Environmental Testing Is a Risky Business

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What Do We Mean by “Preventive Actions”?

The NELAC Institute (TNI)

Volume 1 Module 2 Section 5.4.12 (V1M2, 5.4.12)

NELAC = National Environmental Laboratory Accreditation Conference
What Do We Mean by “Preventive Actions” (continued)?

The laboratory must (V1M2, 5.4.12):

• Identify needed improvements or potential sources of non-conformances

• Develop, implement, and monitor action plans

✓ Apply controls to monitor effectiveness.
What Do We Mean by “Continuous Improvement”? 

Inputs:

- Quality Policy
- Quality Objectives
- Audit Responses
- Analysis of Data and Preventive Actions
- Management Review
What Do We Mean by “Impartiality”?  

- The upcoming revision to ISO/IEC 17025 (and current 2003 version NELAC Standard) requires:
  
  ✓ Laboratory shall demonstrate that it is impartial  
  ✓ Personnel shall be free from commercial, financial, or other undue pressures that influence technical judgement  
  ✓ Management shall be committed to impartiality
A New Way of Thinking: Risk Assessment

- Identify
- Analyze
- Evaluate
- Monitor
- Document

... risks to impartiality
Some Points to Consider:

- There is no such thing as zero risk
- Some risks are acceptable and can be tolerated; a certain level of risk may be acceptable
  - When risks are identified, actions are taken to reduce the risk
  - If the risk cannot be eliminated, it could be reduced to an acceptable level
Conformity Assessment Risks

- Standards-related risks
- Process-related risks
- Systems-related risks
Standards-Related Risks

- Poorly written SOPs, leading to inconsistent implementation
- Vaguely written SOPs, leading to varying interpretations
- Lack of leadership for writing and approving SOPs, leading to errors, inconsistencies, and omissions in testing execution
Standards-Related Risks (continued)

- Frequent changes to SOPs or interpretative guidance, leading to confusion all-around
- Infrequent review of SOPs, leading to complacency
Process-Related Risks

- Lack of client understanding
- Minimal incentive to operate within the laboratory quality system
- Lack of personnel competence (knowledge, skills, and experience)
- Lack of personnel training
Process-Related Risks (continued)

- Overfamiliarity with tests, or clients (leading to lack of impartiality)
- Inconsistency among analysts or management
- Insufficient available trained personnel
Process-Related Risks (continued)

- Inconsistent method development planning (or expansion of method to additional analytes or matrices)
- Lack of coordination in testing activities (sample batching, work loads)
- Inadequate samples received for analysis (sample receiving policies and procedures)
Process-Related Risks (continued)

- Over-use, misuse, and abuse of measuring and testing equipment
- Obsolete or incompatible computer hardware and software programs
- Inadequate data review procedures and quality control evaluations
Process-Related Risks (continued)

- Interpersonal dynamics within the laboratory (plus effect of adding personnel)
- Subcontracting of tests
  - Is my job threatened?
  - Will the subcontractor perform the work?
Systems-Related Risks

- Undercutting prices among labs, resulting in reduced quality
- Clients shopping among laboratories for a more lenient or cheaper alternative
- Potential for corruption (among technical directors, quality managers, clients)
Systems-Related Risks (continued)

- Positive or negative bias by analysts, lack of safeguards
- Difficulty engaging clients when problems with the sample, testing, or reporting occur
- Fraudulent representation of testing services and certification credentials
Systems-Related Risks (continued)

- Inadequate complaint-handling system
- Inadequate data integrity system
- Lack of follow-up on corrective actions
- Preventive actions ignored and opportunities for improvement missed
Let’s Do Some Risk Analysis…

- 1 package (1/4 ounce) active dry yeast
- 2-1/4 cups warm water (110° to 115°)
- 3 tablespoons sugar
- 1 tablespoon salt
- 2 tablespoons canola oil
- 6-1/4 to 6-3/4 cups all-purpose flour
Let’s Do Some Risk Analysis… (continued)

1. In a large bowl, dissolve yeast in warm water. Add the sugar, salt, oil and 3 cups flour. Beat until smooth. Stir in enough remaining flour, 1/2 cup at a time, to form a soft dough.

2. Turn onto a floured surface; knead until smooth and elastic, about 8-10 minutes. Place in a greased bowl, turning once to grease the top. Cover and let rise in a warm place until doubled, about 1-1/2 hours.
3. Punch dough down. Turn onto a lightly floured surface; divide dough in half. Shape each into a loaf. Place in two greased 9x5-in. loaf pans. Cover and let rise until doubled, about 30-45 minutes.

4. Bake at 375° for 30-35 minutes or until golden brown and bread sounds hollow when tapped. Remove from pans to wire racks to cool.

Yield: 2 loaves (16 slices each).
Quality of Reagents, Standards, and Reference Materials

- Use of organically grown flour (+ no GMOs)
  - Impact on taste?
  - Impact on cost?
  - Credentials for organic production?
- Water quality (tap water or DI water?)
Staff Qualifications and Training

Does the relevant staff all know how to:

- Determine when the dough is “soft”?
- Knead flour dough?
- “Punch dough down”?
- Recognize the hollow sound when product is “tapped”? 
Test Method Selection, Validation, and Evaluation

What is the effect(s) on the product if:

• The dough is not allowed to rise before baked in the oven?
• The pans are not greased before the dough is put in?
• Baking temperature is 425° instead of 375°?
  • Temperature scale Celsius or Fahrenheit?
SOPs Written with Sufficient Detail for Generating Comparable Results

Risks to comparable application?

- Stir in “enough” flour?
- Oven preheated to 375° before the 30-35 min baking begins?
- Quality control? Corrective action?
Permissible, Technically-Justified Modifications to the Test Method

- Can I add some rosemary, thyme, sesame seeds, other spices?
- Can I use bacon grease instead of canola oil?
- Can I microwave the dough instead of using the oven?
Review of Requests, Tenders, and Contracts

• How did the customer want his product?
• Crumbs are okay?
• Customer agreed to this recipe, or to any changes or additions?
Review of Requests, Tenders, and Contracts (continued)

- Taste?
- How much product? When?
- If all else fails, will the supermarket bakery product suffice?
What Did We Learn?

- We do risk assessments every day!
  - We take steps to minimize risk
  - We decide what risks are acceptable
  - Sometimes we decide some risks are worth taking
- All testing laboratories should be able to undertake risk assessments and minimize risk to impartiality
Dilbert, by Scott Adams
To protect, promote and improve the health of all people in Florida through integrated state, county, and community efforts.

Risk Analysis Funny Quotes. QuotesGram
Questions?

• Thank you for your attention!

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