



# FINDING AND DEALING WITH IMPROPER LABORATORY PRACTICES

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BACK TO THE FUTURE Movie 1985

“Whatever you do Marty, don’t dial in 2020!”

As an assessor and lab person, I have now gone back to the FUTURE!

- Past
- Present
- Future – What Actions can we take?

## Fraud

- A deliberate deception practiced so as to secure unfair or unlawful gain
- When does improper become fraud? When there is an intent to misrepresent.
- Proven in court of law or legal proceeding

## • Improper Practice

- A scientifically unsound or technically unjustified omission, manipulation or alteration of procedures or data that bypasses required QC making the results appear acceptable
- Unless intent is proven, do not use the term Fraud

# PAST

1988 – 2006

# THE FEDERAL MARSHALL SAID...

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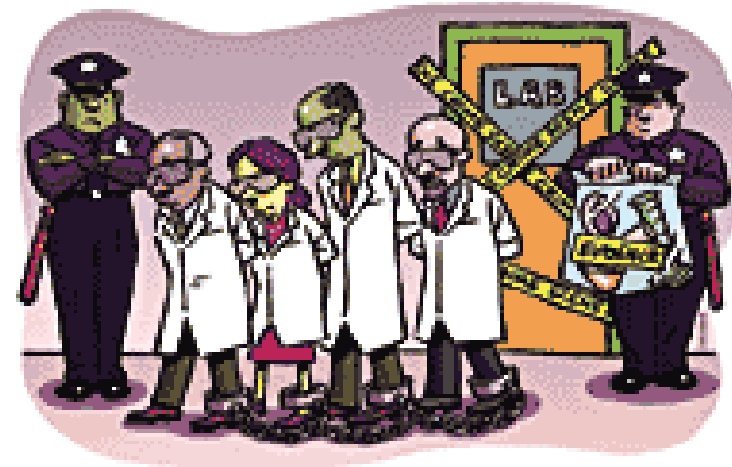
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**“We can do  
this the  
easy way,  
or the hard  
way.”**



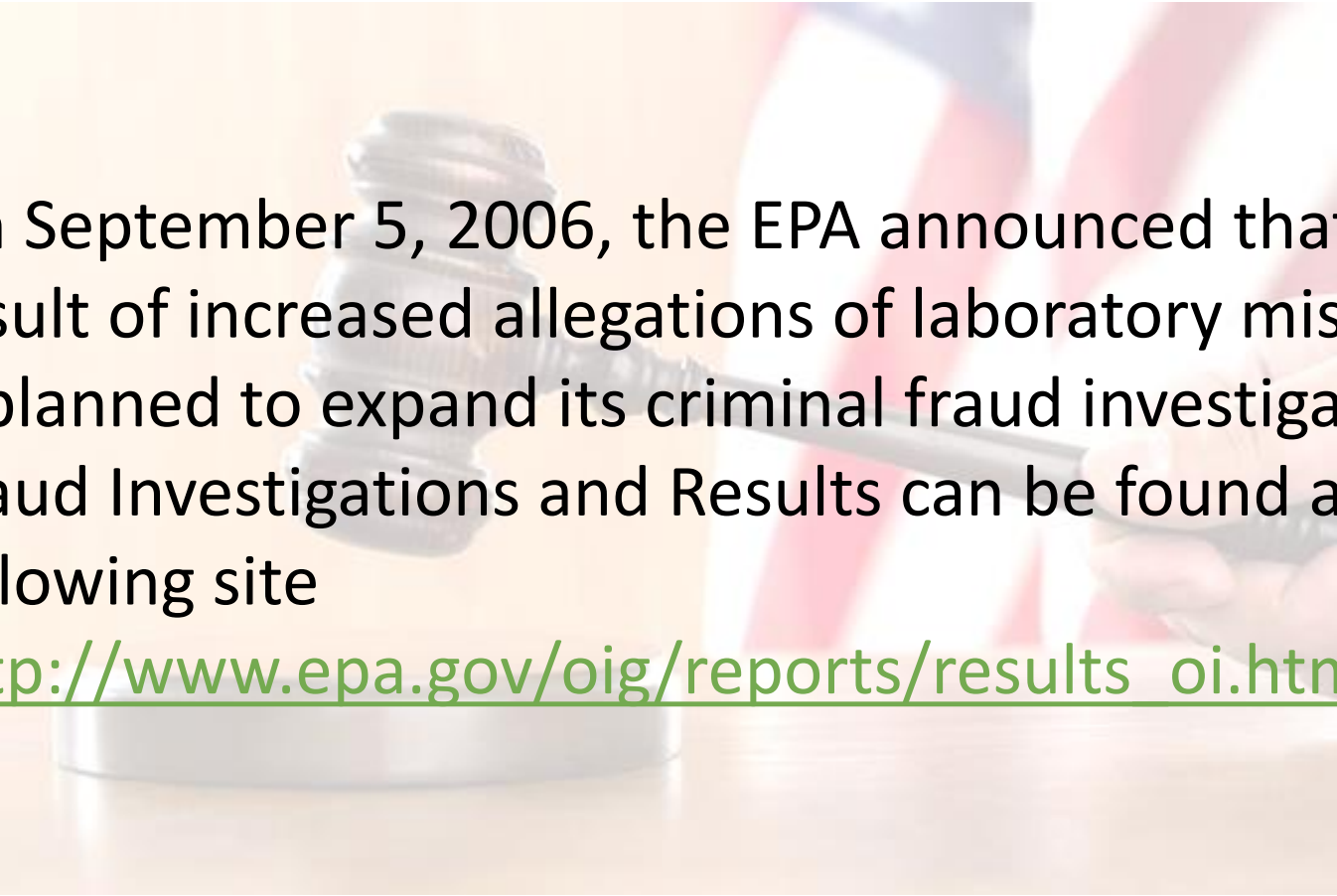
# LABORATORY FRAUD

- EPA IG has created a special “Laboratory Fraud Directorate” specifically designated to investigate laboratory fraud
- Cases Are Investigated Like Typical Crimes
  - Search Warrants
  - Grand Jury Subpoenas
  - Interviews
  - Surveillance
  - Undercover Operations
  - Surreptitious Evidence Gathering



**THINK OF THE CONSEQUENCES BEFORE YOU ACT.**

# THE RESULTS OF FRAUD

- 
- On September 5, 2006, the EPA announced that, as a result of increased allegations of laboratory misconduct, it planned to expand its criminal fraud investigations.
  - Fraud Investigations and Results can be found at the following site

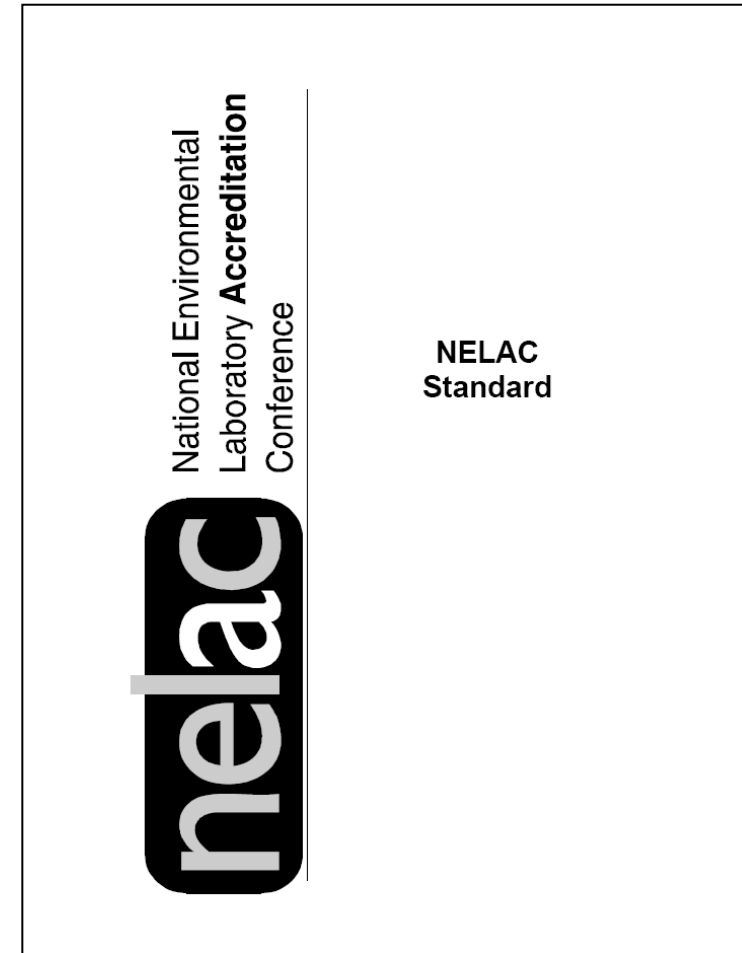
[http://www.epa.gov/oig/reports/results\\_o.htm](http://www.epa.gov/oig/reports/results_o.htm)

**THINK OF THE CONSEQUENCES BEFORE YOU ACT.**



# BEFORE TNI THERE WAS NELAC

- NELAC Standard
  - Approved July 12, 2002
  - Effective July 1, 2003



[https://nelac-institute.org/content/CSDP/standards.php?ap3=1\\_3](https://nelac-institute.org/content/CSDP/standards.php?ap3=1_3)

# PRESENT

2007 – 2022

- From 2006 – 2016 fewer improper practices were observed.
- Beginning 2016 to present, increases in observed improper practices:
  - Owners running samples, approving without QC, signing the name of those approving who are not present in the lab – done to meet client permit
  - Data stating samples weighed, when they are not weighed
  - LCSs failing repeatedly but not rerunning/repreparing samples
  - Improper integrations
  - Cherry-picking points to use in calibration
  - Failure to extract samples with correct stoichiometry and no validation

- Requirements TNI V1M2 4.1.5, 4.2.8.1, 5.2.7:
  - SOPS,
  - Data integrity training,
  - Data review
  - Confidentiality
  - Impartiality



# PREVENTING IMPROPER PRACTICES

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- Causes
- Red flags
- Detection



# CAUSES OF IMPROPER PRACTICES

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- Production pressure
- Conflicts of interest
- Lack of awareness
- Lack of communication
- Misinterpretation of method requirements
- Personality and attitude
- Financial stability



- Lack of data review
- Data review does not REQUIRE review of RAW data
- Inadequate internal audits
- QA staff lacks direct access to senior management
- Unclear roles and responsibilities
- QA staff performing competing responsibilities

- Management must encourage use of corrective action process
- No punishment for finding problems
- Management must encourage finding and fixing problems
- Issues must be openly discussed without berating
- Use lessons learned



# IMPROPER PRACTICES DETECTION TOOLS

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- Data reviews
- Process demonstrations
- Interviews
- Electronic data review
- <http://www.epa.gov/quality/trcourse.html>



# REASONS FOR INCREASED FREQUENCY

1. Senior staff retiring, quitting or leaving environmental
2. Ineffective training, word of mouth training
3. No mentoring or overlap when roles/staff change
4. Failing to plan
5. Too few staff
6. Ineffective or no time for monitoring
7. Senior staff do not believe they will get caught - culture
8. Internal audits, data review ineffective

- Mentoring pays for itself by preventing improper practice, rework, and unhappy clients
  - Ask retirees and those leaving to allow a month to a year or more to mentor
  - Plan for at least 13% attrition [industry standard for 2020 - 13%]
  - Staff with future in mind, technicians become analysts, analysts become leaders, etc.
  - Plan for hands-on training
  - MAKE SURE Mentor lets Mentee take over with oversight
  - Put the time/hiring in the budget
  - Selecting Mentor

- Why is training ineffective?
  - Not enough hands-on, too much read and understand
  - Begin with basics: pipetting, weighing, integrating
    - showing what NOT to do and why
  - Too rushed and not enough oversight, review
  - More electronic review of trainee work
  - TNI committee developing competency training
  - Colleges do not have enough hands-on lab skills



# IMPROVING – TOO FEW STAFF

- Automation helps, or hurts!
- Must have an understanding of automated calcs and systems
- Analysts cannot reconstruct calculations
- Must have good IT staff who know lab data processes
- Validate changes and automated calculations used in LIMS, keep record for life of LIMS
- Map processes to find efficiency improvements
- BUDGET, Pay
- Hard to find skills

- If in 2-4 days I can find improper practice, internal audits should find it!
- Don't wait for an external assessor to find your issues!
- How to find:
  - MUST look at raw electronic data, look for
    - Time travel by file listings
    - Integrations
    - Raw points collected for calibration
    - Show me how you spike and weigh
    - OBSERVE
    - Ask open questions, do not assume

# INTERNAL AUDITS, DATA REVIEW INEFFECTIVE, (CONTD)

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- NOT enough review of RAW data! ONLY look at the summary QC
- DOD/DOE requires 10% by QA staff, in addition to normal process
- Hands-on data review
- New ISO 17025: 2017 – Risk-based internal audits
- LIMS can point out anomalies
- No off-shelf software anymore

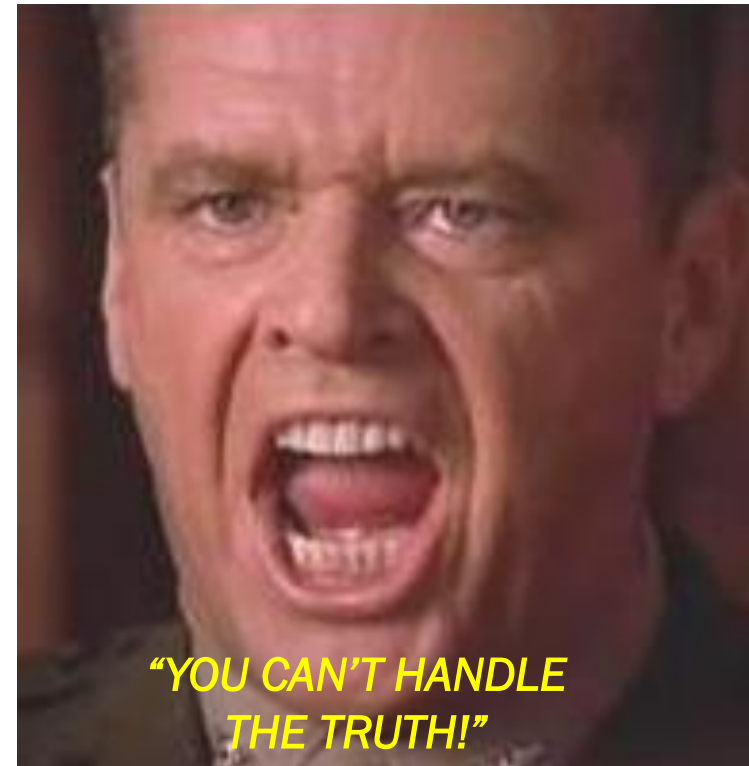
# CULTURE - A FEW GOOD MEN

- The climax of the film is an exchange between brash young Lieutenant Kaffee, and seasoned base commander Colonel Jessup, who previously had given an order that resulted in a man's death and tried to cover up the fact that he had given the order. It proceeds as follows:



# WHAT'S THIS HAVE TO DO WITH ETHICS?

- This fundamental clash of values permeates not only military life but society at large. Indeed, the real impact of A Few Good Men is apparent when it is seen in this context.
- The **fact** of the movie is this: a weak young man (however deplorable personally) was killed to ensure a “code” and to instill in him “honor.” Yet, somewhere, there is a disconnect between real honor, and that honor demonstrated by Jessup. Real honor as one of the accused soldiers notes at the end of the film is to behave admirably and justly, not simply to follow one’s orders, no matter what their cost.



# FUTURE: FIX CULTURE

- MUST TRAIN how your lab views data integrity
  - Discuss the VOC calibration example
  - Staff fearful of telling the boss real problems
- DO not penalize people who find, bring up problems
- Managers must be open to solving problems
- Mentor problem solving
- Staff must not feel beaten when a problem is found
- Last resort – EPA hotline



# FUTURE: IMPROVE - CULTURE

- Management sets the tone for the laboratory. Don't accept minimal quality.
- Quality happens at the time data is collected.....not filled in after the fact!
- Data users trust labs to provide high quality data. Honor that commitment!
- Paraphrasing Gallo Winery....."There will be no data before it's time! Take the time to get it right!"

- We can
  - change culture
  - Improve training
  - Plan to mentor and hire
  - Internal data review and internal audits
  - SOLVE problems
  - Electronic monitoring

Questions??

THANK YOU

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