



Method Safety & Risk Assessment Guide

- ✚ Methods submitted to AOAC *Official Methods*SM Program are subject to undergo a risk assessment.
 - Appropriate safety instructions (in general or specific terms) must be included in the method if there is a likelihood of exposure to actual or potential hazards when using the method.
- ✚ Method authors should complete the safety checklist to assess and expose potential safety hazards. Expert review panels will review methods for safety and all potential or actual hazards must be addressed as a requirement for Final Action *Official Method*SM status. A safety advisor can serve a resource to address any outstanding concerns.
- ✚ The method submitter or Expert Review Panel should make every attempt to be proactive in providing the suitable wording and documentation to address the potential or actual safety hazard.
 - Safety advisors reviewing a method that lacks safety precautions and a suitable wording concerning safety should be suggested for inclusion in the text.
 - May suggest appropriate wording or require additional information.
 - Must clearly state objections if not recommending the method to move forward in the review process until the safety concerns are satisfactorily addressed.
- ✚ For methods that contain numerous hazards, the text may be best improved with a comprehensive safety statement, prominently displayed early in the method, e.g. in the materials and methods section of the text A text hyperlink such as <http://www.ilpi.com/msds/> may be advantageous, as it provides the user with up-to-date pertinent safety information.
- ✚ <http://www.cdc.gov/biosafety/publications/bmb15/index.htm/> is the “Biosafety in Microbiological and Biomedical Laboratories” 2009 Manual. For microbiology methods, it describes the hazardous nature of many pathogens, together with their biosafety level requirements.
- ✚ Methods that contain a small number of specific safety hazards may best be improved with a caution in the text immediately following the first mention of the hazard.
 - For example (a modified version of some of the text below may be appropriate):
 - Use effective ventilation equipment when fumes or aerosols are generated.
 - Keep skin exposure to ultraviolet radiation to a minimum.
 - Conduct reactions behind a safety barrier. Wear face shield and gloves.
 - Wear skin, eye, and respiratory protection when handling.
 - Corrosive substance.
 - Biosafety containment level (1, 2 or 3) required with pathogen.
 - Microbiologically contaminated liquid or solid wastes should be sterilized.
 - See Appendix B of the OMA
 - See MSDS information for safety precautions.
 - See “Biosafety in Microbiological and Biomedical Laboratories” Manual (2009)
- ✚ Following revision, the method should alert the user to hazards / potential hazards in a general or specific way, whichever is considered most appropriate and effective.

Online Technical Resources

Method Development, Optimization & Validation

- ❖ OMA - Appendix F - Guidelines for Standard Method Performance Requirements
- ❖ Homogeneity
- ❖ Guide for Writing Methods in AOAC Format
- ❖ Statistics Protocol Review Form
- ❖ OMA - Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis
- ❖ OMA - Appendix G: Procedures and Guidelines for the Use of AOAC Voluntary Consensus Standards to Evaluate Characteristics of a Method of Analysis
- ❖ OMA - Appendix I: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent
 - ❖ Methods and/or Procedures
- ❖ OMA - Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces
- ❖ OMA - Appendix K: Guidelines for Dietary Supplements and Botanicals
- ❖ OMA - Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation
- ❖ OMA - Appendix M - Validation Procedures for Quantitative Food Allergen ELISA Methods: Community Guidance and Best Practices
- ❖ Safety Checklist

Method Review

- ❖ Examples of Statistical Analysis
- ❖ Statistics Manuscript Review Form
- ❖ OMA - Appendix A: Standard Solutions and Reference Materials
- ❖ OMA - Appendix D: Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis
- ❖ OMA - Appendix H: Probability of Detection (POD) as a Statistical Model for the Validation of Qualitative Methods

Miscellaneous

- ❖ Definition of Terms and Explanatory Notes
- ❖ OMA - Appendix B: Laboratory Safety
- ❖ OMA - Appendix E: Laboratory Quality Assurance
- ❖ OMA - Appendix C: Reference Tables

All resources are accessible at
<http://www.aoac.org/vmeth/guidelines.htm>

For questions, please contact:
P 301-924-7077 x157 E dmckenzie@aoac.org

Safety Checklist Questions

- ✓ Are any materials used or compounds formed that are explosive or flammable?
- ✓ Are there any side reactions that could occur that might produce flammable or explosive products or conditions?
- ✓ Are there any hazards created from electric or mechanical equipment?
- ✓ Are pressure differentials created that could result in an explosion or implosion?
- ✓ Are any substances used or formed which are:
 - radioactive?
 - carcinogenic?
 - mutagenic?
 - tetratogenic?
 - abortogenic:?
 - otherwise a significant health hazard?
- ✓ Would there be increased hazards if the reaction temperature were increased even modestly?
- ✓ Are special procedures required if a spill of the reaction mixture occurs?
- ✓ Is there a risk in producing a dangerous aerosol?
- ✓ Are special procedures required for the disposal of reagents or reaction products?
- ✓ Are there any organisms and/or their products used/present that are:
 - Pathogenic?
 - allergenic?
 - carcinogenic?
 - mutagenic?
 - tetratogenic?
 - otherwise a significant health hazard?
- ✓ Are there any potential hazards in handling or storage of reagents, test samples, or standards?
- ✓ Are there any other hazards that should be addressed regarding the method?
- ✓ Does your method use chlorinated solvents?
- ✓ If "yes" to question13, have non-chlorinated solvents equivalent to chlorinated solvents been investigated?
- ✓ Include appropriate precautionary statements in method write-up.
- ✓ Provide specific information on hazard (MSDS or other supporting documentation)

Online Safety Resources

Useful source information concerning safety hazards is available in:

- Official Methods of Analysis of AOAC INTERNATIONAL Appendix B:
<http://www.eoma.aoc.org>
- US Department of Labor / Occupational Health and Safety Administration (OSHA):
<http://www.osha.gov/web/dep/chemicaldata/default.asp>
- American Chemical Society / Chemical Abstracts Service: <http://www.cas.org/>
- MSDS Solutions Centre MSDS online :
<http://www.ilpi.com/msds/>
<http://www.ilpi.com/msds/#Manufacturers>
<http://www.msds.com/>
- Biosafety information:
<http://www.cdc.gov/biosafety/publications/bmb15/index.htm/>
- Public Health Agency of Canada MSDS for pathogens:
<http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php>
- IATA transportation information for hazardous materials
http://www.iata.org/whatwedo/cargo/dangerous_goods/Pages/index.aspx

Examples of Caution Statements

For example (a modified version of the text given below may be appropriate):

Caution - This procedure uses substances that are neurotoxic, corrosive and hazardous. Care should be taken to avoid ingestion or contact with the skin. Laboratory personnel should follow normal laboratory safety precautions and have ready access to the material safety data sheets (MSDS, <http://www.ilpi.com/msds/>) for all hazardous substances used in the test procedure, should work in a well ventilated environment and be provided with appropriate safety protection including clothing, protective gloves and appropriate eye protection (<http://www.eoma.aoc.org>).

Caution - This procedure uses / detects pathogenic microorganisms and / or their metabolic products. Care should be taken to avoid ingestion, inhalation of potentially infectious aerosols, or contact with the skin. Laboratory personnel should follow normal laboratory safety precautions and have ready access to the appropriate material safety data sheets (MSDS, <http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php>) should use the appropriate biosafety containment (<http://www.cdc.gov/biosafety/publications/bmb15/index.htm/>) and be provided with appropriate safety protection including clothing, protective gloves and appropriate eye protection <http://www.eoma.aoc.org>.