rooms, medication carts
  - Patient rooms – locked wall units if needed

Getting Ready for Implementation

- Containers must be spill-proof, leak-proof, properly labeled for the waste stream
  - Hazardous waste
  - INCINERATE ONLY for medical waste pharmaceuticals
- Keep containers closed when not in use
  - Consider using wire frames with foot pedals to open/shut the container

Getting Ready for Implementation

- Evaluate the hazardous waste storage area
  - The place where satellite hazardous wastes are moved for storage before transport offsite
  - Specific requirements for these areas
  - Your facility may already have a central storage area
    - Make sure there is room for pharmaceutical wastes
    - May need a second area or enlarge the first one
- California Only hazardous pharmaceutical wastes can be stored with regulated medical waste

Getting Ready for Implementation

- Select the right vendor
  - Permitted hazardous waste vendor for RCRA and bulk chemotherapy wastes
  - Permitted medical waste hauler for California Only hazardous waste pharmaceuticals and all other pharmaceuticals being handled in this manner as a Best Management Practice
  - Reverse distributors are NOT waste management services
  - They can take products in original manufacturer's packaging that are eligible for credit

Getting Ready for Implementation

- Conduct a pilot program to find bugs and refine program
- Suggest pilot program be carried out in:
  - Pharmacy
  - In-patient oncology units
  - Outpatient oncology units
- Develop new policies and procedures
- Be prepared for spills
  - First Responder Awareness (FRA) and First Responder Operational (FRO) training

Step #10: *Launching the Program*

- A successful pharmaceutical waste management program depends on the participation of all employees
- Conduct just-in-time training to roll out the program
- Also use Safety Fairs, Nursing Education Expos and other hospital-wide events to train
- Must train all three shifts and have every thing in place for the roll out

Launching the Program

- Complete hazardous waste manifests – two approaches
  - Hospitals can provide their vendors with all P, U, and D waste codes being used and the vendor pre-certifies the list and creates a waste profile and certified waste stream
  - Nursing and pharmacy staff need to document what is discarded in each container
- Use the assistance of your vendor but the generator is ultimately responsible

Launching the Program

- Complete a medical waste tracking document for all non-RCRA, California Only pharmaceutical wastes being sent to a medical waste incinerator
- Track and measure progress

QUESTIONS??