

A122 CALA Checklist for Assessment of Mould Testing Revision 1.4 – February 2011

Laboratory Name: _____

Appendix Name: _____

Appendix Number: _____

Assessors: _____

Date: _____



Please record the following information related to this appendix:

A. EQUIPMENT I.D.

	Manufacturer	Model No.
Auto Sampler (if applicable)	_____	_____
_____	_____	_____
_____	_____	_____
Equipment/Instrument(s) used in analysis	_____	_____
_____	_____	_____
_____	_____	_____
Software used for data collection (including version number), if applicable	_____	_____
_____	_____	_____
_____	_____	_____

B. PROFICIENCY TESTING REQUIREMENTS

Please review Proficiency Testing (PT) information on the cover sheet to the appendix. Make any changes or additions directly on the cover sheet. For requirements on options and number of analytes that must have PT, refer to P02-03 – *Program Description - Proficiency Testing Policy for Accreditation*.

C. ANALYST I.D. (Section 5.2 of ISO/IEC17025)

	Primary Analyst	Back-up Analyst
Name	_____	_____
Position	_____	_____
Degree/Diploma	_____	_____
Years Analytical Experience*	_____	_____
Analyst Proficiency**	_____	_____
Check if interviewed	_____	_____

* Years of analytical experience related to the appendix being assessed.

** Please record the date that the analyst was deemed competent to perform the appendix OR the date that he/she last successfully participated in Proficiency Testing (PT)

CALA CHECKLIST FOR ASSESSMENT OF MOULD TESTING

Item	Clause	Requirement	Document Review				Implementation			
			1	2	3	Comments	1	2	3	Comments
01		DOCUMENT CONTROL								
01	4.3	<p>Document review: verify that there is a documented method.</p> <p>Implementation: verify that the current authorized test method and necessary supporting work instructions are available to the analyst.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
02		TEST METHOD VALIDATION/VERIFICATION								
01	5.4	<p>Document review: verify that there are method validation results, and a statement that the method is fit for the intended use.</p> <p>Implementation: Method is validated or verified in laboratory:</p> <ul style="list-style-type: none"> Successfully participate in PT as per PO2-03 - CALA Program Description - Proficiency Testing Policy for Accreditation <p><u>Enumeration Methods</u></p> <ul style="list-style-type: none"> Repeatability - estimated using a minimum of 10 replicates of a known positive sample (applicable to spore count methods); Estimation of measurement uncertainty. <p><u>Identification Methods</u></p> <ul style="list-style-type: none"> Based upon performance (e.g., inter-analyst comparisons). <p>NOTE: For records of Method Validation, cite B.03.09 in A02.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Item	Clause	Requirement	Document Review			Implementation				
			1	2	3	Comments	1	2	3	Comments
03		TEST METHOD								
01	4.2.1 5.4.1	<p>Verify that all necessary successive steps in the test procedure are adequately documented in the test method, and are based on the latest valid edition of a published reference method, including:</p> <ul style="list-style-type: none"> • details on reagent and media preparation, incl. quality control, storage and shelf-life; • equipment, supplies, etc.; • microscope magnification, counting rules, etc.; • calculation procedure and reporting limits (spore counting); • identification of fungi and/or bacteria; • identification of fungal spores and structures; • taxonomic keys. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
04		SAMPLING								
01	5.7	<p>Verify that sample history requirements are 1) documented, readily available, appropriate and implemented; i.e.,</p> <ul style="list-style-type: none"> • procedures specified to protect integrity of sample during transport, including: <ul style="list-style-type: none"> • sample containers; • storage conditions and holding time of samples (must not exceed time specified by appropriate method/regulation). 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Item	Clause	Requirement	Document Review			Implementation			
			1	2	3	Comments	1	2	3
05		TEST METHOD STOCK CULTURES / REFERENCE SLIDES							
01	5.4.1 5.4.2	<p>Document review: verify that procedures are in place for collecting and maintaining culture collections, and that they are documented and readily available (N/A for microscopic analysis).</p> <p>Implementation: verify that procedures are followed.</p> <ul style="list-style-type: none"> if culture is purchased: verify that there is a certificate with the organism name, plus confirmation on selective medium; if culture was isolated from the environment: verify how it was collected, by whom, and that it was properly characterized; for spore testing the lab has a slide collection with various count levels and genera/groups of spores as a part of spore analysis QC. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
06		METHOD QUALITY CONTROL							
01	5.9	<p>Verify that method (and media) quality control is 1) either included or referenced in the test method and 2) implemented; i.e.,</p> <p><u>Method QC</u></p> <ul style="list-style-type: none"> perform duplicates to monitor within-run precision for quantitative methods applicable to spore counting); monthly inter-technician comparison readings to monitor precision (applicable to spore counting); use of control charts or quality control databases to compare intra- and inter-analyst analysis performance to established control limits; 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Item	Clause	Requirement	Document Review			Implementation				
			1	2	3	Comments	1	2	3	Comments
06		METHOD QUALITY CONTROL (continued)								
01	5.9	<p><u>Method QC (cont.)</u></p> <ul style="list-style-type: none"> for microscopic analysis: a slide from a collection is reviewed on a rotational basis by each analyst on a regular basis (at least monthly), and acceptance criteria is set; for culturing methods: microscopic confirmation is performed by two analysts (at least monthly); use of control charts to compare intra and inter technician analysis performance to establish control limits. <p><u>Media QC (N/A for microscopic analysis)</u></p> <ul style="list-style-type: none"> records kept of all QC performed on media including date of preparation, lot number of dry reagents and/or purchased media, results of QC testing etc. (see 11.01); pH of medium checked after autoclaving (or preparation); sterility checked per batch of media; positive control culture (from a recognized source) performed per batch of media. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
07		TEST METHOD CONTENT-OTHER WORK INSTRUCTIONS (PROCEDURES)								
01	5.4.1	<p>Verify that all necessary supporting work instructions are 1) <u>documented and readily available</u> to the analyst; e.g.,</p> <ul style="list-style-type: none"> glassware cleaning procedures; sample disposal procedures; supporting test methods (e.g., pH); equipment instruction manuals; 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Item	Clause	Requirement	Document Review				Implementation			
			1	2	3	Comments	1	2	3	Comments
07		TEST METHOD CONTENT-OTHER WORK INSTRUCTIONS (PROCEDURES) (Continued)								
01	5.4.1	<ul style="list-style-type: none"> requisite reference texts/reference library; computer software related procedures (including LIMS procedures, such as data entry and approval); disinfection/sterilization and disposal of biohazardous material. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
08		CONDUCT OF TESTING								
01	5.4.1 4.2.1	Verify that the test procedure and all supporting work instructions are performed as documented.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Item	Clause	Requirement	Implementation			
			1	2	3	Comments
09		EQUIPMENT				
01	5.5.1 5.5.2 5.5.4 5.5.12	Verify that all instruments required for the test procedure are available, uniquely identified, functioning properly, and safeguarded from adjustments that would invalidate results, including: <ul style="list-style-type: none"> compound microscope having low, high power, and 100X oil immersion objectives; microscope alignment is checked annually; each microscope has an ocular micrometer that is calibrated annually; biological safety cabinet; Bunsen burners or other flame source available and functioning properly; 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Item	Clause	Requirement	Implementation			Comments
			1	2	3	
09		EQUIPMENT (continued)				
01	5.5.1 5.5.2 5.5.4 5.5.12	<ul style="list-style-type: none"> fridges for sample and reagent storage are maintained within the specified temperature range and temperatures monitored and recorded daily; incubators available and functioning properly; i.e., adequate humidity; maintained within the specified temperature range; incubator temperatures monitored and recorded at least once daily (suggest continuous monitoring or twice daily or using a min-max thermometer); spatial variability in incubators checked annually; availability of back up equipment or a back up plan in case of equipment failure (cite B.04.01); working thermometers are traceable (see A61-Traceability Policy); autoclave available; procedures in place to ensure autoclave is functioning properly (e.g., indicators documenting successful sterilization used with each batch sterilized); monthly test of autoclave performance using a spore strip or spore suspension, capable of demonstrating a 6 log kill of <i>Bacillus stearothermophilus</i>); log of autoclave use - i.e., items, temperature, pressure, time (cite 07.01); a regularly scheduled maintenance program for each piece of equipment, where appropriate and records of service where service was required (cite B.04.02). 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

Item	Clause	Requirement	Implementation			Comments
			1	2	3	
09		SUPPORT EQUIPMENT				
02	5.5.2	Verify that all support equipment required for the test procedure is available, functioning properly, and where necessary, calibrated; e.g., computers, pH meter.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
09		OUT OF SERVICE EQUIPMENT				
03	5.5.7 5.5.9	Verify that out of service equipment is isolated or clearly labeled or marked as being out of service, and that equipment is checked and validated before return to service.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
09		EQUIPMENT REQUIRING CHECKS OR CALIBRATION				
04	5.5.2 5.5.5 5.5.8	Verify that all equipment requiring checks or calibration is labeled to indicate the status, including the date last checked/calibrated and expiry date or date when due* (e.g., checks of biosafety cabinet, calibration of microscopes and thermometers). Not required for equipment checked daily or as-used; see PO7.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10		SUPPLIES - AVAILABILITY				
01	4.6.2 5.5.1	Verify that all supplies required for the test procedure are available and meet requisite requirements and/or specifications (includes test organisms, reagents, reference materials,); specifically: <ul style="list-style-type: none"> records of reference standard/material, certificates slide sealant, lactophenol cotton blue, slides, microscope bulbs; micrometer; if producing water in-house and it is used to make media or reagents, check conductivity daily or as-used and verify it is analyzed for parameters as per the most current version of Standard Methods; 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Item	Clause	Requirement	Implementation			Comments
			1	2	3	
10		SUPPLIES - AVAILABILITY (continued)				
01	4.6.2 5.5.1	<ul style="list-style-type: none"> if purchasing distilled water, and it is used to make media or reagents, verify that total heavy metal requirements are met (see most current version of Standard Methods) and do HPC checks monthly or on each batch purchased; accuracy of dispensing apparatus checked regularly; disinfectants available and used routinely for cleaning bench area. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10		SUPPLIES - STORAGE				
02	5.3	Verify that all supplies are stored under appropriate conditions (as specified in reference method or by regulator etc.) and in a manner which satisfies requirements for safety, security, separation of incompatible materials, and ease of retrieval.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10		SUPPLIES - LABELING				
03	4.13.2	Verify that all reagents and media are labeled with material, concentration or purity, date prepared and/or expiry date; verify that media is appropriately labeled, stored under proper conditions, and storage times are met.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10		SUPPLIES- TEST ORGANISM ID				
04	4.13.2	Verify that all information required to properly identify test organisms appears on their containers (i.e., name or number of organism, and date subcultured).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10		SUPPLIES - LABWARE				
05	5.5.1	Verify that all labware is adequately cleaned and, where required, lab ware quality control incorporates analytical testing; specifically: <ul style="list-style-type: none"> use of sterile labware; documented program for contamination control. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Item	Clause	Requirement	Implementation			
			1	2	3	Comments
11		RECORD KEEPING				
01		maintain records related to the performance of the test method; e.g.				
	4.13.2	• analyst worksheet or notebook (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	4.9	• record of nonconformances and actions taken (2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	4.13.2	• reagent preparation log (3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	5.5.5	• equipment maintenance log (4)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	4.13.2	• culture collection records (5)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	5.6	• records of gravimetric traceability (6)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		• records of volumetric traceability (7)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		• records of temperature traceability (8)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

- (1) includes, as appropriate, calibration data, test date (including QC data), experimental variables (e.g. temperature, etc.); analyst ID; sample ID; equipment ID; test organism lot no; test method ID; date and time of test.
- (2) includes as appropriate, nonconformances related to: test method variances; sample history; method performance; interferences; and data validation.
- (3) includes, as appropriate, supplier, grade, batch no; dates of preparation of verification; measurement of weights, volumes, time intervals, temperatures and related calculations; relevant processes (e.g., pH adjustment, sterilization); verification results; discard date.
- (4) includes, as appropriate, identity of the equipment and its software; manufacturer, model, serial no; checks that equipment complies with laboratory specifications; date commissioned; repair and maintenance history; calibration history; any damage, malfunction or modification to the equipment; location.
- (5) includes, as appropriate, organism name; source and date of acquisition; date of subculture and initial of technician; purity check on non-selective medium each time the working subculture is transferred
- (6) includes, as appropriate, traceability of balance and/or weights to a national standard and daily or as-used checks.
- (7) includes, as appropriate, checks on the delivery volume of dispensing equipment, auto pipettes, dilutors, etc. that play a defining role in analytical accuracy.
- (8) includes, as appropriate, traceability of working thermometers to a national standard for those working thermometers that measure temperatures that play a defining role in analytical uncertainties

OTHER ITEMS TO CHECK; CITE A02	1	2	3	Comments
<ul style="list-style-type: none"> adequate separation between incompatible activities, especially when working with pathogenic fungi (e.g., biohazard signs, isolated area with restricted access, etc.) (cite B.02.05); 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> smooth surface on floors, walls, ceiling and benches (cite B.02.01); 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> air monitoring of the area (cite B.02.05); 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> negative room pressure is encouraged but not required unless the laboratory is involved with Biological Safety Level 3 procedures; 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> person responsible for signing authority and data validation possesses the technical knowledge relevant to the scope of accreditation (cite B.01.01); 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> technicians have demonstrated competency relative to the test being accredited (cite B.01.01); 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> appropriate reporting of non-detects (cite B.09.02). 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	