

# CMS Certificate of Waiver Laboratory Project FY 2002

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September 22, 2004

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# CMS FY 2002 COW PROJECT OVERVIEW

## Regulatory Issues

### ➤ Persistent problems

- *Not having manufacturer instructions*
- *Not following manufacturer instructions*

# CMS FY 2002 COW PROJECT OVERVIEW

## Training

- Project results demonstrate need for robust education and training of testing personnel
- Results of revisits

# CMS FY 2002 COW PROJECT RESULTS

- 897 Visits to labs/facilities
- 916 Actions taken by CMS
  - 3% Statement of Deficiencies
  - 51% Report of Recommendations
  - 48% Letter of Compliance

# CMS FY 2002 COW PROJECT RESULTS

## General Demographics

897 Laboratories- Top Facility Types

- 45% Physicians office labs
- 12% Nursing homes

# CMS FY 2002 COW PROJECT RESULTS

## General Demographics

897 Laboratories- Other Facility Types

- Ambulatory Surgical Center
- ESRD
- Community Clinic

# CMS FY 2002 COW PROJECT RESULTS

## Personnel Types

- Registered nurse
- Physician
- Licensed practical nurse
- Medical assistant
- High school graduate

# CMS FY 2002 COW PROJECT RESULTS

## Personnel & Training

Of the laboratories visited-

- 44% had new testing personnel
- 84% provided staff training
- 83% evaluated staff competency



# CMS FY 2002 COW PROJECT RESULTS

## Good Laboratory Practices

- 7% performed proficiency testing
- 96% correlated patient test results with patient history
- 70% maintained log of tests performed

# CMS FY 2002 COW PROJECT RESULTS

## Laboratory Practices

*Urinalysis and glucose testing are considered so vital to patient care that COW laboratories are willing to upgrade their certificate, if needed, in order to continue testing.*

# CMS FY 2002 COW PROJECT RESULTS

*8% tested beyond the scope of a  
waived certificate*

*- Surveyor discretion concerning  
education or issuance of  
“Statement of Deficiencies”*

# CMS FY 2002 COW PROJECT RESULTS

## Compliance with Manufacturers' Test Instructions

- *14% did not have current manufacturer instructions*
- *24% did not perform quality control as required by the manufacturer*

# CMS FY 2002 COW PROJECT RESULTS

## Compliance with Manufacturers' Test Instructions

- *13% did not use correct units of measure in reporting test results*
- *7% did not use proper expiration date for storage method*

# CMS FY 2002 COW PROJECT RESULTS

## Additional Compliance Issues

*Did not-*

- *perform instrument maintenance*
- *follow manufacturer's storage & handling*
- *use appropriate specimen*
- *add the reagents in prescribed order*

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# Comparison of COW Survey Results

	2001	2002
<i>Did not have manufacturer instructions</i>	32%	14%
<i>Did not perform QC as required by the manufacturer</i>	20%	24%
<i>Test beyond the scope of their certificate</i>	6%	8%

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# Risk of Harm

June 2002-

Identified 1 Immediate Jeopardy (*IJ*)

- Tested beyond the scope of COW
- Used incorrect specimen type for glucose testing



# Risk of Harm

April 2002-

Identified Immediate Jeopardy (*IJ*)

- Complaint survey in a nursing home- not part of 2% COW Project
- Patient death due to incorrect reporting of glucose result
- Surveyors visited additional nursing homes to provide education

# Follow-up Visits

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# Follow-up Visits

- 96% of the 55 laboratories/facilities revisited demonstrated improvement.

# Anecdotal Information

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# Post Laboratory Survey Questionnaire

- 71% strongly agreed that the survey process was explained clearly.
- 72% strongly agreed that the survey did not interfere with delivery of care.
- 71% strongly agreed that the survey assisted in their understanding of the **CLIA** CLIA requirements.

# Comments from the laboratory...

*Informative & educational as promised*

- Tribal facility in Oklahoma

*Provided very useful information, really liked that the visit was all for improvement*

- POL in Kansas

# Summary

- Significant number of COW labs fail to follow manufacturers' instructions
- If instructions are not followed, accuracy is not insured— potential for harm
- Accuracy of testing depends on following instructions
- No data to prove kits perform as intended if instructions are not followed

# CMS Recommendations

- Continue the COW Project
- Implement automated data system
- Make final recommendations for the future based on cumulative data