



Sharon Leitch/R1/USEPA/US
05/24/2007 03:20 PM

To medinad@cleanharbors.com, soltys.jean@cleanharbors.com
cc Lisa Papetti/R1/USEPA/US@EPA, Ernest Waterman/R1/USEPA/US@EPA, william.sirull@state.ma.us, albert.nardone@state.ma.us, Catherine
bcc Sharon Leitch/R1/USEPA/US
Subject RE: Paperless Inspection/ E-signatures on profiles

Dear David,

This is in response to your request for input from EPA regarding Clean Harbor's proposed paperless inspection system and the use of e-signatures on waste profiles. First, I would like to apologize for the time it has taken to get back to you on your question. The request regarding the use of paperless inspection forms is the first of its type that we have dealt with in the Hazardous Waste Unit at Region 1. The development of a response required coordination of input from other offices at EPA with the required expertise we felt was necessary to assist us in our determination. After reviewing your response to the questions we sent on March 14, 2007, we have concluded that the process you propose does not raise any issues for EPA. In addition, we see no problems with the use of e-signatures for waste profiles.

As I have mentioned before, our response is based on the federal RCRA hazardous waste regulations. EPA authorizes states to implement the RCRA hazardous waste program. States promulgate their own hazardous waste regulations and an authorized state's regulations are applicable within the state in lieu of the federal regulations. As you know, the Commonwealth of Massachusetts is authorized to implement the RCRA program. You may wish to further consult with them on this topic.

If you have any additional questions please contact me.

Thank You.

Sharon Leitch
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"SOLTYS, JEAN M" <soltys.jean@cleanharbors.com>



"SOLTYS, JEAN M"
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03/15/2007 03:31 PM

To Sharon Leitch/R1/USEPA/US@EPA
cc Lisa Papetti/R1/USEPA/US@EPA, Ernest Waterman/R1/USEPA/US@EPA, albert.nardone@state.ma.us, william.sirull@state.ma.us, "Medina, David S" <medinad@cleanharbors.com>
Subject RE: Paperless Inspection/ E-signatures on profiles

Hi Sharon,
Dave forwarded me your email with your questions on the electronic inspection project. I work in Compliance with Dave, and have been working with our MIS department on this project. I thought I would try to answer your questions below and see if you want to discuss further.

1. The electronic inspection project is proprietary software that Clean Harbors has been working to develop over the last year. We have created it as a module of our waste management system, WinWeb. Currently the inspection module is being used at three of our operating sites. The first three sites were considered our beta-test of the system, which included procuring tablet PCs and utilizing those in a wireless environment as well as a traditional connected environment. The Beta test was started in July, 2006, so we have many months' worth of experience using the system. Based on the beta sites' feedback, we are working currently on programming improvements to the system for ease of use. The inspection forms themselves are a large part of the project. Each inspection form has to be created as an adobe file, so as you can imagine, the task of creating inspection forms for all of our sites is a large one. We are working to standardize some of the forms where it makes sense. The first three sites are currently utilizing the system, and we would like to work on implementing the program across the company to all of our sites as a way to eliminate paper and provide improved tracking of corrective actions. Because we have three sites already using this, we would be able to demonstrate the system to you using one of these sites as an example, if either agency would be interested.

2. Yes. We actually have one of our 3 beta test sites using this system in parallel right now. They conduct their inspections on paper, but also put the results into the system electronically. We can learn from their use of the system as it is being developed electronically at the same time we are maintaining the system on paper, which is a condition of their permit until it is modified.

3. Yes, security is addressed in the system. In order to access Clean Harbors' systems, each person has a unique login ID and password. Access to particular modules of the system is restricted based on job role/title and or user name, depending on the application.

4. Yes. The person who conducts the inspection is recorded in the system. Any work-tickets that are assigned for failed items are assigned to individuals for follow up. Each time the status of an item is changed, for instance, creating a new work ticket, then resolving a particular work ticket, would be recorded by the system, and the history of those transactions are able to be viewed. Once a form is submitted and saved, there is no ability for a user to edit or delete the data from the server, where it is stored.

5. The first QA/QC that we have done is the beta-test of the system, which has been ongoing since July. The design of the forms also limits the possible entry choices, for instance, each line item has a pass/fail/N/A radio button, and only one of those three options may be selected. The design of the system will also eventually allow for the ability of management to query the system based on many different variables, so a review for anomalies will be possible.

6. Yes. Because this is simply a module of WinWeb, our current waste management tool, we have real-time hardware fail-over support. If one databases server goes down, it switches automatically to a second server. There is also a daily backup of the entire database so if both servers fail, we can recover the data on a new set of servers.

7. Yes. Inspection Logs and forms can be viewed either electronically or printed on paper. The potential to develop reports exists in the system, and the reports could be generated either electronically or on paper.

Generally speaking, the electronic inspection project works like this: We create blank inspection forms as adobe files, and open them up on tablet PCs which we can then carry with us while doing the inspection, similar to carrying a clipboard and paper form in the past. Each inspection question has

a pass/fail choice, and a place to make comments. Anything that fails automatically creates a work-ticket to track the corrective action. When the inspection is complete, we "submit" the form and the results of the inspection are saved and an entry to the inspection log is created. The worktickets move through stages, such as "new", and then "assigned" when someone is assigned to fix the problem, and then "resolved" once the work is completed. The history of these changes can be viewed in the system.

Please let me or Dave know if this answers your questions. If you have computer-type technical questions, we have several programmers working on the project who could probably answer you. A demonstration is also a possibility. Let us know what you think.

Thanks,

Jean M. Soltys
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-----Original Message-----

From: Medina, David S
Sent: Wednesday, March 14, 2007 1:29 PM
To: SOLTYS, JEAN M
Subject: FW: Paperless Inspection/ E-signatures on profiles

-----Original Message-----

From: leitch.sharon@epamail.epa.gov
[mailto:leitch.sharon@epamail.epa.gov]
Sent: Wednesday, March 14, 2007 11:13 AM
To: Medina, David S
Cc: papetti.lisa@epamail.epa.gov; Waterman.Ernest@epamail.epa.gov;
albert.nardone@state.ma.us; william.sirull@state.ma.us
Subject: Re: Paperless Inspection/ E-signatures on profiles

David, this response is regarding your inquiry from February 12, 2007 (e-mail attached) dealing with Clean Harbor's proposed use of paperless inspection forms and e-signatures for waste profiles. This response will only address your request regarding paperless inspections. I will be following-up on your request for the use of e-signatures for waste profiles at a later time.

Please be aware that our response is based on the federal RCRA hazardous waste regulations. EPA authorizes states to implement the RCRA hazardous waste program. States promulgate their own hazardous waste regulations and an authorized state's regulations are applicable within the state in lieu of the federal regulations. A state's regulations may be more stringent and/or broader in scope than the federal regulations. As I am sure you know, the Commonwealth of Massachusetts is authorized to implement the RCRA program.

As you indicated in your e-mail below, the regulations require that a

facility keep an inspection log or summary. These documents need to be available during a facility inspection by a regulatory agency.

Based on the information you provided it is not entirely clear to us how the proposed electronic inspection system will function and if it will meet the regulatory requirements.

Some of the concerns we have with an electronic system is whether it would comply with access and record retention requirements. We would also be concerned with data integrity and security. Having said that, we have the following questions regarding the proposed system:

1. Is the system propriety or COTS (Commercial of the Shelf)?
2. Was parallel testing done between the manual and automated process?
3. Are there security procedures in place for access to the system?
4. Is there an audit trail if data is changed or deleted?
5. Are there any QA/QC checks on the data?
6. Is there a backup and recovery plan in case of hardware or software failure?
7. Can reports be generated electronically as well as hardcopy?

In general, how well will the proposed system replicate the current way of doing inspections, particularly when an inspection uncovers a problem which requires that corrective actions be implemented and those corrective action steps are recorded? How easy will it be to "input" this information into an electronic system?

Please contact me if you have any questions regarding the above.

Sincerely,

Sharon Leitch
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"Medina, David
S"
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02/12/2007 06:36
AM

To Sharon Leitch/R1/USEPA/US@EPA,
Ernest Waterman/R1/USEPA/US@EPA
cc "Albert Nardone (E-mail)"
<albert.nardone@state.ma.us>
Subject Paperless Inspection/
E-signatures on profiles

Hello Ms. Leitch per our phone conversation last week, please see the following regarding the use of paperless inspection forms & electronic signatures on profiles.

The US EPA: 40 CFR § 264.15 General inspection requirements & and MA. DEP 30.515: General Inspection Requirements;
" The owner or operator shall record every inspection in an inspection log or summary. The owner or operator shall keep the records of each inspection for at least three years from the date of inspection or until final closure of the facility, whichever period is longer. At a minimum, these records shall include the date and time of the inspection, the name of the inspector, a notation of the observations made, and the date and nature of any repairs or other remedial actions."

In an effort to save on the use of paper and to improve our inspection program, Clean Harbors would like to document and record these inspections electronically. The forms would be available electronically for inspections and we could print hard copies upon request from an inspector.

E-signatures, please view the attached power point.

<<Electronic Profile Signature v0712062.ppt>>

Please let me know what we can do to accomplish this?

Please do not hesitate to contact me if you have any questions.

I look forward to your reply.

Sincerely;

David S. Medina
Facility Compliance Manager
Clean Harbors of Braintree, Inc.
Phone (781) 380-7134
Fax (781) 380-7193

(See attached file: Electronic Profile Signature v0712062.ppt)