

# RCS Register

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## Potential Risks: SOPs and Master Records

Does your organization have a plan for maintaining and updating your Standard Operating Procedures (SOPs) and Master Records?

Does your organization update SOPs and Master Record information frequently?

Do you know who is authorized to maintain and update your SOPs and Master Records?

Is your documentation storage plan effective?

If you answered "no" or "I don't know?" to any of these questions, your SOPs and Master Records may be at risk.

Information listed in SOPs and Master Records change frequently. With these frequent changes, SOPs and Master Records need to be updated.

To ensure that Compliance guidelines are met, information is current, new organization/corporate guidelines are included and employees are provided with complete and accu-

rate documentation, SOPs and Master Documents must be reviewed regularly.

SOPs and Master Records that are not maintained may

cause errors in your organization. These errors can put your organization at risk. A SOP and Master Record maintenance program will help elimi-

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## EPA: Cincinnati Company faces EPCRA Reporting Violations

The U.S. Environmental Protection Agency (EPA) in Region 5 has recently filed an administrative complaint against Caraustar Industries Inc. The administrative complaint was filed for alleged hazardous chemical reporting violations at the company's paper processing plant in Cincinnati, Ohio. The EPA has proposed a \$73,689 penalty.

The EPA complaint against Caraustar Industries Inc. falls under the federal Emergency Planning and Community Right-to-Know Act (EPCRA) reporting requirements. EP-

CRA requires companies handling hazardous chemicals to keep detailed records provide these records to state and local emergency responders.

Under EPCRA, any hazardous chemicals kept on-site in excess of 10,000 pounds must be listed on a hazardous chemical inventory form and submitted to state and local authorities.

The EPA complaint alleges that Caraustar Industries Inc. failed to submit the inventory form to the Ohio Emergency

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## **DEA :**

# **King Soopers / Kroger Co. Agree to Pay Record Settlement**

The Drug Enforcement Agency (DEA) announced on October 21, 2005 that King Soopers, City Market, and their parent company, Kroger, have agreed to pay a record \$7 million dollar settlement for systemic violations of the Controlled Substances Act (CSA) by the company's pharmacies.

In addition to the penalty, the Kroger, Co., including King Soopers and City Market, has agreed to implement a pharmacy compliance program estimated to cost over \$6 million dollars. The pharmacy compliance program will be implemented in nineteen-hundred (1900) of the Kroger Co.'s pharmacies nationwide. The DEA reports that they had no evidence of any CSA violations outside of the King Soopers and City Market pharmacies.

According to Jeffrey D. Sweetin, Special Agent in Charge (SAC) of the DEA, *"Americans trust corporations like Kroger to supply them the medications they need. They also trust them to ensure that controlled substances aren't diverted to the illicit market. This record settlement is a clear message that DEA will hold companies accountable for not safeguarding these potentially dangerous sub-*

*stances, as well as an acknowledgement by Kroger that their internal monitoring systems need to be changed."*

*"As a result of DEA's investigation, Kroger is initiating a corporate-wide compliance program to improve their pharmaceutical controls. Seven million dollars is a very large settlement. But, because diverted pharmaceuticals account for a large percentage of the drugs illegally abused, the cost of not imposing such settlements is much larger,"* SAC Sweetin added.

Responding to information concerning possible illegal diversions of controlled substances, the DEA initiated an investigation, which included audits of seven (7) King Soopers pharmacies.

The audits revealed multiple discrepancies. Record-keeping and controlled substance security problems at King Soopers made it impossible to determine how many drugs had been lost or diverted from the stores. The record-keeping problem also complicated the determination of who was responsible for potential diversions of the

controlled substances. According to DEA reports King Soopers' inadequate accountability and security for controlled substances began at the time they were ordered to the time they were dispensed. The DEA conclude that many of the CSA violations were the result of systemic weaknesses present in all King Soopers and City Market pharmacies.

As a result of the investigation, Kroger volunteered to implement a nationwide training program of all pharmacy employees, as well as institute a Comprehensive Regulatory Compliance Program. In addition to the \$7 million dollar penalty, both parties have agreed to an additional \$3 million dollar penalty, which will be suspended as long as Kroger complies with their Comprehensive Regulatory Plan. The DEA states that they will *"work closely and cooperatively with Kroger to ensure the plan is implemented."*

*"Today's historic settlement against one of our nation's most well-known pharmacy chains is a massive financial strike against those who fail to fulfill their responsibility to pre-*

## A Note From the President

*A wise man should consider that health is the greatest of human blessings, and learn how by his own thought to derive benefit from his illnesses.*

*Hippocrates (460 BC - 377 BC), Regimen in Health*



It has been known for a long time that avian influenza (H5N1) existed in animals, often infecting and killing wild and domestic populations. These viruses belong to influenza strains that have evolved and mutated just like any other virus. Historically the main concern was with losing live stock that was providing eggs or meat. In 1997, Eighteen (18) people in Hong Kong were stricken with a severe respiratory disease. Six (6) of them died. The cause was identified as the H5N1 strain of avian influenza. Health officials determine that close contact with live infected poultry was the source of human the infection. This was the first time that there was proof that the virus had infected humans directly from birds.

Local officials ordered the destruction of Hong Kong's entire poultry population. More than 1.5 million birds were destroyed in three (3) days. Some health experts say the action may have averted a pandemic at that time.

In 2004, there were eight (8) new cases of the avian influenza in humans in Vietnam, six (6) of those people died from complications related to Avian Flu. Officials ordered the cull-

ing of millions of birds to try to minimize the threat to people. This time killing millions of birds did not eliminate the threat to humans. By 2005, people in Vietnam, Cambodia, Thailand Indonesia, had come down with the disease. As recently as October 2005, H5N1 was confirmed to have spread to birds in Romania and Turkey. A few days later, a bird on the Greek Island Oinousses was found to have Avian Flu, although officials have not immediately identified the strain.

Due to the lack of data, The World Health Organization (WHO) says it cannot rule out the possibility of human-to-human transmission of Avian Flu. Some of the infected had no direct contact to live poultry.

The WHO states that influenza pandemics can be expected to occur three or four times each century, when new virus subtypes emerge and are readily transmitted from person to person. The last great pandemic occurred in 1918-19, when Spanish flu swept the world, killing 40-50 million people, including more than 50,000 in Canada. Experts agree that another pandemic is inevitable and possi-

bly imminent. To put the outbreak of H5N1 into recent historical perspective, Severe Acute Respiratory Syndrome (SARS) has killed around eight hundred (800) people worldwide and infected at least eight thousand four hundred (8400) since it first emerged in November 2002.

The WHO is paying particular attention to H5N1 for several reasons:

- It mutates rapidly and has a history of being able to acquire genes from viruses infecting other animal species.
- It has caused severe disease in humans.
- Laboratory studies have demonstrated that isolates from this virus have a high pathogenicity and can cause severe disease in humans.
- Birds that survive infection excrete virus for at least ten (10) days making it easier to spread the virus at live poultry markets and by migratory birds.

As in the case of every flu strain, the symptoms of Avian Flu in humans are similar to

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## OSHA: *Injured Employee to Receive \$8M*

A construction worker, Natalio Elias, and his family will receive at least \$8 million to settle an employee injury case involving contractors working on a project that began in 1991.

The accident occurred when the construction worker was working on the "Big Dig," Boston's Central Artery / Tunnel system. 42-year-old Elias was approximately twenty (20) feet underground, in a confined space with the dimensions of 5 by 7 feet. Elias was permanently brain-damaged when a bundle of steel cross braces being moved by crane collapsed on him.

The steel brace that lacerated his skull was eight (8)-feet long. The length of the steel brace prevented his immediate removal from the accident site. Rescue workers had to cut off both ends of the brace, leaving more than a foot of steel protruding from each side of his head, before he could be removed. According to doctors, the worker needs constant care and will not be able to work again.

In this case, Elias sued two (2) firms managing the "Big Dig" project, Bechtel Corp. and Parsons Brinckerhoff, subcontractor.

## Quality Corner: *Process Analysis Tools*

When a process or part of a process gives you difficulty, try these process analysis tools, which can help you understand and work through a work process more thoroughly.

### 1. Create a Flowchart:

- A flowchart is a picture of each step of a process in sequential order.
- A flowchart includes all materials and/or services entering or leaving the process (inputs and outputs). Including, decisions that need to be made, all people involved, time involved at each step and/or process measurements.

### 2. Failure modes and effects analysis (FMEA):

- A step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service;
- Studying the consequences, or effects, of those failures; and
- Eliminating or reducing failures, starting with the highest-priority ones.

### 3. Mistake-proofing:

- The use of any automatic device or method that either makes it impossible for an error to occur, or makes the error immediately known once it occurs.

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*Risk con't from Page 1*

nate potential risks to your organization. Current and accurate SOPs and Master Records ensure that current information is available including changes to procedures, emergency contact information, etc.

If you have a regular document maintenance schedule, review it periodically to determine if it is up-to-date and effective. A poor document maintenance plan and schedule affects the quality of information in the documentation.

In addition to reviewing your documentation maintenance schedule, you should also review the process for reviewing and approving document revisions. This process needs to be updated because as internal organizational changes, including personnel changes and/or technology changes, the review and approval process may also need to be revised.

Reviewing the documentation maintenance schedule should include determining if the team responsible for maintaining the SOPs and Master Records is current. If team responsibilities have changed, ensure that new members understand their position, have been trained on all the processes for maintaining and updating SOPs and Master Records, and are also included in all process reviews and updates.

SOP and Master Record storage is an essential part of their effectiveness. Document storage should be easy to use, documents should be easy to find, and a archival system should be implemented.

In conclusion, all aspects of SOPs and Master Records should be reviewed and updated on a regular basis to ensure that all compliance guidelines are met, all information is current and that any new guidelines are included in a timely manner. Employees must be provided with accurate information and training to ensure procedures are followed and all potential risks are minimized.

*Note from Pres. con't. from Page 3*

other strains of the flu and include fever, fatigue, cough, sore throat, eye infections and muscle aches.

The most disturbing issue regarding H5N1 is that the virus engages such a strong immune response that the body ends up actually killing itself by causing a collapse of the circulatory system. Taking into account the pandemic of 1918, the highest number of deaths by far occurred in those 20 to 40 years of age. Even in today's modern, intensive care units, these patients often have a very, very poor outcome. At this time, H5N1 is not very effective at infecting humans. It has not yet mutated into a virus that can pass easily from person

to person.

The following is a brief FAQ regarding the Avian Flu.

### **How do you catch the flu from birds?**

In order to get it from birds, H5N1 has to be already in the bird population. The bird sheds the virus in its droppings, then the human inhales it or ingests it, and each time that happens, the virus has a chance to mutate into a more effective human pathogen

### **Can we produce a vaccine to protect us from this flu? If we can, why don't we start producing this vaccine now?**

Flu vaccines are updated every year because the viruses are always mutating into another form of the virus. As an experiment, U.S. scientists created a test vaccine against an old version of H5N1, and it does seem to work, but only when given in large amounts. The test vaccine may offer some protection against a future pandemic version of H5N1. A new version of the vaccine is under development but cannot be finalized until the pandemic version of the virus appears. Another fact is that at the moment, there is not enough production capacity on the planet to make enough of the vaccine to protect everyone.

### **Is there any way to prevent getting the Avian Flu?**

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## 'Urgent' Recommendations Made by Chemical Safety Board

The U.S. Chemical Safety and Hazard Investigation Board (CSB) is calling for the safer placement of trailers for workers at petrochemical facilities throughout the United States.

The board has issued two (2) new 'urgent' safety recommendations in its investigation of the March 2005 refinery disaster at BP Products North America Inc. in Texas City, Texas.

Fifteen (15) workers died in or around trailers at BP Texas City, that investigators say were located too close to hazardous process equipment that released flammable hydrocarbons during startup.

The first recommendation calls on the American Petroleum Institute (API) to develop new industry guidance "to ensure the safe placement of occupied trailers and similar temporary structures away from hazardous areas of process plants."

The second recommendation, directed towards the API and

*DEA Settlement con't. from Page 2*

*vent diversion of prescription drugs. DEA will never tolerate irresponsible record-keeping and reckless practices that often lead to dangerous prescription drug abuse,"* concluded Joseph T. Rannazzisi, Acting Deputy Assistant Administrator at DEA Headquarters.

the National Petrochemical & Refiners Association (NPRA), called on both organizations to immediately contact their members urging "prompt action to ensure the safe placement of occupied trailers away from hazardous areas of process plants."

*"In many cases, trailers are positioned for convenience during maintenance and are not essential for facility operations,"* CSB Chairperson Carolyn W. Merritt stated.

The recommendations were only the second and third designated as "urgent" of more than 300 recommendations issued in the Board's eight (8)-year history.

The CSB is an independent federal agency charged with investigating industrial chemical accidents. Agency's board members are appointed by the president and confirmed by the Senate.

*OSHA con't. from Page 4*

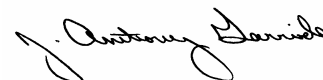
tor, Mark Equipment Corp. and crane operator Robert Moreira. The suit made claim that all parties involved in this case were negligent. At the time of the injury, Elias was an employee of Modern Continental Construction of Cambridge. A source claims that none of the defendants acknowledged liability in the settlement.

*Note from Pres. Con't. from Page 5*

Get a seasonal flu shot, wash your hands, cover your mouth when sneezing, stay home if you are sick, and consult your doctor.

### What can I do if I get The Avian Flu?

A healthy body's immune system can often combat the flu. Antiviral drugs may help. Antibacterial drugs such as Penicillin, Amoxicillin, Cefprozil are ineffective. Consult your health care professional for your best course of action.



*EPA con't. from Page 1*

Response Commission, the Hamilton County Emergency Planning Committee and the Cincinnati Fire Department. The company's paper processing plant in Cincinnati, Ohio was allegedly storing 40,000 gallons or 330,000 pounds of #6 fuel oil on company property. That amount is thirty-three (33) times the minimum reporting threshold listed in the right-to-know law. The #6 fuel oil is flammable, therefore considered a hazardous chemical.

