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.

Let's Do Some Risk Analysis… (continued)

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

Risk Analysis Funny Quotes. QuotesGram

Questions?

- Thank you for your attention!

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