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From the IJCA Executive Editor's Desk

Welcome to the 3rd edition of the International Journal of Conformity Assessment (IJCA), the premier source of insight and analysis in the field of Conformity Assessment. As industries across the globe navigate increasingly complex regulatory landscapes, the importance of conformity assessment processes—spanning testing, certification, and accreditation—has never been more critical. These processes ensure that products, systems, and services meet specified standards, fostering trust, safety, and quality in the marketplace.

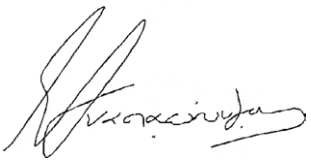
In this issue, we delve into the latest advancements, challenges, and innovations in conformity assessment, particularly in the realm of food safety. Our contributors, leading experts and practitioners in the field, provide a comprehensive overview of current trends, emerging technologies, and best practices that are shaping the future of food safety-related conformity assessment.. With global supply chains becoming more intricate, the ability to verify compliance with regulations, at every stage of the food production and distribution process is essential to protect public health and maintain consumer trust.

Additionally, this issue focuses on the methodologies and frameworks that are strengthening food safety conformity assessments, addressing both current challenges and future opportunities. The selected articles are provided by industry experts who are pioneering new approaches to ensure compliance and enhance the efficiency of conformity assessment processes. Their experiences and insights offer valuable lessons for professionals working across various sectors, with a particular emphasis on food safety— but not limited to that alone.

We hope this issue inspires you to think critically and equips you with the knowledge to navigate the complexities of this essential field.

Thank you for being a part of our community. We look forward to your continued engagement and contributions as we explore the intersections of science, technology, and conformity assessment.

Sincerely,



Dr. George Anastasopoulos
Executive Editor
International Journal of Conformity Assessment (IJCA)
September 2024

Section A

dedicated to peer-reviewed publications and scholarly articles

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Observations on the Value of Laboratory Samples in Food Safety Testing

By Jesse L. Calvillo, Head of New Initiatives, Analytica Alimentaria GmbH; and
Udo Lampe, Managing Director, Analytica Alimentaria GmbH

DOI: 10.55459/IJCA/v3i1/JC.UL

-ABSTRACT-

This paper discusses critical parameters that contribute to or detract from the value of analytical testing samples in the context of food safety risk assessments. A basic framework is proposed for assigning value to analytical results considering scientific validity, interpretability, and impact.

Keywords: *Food safety, Food testing, Multiresidue pesticide analysis, Microbiological testing, Contaminants testing, Risk assessment, Risk mitigation, Laboratory sample, Field sampling, ISO/IEC 17025*

Introduction

The global food safety testing market is projected to exceed 27 billion USD by 2025 [1]. This represents only a fraction of a percent of the expected 10.8 trillion USD in revenue to be generated through the trade of over 2,800 billion kilograms of food next year [2]. Laboratory testing is an essential tool used throughout the food supply chain to verify conformity with food safety regulations and toxicological limits, but analytical results are often poorly understood or misinterpreted. Nonetheless, testing is foundational in food safety and consumer protection.

While there are many other tools that can also be used to buttress food safety throughout the supply chain—inspections, audits, third-party certifications, Hazard Analysis Critical Control Point (HACCP) or Hazard Analysis and Risk-Based Preventive Controls (HARPC) plans, etc.—the use of testing is almost always included in holistic risk-based preventive approaches. In some cases, as with complex systems like agricultural production, or a lack of transparency during import/export trading through intermediaries, testing may be the only tool available to assess specific food safety risks. Nevertheless, in all cases, the integrity of the collected, manipulated, and tested sample must remain intact for the analytical results to be interpreted in a meaningful way.

When we do not fully conceptualize the value of a sample, we can fail to assign it appropriate worth considering the tangible and intangible risks addressed by the testing activity. In practice, it is common to assign too much value to a meaningless sample ("some information is better than none") or too little value to a meaningful preventive action ("why test at all if results are usually negative?"). In this paper, we provide an overview of common failures that negatively impact the value of laboratory samples in food safety testing and propose a simple framework for considering the full worth of a sample in a more comprehensive fashion.

Common Critical Failures Affecting Scientific Validity

A fair evaluation of sample value must consider the ways in which a testing activity may inadvertently be rendered meaningless. In the following section, we enumerate several commonly observed points of concern.

REPRESENTATIVITY

Testing can take many forms, each appropriate for its goal. A packing house might test as part of its HACCP strategy (control testing), a buyer may test before trading (for regulatory compliance), a producer may test prior to harvesting (to prevent the economic risk of a buyer rejecting their harvested lot), and so on. Actors in the supply chain might test for process verification or in the context of dispute resolution; regulators may test to monitor trends in industry practices; laboratories may test to evaluate interlaboratory performance. One cannot exhaustively list all possible circumstances, objectives, and relevant parameters which can come into play when designing and executing a testing strategy, but by far the most common scenarios require the test to be representative.

As sampling design and execution are not addressed by the ISO/IEC 17025 quality standard, laboratories and conformity assessment bodies must therefore evaluate sampling protocols under other—more general—quality management system standards. Because sampling is not a core competency of all laboratories, much of today's food safety testing is performed on samples collected in an uncontrolled manner. If steps are not taken to guard the representativity of a sample, the results may be skewed or useless.

TRACEABILITY

In a similar fashion, if sample traceability is not maintained from the original lot through the chain of custody to the laboratory and within an analytical procedure, results cannot be guaranteed to represent the lot of interest. When lots are mixed, for example, residues may be diluted, and limits of quantitation may not be met (when evaluated against the original lots) due to the dilution. If a critical result is found, it cannot be determined without further testing which of the mixed lots may be unfit for market.

CONTAMINATION

While it is difficult to prevent contamination 100 percent of the time, many practical steps can be taken to avoid inadvertently invalidating a collected sample: proper use of personal protective equipment and hygiene, correct execution of validated protocols, use of materials previously verified to be free from background presence of analytes, and proper training of staff throughout the chain of custody.

Common Critical Failures Affecting Impact or Use of Information

DELAYS IN TIME

It is vital to ensure that analytical results are reported before pivotal decisions are taken. For example, if a load of perishable goods must be offloaded by 08:00 but the results are not ready until 12:00, the buyer loses the opportunity to evaluate results before accepting the load. Or, if meta-control samples are collected at the point-of-sale and microbiological pathogens are detected, the information may arrive too late to prevent consumers from ingesting these foodborne pathogens.

ANALYTICAL ERRORS

It is possible for errors to occur even when laboratories are accredited under ISO/IEC 17025, participate in regular interlaboratory tests, use validated analytical procedures, and maintain appropriate quality controls. In such cases, results may be entirely or partially invalidated simply due to laboratory error. Storing counter samples may provide options for remedying such mistakes, but counter sample results can only be used for risk prevention when the decision time frames are sufficiently wide.

FAILURE IN COMPETENCE

Compliance is not always straightforward in food safety, as regulations may not always be clear in their intent or technical details, and regulators may differ from published texts in their enforcement approaches. Even if the integrity of a sample is maintained and analytical work is appropriate, incorrect compliance evaluations and misguided decisions can result from out-of-date information, inadequate breadth or depth of knowledge, or a lack of familiarity with changes in the legal and regulatory landscape.

Common Critical Failures Affecting Interpretability

INCORRECT SCOPE OF TESTING

Appropriately defining the scope for a given test is as important as performing the test correctly. It is a common occurrence that residues in food remain undiscovered simply because they are not tested. However, not knowing that a critical residue is present does not absolve those involved in food trade of their responsibility towards the consumer.

Here's a specific example: When a broad-spectrum multiresidue pesticide analysis does not include well-known metabolites of toxicological and regulatory relevance, decision-makers may be misled by interpreting "clean" reports as truly residue-free. When one is unsure of scope, consulting a competent subject matter expert for risk assessment is highly recommended.

INADEQUATE LOQs

Similarly, relevant low quantities of residues may not be detected or reported if appropriate Limits of Quantitation (LOQs) are not met in quality controls or Reporting Limits (RLs) are set unjustifiably high. It is not uncommon for testing scopes to be broad enough to cover the breadth of testing needs but fail to reach the rigorous LOQs required to make legitimate compliance evaluations.

LACKING ACCREDITATION OR VALIDATION

Ensuring proper laboratory method validation prior to reporting findings is central to the reliability of test results. Here, conformity assessment bodies play a vital role in verifying that these method validation

requirements are met before approving accreditation scopes, following standards like ISO/IEC 17025.

Analogous to providing inadequate LOQs, the absence of accreditation within a testing scope can indicate poor recovery, lack of repeatability, or high uncertainty in the results. Although it may be unavoidable in some cases to perform tests outside of accreditation, the general recommendation (for when decisions impacting consumer safety will be made) is to seek testing that has been vetted by a conformity assessment body. Notably, scopes of accreditation can be granted in flexible or fixed modalities under ISO/IEC 17025, and it is important to ensure that the analyte-method-matrix combination of interest falls within the scope of accreditation. Otherwise, non-detect results may be meaningless or misleading.

The 'Holistic Sample Value' Framework

We propose a simple framework to aid in assigning value to an analytical sample. Although not a formulaic or quantitative approach, it has demonstrated utility in case-by-case applications and can serve as a basic building block to prevent common critical errors.

STEP 1: Define cost and risk for each stakeholder

In industry, the financial costs associated with food safety testing are usually calculated on a per-lot or per-unit basis. However, the true cost of foodborne illness is likely much higher. Currently, there are no consensus global estimates for the economic cost of foodborne illness, but a few governmental and regional approximations exist (for example, 77.7 billion USD in 2011 for the US; 171 million EUR in 2016 for the Netherlands [3]).

It is impractical to assume that all goods being traded can or will be tested, as resources for this are limited and testing costs impact both product margins and product pricing. Still, in the event of a food safety crisis, growers, packers, shippers, processors, distributors, and grocery retailers incur both tangible and intangible costs. Regulators may block regional exports or imports; loss of consumer confidence may threaten long-lasting decreases in sales; brand damage may destroy reputations built over decades.

For these reasons, we propose considering the costs for all stakeholders (including the consumer) both of testing and of not testing. All risks bear costs even if they are unrealized. For the consumer for whom foodborne listeriosis becomes fatal, the cost is both tangible and manifest. Similarly, the costs are quantifiable for the company that suffers a recall, or the responsible staff members who face criminal and civil litigation for introducing contaminated food into commerce.

STEP 2: Assign value

In contrast to defining the cost, assigning value to food safety testing activities should give weight to the sum of all possible scenarios and likelihoods. The most ethical and often least expensive option is to avoid a food safety crisis when possible. This is precisely because the value of prevention often exceeds the cost of testing. The true value of a sample is not represented only by the cost of testing, nor the commercial value of unrecoverable product lost to destructive analyses, but rather is the sum total of all important utility gained by the activity of testing that sample.

If a sample is taken properly (in a representative fashion), manipulated appropriately (to maintain traceability, representativity and prevent contamination), and tested according to a relevant scope—with fitting LOQs—that meets standards of accreditation; if such a sample is then reported on time, without errors, and interpreted competently and in context, then such a sample holds value. To the contrary, its value is questionable.

STEP 3: Consider available resources

Usually, it is not possible to fully eliminate a risk, and attempts at mitigation can fall short of achieving their desired outcomes. When not all risks can be controlled, actors in the supply chain should take cautious, sensible, and strategic approaches based on careful risk assessments.

Using this framework to evaluate 'holistic sample value' requires balancing needs and resources. Any of the common failures can leave both traders and consumers in precarious positions, and so it is often better to leverage well-chosen, properly executed sampling activities over arbitrary testing of questionable quality. It is worth considering what will be done with the sample results, how this information is to be used, and which tradeoffs make sense considering specific risks. While this may seem obvious in theory, balancing available resources is not always straightforward in practice. For this reason, we propose a general framework rather than a calculation. Considering "holistic sample value" creates a proper frame of reference for decision-making, placing focus on core relevant questions: what are we controlling or verifying with

a given laboratory test; does our overarching testing strategy make sense in the context of the risks we're mitigating; and are we making the best use of the resources we have?

Summary/Conclusion

In conclusion, this paper discusses critical parameters that contribute to or detract from the value of analytical testing samples in the context of food safety risk assessments. By proposing a basic framework for assigning value to analytical results which considers scientific validity, interpretability, and impact, it sheds light on the complexities involved in assessing the true worth of testing activities within the food supply chain.

The analysis underscores the importance of holistic, risk-based preventative strategies, which may encompass various tools beyond testing, such as inspections, audits, risk assessments, and certifications. However, it acknowledges that testing remains indispensable in certain scenarios, particularly when assessing specific food safety risks, such as those associated with agricultural production or import/export trading.

The paper identifies common critical failures that can affect the scientific validity, interpretability, and impact of analytical results, including issues related to representativity, traceability, contamination, delays in reporting, analytical errors, and failures in competence. These failures emphasize the necessity of maintaining integrity throughout the testing process to ensure the reliability and usefulness of the results.

Moreover, the proposed framework for assessing the value of analytical samples emphasizes the importance of considering costs and risks to all stakeholders, as well as the need to assign value based on potential scenarios and likelihoods. It underscores the ethical and practical significance of prevention over reactionary measures, highlighting that the value of a sample transcends mere testing costs and commercial losses.

Ultimately, this paper emphasizes the importance of strategic decision-making informed by careful risk assessment, considering available resources and striving for a balance between mitigating risks and achieving desired outcomes. By adopting such an approach, stakeholders in the food supply chain can better navigate the complexities of food safety testing and ultimately safeguard consumer health and confidence.

Author Biographies

Jesse L. Calvillo is Head of New Initiatives at Analytica Alimentaria GmbH, a global food safety laboratory based in Berlin, Germany. Jesse has 15 years of experience in food safety testing and regulatory compliance. He studied Chemistry at Pepperdine University in Malibu, California; holds a Master of Information and Data Science from the University of California, Berkeley; and is a recognized trainer for various food safety topics including U.S. Seafood HACCP and U.S. FSMA programs.

Udo Lampe is Founder and Managing Director of Analytica Alimentaria GmbH. He has 25 years of experience in food safety and holds the title of state-approved private expert for pesticide residues and pathogens crosscheck analyses in Brandenburg, Germany. He studied Geoecology at the Technical University Carolo Wilhelmina in Brunswick, Germany.

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- Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Produce Safety Rule)
- Hazard Analysis and Critical Control Point (HACCP) Systems (Juice HACCP)
- Fish and Fishery Products (Seafood HACCP)
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Conformity Assessment of Sampling for Food Safety

By J.Peter Krause, Sci. Advisor; and Udo Lampe, Managing Director, Analytica Alimentaria GmbH

DOI: 10.55459/IJCA/v3i1/PK.UL

-ABSTRACT-

Decisions on the food safety of generally large, mostly inhomogeneous batches of foods are based on evaluated residue analyses of very small subsamples. The value of such a residue result primarily depends on the representativeness of the primary sample, the laboratory subsample, and the reliability of the analytical testing of the subsample. Many studies in the literature on sampling focus on sources of error, statistical considerations, sampling guidelines, etc. However, little information is available on the conformity testing of guidelines for sampling and the samplers themselves.

This study presents a conformity assessment guideline for sampling developed by Analytica Alimentaria. The guideline aims to check either the conformity of a changed procedure or the work of a sampler. The test consists of a quality criteria evaluation of the entire sampling process and the quantitative analysis of the sample material. If the results are within an acceptable global estimation error, the test is considered to have passed. Otherwise, a root cause analysis is conducted. The results have demonstrated considerable benefits for robust and representative sampling in the field, reducing the probability of incorrect food safety decisions.

Keywords: *Sampling crops, Pesticide residues, Uncertainty of measurements, Conformity test, Guideline*

Introduction

The verification of the absence of harmful contaminations in foods, such as pesticide residues, heavy metals, or microorganisms, play a significant role in ensuring food safety. Typically, a large unit of food, for instance a batch of packaged or bulk goods, or crops from a field of several hectares, must be checked for food safety-relevant properties. As a 100% inspection of the food is unrealistic for many reasons, acceptance sampling is more widely used in practice.

There are many recommended guidelines for acceptance sampling that include the required sample size [1], and acceptance benchmark for the lot disposition [2, 3, 4]. In case of pesticides in fruits and vegetables, for example, relevant regulations in the European Union include the EC Directive 63/2002 (sampling for pesticide residues) [5] and the EC Regulation 396/2005 (maximum residue levels) [6], respectively. Sample size (mostly some kg) and sampling plan are defined for a unit of food products. The food sample must be further reduced to the laboratory size. The total reduction factor is often in the order of 10-12, starting from tons of foods in the original unit to 1 microgram of laboratory sample for analysis. The reduction of the food sample to the analysis sample can be validated quite well, as it is possible to work with relatively homogeneously or randomly distributed analytes in spiked food samples before analysis [7]. Sampling and chemical-microbiological laboratory analysis for safe foods are unthinkable without a robust quality assurance system. The market therefore demands appropriate accreditation from the laboratory provider to keep the product owner capable of making decisions. ISO 17025 accreditation requires conformity assessment procedures for every method used in the laboratory, including the taking of a food sample.

There are many studies in the literature about sampling for food safety. Besides the difficulties in determining the uncertainty of sampling, new statistical approaches and proposals for guidelines are available [8, 9, 10, 11, 12, 13]. Information about validation and/or conformity assessment of sampling is quite rare. Conformity testing means a systematic examination of the extent to which an entity conforms to a specified criterion [14]. In the case of sampling for pesticide residue determination in crops, the analytically determined residue concentration of a sample, evaluated according to a given specification, shall be valid for the entirety, i.e., according to food law, not exceeded by any item.

No procedure was found in the literature for real product populations that allows testing this claim. There are two main reasons concerning real product populations:

- A multivariable dependency of the distribution of analytes
- No reference target for pesticide residue samples.

This leads to the approach for conformity assessment of sampling to demonstrate that during the sampling process the following requirements are fulfilled:

- Evaluation of a very probable distribution of analytes from the main influencing parameters.
- Adaptation of the sampling plan to the distribution.
- Taking single items under consideration of their characteristics.
- Correct documentation of the sampling.
- Value-preserving transport to the laboratory.

The experience of the sampler has a considerable influence on the result due to the evaluation of the multivariable distribution dependency on-site. This allows a reference sample to be generated, which is only valid for the respective product at the location and time of sampling. Other samplers or sampling methods can be tested against the reference. The analytical information about pesticide residues and their concentrations in the sample is an important source for assessment and shall be included. Many studies are available for two further statistical measures that are necessary for the assessment: the unit-to-unit variability of pesticide residues in fruits and vegetables [15, 16, 17, 18] and the uncertainty of sampling crops [7, 8, 19, 20]. For the former there is a requirement in the EU regulation; for the latter, only case studies so far.

This study presents a conformity assessment for sampling with some practical results.

Materials and Methods

The underlying idea is to carry out sampling and evaluate it for the suitability of the selected sampling plans and the plausibility of the analytical results. A reference sample and a test sample are taken from the same basic population and at the same time. The test sample is evaluated regarding the results of the reference.

The head of the test selects the population to be sampled according to the examination requirements, particularly related to parameters or risks that might affect the distribution of the analytes. Such risks include applied spraying technique, natural or artificial hindrances, edge zones, plant physiognomy, or vegetative characteristics of plants. The current spraying plan for the population can also be used for evaluating the plausibility of the residue concentrations in the samples.

The reference sampling is planned according to the sampling order, executed according to the corresponding Standard Operating Procedure (SOP), and documented by an authorized sampler. The head of the test is present, evaluates the sampling, and countersigns the sampling protocol. Critical non-conformities during the sampling lead to aborting the sampling procedure and repeating the aptitude test. Non-critical non-conformities are taken into account in the evaluation of the conformity test. The sample is transported to the laboratory, registered, and analyzed. The result is delivered to the head of the test as a complete laboratory report.

The checklist contains general data (report number, sampler name, according to SOP) and evaluates the sampling and documentation (the sample is clearly identified and traceable, the scope is defined including recognized risk parameters, there is documentary evidence, the quantity of the sample is adequate) and the analytical results (analytes were found qualitatively and quantitatively within the uncertainty of measurement).

The combined expanded uncertainty of the measured residue (UE) was used when deciding compliance of the residue concentration of the test sample (CT) with the reference sample (CR) [21]: $C(T,R) \pm (2 \times UE \times C(T,R)$. The default value of UE is 25% in the European Union [22]. By comparison, the test was also assessed by a simple laboratory uncertainty (UL)

of 0.25. The test of the residue concentrations in the test sample is passed if the measured residues are equal to the reference within the total uncertainty. Results smaller than the report limit are set to 0.01 mg/kg. All analytes in the reference must also be found in the test sample.

The conformity test is considered passed if all inspection criteria of the reference sample are also present in the test sample according to the checklist. Therefore:

- The documented information is sufficient for the unambiguous identification and traceability of the sample.
- The analytical data of both samples, qualitatively and quantitatively, lead to the same decision about the basic population.

The result of the evaluation is reported to the management and serves as a basis for further internal training and evaluation of samplers and/or methods.

Results and Discussion

The following conformity assessments for sampling methods and authorization of a sampler shall be discussed (Table 1).

Case 1: Unit items were taken by the same technician from 12 sampling points, evenly distributed along a "W" covering the entire field consisting of 35 rows. The difference was the mirrored position of the apex points of the "W." The "W" of the reference sample started at the track perpendicular to the rows. The "W" for the test sample started at the end of the row

Table 1. Case studies for conformity tests

CASE	1. SAMPLING METHOD	2. SAMPLING METHOD	3. SAMPLING METHOD	4. SAMPLE TAKER	5. SAMPLE TAKER
Location	Greenhouse with separate rows	Greenhouse with separate rows	Greenhouse with separate rows	Cooling storage	Historic sewage fields
Analyte	Chlormequat	Pesticides	Pesticides	Pesticides	Heavy metals
Application	Spraying	Spraying	Spraying		Sedimentation
Local conditions/ features	Reversing ranges of the spraying machine	Reversing ranges of the spraying machine	Reversing ranges of the spraying machine	180 collis in 6 stacks	Enrichment zones
Population	Tomatoes	Tomatoes	Tomatoes	Grapes	Soil
Sampling item	Leaves	Leaves	Fruits	500 g box	30 cm drill core
Test aim	Alignment of the sampling "W" in the field	Sampling "W" vs. "ladder"	Sampling "W" vs. "ladder"	Authorisation of a sampler	Authorisation of a sampler

near the greenhouse wall. Here, in addition to the effect of the reversing area of the spraying machine, there are possible rebound effects from the wall, which can also influence the residue concentration. In contrast to the passed test of the sampling plan, the analytical test failed for the laboratory uncertainty (UL), but passed for the expanded uncertainty (UE) (Table 2).

Table 2. Assessment (F = failed, P = passed) of the test for the residue concentration c (mg/kg) for expanded uncertainty UE and laboratory uncertainty UL

ANALYTE	C (MG/KG)		ASSESSED FOR	
	CR	CT	UE	UL
Chlormequat	1.0	1.3	P	F

Case 2: The reference sampling was an area-covering "W" with 12 sampling points. The test sampling was set to three equidistant "ladders" with four equidistant sampling points each. The new plan should reduce the sampling time because fewer rows have to be committed. For UE and UL, the analytical test failed, indicating objective reasons (Table 3).

Table 3. Assessment (F = failed, P = passed) of the test for the residue concentration c (mg/kg) for expanded uncertainty UE and laboratory uncertainty UL

ANALYTE	C (MG/KG)		ASSESSED FOR	
	CR	CT	UE	UL
Chlorantraniliprol	0.330	0.094	F	F
Cyprodinil	0.016	0.014	P	P
Pyridalyl	0.670	0.04	F	F

Case 3: The aim of the trial was as in Case 2 but the number of sampling point has been increased to 30 and the number of ladders to 6. It seems that an increase in ladders and/or sampling points improves the consistency of the sampling methods with regards to the analytical result (Table 4).

Table 4. Assessment (F = failed, P = passed) of the test for the residue concentration c (mg/kg) for expanded uncertainty UE and laboratory uncertainty UL

ANALYTE	C (MG/KG)		ASSESSED FOR	
	CR	CT	UE	UL
Boscalid	0.071	0.057	P	P
Pyraclostrobin	0.015	0.016	P	P
Pyriproxyfen	0.010	0.010	P	P
Abamectin Sum	0.010	0.010	P	P
Fluopyram Sum	0.010	0.010	P	P

Case 4: Four packs of 500g each were taken from the total. The reference sample was taken from four different colli stacks, but the test sample was only taken from three stacks (one stack sampled twice). The test sampling protocol passed. The analytical results also passed within the uncertainty of 50%, but taking only the laboratory measurement uncertainty of 25% as a basis, the test would have to be rated as failed (Table 5).

Table 5. Assessed test (F = failed, P = passed) for the residue concentrations c (mg/kg) of the reference (CR) and test (CT) sample for expanded uncertainty UE (± 50%) and laboratory uncertainty UL (± 25%)

ANALYTE	C (MG/KG)		ASSESSED FOR	
	CR	CT	UE	UL
Mandipropamid	0.025	0.01	P	F
Spirotetramat-enol	0.026	0.029	P	P
Spirotetramat -enol-glucosid	0.091	0.1	P	P
Spirotetramat Sum	0.11	0.12	P	P
Difenoconazol	0.01	0.012	P	P
Dithiocarbamate	0.01	0.018	P	F
Phosphonic acid	3.4	8.5	P	F
Fosetyl-Al	4.5	11.4	P	F

Case 5: A historical sewage field with areas of distinctly different lead and copper concentrations, but relatively stable distribution was used for technician authorisation. Exposed areas should be identified from a technical description and excluded from sampling.

The sampling plans matched except of the selected areas. The test sample also included exposed areas whereas the reference did not.

The test of the analytical result passed despite the differences in the sampling plan (Table 6). The reason could be a dilution effect.

Table 6. Assessed test (F = failed, P = passed) for the residue concentrations c (mg/kg) of the reference (CR) and test (CT) sample for expanded uncertainty UE (± 50%) and laboratory uncertainty UL (± 25%)

ANALYTE	C (MG/KG)		ASSESSED FOR	
UE	CR	CT	UE	UL
Copper	37.3	26.6	P	P
Cadmium	2.92	2.16	P	P
Mercury	1.24	0.93	P	P
Lead	60.09	68.16	P	P

Summary/Conclusions

The described test procedures for conformity assessment of sampling have proven to be of practical use. Deviations in planning, sampling, and analytical results can be used for a well-founded evaluation. Determining the sampling uncertainty is essential for the evaluation of analytical results as the decisive factor in assessing food safety. Based on approaches in the literature, a corresponding project is in preparation. The underlying assumption of a normal or log-normal residue distribution reaches the limits known in practice. Terrain topography, pesticide application technology, weather influences, microclimate, or individual plant growth can lead to considerable deviations that can also be reflected in the test results. Unit-to-unit variability factors are therefore considered, e.g., in the calculation of the Acceptable Daily Intake (ADI) or the Acute Reference Dose (ARfD). This makes harmonized sampling rules, such as those laid down in the EU regulation, all the more important in order to create a uniform basis for evaluation. As long as non-destructive measurement methods for residues are not available directly in the field [23], the competence of the sampler will continue to play a decisive role in the value of the sample in terms of food safety.

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ISO 15189 Laboratory Accreditation Utilization Rate and Challenges Among Accredited Laboratories in Ethiopia, 2021

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-ABSTRACT-

Background: Accreditation is a procedure in which a third party verifies a conformity assessment body's competence to carry out specific tasks. It is crucial for maintaining quality, and accredited laboratories should consistently utilize their quality performance throughout the accreditation cycle as long as they are in service. In this regard, there is limited documented evidence available in Ethiopia. Thus, this study aimed to assess the ISO 15189 laboratory accreditation utilization rate and to identify hindering factors among accredited laboratories in Ethiopia, 2021.

Methods: A cross-sectional study design was employed in 46 government and private accredited health facility laboratories from January 2021 to June 2021 in Ethiopia, comprising both quantitative and qualitative data. Data was entered and analyzed using SPSS version 20 software. A p-value <0.05 was considered statistically significant. Qualitative data was categorized and described thematically.

Result: There were 276 respondents from 46 accredited Conformity Assessment Bodies (CABs) participating in this study. Among the currently accredited laboratories, 82.6% utilized accreditation. Personnel incompetence (0.4, CI [0.003-0.560], p-value = 0.041), no appointment of a quality manager (0.13, CI [0.3-0.595], p-value = 0.008), and inadequate regulatory follow-up (0.014, CI [0.00-0.47], p-value = 0.017) were found to be major challenges for accreditation and had significant association with accreditation utilization. Non-commitment and low attention from top management, inadequate training, inconsistent mentorship, and workload were also identified as factors.

Conclusion: In Ethiopia, despite ongoing efforts to implement medical laboratory accreditation, the utilization rate remains irregular and inconsistent, primarily due to inadequate differentiation between the accredited and non-accredited laboratories by the regulatory body. Hence, we strongly recommend better engagement, commitment, and advocacy with all stakeholders to harmonize and enhance accreditation utilization service for superior quality performance that benefits community.

Keywords: *Accreditation, Accreditations utilization, Accreditation standards, Ethiopia*

Introduction

Quality management is an essential component for healthcare laboratories to achieve their goals and deliver quality results to their customers. Currently, healthcare laboratory managers and owners are increasingly concerned with quality issues. Several uncertainties regarding market competition in private and public sectors challenge their management. Due to these challenges, healthcare laboratories needs to improve the quality and cost-effectiveness of their services (1). To be competitive and to implement quality, accreditation is essential (2).

Accreditation involves third-party verification of a conformity assessment body, providing formal demonstration of its competence to carry out specific tasks. It serves as a benchmark for performance that assures high standards, such as ISO15189, within the organizational system by the conformity assessment body (3).

Accreditation bodies assess and accredit conformity assessment bodies, specifying requirements for competence, consistent operation, and impartiality. These bodies serve as sole implementers of the ISO 17011 standard (4) (5).

The International Laboratory Accreditation Cooperation-Mutual Recognition Arrangement (ILAC MRA) is an agreement signed by signatory accreditation bodies to recognize the equivalence of the accreditation schemes operated within the scope of their signatory status. The ILAC MRA ensures that CABs in different economies operate to the same international standards (6).

ISO 15189 is a standard established by Technical Committee-TC212, first published in 2003 and updated in 2007 (second edition), for the quality and competence of medical laboratories (7). It is derived from ISO 17025, the general requirement for testing and calibration. Currently, ISO 15189 is used as the standard for medical laboratory quality management systems, declaring quality and competence (8).

The accreditation of healthcare programs began in the 1980s globally (9) and around the 1990s in Europe during the period of quality healthcare improvement. The pioneer accreditation programs were the North American models for the joint commission on hospital accreditation and then expanded to include healthcare organizations and the Canadian council on hospital accreditation (10).

Several key meetings have taken place to strengthen and standardize medical laboratories in Africa, including gatherings in January 2008 (Maputo, Mozambique), April 2008 (Lyon, France), September 2008 (Yaoundé, Cameroon), September 2008 (Dakar, Senegal), July 2009 (Kigali, Rwanda), and September 2009 (Kigali, Rwanda). In each meeting, WHO and CDC were involved, leading to the creation of the WHO-AFRO checklist. Laboratories that demonstrated outstanding performance in the WHO-AFRO process were encouraged to apply for ISO 15189 accreditation (10).

Few laboratories in developing countries have established the international ISO 15189 standard easily and affordably, often by designing customized implementations. In response, the World Health Organization Regional Office for Africa created a stepwise approach called Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA), implemented through the Strengthening Laboratory Management Toward Accreditation (SLMTA) program, due to financial limitations for accreditation. SLIPTA uses a star rating system from 0 to 5 to grade laboratories, acknowledging their current status rather than bringing radical changes in competence. It aims to provide consecutive technical support and recognize their progress using a scaled method (11).

ISO 15189 is a comprehensive standard for medical laboratories that covers all stages of laboratory activities, from pre-analytical to post-analytical, including personnel competence, equipment, methods, environment, and proper utilization of reagents and supplies. Medical laboratories are regularly reassessed by qualified assessors to ensure sustained quality and are required to participate in proficiency testing programs (EQAs). ISO 15189 accreditation necessitates competent technical staff, committed management, efficient resources, adequate time, and well-equipped laboratory infrastructure (10, 11).

Quality laboratory services depend on trained and competent laboratory professionals who gain knowledge and skills through continuous professional education. However, in sub-Saharan countries, most healthcare organizations neglect this. The quality provided by individual laboratories is questioned, and not all facilities are enrolled in proficiency testing programs (11).

As of December 2019, five regional cooperation bodies were recognized under the ILAC MRA: African Accreditation Cooperation (AFRAC), Asia Pacific Accreditation Cooperation Incorporated (APAC), Arab Accreditation Cooperation (ARAC), European Cooperation for Accreditation (EA), and Inter-American Accreditation Cooperation (IAAC). Additionally, there were 101 accreditation body signatories via the MRA from these recognized regional cooperation bodies from 103 economies, and one unaffiliated accreditation body, KCA from the Kyrgyz Republic (5).

Out of 104 economies, some are full ILAC MRA signatories, some are ILAC-associated members, and some are affiliate members under 102 signatories. The Ethiopian National Accreditation Office (ENAO), South African National Accreditation Service (SANAS), and Kenyan National Accreditation Services (KENAS) are examples of full MRA signatories. Accreditation bodies that are associate members of ILAC and signatories to a recognized regional MRA are automatically accepted as signatories to the ILAC MRA (12). In addition to evaluations carried out directly by ILAC, recognized regional cooperation bodies conduct peer evaluation visits, such as ENAO's evaluation by Africa's regional accreditation body, African Accreditation Cooperation (AFRAC) (5).

Accreditation in Ethiopia began in 2010 following the establishment of the Ethiopian National Accreditation Office by the Council of Ministers under regulation number 195/2010. It was re-established under regulation number 279/2012 as the sole national accreditation body to provide accreditation services in medical laboratory (ISO 15189), testing laboratory and calibration (ISO 17025), system certification (ISO 17021), inspection (ISO 17020), personnel certification (ISO 17024), and product certification (ISO17065) schemes, in accordance with ILAC rules (13, 14).

So far, more than 60 medical laboratories across different scopes under healthcare institutions are accredited in Ethiopia against ISO 15189 requirements. However, there are various challenges, as accreditation is voluntary. Creating an accreditation market has been very challenging, and regulatory support is still needed due to many documented and undocumented hindering factors. Proficiency testing (PT) providers in the country are lacking, forcing CABs to participate in EQAs outside the country, which incurs high costs. Major equipment calibrators and materials are also very costly and not readily accessible in the country (15). While documented information is limited, these challenges might hinder proper accreditation utilization. Therefore, this study aims to assess the current accreditation utilization rate and identify the major challenges faced by accredited laboratories in Ethiopia.

Despite the implementation of accreditation services in Ethiopia, many accredited laboratories struggle to maintain their quality services. Various challenges, such as regulatory failure, lack of PT providers, lack of calibration materials and calibrators, and lack of awareness, have emerged since ENAO's intervention in 2017. (15).

Although efforts are being made to meet accreditation requirements, no study has yet examined the sustainability and utilization of accreditation throughout the country. Addtionally, there is a lack of data on the hindering factors affecting accreditation utilization in Ethiopia. Thus, this research project aims to identify the challenges in the accreditation process that pose potential threats to the sustainability of accreditation services among Ethiopian medical laboratories.

Materials and Methods

STUDY DESIGN, STUDY AREA, AND STUDY PERIOD

A cross-sectional study design, incorporating both quantitative and qualitative data, was employed among accredited laboratories providing laboratory services in Ethiopia. The study was conducted in Ethiopia, located in the Horn of Africa. According to the 2019 revision of the World Population Prospects, Ethiopia's total population was 109,224,414. The capital city, Addis Ababa, is one of the world's major diplomatic hubs and hosts the African Union. As of the 2019 report, the health coverage index in Ethiopia was 39%, and the quality of care was inadequate, with only 31% of quality processes and outputs meeting standards (16). The country comprises 10 regional states under a federal democratic arrangement and 68 administrative zones (17).

In Ethiopia, there are 353 functional hospitals and 107 under-construction hospitals, as well as 3,735 functional health centers and 96 under-construction health centers, all of which are equipped with recommended levels of diagnostic laboratories (16). This indicates significant investment by the government. However, not more than 46 medical laboratories have been accredited by ENAO, of which 36 are government healthcare facilities and 10 are private hospitals and standalone advanced medical laboratories. Out of these, 22 are located in Addis Ababa, and the remaining 24 are distributed across different regions of the country. The study was conducted between January 2021 and June 2021. Figure 2 illustrates the location of accredited healthcare facilities in Ethiopia in 2021.

SAMPLE SIZE DETERMINATION

All key personnel in 46 accredited laboratories across the country were included in this study. A total of 276 personnel participated, providing both quantitative and qualitative data. The key personnel included the medical director/CEO, laboratory head, quality officer, equipment officer, and two additional laboratory personnel.

Sampling method: A purposive sampling technique was applied to select key healthcare accreditation personnel: medical director/CEO, laboratory head, quality manager, purchase personnel, and equipment focal personnel. These individuals were chosen for their substantial engagement with accreditation requirements, which was essential for generating objective evidence for the assessment of accreditation utilization and the associated factors. A questionnaire incorporating a Likert scale was administered to each accredited laboratory to ensure credible research findings. The questionnaire was prepared in English, as all selected key personnel were proficient in the English language, eliminating the need for translation to local languages.

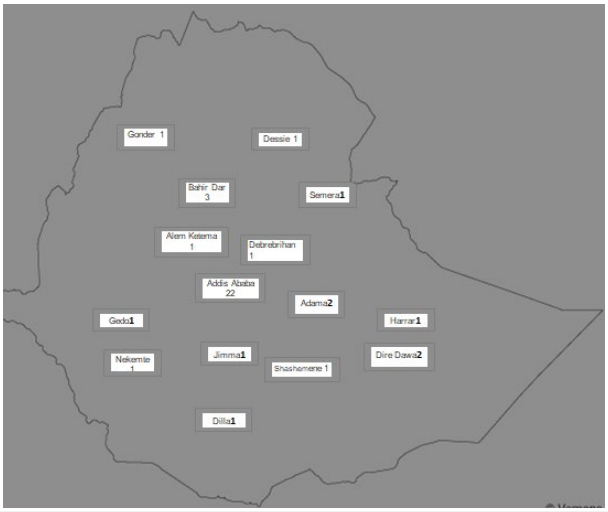

Figure 1: Map of Ethiopia with cities where accredited healthcare facilities are located, 2021. The names of each accredited lab are listed in Appendix III. Note: Tigray Region accredited labs are not indicated on this map.

DATA COLLECTION PROCEDURE

The data collection instrument consisted of an anonymously administered Likert scale questionnaire, prepared by reviewing different standards, guidelines, and documents. The questionnaire aimed to determine the utilization rate of accreditation and identify the hindering factors affecting accreditation utilization. It included questions on several topics: laboratory profile, current laboratory status, key personnel's educational background, characteristics of laboratory QMS implementation, work experience of personnel, laboratory stakeholders, proficiency testing (PT) issues, calibration issues, and knowledge and attitudes towards laboratory accreditation.

Two senior laboratory technologists were trained to use the questionnaire for data collection. The principal investigators were involved in overseeing the entire data collection process, assisting the data collectors throughout. They also regularly collected the filled questionnaires and checked them for consistency.

DATA QUALITY ASSURANCE

To ensure data quality, two data collectors were trained via email on the data collection procedures. The questionnaire was pre-tested at the Ethiopian Public Health Institute (EPHI) bacteriology reference laboratory in Addis Ababa before the actual data collection (pre-analytical phase).

During the analytical phase, the principal investigator checked the completeness, accuracy, and consistency of the collected data on a daily basis. In the post-analytical phase, the principal investigator reviewed the overall data consistency. Any questionnaires found to be incomplete, inaccurate, or inconsistent were returned to the data collectors for correction. Additionally, the data was cleaned, edited, and coded after data entry.

DATA ANALYSIS AND INTERPRETATION

Quantitative data was entered, cleaned, and analyzed using SPSS version 20.0 software. For qualitative data from in-depth interviews and open-ended questions, the information was organized, categorized, summarized, and discussed by narrating the findings thematically. Descriptive statistics were computed for most of the study variables. Frequency distribution, tables, and graphs were used to present the findings. A p-value of less than 0.05 was considered statistically significant when examining associations between accreditation utilization and its hindering factors.

For this study, accredited medical laboratories were classified into the following categories: laboratories that were accredited and later withdrew; laboratories that sustained their performance and reapplied for the second round of accreditation according to the accreditation cycle; laboratories that applied for accreditation but were terminated or did not reapply; and laboratories that were accredited but suspended for a defined period.

ETHICAL CONSIDERATIONS

The study was conducted after obtaining ethical clearance from the department research and ethical review committee of Addis Ababa University, College of Health Sciences, with a protocol number of DRERC/037/21/MLS. A formal letter of cooperation was secured from the Ethiopian National Accreditation Office and sent to the concerned accredited healthcare facilities in Ethiopia. The general objective and significance of the study were communicated to the administrators of these facilities through an official letter.

Oral consent was obtained from study participants after explaining the aim of the study and their rights during data collection. Given that the study institutions are scattered, data was collected via email, a method approved by the research and ethical committee. A coding system was used to maintain confidentiality while identifying each study participant's results.

RESULTS

Background information of the study area

Data was collected from 46 government and private health facility laboratories; of these, 22 laboratories were in Addis Ababa, while the remaining 24 were in various towns across different regions. According to the study, the Ethiopian National Accreditation Office (ENAO) categorized these laboratories as well-utilized, terminated, suspended, or withdrawn. Of the 46 laboratories, 38 had well-utilized accreditation, one had been terminated, three had been suspended, and four had withdrawn. Most of the accredited laboratories included in this study were accredited in the scope of GeneXpert.

Among the total accredited health facilities in this study, 36 (78.3%) were government-owned, and 10 (21.7%) were privately owned. The service years of the health facilities after establishment ranged from five to 10 years for 12 facilities, 11 to 15 years for 11 facilities, and more than 15 years for 23 facilities. The majority of the health facilities, 17 (37.0%), were general hospitals, followed by public health institutes, 12 (26.1%). The other organizational levels included six comprehensive hospital, four primary hospitals, three specialized hospitals, three diagnostic laboratories, and one health center. The number of employees in these organizations ranged from four to 10 employees for four facilities, 11 to 20 employees for 12 facilities, 21 to 30 employees for 11 facilities, and more than 30 employees for 19 facilities. Regarding responsibility hierarchy of the health facilities, 26 (56.5%) were responsible to the Ministry of Health, 19 (41.3%) to the regional health bureau, and the remaining one (2.2%) to the zonal health bureau, as detailed in Table 1.

Table 1: Demographic characteristics of the study area of public and private health facilities (n=46), Ethiopia, 2021

VARIABLES	DEMOGRAPHIC ITEM	FREQUENCY	PERCENT
Type of organization	Public	36	78.3
	Private	10	21.7
	Total	46	100
Service years of the organization since established	6-10	12	26.1
	11-15	11	23.9
	>15	23	50.0
	Total	46	100
Facility type	Health center	1	2.2
	Primary hospital	4	8.7
	General hospital	17	37.0
	Comprehensive hospital	6	13.0
	Specialized hospital	3	6.5
	Public health	12	26.1
	Diagnostic lab	3	6.7
	Total	46	100
No. of laboratory employees	4-10	4	8.7
	11-20	12	26.1
	21-30	11	23.9
	>30	19	41.3
	Total	46	100
Responsible to	Ministry of health	26	56.5
	R. health bureau	19	41.3
	Zonal health office	1	2.2
	Total	46	100

Background characteristics of the respondents

The study population exhibited varying demographic and background characteristics, including sex, age, educational level, length of service, and position. A total of 254 laboratory professionals and 22 other health professionals—medical directors/chief executives/director generals (MD/CEO/DG) were included in this study. Out of 282 questionnaires distributed, 276 were completed and returned, resulting in a response rate of 97.8%.

The distribution of the respondents by position included 40 laboratory heads, 44 quality officers, 36 store managers, 22 MD/CEO/DGs, and 134 operational workers. These individuals were interviewed to provide their opinions on the utilization of accreditation and the challenges faced by medical laboratories in utilizing ISO 15189 accreditation.

Among the respondents, 214 (77.5%) were male. The majority, 147 (53.3%), were in the age group of 26 to 35, followed by 70 (25.4%) in the age group of 36 to 45. In terms of educational attainment, the majority of the respondents, 120 (43.5%), held a master's degree, followed by 108 (39.1%) with a bachelor's degree. The working experience of the study participants in their respective organizations ranged from five to 10 years for the majority of participants, 152 (55.1%). The detailed demographic characteristics are illustrated in Table 2.

Table 2: Demographic characteristics of respondents from public and private health facilities who participated in this study (n= 276), Ethiopia, 2021

VARIABLES	DEMOGRAPHIC ITEM	FREQUENCY	PERCENT
Sex	Female	62	22.5
	Male	214	77.5
	Total	276	100
Age Group	20-25	28	10.1
	26-35	147	53.3
	36-45	70	25.4
	46-55	31	11.2
	Total	276	100
Educational Level	College diploma	28	10.1
	Bachelor's degree	108	39.1
	Master's degree	120	43.5
	PhD	20	7.3
	Total	276	100
Work Experience	6-10	152	55.1
	11-15	76	27.5
	>15	48	17.4
	Total	276	100
Management Level	Laboratory head	40	14.5
	Quality manager	44	15.9
	Store manager	36	13.0
	Operational	134	46.8
	MD/CEO/DG	22	5.8
	Total	276	100

ACCREDITATION UTILIZATION RATE

The results indicated that in Ethiopia, 38 (83% n=46) accredited health facilities were effectively utilizing accreditation practices in accordance with the ISO 15189 standard. These facilities had competent laboratory personnel and committed management, which facilitated proper utilization of the accreditation. Conversely, eight (17% n=46) accredited health facility laboratories were not utilizing the accreditation due to various challenges.

Among the accredited facilities, three (6% n=46) had their accreditation suspended for specific periods. The reasons for suspension included calibration failures of major equipment within the accreditation scope. These laboratories received suspension letters from ENAO and were required to refrain from using any ENAO/ILAC symbols during the suspension period.

Another significant reason for suspension of accreditation was the cost involved. Respondents indicated that accreditation fees and related costs such as proficiency testing (PT) and calibration, were additional financial burdens. Some respondents believed that accreditation added no value to their business. These cost-related reasons for suspension and withdrawal were predominantly observed in private healthcare facility laboratories.

One facility (1%) had its accreditation terminated due to the incompetence of its staff and uncommitted management, which hindered the continuation of the accreditation process. The termination occurred during the document review processs by ENAO. After the laboratory submitted its available documents and necessary requirements, ENAO requested all documents required by ISO 15189. When these documents were not submitted within the specified timeframe, the laboratory's accreditation was terminated for non-compliance with competence requirements.

Additionally, four healthcare facility laboratories in the Tigray region were not included in this study due to unsuitable situations during the data collection time.

The accreditation utilization status is illustrated in Figure 2. A detailed categorization of the hindering factors is provided in the section below.

Challenges of Accreditation Utilization

The study found that eight out of 46 (17%) accredited healthcare facility laboratories were not utilizing their accreditation. Specifically, four facilities (9% n=46) withdrew from accreditation due to high staff turnover, management negligence, lack of appropriate training, and incompetent staff. During focus group discussion, respondents explained that accredited and non-accredited laboratories are often treated

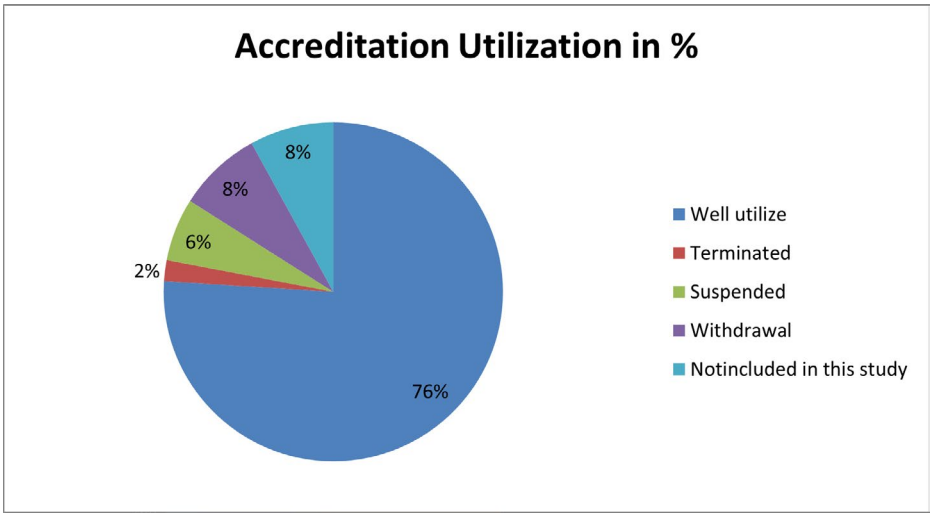

Figure 2: Accreditation utilization statuses in Ethiopia, 2021

similarly by regulatory bodies, leading them to believe that accreditation had little to no impact on their laboratory operations. This perception was cited as the primary reason for improper accreditation utilization, eventually leading to withdrawal.

Inconsistent regulatory follow-up (0.014, CI [0.00-0.47, p-value 0.017), lack of appointment of a quality manager (0.13, CI [0.3-0.595], p-value 0.008), and personnel incompetence (0.4, CI [0.003-0.56], p-value 0.04) were found to have significant associations with accreditation utilization (Table 4). Other hindering factors for accreditation utilization included inadequate training of personnel, lack of upper management commitment, limited resource allocation, lack of incentives for accreditation awards, inadequate awareness of ISO 15189 and QMS among personnel, improper mentoring, and insufficient follow-up by regulatory bodies.

Almost all accredited healthcare facility laboratories reported that no incentives were provided to employees for their efforts in achieving accreditation. Among the 276 participants in this study, 26 (9%) expressed a desire to leave their institutions due to the lack of recognition for their accreditation efforts. Around 109 (39.5%) participants noted that management was not committed to the implementing of a quality management system (QMS) or achieving accreditation. More than half of the participants rated resource allocation for accreditation as ranging from "very small extent" to "moderate extent." The budget for accreditation was not intentionally allocated by upper management but was instead sourced from other budget lines.

Regarding equipment calibration, 166 (60.1%) of respondents stated that some of their equipment was not calibrated due to inaccessibility or unaffordability of calibrators. Calibration institutions were also not decentralized. However, for assay calibration, companies calibrated the machines, and most calibrators were traceable and affordable. Despite these challenges, nearly all laboratories did not plan to cease accreditation due to calibration issues.

Around 112 (40.5%) participants were not knowledgeable about ISO 15189. Thirty (10.9%) participants complained that the standard (ISO 15189) was very complicated to understand. Seventy-seven (27.9%) participants believed that accreditation was not important and saw it as an additional burden. However, 199 (72.1% n=276) participants gave their answer as "moderate extent," indicating their belief that accreditation has at least some modest advantage to the customer.

Six (13% n=46) laboratories did not have mentors, while the remaining 40 (87% n=46) healthcare facility laboratories had mentors. Only 44 (15.9% n=276) participants felt that mentors were used to a "moderate extent," whereas the other 232 (84.1% n=276) rated the extent as "very small" to "small." Respondents indicated that mentors did not effectively demonstrate how to implement a quality management system or acheive accreditation. Nearly all laboratories believed they could sustain their accreditation status without mentors and had no plans to cease if mentoring stopped.

Almost half of the accredited laboratories were evaluated by regulatory bodies, yet nearly all accredited

laboratories reported a lack of support from regulatory bodies for achieving accreditation. Regulatory bodies did not differentiate between accredited and non-accredited laboratories and did not encourage accredited laboratories. Respondents confirmed that there were no incentives from regulatory bodies for accredited laboratory employees.

Effect of the COVID-19Pandemic on the Utilization of Accreditation

This study was conducted during the COVID-19 pandemic, providing an opportunity to observe its impact on the accreditation system in Ethiopia. This section offers a a highlight and an overview for readers rather than a detailed analysis.

COVID-19, an ongoing global public health crisis, has affected many services, including the accreditation process. The Ethiopian accreditation system was not exempt from these challenges. One out of three suspended accredited healthcare laboratories was suspended due to the COVID-19 pandemic. The study findings indicate that the pandemic forced the CAB to prioritize pandemic prevention. Laboratory personnel who were signatories to ENAO were also assigned to pandemic prevention efforts. The study shows that the COVID-19 pandemic dramatically impacted the accreditation utilization processes, potentially necessitating changes or adjustments to the timeline rules and requirements of the Ethiopian national accreditation body due to the challenges faced by CABs during this period.

Healthcare facility laboratory accreditation is an essential measurement for any conformity assessment body's performance, as it is a significant means of assuring quality service. Thus, accreditation utilization is a cornerstone for healthcare facility laboratories. Some CABs were assessed offsite by sending all requirements to ENAO. Respondents from this study noted that the sudden shift from onsite assessments to offsite and desk review assessments did not allow CABs sufficient time to adjust their necessary requirements, nor did it give ENAO assessors adequate time to review the needed documents for accreditation. This situation created a dilemma for all conformity assessment bodies involved in the accreditation process.

Trend of Accreditation

The Ethiopian National Accreditation Office (ENAO) was established in 2010 via the ministry of council by proclamation number 195/2010 as the sole accreditation body in Ethiopia. It began providing accreditation services in 2013 for three CABs after being recognized as an affiliated member by ILAC in 2012. In 2017, ENAO became a full member of ILAC MRA, accrediting seven healthcare laboratories during that fiscal year, bringing the total number of accredited CABs to 17 over four previous fiscal years. By 2019, the healthcare facility laboratory accreditation rate had increased by 10. Currently, there are around 46 accredited CABs, irrespective of their utilization status. Four accredited laboratories were not included in this study, as illustrated in Table 3.

Table 3: Accreditation trends in Ethiopia from the beginning (2013) to 2021

YEAR	FREQUENCY	PERCENT
2013	2	4.0
2014	4	8.0
2015	3	6.0
2016	1	2.0
2017	7	14.0
2018	2	4.0
2019	12	24.0
2020	13	26.0
2021	6	12.0
Total	50	100.0

Summary of Associated Factors for Accreditation Utilization in Ethiopia

A binary logistic regression analysis was performed to determine whether there is an association between accreditation utilization and independent factors. Not appointing a quality manager was 0.13 times less likely to utilize accreditation than appointing (0.13, CI [0.3-0.595]). Healthcare facility laboratories without committed upper management were 0.2 times less likely to utilize accreditation compared to those with committed management (0.22, CI [0.01-3.85]). Respondents from laboratories that affirmed accreditation budget allocation to a "large extent" were 1.5 times more likely to utilize accreditation than those affirming a "moderate extent" or "small extent" (1.52, CI [0.7-3.3]). Laboratories affirming competency declaration to a "very small extent" were 0.4 times less likely to utilize accreditation than those affirming to a "small extent" or "moderate extent" (0.4, CI [0.003-0.56]). Laboratories supported by regulatory bodies to at least a "moderate extent" were 0.014 times less likely to utilize accreditation than those supported to a "large extent" or "very large extent" (0.014, CI [0.0-0.47]).

Table 4: Impact of laboratory personnel, management, competency, training, and regulatory follow-up practices on accreditation utilization in accredited healthcare laboratories, Addis Ababa, Ethiopia, 2021

INDEPENDENT VARIABLES		ACCREDITATION UTILIZATION UTILIZED	NOT UTILIZED	95% CI COR	P-VALUE	95% CI AOR	P-VALUE
Competency	V.S.E	52	4	0.26(0.08-0.86)	0.03*	0.4(0.003-0.56)	(0.041)*
Assessment	S.E	43	15	1.18(0.5-2.78)	0.70	4.2(0.64-26.5)	0.133
	M.E	89	16	0.6(0.27-1.38)	0.233	0.78(0.13-4.5)	0.78
	L.E	4	13	√			
Management	V.S.E	15	2	0.38(0.08-2.1)	0.25	0.03(0.001-1.2)	0.06
Commitment	S.E	76	16	0.55(0.58-1.75)	0.31	0.23(0.001-1.2)	0.230
	M.E	62	12	0.5(0.15-1.67)	0.26	0.22(0.01-3.85)	0.302
	L.E	62	13	0.55(0.17-1.8)	0.32	0.07(0.6-1.1)	0.059
	V.L.E	13	5	√			
QM appointment	L.E	138	15	0.3(0.12-0.57)	0.000*	0.13(0.3-0.595)	0.008*
	V.L.E	90	33	√			
Budget for Accreditation	V.S.E	49	1	√			
	S.E	41	12	0.10(0.013-0.8)	0.03*	0.336(0.01-8.7)	0.51
	M.E	77	23	1.49(0.61-3.6)	0.383	2.52(0.33-19.1)	0.37
	L.E	61	12	1.52(0.7-3.3)	0.29	1.02(0.176-5.97)	0.797
Evaluated by Regulatory body	S.E	53	2	√			
	M.E	27	10	0.14(0.03-0.61)	(0.036) *	0.014(0.0-0.47)	0.017*
	L.E	76	16	1.33(0.55-3.2)	0.521	2.6(0.35-19.6)	0.349
	V.L.E	72	20	0.76(0.36-1.58)	0.458	0.412(0.08-2.1)	0.282

Key: * Shows significant association at α=0.05 √ shows reference category, V.S.E=very small extent, S.E=small extent, M.E= moderate extent, L.E=Large extent, V.L.E=very large extent

Based on the results, the null hypothesis for competency assessment (p-value=0.04), budget for accreditation (p-value= 0.03), and regulatory follow-up (p-value= 0.017) were rejected, indicating significant statistical differences in the accreditation services utilization. The regression analysis also showed that provision of comprehensive basic laboratory test training, management commitment, availability of mentors, and awareness of ISO 15189 had no significant association with healthcare facility laboratory accreditation utilization. Table 4 summarizes the crude odds ratio, adjusted odds ratio, and p-value on the impact of laboratory personnel competency, accreditation budget allocation, appointment of quality managers, training on QMS, and regulatory follow-up practices.

Discussion

This research aimed to assess the utilization rate of accreditation and identify the factors hindering accredited healthcare facility laboratories. Nearly half of the respondents had received basic training helpful for ISO 15189 accreditation and utilization. In 2019, the health facility laboratory accreditation utilization rate increased by 10 (24%), with around 38 accredited CABs four withdrawals, and three suspensions.

The majority of respondents (26, 9.4%) indicated that management does not facilitate the accreditation process by providing training or incentives for accreditation awards, leading to staff attrition. This finding aligns with studies by Ng G., Leung et al., in Hong Kong Medical Journal (Xiangtan yi xue za zhi), and El-Jardali, F. et al., which identified

top management resistance, lack of awareness on QMS, inadequate training, and insufficient support for the quality improvement process (18, 19). Laboratory professionals believe that awareness and commitment from top management are crucial for successful accreditation. Despite some support from upper management in certain laboratories, full participation and commitment were still lacking.

Healthcare facility staff lack adequate knowledge about the importance of accredited laboratories beyond support for clinical management, discouraging laboratory professionals from striving for better quality and accreditation utilization. This is similar to a report from Addis Ababa Public Health Laboratories in 2019 by Misganaw A. et al. (20).

The low incentive levels for lab personnel significantly contributed to the high turnover of laboratory professionals. According to the respondents, there is a high turnover, especially among experienced professionals who frequently plan to join higher-paying organizations for a better lifestyle and experience. This finding is supported by research conducted in the Caribbean Region, which highlighted that maintaining a sufficient number of well-qualified laboratory workers is an ongoing challenge, exacerbated by attrition rates as staff leave the public sector for more lucrative jobs in the private sector (21).

Inadequate upper management commitment, laboratory personnel incompetence, and viewing accreditation as a one-time achievement rather than an ongoing process were identified as challenges. Accreditation requires daily effort, not just a single assessment cycle. Similar research conducted in China supported these findings, showing that laboratory professionals still do not recognize the importance of accreditation and consider it as unnecessary extra work mandated by the Ethiopian national accreditation body (22).

Findings showed that management is concerned not only with the allocation of resources but also with how these resources translate into an improved quality management system for the laboratory. In this study, 50 respondents (18.1%) indicated that upper management allocated budget for accreditation to a "very small extent," and 53 (19.2%) to a "small extent," showing that management often did not prioritize budget for accreditation purposes, instead using other budget lines. The results showed that laboratories with better budget allocation for accreditation were 1.5 times more likely to utilize accreditation than those where respondents answered "moderate extent" and "small extent" (1.52, CI [0.7-3.3]). Inadequate budget allocation for proficiency testing (PT) and calibration was also a significant challenge, as 110 respondents (39.9%) complained about insufficient funds for these purposes. Despite this, the budget for PT and calibration was often covered by the CDC trough EPHI. Studies by Koplan JP, published in the Bulletin of WHO, and by Gurmessa A. and A. Misganaw at Addis Ababa governmental hospital laboratories, support the finding that financial resource limitations for PT and calibration are significant challenges for accreditation in sub-Saharan countries (11, 23).

Facility and infrastructure significantly contribute to low accreditation utilization and slow progress. Some laboratories lacked adequate space for testing, with various machines located in a single room. The result showed that 98 respondents (35.5%) reported inadequate infrastructure to a "small and very small extent." Previous research by Abay S. indicated that laboratory design and floor quality contributed to a low success in accreditation implementation (24). Many respondents noted that their laboratory facilities or infrastructure of their laboratories were far below standard, leading to failure before the assessment process. This situation often resulted in termination and withdrawal from accreditation. This is also supported by the report in Addis Ababa by Sisay A., which indicates that achieving and maintaining accreditation status requires a significant investment of resources. Additionally, the report "Factors Affecting Implementation of Laboratory Quality Management System in Addis Ababa Public Health Laboratories" highlights similar challenges (25).

Some respondents noted that without calibrated equipment traceable to higher reference materials, participation in the accreditation process is challenging. In 2017, ENAO reported the advantages and disadvantages of decentralizing the calibration institute, which improved calibration efficiency but raised issues in the provision of quality of calibration services and the stimulation of local private participation in their own calibration. Among the disadvantages were issues of traceability for meeting national policies and international requirements (15). In the current study, respondents criticized the centralized system, arguing that it hindered the provision of calibration services and their overall journey toward accreditation. Reagent and quality control material stock-outs, followed by test interruptions, were other challenges reported by

respondents in most of the accredited laboratories visited. These challenges contributed to the gaps faced in different assessment experiences and remain unresolved problems.

The majority of respondents agreed that good quality equipment, due to proper calibration, is crucial for the accreditation process. However, some equipment, such as microscopes, were difficult to calibrate due to the absence of calibrators in the country, while others, like hygrometers, were calibrated without traceable evidence. More than half (166, 60.1%) of the respondents claimed that it is difficult to get affordable calibration services, and 20 (7.2%) affirmed that the calibration institute is decentralized to a "moderate extent." This poses a significant challenge for effective accreditation utilization. However, none of the respondents indicated that their lab planned to cease accreditation due to calibration unaffordability and inaccessibility (17).

Almost all accredited healthcare facilities participated in proficiency testing (PT), a mandatory requirement for accreditation. They accessed PT through EPHI and One World Accuracy, with the budget centrally allocated by the CDC through EPHI, alleviating affordability concerns. Laboratories implementing accreditation well did not plan to cease due to PT inaccessibility or unaffordability issues, as successful PT participation is a mandatory requirement by Ethiopia's accreditation body (ENAO).

Of the 46 laboratories visited, most were accredited for GeneXpert. Most respondents (160, (60.1%) stated they could not afford PT for all scopes, leading to most of the accredited laboratories being accredited with limited scope: GeneXpert. Some respondents received PT samples from the Ethiopian Public Health Institute without any expenditure, which facilitated their accreditation. However, the Ethiopian Public Health Institute sourced these PT samples from the CDC. The study done by Greenfield D. and Braithwaite J. ("Health sector accreditation research: a systematic review") confirmed the high costs of proficiency testing (26). Due to these challenges, it was noted that the government should not necessarily force laboratories to establish a PT provider in the country.

Around 77 respondents (27.9%) claimed accreditation is not important, seeing it as merely extra work, affirming this to a "very small extent" and "small extent." In the current study, awareness of ISO 15189 and quality management systems, as well as the initiation of laboratory staff regarding accreditation utilization, varied from institution to institution. Greater than half of the respondents agreed they are aware of ISO 15189 and quality management systems. Around 20 respondents (7.2%) believed that accreditation adds nothing to the user's results, considering it an extra burden for lab personnel. This aligns with a study by Alkhenizan A. and Shaw C. on the attitude of healthcare professionals towards accreditation (27). This perception has created disagreements and conflicts between lab personnel and management, which is a barrier to successful accreditation utilization.

Routine workload was also a challenge, making staff too busy to accomplish the extra tasks required for accreditation, which demands a considerable increase in the number of laboratory professionals. Even though a little more than half of the respondents had awareness and training related to either QMS or accreditation process or both, 36 respondents (13%) had difficulty understanding the standard (ISO15189) to a "large extent" and "moderate extent." Quality management system training was believed to be the key for a successful accreditation utilization process, requiring all staff to be trained. However, 114 respondents (41.4%) believed that the trainings were inadequate in terms of quality and quantity for successful accreditation utilization. The trainings in our country were unplanned and not based on the actual gaps that the accreditation requires. Similarly, research done in Ethiopia by Tilahun M. et al. in 2013 and Abay S. et al. 2015 reported that training inadequacy and inconsistency were challenges for laboratories participating in the accreditation process (28, 29).

The lack of adequate training regarding QMS and accreditation remains a challenge, with 112 respondents (40.5%) unaware of the ISO 15189 standard. Around 246 respondents (89.1%) stated their institution had a mentor (30) ([10.9%] noted they did not have a mentor), but in most of the study sites, the quality and adequacy of mentorship were questioned. Some mentors had the same training experience and knowledge as the mentee lab personnel, providing little additional support. All respondents did not believe they received the expected support from external mentors. Some mentors did not show mentees how to implement ISO 15189, instead producing documents centrally and distributing them to each CAB (mentee). This is a significant problem that can affect those who sustain accreditation status and didn't plan to cease from

accreditation whether the mentor stops mentoring or not. This finding is consistent with research reported conducted in the Caribbean Region and Kenya, which supports the current by indicating that low adequacy and quality of mentorship contribute to slow accreditation utilization (30, 31).

Most respondents (221, 80.1%) felt their laboratory was wrongly evaluated by regulatory bodies for their own interests, not providing supportive and helpful feedback for accreditation. According to this study, the healthcare facility laboratories supported by regulatory bodies to at least at "moderate extent" were 0.014 times less likely to utilize accreditation than those supported to a "large extent" or "very large extent" (0.014, CI [0.0-0.47]).

There is no clear difference between accredited and non-accredited laboratories, which was mentioned as a major challenge for the accreditation process. All 276 respondents (100%) in this particular study confirmed that regulatory bodies did not support healthcare facilities through financial support or acknowledgment incentives for accreditation. Respondents suggested that regulatory bodies need to consider the actual situation and capacity of the country's accreditation body (ENAO) and rethink their approach. The lack of distinction between accredited and non-accredited laboratories leads to improper accreditation utilization, suspension, and withdrawal from accreditation. Regulatory bodies should address this issue for better quality laboratory services and improved accreditation status.

Conclusion and Recommendation

Despites effort to implement accreditation utilization effectively, maintaining accreditation remains a challenge for many facilities visited in this study. The findings highlight the need for stronger engagement, commitment, and advocacy among all stakeholders to harmonize and lead the accreditation program effectively. Of the 276 respondents, about 187 (67.8%) had training experience related to QMS, while all were aware of ISO 15189. However, gaps in the adequacy and quality of training and mentorship remain.

Given that the accreditation status of most medical laboratories is unstable, can be concluded that there is a gap and limited effort to support medical laboratory accreditation utilization. Tthe regulatory body is not yet fully prepared to support or facilitate the accreditation effectively.

The high turnover of trained and experienced laboratory professionals, largely due to inadequate incentives, has significantly impacted accreditation utilization. Staff competence, management commitment, and budget allocation were identified as key factors for successful accreditation. Although there have been slight improvements in management commitment and lab personnel competence, some management members and laboratory staff still view accreditation as an extra burden or as a one-time achievement that ends after the assessment cycle. Workload challenges also prevent staff from dedicating the necessary time to accreditation tasks. In most of the healthcare facility laboratories, the awareness and support by upper management for accreditation utilization was not as the laboratory personnel expected.

Calibration and traceability of laboratory equipment were among the challenges for accreditation utilization, and these issues were found to be unavoidable for some healthcare facility laboratories. Additionally, problems with laboratory infrastructure, the lack of clear separation between accredited and non-accredited laboratories by the regulatory body, and reagent stockouts were not aligned with ISO 15189 standards, making them difficult to resolve quickly. Based on the findings of this study, the following recommendations should be considered, and any concerned body should give due attention to improving accreditation utilization in Ethiopia

Healthcare facility management should better understand the importance of having accredited laboratories within their facilities and support these efforts to strengthen accreditation utilization and improve healthcare delivery. Top management and staff should take pride in their profession and strive to increase the reputation of their field through effective accreditation utilization.

The Ministry of Health and relevant stakeholders should differentiate between accredited and non-accredited laboratories, recognizing the importance of accredited laboratories in the country's healthcare plan, and should closely monitor and support accreditation utilization.

Universities should consider revising their curricula to incorporate concepts of medical laboratory quality management systems and accreditation, ensuring that laboratory professionals are more informed and competent regarding QMS and accreditation at the undergraduate level.

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Supporting information

S1 Appendix III: List of CABs accredited by ENAO and included in this study.
S2 Figure 1: Map of Ethiopia with cities where accredited healthcare facilities are located, 2021.
S3 Table 1: Demographic characteristics of the study area of public and private healthcare facilities (n=46), Ethiopia, 2021
S4 Table 2: Demographic characteristics of respondents from public and private health facilities who participated in this study (n= 276), Ethiopia, 2021.
S5 Figure 2: Accreditation utilization statuses in Ethiopia, 2021
S6 Table 3: Accreditation trends in Ethiopia from the beginning (2013) to 2021
S7 Table 4: Impact of laboratory personnel, management, competency, training and regulatory follow-up practices on accreditation utilization in accredited healthcare laboratories, Addis Ababa, Ethiopia, 2021.

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Section B

an informative section that includes general articles, announcements, white papers, etc.

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Ensuring Your Safety, Every Step of the Way: The Role of Standards, Audits, and Conformity Assessments in the Design of Food Manufacturing Facilities

By Angela Anandappa, Ph.D, Chief Executive Officer, Alliance for Advanced Sanitation.

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-ABSTRACT-

Incorporating innovative materials and design elements in producing equipment and materials has proven to be valuable for facilities. The rationale for expenditures that include these elements lies in their effectiveness at reducing contamination risks. This is only one crucial element, as productivity, efficiency, and the reduction of unplanned downtime play vital roles as well. This article provides a broad array of the elements against which conformity can be evaluated while providing some of the background about why it is important to continue the search for more materials and designs that deliver results for risk management as well as productivity.

Keywords: *hygienic design standards, GFSI, audits, conformity, 3A, EHEDG, Alliance for Advanced Sanitation, material science, food safety*

Introduction

As the tally of multimillion-dollar fines levied against food companies for inadequate hygiene and management practices rises, public scrutiny of hygienic infrastructure in the food industry has intensified.

Food companies bear a dual responsibility: protecting consumers and safeguarding their own interests. Implementing food safety practices not only ensures consumer well-being but also protects brand reputation, reduces costly product recalls, and helps control insurance expenses.

Hygienic Design

Regarding facilities and equipment, adhering to hygienic design principles is crucial. This approach, also known in the United States as sanitary design, prioritizes ease of cleaning and minimizes areas where contaminants can accumulate.

Two major organizations set hygienic design standards for equipment: the 3-A Sanitary Standards (in the U.S.) and the European Hygienic Engineering & Design Group (EHEDG). These organizations not only develop design standards for equipment but also conduct conformance audits of manufactured equipment against the standards. Subsequently, certificates and seals are issued for each piece of equipment. Certification involves inspection and testing to verify that the equipment meets specific criteria, thus ensuring it is easy to clean, minimizing contamination risks.

Layout

Designing food processing facilities requires careful consideration of both human and mechanical activity. The layout should utilize approved materials, provide ample space, and ensure smooth movement of equipment, personnel, and products. This minimizes risks to food safety and accommodates future expansion, as most facilities tend to undergo changes in product lines, equipment, capacity, or processes over time.

Pest exclusion is a crucial aspect of facility design. A comprehensive plan should address all potential entry points, including:

- Doors
- Air intake and exhaust vents
- Water lines
- Solid waste disposal
- Product intake and exit points
- Drains and sewage systems

To prevent flooding and rodent entry, consider building the facility at a slightly elevated level compared to the surrounding ground. Additionally, avoid having exterior doors open directly into production areas, and eliminate windows from these zones.

Loading docks require particular attention in design and maintenance. Having adequate space between

the ground and the dock entry is important not only for preventing pests but also for facilitating easy transfer of materials between trucks and the warehouse. The design should actively eliminate potential pest harbors, considering both visible pests like cockroaches, mice, and birds, as well as less readily apparent ones like small flies and drain fly larvae, which thrive in various moisture and temperature conditions.

Strategic placement of air curtains and adequate lighting can further deter pests and effectively manage traffic flow.

Components

While automation offers efficiency, equipment like electronic controls, switches, robots, and light fixtures can pose risks to worker safety and create cleaning challenges. To minimize these issues, it is crucial to plan equipment needs upfront. This way, entryways, enclosures, and transport systems can be designed to achieve the following:

- Minimized handling: Reduce the need for workers to physically interact with equipment during cleaning.
- Full accessibility: Ensure all equipment surfaces are easily reachable for thorough cleaning, utilizing tools such as hoses and cleaning stations.

Organizations like UL Solutions (formerly Underwriters Laboratories) and NSF International play a vital role in ensuring food safety. UL conducts conformity testing on individual components, products, or entire systems destined for food processing facilities. Both UL and NSF also offer audits that assess entire facilities and processes, helping to ensure compliance with safety and hygiene standards. Additionally, the audits test for conformity against standards for safety, efficacy, and cleanability.

Designing Out Hazards Through Infrastructure Design

When designing or modifying a food processing facility, it is essential not only to ensure that the facilities suit their intended purpose but also comply with legal requirements. For instance, companies in the U.S. should refer to the U.S. Code of Federal Regulations and relevant state food codes for specific requirements. Beyond legal requirements, hygienic design prioritizes protecting food from various contaminants, including:

- Biological agents (harmful microorganisms).
- Foreign material hazards such as glass, metal, plastics, or paints that, if not designed properly or are misplaced, can chip or crack from equipment or surfaces of the facility and enter the food. Additionally, facility design should ensure a secure enclosure that protects the food from filth, soil, animal hairs, and other extraneous items.
- Materials being used on surfaces or as part of the equipment and infrastructure, which should adhere to hygienic standards. Hygienic design should guarantee these do not dissolve or contribute to chemical hazards in the food. This includes ensuring that most surfaces are made of substances such as stainless steel, nickel, platinum, silver, gold, carbon, aluminum, chromium, or copper, and should be carefully selected based on the application and the types of detergents, sanitizers, or disinfectants that might be used in this specific operation.

Furthermore, relevant assessments may be carried out by government and city organizations to comply with building codes and local ordinances. These assessments aim to verify that the building, its site,

and associated traffic meet regulatory standards, such as the use of materials that suit the location and that meet or exceed local building codes; protection of processing lines and adjacent areas from unwanted elements like debris, pollutants in water and the air from other facilities or operations; building code compliance in conjunction with personnel safety (for example OSHA, Department of Labor, and the EPA) that includes ceiling heights, staircases, easements, effluent water, and the location and placement of chemical storage areas; and many other considerations that go into providing safe and hygienic facilities.

Conforming to Food Safety Standards

The Global Food Safety Initiative (GFSI) standards represent one of the most widely accessible sets of standards, offering globally aligned minimum requirements for food manufacturing facilities. Standards such as the British Retail Consortium standard (BRC), FSSC22000, Safe Quality Food (SQF), International Featured Standards (IFS), and others are benchmarked against the GFSI standard and regularly updated to maintain international alignment and calibration.

Choosing Materials

The materials used in construction and in utility piping must be carefully selected to ensure they are easily cleanable and resistant to chipping or damage. They should be made from smooth, non-absorbent materials. Different materials may be used for constructing process and utility systems in non-food contact areas compared to those in food contact zones. However, it is crucial that all materials resist cracking, chipping, flaking, and are free from coatings or paint that can lead to chips and flakes. Depending on the material in question, numerous ISO standards may be referenced, with manufacturing and quality control procedures varying considerably.

Continually Adapting and Improving Towards Sustainability

The drive to incorporate more sustainable materials into these applications offers an opportunity for standards to reassess the effectiveness of products or processes from the lens of sustainability and human health implications. This entails ongoing efforts to enhance standards and elevate the quality of manufactured products. Mitigating environmental pollution requires a long-term approach with far-reaching effects. It is essential for standards to keep up with risk assessment and foster the advancement of superior, sustainable products to prevent the gradual release of pollutants into the environment and the subsequent reintroduction into the food supply chain.

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- UL Solutions https://www.ul.com/
- NSF https://www.nsf.org/

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Exploring Globalization's Effect on Accreditation and Certification Practices Through Time

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-ABSTRACT-

This article provides a comprehensive exploration of globalization's impact on accreditation and certification practices—from their inception to the present day. It digs into the historical context of the first known accreditation and certification systems, tracing their evolution in response to the globalizing world. The study further investigates how globalization has influenced these practices, affecting their standards, procedures, and overall significance in various professional fields. Through critical analysis of data, the article presents a detailed overview of the current state of global accreditation and certification practices. It also projects potential future trends in this area, considering the ongoing dynamics of globalization. The article aims to provide a valuable resource for those interested in the intersection of globalization, accreditation, and certification.

Keywords: *Globalization, Impact, Accreditation, Certification Practices, Inception, First Known Accreditation, First Known Certification*

Introduction

In recent years, the winds of globalization have swept through not only economies and political systems but also the domains of accreditation and certification. As a reader, you might have observed this trend and pondered the driving forces behind it, or perhaps considered how it could impact you as a professional, employer, or policymaker. In this article, the aim is to demystify the topic by putting all the relevant aspects of globalization in accreditation and certification under the microscope and linking them to different perspectives.

Before venturing into the contemporary trends, it's essential to set the historical stage. The practice of certification can be traced back to the guilds of medieval Europe, which implemented a system of checks and evaluations to ensure their members possessed adequate skills for their trades. On the other hand, accreditation, specifically in the field of education, originated in the United States during the late 19th century. Accrediting bodies were formed to establish standards and ensure that individual institutions adhered to them.

Globalization has introduced a new dynamic to the fields of accreditation and certification, significantly altering their landscape. It fosters the universalization of standards, integration of economies, and a global approach to assurance in professional practices. As an example, you can now be granted a certificate for compliance of your management system in the Middle East, recognized by an authorized accreditation body in the United States. Such practices were unthinkable before globalization took root.

Examining the roots of these practices, the first known endeavors in certification and accreditation can be traced back to early professional societies of engineers and doctors in Europe and

North America during the 19th century. The drive to set standards and ensure proficiency within these professions marked a significant step forward. However, the concept of international recognition only emerged with the advent of globalization in the late 20th century.

To provide a statistical context, as per the data from the International Accreditation Forum (IAF), there are now 96 members globally, representing accreditation bodies from various countries and economies. This reflects the growing trend towards a global approach to these practices. As of 2019, certified organizations within IAF members numbered in the millions, a testament to the significant reach and influence of global accreditation and certification practices.

Globalization exerts a transformative influence on accreditation and certification. Standards are now universal, transcending geographical limitations, further fueling globalization. However, it's not without its downsides; cultural intricacies and regional compliance regulations often pose challenges, and a one-size-fits-all approach to standards might not always be suitable.

Yet, the promise of globalization in these practices is undeniable, and the trend towards global integration is compelling. It brings prosperity from wider market access, mutual recognition, and boosted competitiveness. With the ongoing technological advancements, we can only expect this trend to accelerate further.

Globalization and Accreditation

The influence of globalization on accreditation and certification practices is profound. With the emergence and expansion of globalization, organizations can no longer thrive solely within local or national markets. To remain competitive and innovative, they must extend their reach globally. This shift has been facilitated by globalization and is evident in accreditation and certification practices.

For instance, with the advent of international bodies such as the World Trade Organization (WTO) and World Bank (WB), standards and practices are established across borders, making unified accreditation and certification practices a reality.

The International Organization for Standardization (ISO), established in 1947, was one of the first organizations to take a global approach to conformity assessment, creating standards that could be used universally, breaking down technical barriers to global trade.

Statistics and Facts

According to the World Trade Organization, the number of internationally recognized certifications has seen exponential growth over the years. Moreover, the McKinsey & Company report of 2017 revealed that more than 70% of professionals believe that certification leads to higher earning potential, signifying the importance of globally recognized certifications in the professional world.

Globalization is not merely an economic event, it is a transformational force, changing the way we accredit and certify. In this ever-evolving landscape, the importance of staying updated and informed cannot be overstated.

As we proceed further into this new era of global interconnectivity, the role of accreditation and certification continues to gain relevance. Serving as a proof of competence and a standard of quality assurance, the importance of this practice remains glaringly evident.

Let's delve deeper into this realm, dissecting how the regulation and validation processes are adapting to the dawn of globalization. Traditional methods of accreditation and certification involved extensive paperwork and manual verification. However, as technology saturates every aspect of our lives, these laborious procedures have become obsolete. The norm is now digitized, expedited, yet rigorous certification and accreditation practices.

The new era calls for harmonization in accreditation and certification standards across the globe. It entails ensuring consistency, eliminating any disparity in standards between countries, and ensuring that a certified entity or professional in one part of the world is bestowed the same regard and opportunities anywhere else. The embrace of standardized global accreditation and certification maximizes opportunities, endorses professionalism, and enhances the universality of skills recognition.

Yet, it is essential to remember that this globalization of accreditation and certification isn't without its challenges. The disparities in economic development, educational institutions, cultural preferences, and technological capabilities around the globe can make the implementation of standardized practices a daunting task. Bridging these gaps will require significant efforts, collaborations, and investments.

As a community, we must collaborate and establish shared aspirations for global standards

that strike a balance between flexibility and uniformity, accessibility and rigor, and inclusivity and competitiveness. As the world navigates this exhilarating road ahead, the question remains: Are we prepared for globally standardized accreditation and certification?

Fast-forward to the 21st century, and we see that globalization has propelled both accreditation and certification practices toward a borderless world. Nowadays, it's common for professionals to seek international recognition through globally recognized accreditations and certifications. This paradigm shift has, in return, bolstered international cooperation among accreditation and certification bodies.

According to the World Bank, in 2018, approximately 85% of developing countries included provisions in their National Qualification Frameworks the intention to recognize foreign qualifications. Similarly, the International Accreditation Forum (IAF) reported in 2017 that, among its 78 members, cross-frontier accreditation activities had increased by 48% compared with the data from 2007.

Considering the statistics provided by these professional bodies, it's evident that globalization has disrupted the traditional boundaries of accreditation and certification. It suggests a shift toward global validity and credibility, making international recognition not an option but a necessity in this globalized world.

As we prepare ourselves for a future that leverages globalization in these practices, we must align our collective efforts in setting a common global standard. A standard that ensures rigor, accessibility, and inclusivity, while fostering competitiveness. Are we prepared to ride the tides of this change?

Jumping forward a bit in the quest for understanding, let's explore the critical role that globalization plays in certification practices. In the past, certification usually revolved around national standards and regulations. However, with firms extensively competing on a global platform, the boundaries have expanded. Today, certification has assumed a larger role that encompasses international standards, aspiring to maintain consistent quality across the globe and in every industry.

As globalization has sunk its teeth deeper into our systems, accreditation and certification bodies started to recognize the undeniable necessity to adopt globally recognized standards. The purpose? To ensure that services, products, and systems are safe, reliable, and of a good quality—regardless of the location where they are made or the market into which they are sold.

These international standards envelop various areas that range from technology and safety to the environment, helping companies to minimize errors, improve productivity, and enhance customer satisfaction. The correlation between certification practices and globalization was thus born, creating a harmonious system of standards that is recognized worldwide.

But how exactly does the whole system work? To put it in simple terms, upon applying for accreditation, a professional or a company must demonstrate competence, impartiality, and capability. By complying with internationally recognized standards, they ensure that they are tested, assessed, and certified based on the same benchmarks globally. Such an approach not only rationalizes processes but also reassures stakeholders that products or services are of a standard quality, whether they are made in Chicago or Shanghai.

In hindsight, this globalization trend in accreditation and certification practices has created a competitive advantage. It breaks down technical barriers to trade, boosts user confidence, and sets a level playing field. No more will geographical factors play a role in assessing the quality of a product or service. No matter where you are, the standards are the same worldwide.

Thus, the marriage of globalization and accreditation and certification practices promises a bright future, one that values quality above all, regardless of the region of origin. It's a promising path to global unity, breaking down barriers, creating common ground, and collectively striving towards the shared goal of worldwide quality.

Envision a world where isolated pockets of knowledge no longer exist, where global standards ensure quality and competency across borders. This isn't a far-off dream; it's our reality in the making. The integration of globalization with accreditation and certification serves as a cornerstone in constructing this universal language of quality on a global scale.

Thanks to the magic of the worldwide web, we're more connected than ever before. Technology allows the exchange of knowledge and ideas from one side of the globe to the other in mere seconds—and it's in this shifting landscape where cross-continental accreditation and certification gain their power.

Picture, for instance, a cardiovascular surgeon from Japan sharing best practices with a peer from Germany—it's tangible proof of our joined pursuit of universal health standards. When we certify that a professional has met established standards, irrespective of their geographical location, we level the playing field. We create a global community of experts, each working towards their shared goals.

However, the path towards globalizing accreditation and certification is not without challenges. Differences in governmental policies, legislation, and localized industry standards can present obstacles. But as we navigate these issues, we remain steadfast in our commitment to uphold the highest quality standards.

Looking into the future, a seamlessly interconnected world seems more attainable. Globalized accreditation and certification open doors to greater collaboration, recognition, and even competition—fostering a professional landscape deeply rooted in quality and driven by a devotion to continuous improvement.

So, let's unite under the banner of universal quality standards. It's not just about raising the bar; it's about ensuring the bar is the same for everyone, regardless of their geographic location. As a professional or someone aspiring to be one, wouldn't you want to be part of this global revolution?

International borders are no longer impenetrable barriers but rather porous membranes allowing for the fluid movement of people, ideas, and practices. This means that the quality of education, training, or professional qualifications obtained in one country can significantly impact the opportunities available in another.

Accreditation and certification, therefore, provide a form of standardized "currency" recognized worldwide. For a college or university, accreditation adds prestige, signaling the quality and value of its programs. For professionals, certification gives portability, allowing qualifications to be recognized beyond national borders.

Yet, the soaring numbers of both accredited institutions and certified professionals also imply increased competition and more rigorous benchmarks to meet. The need for individuals and institutions to differentiate themselves in an increasingly crowded global market has never been greater, and having the right accreditations and certifications plays a critical part in this.

However, globalization, while opening doors and creating opportunities, also brings about certain challenges to accreditation and certification processes. With varying standards and practices across countries, how do accreditation bodies ensure a consistent, fair, and relevant benchmark? How do individuals and institutions navigate the complex web of certifications available globally? These questions prompt a deep and intricate discussion about the role and value of accreditation and certification in a global context—a discussion that continues to evolve in tandem with our globalizing world.

The forces of globalization have fundamentally shifted the dynamics of the business world and influenced how accreditation and certification practices are perceived and executed. These global dynamics have made certification, recognition, and quality assurance even more crucial. Achieving global acceptance has become a massive challenge in the pursuit of uniformity and consistency in accreditation practices. As a result, it's evident that accreditation institutions face a pressing issue of harmonizing the standards globally to ensure credibility, transparency, and recognition.

The International Organization for Standardization (ISO) serves as the custodian of standardization, providing a clear framework for certification. ISO allows businesses to demonstrate their adherence to international standards, thereby fostering confidence and facilitating global trade. However, with more than 21,000 standards in existence, it is clear that globalization has influenced the growing complexity and range of ISO certification. Nonetheless, this allows businesses across diverse industries to meet the specialized needs of their global clientele in a more consistent and standardized manner.

Moreover, the internationalization of industries and frequent cross-border activities have prompted the need for institutions to rethink their accreditation practices. Educational institutions, in particular, have

felt this impact significantly as they evolve to meet the diverse expectations of international students. The Association to Advance Collegiate Schools of Business (AACSB), for instance, recognizes the need for harmonizing accreditation amidst globalization. AACSB has worked tirelessly to ensure that accreditation practices are globally accepted and recognized, further solidifying the vital role played by accreditation in an increasingly global context.

In conclusion, the effects of globalization on accreditation and certification are broad, deep, transformational, and undoubtedly here to stay. This impact highlights the importance of aligning accreditation standards and practices with global trends, emphasizing the crucial role that major stakeholders must play in standardizing and harmonizing these practices to cater to an increasingly globalized world.

Latest Trends in Accreditation and Certification Due to Globalization

In today's world, the trend towards global accreditation and certification is becoming more prominent. The broadening scope of globalization has had a significant impact on various sectors, prompting major accrediting bodies and organizations to expand their reach internationally.

This trend towards global accreditation reflects an increased recognition of international academic degrees and qualifications. It is becoming essential for institutions to gain international accreditation to ensure that their qualifications are recognized worldwide. This, in turn, can lead to a greater number of opportunities for their graduates in the increasingly global job market. Gaining momentum as well is the development of international certification programs, which have been shown to significantly boost productivity and sales, particularly in developing countries. Businesses are realizing that obtaining globally recognized certifications can enhance their competitive edge, improve their reputation, and potentially boost their market share.

It's also worth noting the growing interest in collaborative efforts among national organizations in support of the global accreditation concept, a trend that is being facilitated by technology and the continued push towards a more interconnected world. This cooperation among national organizations is widely deemed as a critical building block for establishing trust and reciprocal recognition of accreditation systems.

Furthermore, the shift towards more complex and specialized accreditation requirements highlights another key trend. As industries continue to evolve and become more intricate, the need for more specific knowledge and skills increases. In response, accreditation programs worldwide are beginning to implement more complex and specialized standards to ensure that those they are accrediting have the necessary skills and knowledge to meet the demands of the evolving job market.

The ongoing globalization has triggered significant changes in accreditation and certification practices. The latest trends reveal a movement towards global standards, mutual recognition of accreditation systems, more complex and specialized requirements, and the increasing importance of collaborative efforts. Bearing witness to these trends, it becomes evident that the importance of global accreditation and certification practices to ensure quality and universal recognition is only poised to increase in the future.

International Collaborations and Partnerships in Accreditation and Certification

As the world continues to shrink into a global village, the landscape of accreditation and certification practice is evolving to keep pace with international standards. This realization has led to a surge in global partnerships and collaborations. These international alliances open up opportunities to bring worldwide expertise together and harmonize accreditation standards.

The International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC) have been instrumental in shaping the global uniformity of accreditation systems. Their comprehensive approach has contributed significantly towards creating a harmonized ecosystem for certification and accreditation processes that transcends national borders.

IAF is a global association for Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessments. It provides a platform that encourages and facilitates cooperation among its members and stakeholders. By enabling the balanced use of accredited conformity

assessments worldwide, IAF plays a pivotal role in endorsing the equivalence of national or regional accreditation systems.

Meanwhile, ILAC functions primarily in the field of laboratory and inspection accreditation. It works to establish and promote mutually recognized arrangements among accreditation bodies. These schemes facilitate acceptance of test and calibration results, thereby smoothing international trade and encouraging the use of accredited services globally.

IAF and ILAC have together developed a network of mutual recognition agreements that enhance trade by promoting acceptance of accredited test, certification, calibration, and inspection results worldwide.

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Verifiable and Traceable Product Conformity Data

By Brett Hyland, UN/CEFACT Project Lead | DOI: 10.55459/IJCA/v3i1/BH

-ABSTRACT-

The alignment of digital product passports, digital trade single windows, product sustainability legislation, and the pervasive digitalization of trade-related documents marks a critical juncture in the transmission of product conformity data. Simultaneously, the evolution of accountancy standards is prompting fresh requirements for disclosing sustainability performance, emphasizing the need for dependable and traceable supplier sustainability data. This paper delineates the endeavors of the United Nations Centre for Trade Facilitation and E-business (UN/CEFACT) in developing an interoperable framework to incorporate product conformity data into digital trade processes.

Keywords: *product conformity data, digital trade processes, UN/CEFACT draft specification, conformity assessment community, sustainability performance, digitalization of trade-related documents, CAB outputs, supplier sustainability data, verifiable assurances, international engagement*

Introduction

Digital product passports[1], digital trade single windows[2], product sustainability legislation[3], and widespread digitalization of trade-related documents[4, 5] are all converging in ways that represent an inflection point for the exchange of product conformity data. At the same time, accountancy standards[6, 7] are evolving to drive new requirements for the reporting of sustainability performance, requiring access to supplier sustainability data that is both reliable and traceable. This paper details recent efforts by the United Nations Centre for Trade Facilitation and E-business (UN/CEFACT) to produce an interoperable framework for the integration of product conformity data within digital trade processes.

Product Conformity Data Exchange and UN/CEFACT

Conformity assessment processes are a key mechanism for providing global product assurance. However, the data resulting from these processes is still largely paper-based or in electronic formats that do not facilitate easy data processing, primarily due to the lack of agreement on commonly used data elements and definitions. This, in turn, creates challenges in determining the status of certificates and their linkages with physical product supply, as well as the authority under which such certificates were issued[8]. While these matters represent longstanding problems in relation to product quality and safety, the emergence of regulatory drivers in the sustainability space brings new urgency to the matter. Addressing this problem is central to many government and private sector initiatives, including those aimed at achieving objectives aligned with UN Sustainable Development Goals.

In the case of sustainability claims, the standard of evidence needed to support such claims may already be increasing due to a rise in so-called 'greenwashing' prosecutions[9] as well as emerging laws regarding corporate accounting for climate performance. In the absence of supply chain traceability, sustainability certificates alone may not be sufficient to give comfort to company directors. In mid-2022, a UN/CEFACT work program commenced with the objective of exploring the prospects for verifiable and traceable product conformity data. This work has centered around the development of an electronic protocol designed to deliver digitally verifiable assurances for conformity data, while recognizing that paper-based certificates, including PDFs, will continue to exist into the foreseeable future.

A UN/CEFACT Business Requirements Specification[10] was published in July 2024. This specification describes a set of digital elements and linkages to enhance utility of data issued by conformity assessment bodies (CABs), supplementing non-digital certificates that may be provided. Specifically, the presence or absence of elements exposed during discovery of conformity data provides distinct insights, including any verifiable connection to the physical product of interest, the status of an issued certificate, and the authority under which it was issued (such as an accreditation authority). The concept does not replace any of the existing governance structures within the conformity assessment community, but simply proposes a means for adapting these to a digital context. The

protocol is seen as complementary to numerous other digitalization initiatives already underway within the conformity and accreditation sectors, such as the Digital Calibration Certificate[11] and the emergence of electronic accreditation seals[12].

The approach recognizes the role of CABs as the valid custodians of the data that they produce and their authority over any revisions to such data. At the same time, the obligation of CABs to respect and implement the confidentiality requirements of their customers remains central to the work. The described approach does not preclude other concurrent processes for conformity data exchange, so the adoption of this model by individual parties may occur on any timeframe without disrupting existing trade provisions. Also, since the provision of conformity assessment data is a relatively self-contained aspect of trade, it is intended that the approach could be adopted as a component of any comprehensive digital trade process. The ideas put forward have found fertile ground in related United Nations initiatives, most notably the United Nations Economic Commission for Europe (UNECE) Recommendation #49 - Transparency at Scale[13].

As an important caveat to the proposed protocol, in cases where legislative processes exist for establishing product conformity within a jurisdiction (such as CE Marking[14]), this work only seeks to describe the exchange of CAB outputs up until the point in the value chain at which a regulator, or other authority, takes control of product conformity. Any further exchange of CAB outputs beyond that point would occur in a manner defined by the legislator. Outside of the defined jurisdiction, the proposed protocols may still have relevance for the purpose of export (that is, to address overseas market requirements). Additionally, even within the defined jurisdiction, products may still be subject to voluntary conformity assessment processes that relate to product attributes not covered by legislative approvals.

Suppliers may see increasing pressure from their customers to provide higher standards of conformity evidence, commensurate with corporate reporting obligations as well as to support opportunities to generate pricing premiums for well-substantiated green claims. CABs or scheme owners may determine that the described data model can address the needs of their customers by providing a reliable and safe mechanism for data discovery. Parties already acting as hosting platforms for conformity data (e.g., some scheme owners and verifying bodies) could deliver these new provisions on behalf of CABs, serving a complementary purpose to existing hosting activities. Some CABs may prefer such parties to act on their behalf in implementing these provisions.

Conclusion

To enable integration of product conformity data with digital trade processes, there is a need to address short-term and medium-term trade digitalization demands, while providing a transition pathway towards full digitalization on a timeframe that may be more manageable for CABs. It is hoped the UN/CEFACT specification will generate constructive international discussion among key quality infrastructure institutions, relevant representative bodies, and the wider conformity assessment community regarding the merits of such an approach. Such international engagement and dialogue is important in helping to define and shape the role of conformity assessment in a future digital trading environment.

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Food Safety: An Essential Aspect of Due Diligence

By Lisa Jo Lupo, Director of Communications, The Acheson Group | DOI: 10.55459/IJCA/v3i1/LJL

-ABSTRACT-

The investment in a food company is an investment in its brand and consumer trust. Ensuring a solid investment means including a full food safety assessment and inspection in the pre-investment due diligence. This assessment focuses on evaluating the company's regulatory compliance, operational practices, and reputational standing to identify any risks that could later jeopardize or weaken the investment. Because due diligence is a standard practice for the successful investor, it behooves the food company being considered for investment to conduct its own pre-transaction due diligence. Both the investor and investee due diligence should be conducted by a person with extensive food safety experience and expertise, which may warrant the employ of a qualified food safety consultant. With the purpose of a due diligence being to ensure a safe and financially solid buy, the food safety assessment of a food company is an uncompromisable aspect of the pre-investment process.

Keywords: *Food Safety Regulation, Due Diligence, Food Safety Certification, Internal Audit, Food Safety Modernization Act (FSMA), Investment, Merger, Acquisition, Food & Drug Administration (FDA), Risk Mitigation*

Introduction

On January 4, 2011, President Obama signed the Food Safety Modernization Act (FSMA) into law. Although there had, of course, been food safety laws prior to this, FSMA was heralded as the most sweeping reform of U.S. food safety laws in more than 70 years. Its primary modernization was the transition from foodborne illness reaction to food contamination prevention—now mandated by law and enforced by the Food & Drug Administration (FDA), which oversees the safety of about 80% of the U.S. food supply.

Although FSMA has been in place for over a decade, the food industry is still adapting to some of the more complex aspects of the rules, even as the FDA enforces them with inspections, citations, warning letters, fines, and even closures. Even with the modernization and enforcement, however, the regulations provide only the minimum parameters for food safety, with quality businesses going well above the rules to keep their products safe. This not only protects consumers but also fosters more efficient and streamlined operations, high-quality products, and satisfied customers. Consequently, companies with strong food safety practices are likely to achieve greater profits and future success.

On the other hand, the lack of a strong food safety culture in a food establishment, even when the company is technically following regulations, can lead to serious food safety issues resulting in recalls, consumer illnesses, and even deaths.

Thus, when investors are seeking involvement with a food company, these key aspects of the business should be assessed. From the perspective of the seller (sell-side), the knowledge that a reputable investor will conduct food safety due diligence should be the impetus for a food business seeking investment, acquisition, or merger to conduct its own internal due diligence prior to seeking such investment. This proactive measure enables it to address any potential problems that may emerge down the road.

What Is Food Safety Due Diligence?

Due diligence is the comprehensive appraisal of a business undertaken by a prospective buyer or investor to assess the business' assets and liabilities and evaluate its commercial potential. It is about assessing the pros and cons of the company being considered to determine if it is advisable to move forward with the investment. Thus, food safety due diligence focuses on the assessment of the company's processes, procedures, and operations related to food safety to identify any "red flags" (i.e., food safety risks) that could later jeopardize or weaken the investment.

Food safety risks can be broken down into three key areas of concern: regulatory, operational, and reputational, all of which must be considered in a due diligence investigation. Because each involves different risks, with some overlap in the assessment process, the food safety due diligence can be quite complex, but it is critical in making a sound investment.

Whether the due diligence is being conducted by the food establishment, the investor, or an external consultant, the process will be similar. There are, however distinct differences in each, as noted below.

Food establishment internal due diligence (sell-side) serves the purpose of providing a true and accurate portrayal of the company's food safety practices, programs, and culture. This ensures that everything is in order and allows the establishment to demonstrate that it is a good buy. Internal due diligence enables the food establishment to prepare for investor due diligence, but it will only be helpful if it is objective and thorough. Do not try to hide or gloss over anything; a good investor due diligence will uncover it and it could disrupt the entire transaction. Rather, by being diligent and proactively preparing prior to any transaction, a food company can demonstrate its readiness for investment, build credibility with potential investors, and facilitate a smoother and more efficient due diligence process. Going through the process also enables the company to ensure it has all the information, records, and documentation that will be requested, and have them readily available for the potential buyer. It provides the ability to identify and address potential issues, discrepancies, or gaps in advance, then proactively mitigate risks, resolve concerns, and strengthen the position of the company.

Even beyond proving anything to a potential buyer, a due diligence can make the business better, as the review enables a company to ensure it is compliant with all applicable regulations and standards, update any lagging practices, and make any corrections before issues arise. Conducting the pre-investment due diligence demonstrates a commitment to food safety and responsible business practices, putting the company right where it needs to be to be considered investment grade.

Investor due diligence (buy-side) plays a critical role in the investment process of a food establishment. While the internal due diligence conducted by the food establishment can enhance its attractiveness to potential investors, investor due diligence is more than a benefit—it is a necessity. This diligence, especially regarding food safety, is essential due to the many areas of potential risk inherent in investing in a food company. It requires special attention focused on both the company's food safety practices and regulatory compliance to ensure there are no surprises or "red flags" discovered after the investment is made.

To that end, the food safety due diligence should encompass various components, including document review, facility tours, management and worker interviews, and potentially, product sampling. But, above all, those doing the due diligence need to understand exactly what is required for food safety, what makes a company a quality producer, what should be looked for in the document review and tour, and what questions to ask. For example, there can be unexpected capital expenditures related to an aging food plant that can lead to financial and reputational risks due to recalls.

Food safety incidents can have significant financial repercussions, including the cost of recalls, legal fees, and a decline in sales. By assessing food safety practices before investing, investors can better understand the potential financial impact on their investment. Developing an in-depth, holistic assessment of all hazards and risks, along with an understanding of the food company's preparedness for and management of these, is critical to making a sound investment.

A robust due diligence process will allow the investor to make an informed decision about a potential purchase. Understanding the risk and any necessary future investment will help the investor plan for capital expenditure and can even be leveraged during negotiations.

Employing an external consultant. Determining the advisability of employing an external consultant to conduct or assist with your food safety due diligence can be answered by one simple question for each stakeholder category:

- *For food establishments:* Can you look at your facility and processes with critical eyes and be completely impartial in evaluating your food safety?
- *For investors:* Do you have a full understanding of and expertise in food safety, its risks and regulations?

Working with a qualified food safety consultant who has experience in due diligence will bring a new set of expert eyes into the operation to see gaps that can be easily overlooked by an internal team and unrealized by a financially focused due diligence team. It enables a more critical look at the processes and operations from an independent, objective perspective. Additionally, an experienced food safety consultant will have worked with many food companies in various industry segments, enabling them to bring fresh insights on potential food safety risks and opportunities for risk management. Their expertise will enable them to compare the company's food safety performance against industry benchmarks and best practices to help the investor gauge the relative strength of the company's food safety program.

Food Safety Due Diligence Process

So, how is food safety due diligence conducted? As a general rule, it involves identifying regulatory, operational, and reputational hazards, and risk mitigation through document reviews, on-site inspections, staff interviews, gap assessments, and the issuance of a final report containing overall analysis and recommendations. The final due diligence report should include both the positive and the negative aspects—identifying risks and non-compliances, while also recognizing good (or great) practices and programs. The following are key areas of focus for each of the three hazards:

Regulatory. Although 80% of all food in the U.S. is subject to FDA governance, there are other regulatory agencies and standard bodies to which food companies are held. For example, meat, poultry, and eggs are subject to USDA regulations, while food service and retail companies are primarily answerable to state health inspectors, in alignment with the FDA Food Code. Within these realms, however, there are further differentiations. For instance, FDA's FSMA regulations include specific rules for produce safety, human foods, and animal foods; imported foods or ingredients undergo additional oversight before entering the country; seafood and juice are required to implement Hazard Analysis Critical Control Point (HACCP) systems; and foods intended for infants or other vulnerable populations have highly specific requirements. Thus, it is critical that those conducting due diligence know and understand all regulations to which the particular company is liable.

In addition to regulations, the food industry has standards and certifications that are often required by their downstream customers. The most common of these is the Global Food Safety Initiative (GFSI), to which a company can obtain certification through different schemes. A high score on a GFSI certification may indicate a quality company that is likely to be compliant with all applicable laws. However, sometimes GFSI audits are questionable in their accuracy. Therefore, it is not advisable for an investor to rely solely on a GFSI audit as its due diligence. A company required to have a HACCP plan can also obtain HACCP certification through third-party accreditation, further demonstrating its qualifications. In the food service arena, most states require food handler certifications, with many also requiring a certified food protection manager to be onsite whenever food is handled.

Documentation should also be assessed for the company's management of its supply chain, ensuring that both regulations and best practices are followed, and showing evidence of a full traceability program should a recall be required. Understanding the company's supply chain and the sources of its raw materials are critical to assessing potential risks, as issues in the supply chain can directly impact food safety.

Regulatory assessment is a matter of document review of current and archived records related to the company's supply chain, processing practices, and distribution. The review should be conducted by a person who has full knowledge of the requirements for the specific company and food. Ideally, this document review should be complemented by an on-site visit to determine whether the company is operating in a regulatory compliant fashion. The combined review should provide a full picture of the company's regulatory compliance, identifying any instances of non-compliance (e.g., FDA inspection observations, warning letters, recalls, etc.). While these should be investigated, they do not necessarily provide cause for current concern if they have been

fully resolved with the root cause determined and corrective action taken.

Operational. The document review will also be a part of the operational assessment of the food company, with some regulatory considerations as well. For example, FSMA requires that food companies develop and implement a supplier approval program, a foreign supplier verification program (where applicable), and a food safety plan for internal operations. While the regulatory assessment needs to confirm that these meet all requirements, the operational aspects should also be assessed to determine if they go beyond the basics to ensure effective protection of all products. Additionally, training is a critical aspect of food safety, and records should reflect ongoing food safety training for all applicable employees.

Another key area of assessment in the operational review involves the company's controls against cross-contamination (e.g., separation of raw from ready-to-eat foods and ingredients) and cross contact (e.g., separation of allergens from non-allergen foods and ingredients). Examine the company's recall plan—assess their preparedness for a recall or other crisis; ascertain if a response plan is in place; determine if they have conducted mock simulations to ensure all is in order. Review the packaging line—confirm that all materials are food grade; identify any potential for finished products to be contaminated before packaging. Additionally, check if the company repossesses any packaging standard certifications required by customers.

Operational due diligence involves a combination of record review and facility inspection. The reviewer should conduct a walkthrough of the plant, following the food processing steps to ensure that the facility is, in fact, implementing all the food safety practices that its records state it is. Identify potential food safety risks, such as sanitation deficiencies or structural defects that could lead to contamination or indicate any intentional adulteration vulnerabilities. This also presents an opportunity to examine the products and their testing procedures in the in-house and external labs, and to investigate anything that seems "off" for any reason.

Attention should also be directed towards the workers as you navigate the facility. Observe whether they are diligently carrying out their duties and adhering to food safety protocols. Assess whether there is evidence of a food safety culture throughout the company—i.e., is food safety ingrained in the behaviors at all employee and management levels? A company-wide culture of food safety has been recognized as an integral component of effective food safety management. It is not only considered a "good to have," but it is also required by GFSI and included in FDA inspections.

Reputational. Any concerns found while considering the regulatory and operational due diligence can also significantly derail a company's reputation, leading to decreased customer loyalty and sales, and quickly impacting the bottom line. In today's digital age, where communication is accelerated through the internet's capabilities for both media and social media, reviewing consumer complaints should not be neglected. Although the old adage "one person tells 10 people who tell 10 people" now spreads exponentially online, complaints should not automatically give a company a black mark. Rather, they should be judged and weighed based on the number of complaints, the reasons behind them, and the company's resolution.

Risk Mitigation

Once the assessment is completed, the gathered information can be amalgamated, and a comprehensive due diligence report developed. The report should include a compilation of the findings, an analysis of the data, identification of risks and opportunities, and an overview of key aspects of the company's food safety—both positive and negative. It should also summarize the due diligence process, any legal and financial considerations relevant to food safety, and any other pertinent information.

If the due diligence was undertaken as an internal review prior to soliciting investment, steps should be taken to correct any deficiencies and mitigate identified risks. If conducted by or for an investor, the report should be diligently reviewed by all stakeholders to gain a thorough understanding of the potential benefits and risks associated with the investment to make an informed decision. A due diligence conducted by a qualified food safety consultant should always include recommendations regarding the feasibility of deficiency correction and risk mitigation, as well as an assessment of the strength of the company's food safety. It is only through of all these steps that a due diligence will enable an investor to make a well-informed decision and mitigate potential challenges that may arise in the future.

Conclusion

An investment in a food company is an investment in its brand reputation and customer trust, both of which a food safety crisis can dispel in an instant. Thus, the food safety assessment is a critical and necessary aspect of any food company due diligence.

While the food safety due diligence process will generally follow the process outlined here, every food product and plant process is unique. Therefore, no two due diligence assessments will be exactly the same, and the specifics provided are just examples of the many areas that need to be considered. It also is important to remember that the identification of risks does not necessarily make the investment a bad buy. Instead, it provides insight into areas where improvements should be made and risk mitigation implemented. Addressing these areas may ultimately strengthen the company's position, making it a strong buy.

Author Biography

Lisa Jo Lupo has more than 30 years' experience working in and with the food industry, with a key focus on food safety and quality communications. Currently the Director of Communications for The Acheson Group (TAG), Lupo was previously the Editor and Lead Writer for Quality Assurance & Food Safety (QA) magazine for 15 years. Having gotten her start in the industry with Ecolab Pest Elimination, she went on to found LJ Writing Services in 2003, which gave her her start at QA in 2004 and TAG in 2010. Lupo is a chapter author of Food Traceability (Springer, 2019) and editor of multiple books, including the PCT Guide to Commercial Pest Management. She holds certificates in Preventive Controls Qualified Individual in Human Food (PCQI) and Foreign Supplier Verification Program (FSVP), has completed the PAACO/AMI Meat Plant Welfare Auditor Training Course, is a member of IAFP, and is a Past President of the Twin Cities Chapter of ASBPE. Lupo has spoken on industry communication, evolutions, trends, and expectations at the Food Safety Summit, Sigma Xi Science Society Food Safety Symposium, Southern California Food Industry Conference, GMA Science Forum, and corporate conferences.

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The AOAC Africa Laboratory Performance Benchmarking Program

By the AOAC Africa Scientific Committee
The AOAC Scientific Subcomittee members include: Yolande Ake-Assi, Augustus Babarinde, Talatu Ethan, Dr. Maria Fernandes-Whaley, Owen Fraser, PhD, Cheetham Lawrence Mingle, Ephram Moruke, Michael Ndlovu, Rosemary Njeri Nganga, and Dr. Liberty Sabanda

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-ABSTRACT-

AOAC AFRICA has done extensive work to establish the state of analytical capacity on the continent and to make practical remedial recommendations. The most recent iteration of its Laboratory Performance Benchmarking Survey (LPBS), in which 38 laboratories from eight countries participated in a series of six tests to assess the accuracy and reliability of the participating laboratories' results, revealed some concerning trends:

- Nearly half of laboratories testing for aflatoxins in peanut slurry did not pass.
- 75% of those testing for aflatoxin in maize did not pass.
- On average, up to half the testing for vitamins in fortified maize did not pass.
- Evidence of inappropriate result sharing between laboratories undergoing accreditation.

Keywords: *Analytical capacity, Food safety, Aflatoxins, Laboratory performance benchmarking survey (LPBS), AOAC Africa, ARSO, Foodborne illnesses, Conformity assessment, African Continental Free Trade Area (AfCTA)*

Introduction

AOAC Africa Section has continued consolidating its emerging partnership with the African Organisation for Standardisation (ARSO) throughout 2023 to develop analytical methods suited to the continent's most widely consumed foodstuffs. At the same time, AOAC Africa—which represents the continent's analytical science community, working in conformity assessment and food safety laboratories all over the continent—has warned that a quantum leap in analytical capacity investment is needed if Africa is to resolve its food safety challenges and meet its food security need and international and continental agrifood trade ambitions.

Partners' Views

AOAC Section President Mrs. Winta Sintayehu described the ARSO partnership as a significant step in helping the continent achieve the objectives of the African Continental Free Trade Area. "It might seem hard to believe, but until recently, there were hardly any testing methods for the most commonly consumed African foodstuffs. This is especially concerning as the African Continental Free Trade Area (AfCFTA) really gathers pace, because the testing methods being used aren't designed for the specifics of African foods. As we end the African Union 2023 theme, 'Year of AfCFTA: Acceleration of the African Continental Free Trade Area Implementation,' we believe it's high time for action in this area, which is why we have been hard at work with ARSO on a method to test for contaminants and nutritional contents in cassava. The standards will improve the safety and quality of cassava and cassava products."

According to ARSO Secretary General Hermogene Nsengimana, the new method is a welcome development and will open the door to much-needed collaboration. "If we are going to test conformity in our indigenous foods reliably, we need testing methods that are fit for purpose, so that wherever we sell them—domestically, elsewhere in Africa, or beyond—we can be assured of their safety and quality. This way, African-developed analytical methods will ensure that African foods can compete for quality and nutritional value across the continent and across the world. This is a significant step on ARSO's path toward our goal of 'One Standard One Test Accepted Everywhere.' We are delighted with our collaboration with AOAC and believe this will be the first of many such testing methods specific to our staple African foods."

Continuing, Winta Sintayehu said, "AOAC Africa has a proven track record in capacity building programmes in recent years. This partnership with ARSO complements existing programmes with laboratories

and analysts aimed at closing some of the knowledge and infrastructure gaps in the local and regional context. These collaborations not only bring marked improvements in public health and contribute to reducing the 137,000 annual deaths in Africa from foodborne illnesses, they also support Africa to fulfill its agrifood trade potential. The partnership with ARSO is very exciting, and it represents the practical steps our community is taking to make Africa's food safe and improve laboratory capacities. But as we keep on moving forward, there is much more to be done, and we call on governments, the international community, and other stakeholders to join ARSO and AOAC Africa to prioritise investment in food safety and conformity assessment analytical capacity."

The Africa Section has done extensive work to establish the state of analytical capacity on the continent and to make practical remedial recommendations. The most recent iteration of its Laboratory Performance Benchmarking Survey (LPBS), in which 38 laboratories from eight countries participated in a series of six tests to assess the accuracy and reliability of the participating laboratories' results, revealed some concerning trends:

- Nearly half of laboratories testing for aflatoxins in peanut slurry did not pass.
- 75% of those testing for aflatoxin in maize did not pass.
- On average, up to half the testing for vitamins in fortified maize did not pass.
- Evidence of inappropriate result sharing between laboratories undergoing accreditation.

Some of the main identified root causes for the results included unsuitable storage, poor physical infrastructure, and lack of competence among laboratory analysts (not adequately trained) — all of which point to a lack of investment and resources.

AOAC Africa is currently supporting laboratories where funding can be mobilised. Unfortunately, there is increasingly concerning evidence that resources remain unavailable or limited.

Summary

Summing up, Winta Sintayehu said, "We, Africa's analytical scientists, conclude that significant work and resources are needed to fill the very significant physical and human capacity gaps that have been identified. We are already engaged in partnerships to develop analytical methods specific to African raw materials, which did not previously exist. And we are concluding further partnerships to build laboratory and analytical staff capacities across various countries. These are all a good start, but they're not enough. Our community calls for additional support from intergovernmental organisations, member state governments, and private sector partners, to support this essential work, with AOAC Africa as the professional technical support resource."

About AOAC International Africa Section

AOAC INTERNATIONAL Africa Section is a leading regional professional scientific association, building confidence in analytical results. It is a not-for-profit organisation based purely on the active volunteer work of scientists and like-minded stakeholders, dedicated to advancing and promoting knowledge and best practice in analytical science in the region. Currently there are 300 active members in 46 countries. The Section aims to achieve its goals through collaboration, training, and education; analytical methods development and harmonisation; the extension of the scope of official methods (to include indigenous foods where required); and to serve as an independent, impartial scientific advisory body.

About ARSO

ARSO was formed in 1977 with the principal mandate to harmonise African standards, conformity assessment, and procedures to reduce technical barriers to trade and, therefore, promote intra-African and international trade as well as to enhance the industrialization of Africa. ARSO is a member intergovernmental organisation with 43 members in Africa as of December 2022. As of February 2023, ARSO has 87 technical committees and has achieved 1,651 harmonised African standards.

Application of ISO 16140-3:2021 – Key Concepts and Examples of Verification of Alternative Methods

By DeAnn L. Benesh, Global Scientific Affairs Manager, Neogen | DOI: 10.55459/IJCA/v3i1/DB

-ABSTRACT-

Verification of the methods routinely used in the laboratory is a requirement for laboratories accredited to the International Organization for Standardization (ISO) standard: ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*.[1] A method verification protocol is not specified within the ISO 17025:2017 standard, and until now, laboratories have been required to conduct their verification studies based on protocols either developed in-house, or using locally recognized protocols, such as: NATA Technical Note 17,[2] Health Canada Compendium of Methods,[3] etc. The publication of ISO 16140-3:2021 *Microbiology of the food chain — Method validation — Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory*[4] now provides an internationally developed and recognized protocol that may be used to fulfill this requirement. An orientation to some of the key concepts within the ISO 16140-3:2021 standard is presented and demonstrated using examples of verification of both a qualitative method (Neogen® Molecular Detection Assay 2 – Salmonella (MDA2 SAL) and a quantitative method Neogen® Petrifilm® *Enterobacteriaceae* Count Plate (Petrifilm EB Plate).

Keywords: *ISO 17025, ISO 16140-3, ISO TC34/TC9, AOAC Official Methods of Analysis, MicroVal Certification, AFNOR Certification, method verification*

Introduction

Food microbiology laboratories are tasked with testing a diverse range of foods and beverages. They must ensure that the methods they employ for testing are both validated and verified, particularly for the specific sample types that they routinely analyze.

The ISO standard, 16140-3:2021, was developed to demonstrate user competency to perform and implement validated laboratory methods. This standard, published in 2021, is designed for verifying both qualitative and quantitative methods, along with confirmation and typing methods. This article provides an overview of key concepts covered in the standard and subsequently guides readers through the verification process using specific examples for qualitative and quantitative methods. It is the hope that this overview and the examples provided will instill confidence in readers, equipping them to navigate the standard's intricacies and apply it effectively for verifying validated methods in their laboratories.

General Concepts Within the Standard

Fully validated methods

The ISO 16140-3 standard on method verification can be applied to methods that have been "fully" validated. "Full" validation refers to a method validation compared to a reference method that included both a comparative study and an inter-laboratory study, as described below:

- **Comparative study**—a method comparison to a reference method, usually conducted within one laboratory.
- **Inter-laboratory study** (ILS)—a method comparison to a reference method, conducted between many laboratories.

Validation vs. verification

The terms validation and verification are often (incorrectly) used interchangeably, so it is important to understand their distinction and definitions. Method verification always follows validation. A method is first *validated,* demonstrating that the method performs equivalently to the reference method, based on key, defined method criteria. Then, before a laboratory puts the validated method into routine use, it needs to *verify* that its personnel can correctly use the validated method and achieve those key method criteria. In simple terms:

- **Validation** is proof that the *method* "works."
- **Verification** is proof that *the user* can perform the method correctly.

Figure 1: Food and non-food categories for AOAC and ISO method validation

CATEGORIES					
Raw milk and dairy products	Heat-processed milk and dairy products	Raw meat and ready-to-cook meat products (except poultry)	Ready-to-eat, ready-to-reheat meat products	Raw poultry and ready-to-cook poultry products	Ready-to-eat, ready-to-reheat meat, poultry products
Eggs and egg products (derivatives)	Raw and ready-to-cook fish and seafoods (unprocessed)	Ready-to-eat, ready-to-reheat fishery products	Fresh produce and fruits	Processed fruits and vegetables	Dried cereals, fruits, nuts, seeds, and vegetables
Infant formula and infant cereals	Chocolate, bakery products and confectionary	Multi-component foods or meal components	Pet food and animal feed	Environmental samples (food or feed production)	Primary production samples (PPS)

Distinction between scopes

The scope specifies the different categories, types, and items for which a method can be applied. There is a distinction between the scope of the method, the scope of the validation of that method, and the scope of the laboratory's application of that method.

- The scope of the method includes those matrices and/or matrix categories that the method claims it covers. It is often assumed that the scope of method for a reference method applies to all matrices. However, not all reference methods have been validated for use with all matrices.
- The scope of validation for these methods is limited to only those matrices or matrix categories that were included in the method's validation study.
- The scope of laboratory application would include those matrices that are within the scope of validation of the method and are routinely tested within that laboratory.

Food and non-food categories

A method may claim to be valid for use with all foods, as many reference methods do, but it is not possible to validate a method for *all* foods. No one can possibly include every existing food in a validation study to be able to make such a claim. Because of this, both AOAC INTERNATIONAL and ISO have agreed to use the phrase "broad range of foods" versus an "all foods" claim for method validation studies. To support this terminology, both organizations agreed on the classification of "all foods" into fifteen (food) categories (plus three 'Other' non-food categories), as found in Annex A of the standard and shown in Figure 1.

- **Broad range of foods:** To make a claim that a method is validated for the scope: "a broad range of foods," a defined number of (food) items must be tested from at least five of these 15 (food) categories.
- **Limited range of foods:** To make a claim that a method is validated for less than five food categories (called a "limited range of foods"), only selected (food) categories from the 15 (food) categories are included in the method validation (less than five).
- **Other (non-foods):** To claim validation for one or all three of the non-food categories, additional items from each of these categories would also need to be validated.

Verification is conducted in two stages:

1. **Implementation verification** is conducted first, to demonstrate the user laboratory can conduct the method correctly. This is conducted using one (food) item.
   - **For qualitative methods**, this one (food) item must be an item that was tested during the method's validation study, and the same sample size must be used as was tested during the validation study.
   - **For quantitative methods**, this one (food) item can be any (food) item from within the scope of the validation of the method.
2. **(Food) item verification** demonstrates that the user laboratory can conduct the method with the types of (food) items that are routinely tested in the user's laboratory. The number of items required for testing will depend on the number of categories for which the laboratory would routinely use this method.

   Because not many (food) items are tested during verification, the standard prefers that the user

chooses "challenging" foods that are claimed in the validation of the method but were not tested during the validation study. In this context, "challenging" refers to items with characteristics such as low pH, low water activity, high particulate content, etc. These factors could perhaps be inhibitory (a challenge) to the performance of the method.

Conducting Method Verification—*Examples*

Verification of a QUALITATIVE Method: Neogen Molecular Detection Assay 2 – *Salmonella*

STEP 1: DEFINE THE SCOPE OF LABORATORY APPLICATION

Suppose a laboratory intends to verify the Neogen Molecular Detection Assay 2 – *Salmonella* (MDA2 SAL) for use within their facility. Initially, the laboratory must identify the (food) items routinely tested for *Salmonella*, and then determine the number of (food) categories these items encompass, as per the Category list outlined in Figure 1.

For example, the laboratory depicted in Figure 2 primarily tests (food) items falling within one main (food) category: "raw poultry and ready-to-cook poultry products." Additionally, the laboratory tests sponges collected from the manufacturing environment, which fall into one of the "Other" (non-food) categories: "Environmental samples."

This laboratory will need to test items from both categories to complete verification of this method for use in their laboratory.

STEP 2: REVIEW METHOD VALIDATION DATA, AND CHOOSE (FOOD) ITEMS FOR THE VERIFICATION STUDY

Next, this laboratory will need to confirm that the food and non-food items it routinely tests have been fully validated either through AOAC INTERNATIONAL following Appendix J: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces[5] and/or a certification organization (such as: NF Validation by AFNOR Certification or MicroVal Certification) that follows the protocol defined in ISO 16140-2:2016 Microbiology of the food chain – Method validation – Part 2: *Protocol for the validation of alternative (proprietary) methods against a reference method*.[6]

AOAC validation data

AOAC validation data for Neogen Molecular Detection Assay 2 – *Salmonella* is accessed in two parts. The comparative study data can be found in the AOAC® Performance Tested Method℠ Certificate 091501 for the method, available on

THE USER LABORATORY			
(FOOD) CATEGORY	**LOCATION 1 RAW**	**LOCATION 2 FROZEN**	**LOCATION 3 READY-TO-COOK**
Raw poultry and ready-to-cook poultry products	**Ground chicken** Breast	**Boneless skinless** Breast, Thighs, Tenders	**Chicken wings** Seasoned 1, Seasoned 2, Seasoned 3
	Ground turkey 85% lean, 93% lean	**Thin sliced chicken breast** Seasoned 1, Seasoned 2, Seasoned 3	**Chicken tenders** Breaded, Seasoned 1, Seasoned 2, Seasoned 3
	Boneless skinless Chicken breast, Tenderloins, Thighs, Legs	**Seasoned breast pieces** Fajita, Spice garlic herb, Barbeque, Lemon pepper	**Nuggets** Breaded, Seasoned 1, Seasoned 2, Seasoned 3
	Bone/skin Chicken breast, Thighs, Drums, Wings, Leg		**Chicken strips** Breaded, Seasoned 1, Seasoned 2, Seasoned 3
Environmental samples (food and feed production)			**Sponges from equipment (EM)** w/ Letheen broth

Figure 2. The "User" laboratory (food) items routinely tested for Salmonella (Qualitative method)

the AOAC website. This will contain the list of (food) items tested in the comparative study, and a summary of the data. The AOAC® Official Method of Analysis℠ 2016.01 (Neogen Molecular Detection Assay 2 – *Salmonella*) was granted after an inter-laboratory study of the method. This study report is published in the Journal of AOAC and can be accessed through the AOAC website[7].

ISO 16140-2:2016 validation data

Neogen MDA2 SAL validation per the ISO 16140-2:2016 protocol was validated via NF VALIDATION by AFNOR Certification. The AFNOR certificate 3M 01/16-11/16 and summarized validation study report can be found on the AFNOR Certification website.

(Food) item for implementation verification. This laboratory will need to select one (food) item tested during the validation study that also belongs within the scope of laboratory application of the user laboratory. For implementation verification of this method, the laboratory chose: raw ground chicken breast.

(Food) items for (food) item verification. Only one (food) category is tested within the laboratory application, so the laboratory is only required to choose one (food) item for the (food) item verification study, as well as testing environmental sponges with Letheen broth to verify the "Other" (non-food) category under their laboratory application.

STEP 3: IMPLEMENTATION VERIFICATION USING $eLOD_{50}$ (EXAMPLE: PROTOCOL 1)

For qualitative methods, *both* implementation and (food) item verification entail determining the *estimated* LOD_{50}. The Estimated LOD_{50} ($eLOD_{50}$) is a definition unique to this standard. In microbiology, the term LOD ("level of detection") is utilized for qualitative methods, based on *replicate* analyses at three distinct inoculation levels of the target analyte in a matrix. The verification study is termed $eLOD_{50}$ because, although the laboratory conducts a study with replicates at different inoculation levels, it does not test enough samples to fulfill the requirements for an actual LOD_{50}, as generated during method validation.

The standard offers three protocols to select from for determining the $eLOD_{50}$. For each protocol, the laboratory will need to inoculate test portions. Protocols 1 and 2 require the use of your own culture for inoculation and require inoculation of test portions at three levels: high, intermediate, and low. Protocol 3 allows for the use of a standardized reference material—inoculating with a known concentration of the target microorganism—and requires inoculation of replicates at only a low level of inoculation.

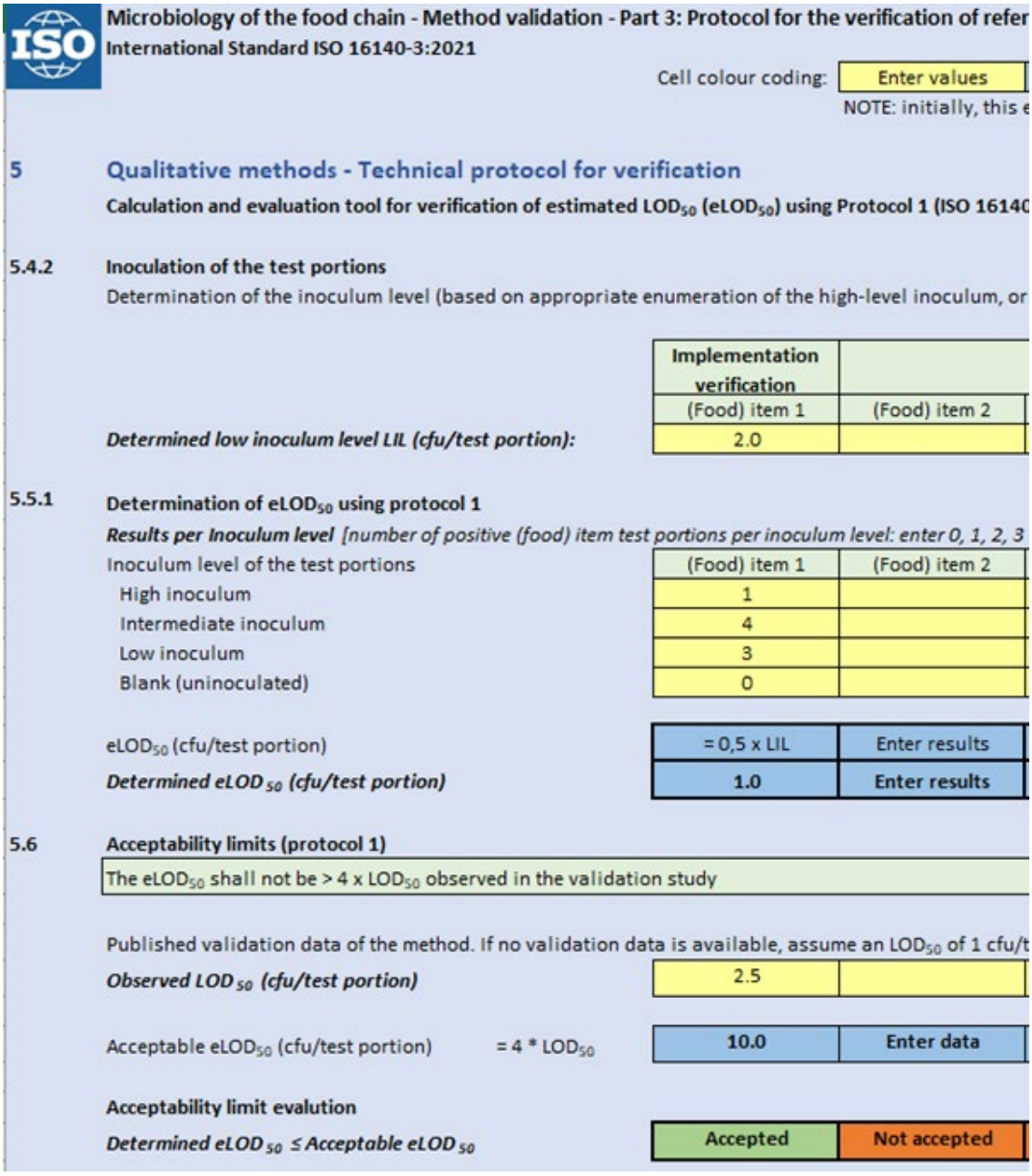
Suppose the laboratory opts to follow Protocol 1. The laboratory must initially determine what the LOD_{50} was for raw ground chicken breast in the validation study in order to determine how to begin inoculation of their (food) items. A culture of *Salmonella* is grown overnight, serially diluted, and plated to determine the concentration of the inoculum. This will help to prepare to dilute to the required concentrations of inoculation for each level (per the standard).

The standard instructs to inoculate to 9x the LOD_{50} determined in the validation study for the high inoculation level, 3x the LOD_{50} for the intermediate inoculation level, and 1x the LOD_{50} for the low inoculation level. If an LOD_{50} wasn't provided in the validation study (or there isn't one available to use for verification), then the standard advises to assume an LOD_{50} of 1 for the low inoculation level, which then is used to determine all three inoculation levels.

After inoculating the test portions, they should be analyzed according to the instructions for the method to be verified, specifically the Neogen Molecular Detection Assay 2 – *Salmonella* in this instance. Record the number of positive results at each inoculation level and use the most probable number (MPN) tables provided within the standard to determine the multiplier applicable for the low inoculation level. This multiplier is used to ascertain the $eLOD_{50}$ and assess whether the result aligns with the Acceptability Limits as defined in the standard.

Because there was no LOD_{50} listed in the Neogen Molecular Detection Assay 2 – Salmonella AOAC OMA validation report, the laboratory assumed an LOD_{50} of 1. To determine if they had met the Acceptability Limit for verification of qualitative methods, the laboratory looked within the standard to Table 16 (Acceptability Limits for the verification of validated methods), which says the $eLOD_{50}$ should be ≤ 4x LOD_{50}. ISO has an Excel®-based program (workbook)[7] available on the ISO TC34/SC9 website[8] to make calculations and to determine whether your results meet Acceptability Limits, as shown below in Figure 3. In the example shown, the $eLOD_{50}$ was determined to be 0.98 (the program rounded the Observed $eLOD_{50}$ of 0.98 to 1.0), which is ≤ 4x LOD_{50}, and therefore met the Acceptability Limit. This completed implementation verification for this method.

Figure 3. Qualitative implementation verification results: $eLOD_{50}$ using Excel®-based program on ISO TC34/SC9 website



Microbiology of the food chain - Method validation - Part 3: Protocol for the verification of refer
International Standard ISO 16140-3:2021

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5 Qualitative methods - Technical protocol for verification

Calculation and evaluation tool for verification of estimated LOD_{50} ($eLOD_{50}$) using Protocol 1 (ISO 16140

5.4.2 Inoculation of the test portions

Determination of the inoculum level (based on appropriate enumeration of the high-level inoculum, or

	Implementation verification	
	(Food) item 1	(Food) item 2
Determined low inoculum level LIL (cfu/test portion):	2.0	

5.5.1 Determination of $eLOD_{50}$ using protocol 1

Results per Inoculum level *[number of positive (food) item test portions per inoculum level: enter 0, 1, 2, 3*

Inoculum level of the test portions	(Food) item 1	(Food) item 2
High inoculum	1	
Intermediate inoculum	4	
Low inoculum	3	
Blank (uninoculated)	0	

$eLOD_{50}$ (cfu/test portion)	= 0,5 x LIL	Enter results
Determined $eLOD_{50}$ (cfu/test portion)	**1.0**	**Enter results**

5.6 Acceptability limits (protocol 1)

The $eLOD_{50}$ shall not be > 4 x LOD_{50} observed in the validation study

Published validation data of the method. If no validation data is available, assume an LOD_{50} of 1 cfu/t

Observed LOD_{50} (cfu/test portion)	2.5	
Acceptable $eLOD_{50}$ (cfu/test portion) = 4 * LOD_{50}	**10.0**	**Enter data**

Acceptability limit evalution

Determined $eLOD_{50}$ ≤ Acceptable $eLOD_{50}$	**Accepted**	**Not accepted**

STEP 4: (FOOD) ITEM VERIFICATION USING $eLOD_{50}$ (EXAMPLE: PROTOCOL 1)

Since the estimated LOD_{50} is utilized for *both* implementation and (food) item verification, this same protocol is repeated for each of the (food) items required to fulfill (food) item verification. In the case of this laboratory, this equated to one (food) item and one "Other" non-food item, completing the verification process for the one (food) Category and one "Other" non-food Category claimed to be within its Scope of Application.

Verification of a Quantitative Method: Neogen Petrifilm *Enterobacteriaceae* Count Plate

STEP 1: DEFINE THE SCOPE OF THE LABORATORY APPLICATION

For this example, let's assume a manufacturing plant makes ice cream products, infant formula, frozen pizzas, and refrigerated, ready-to-cook pasta, and it also collects environmental samples as part of its environmental monitoring program. Sorting these items into the 15 food + three other Categories using

Figure 1 shows that this laboratory tests (food) items from three different (food) Categories: Heat processed milk & dairy product; Infant formula and infant cereals; Multi-component foods or meal components; and one "Other" non-food Category: "Environmental samples."

This laboratory will need to test items from all four of these categories to complete verification of this method for use in their laboratory.

STEP 2: REVIEW METHOD VALIDATION DATA, AND CHOOSE (FOOD) ITEMS FOR THE VERIFICATION STUDY

Once again, this laboratory will first need to confirm that the food and non-food items they routinely test have been (fully) validated by either the AOAC® Official Method of Analysis℠ program and/or a method Certification organization that follows the protocol defined in ISO 16140-2:2016.

AOAC validation data

The AOAC® *Official Method of Analysis*℠ 2003.01 study report for Neogen Petrifilm *Enterobacteriaceae* Count Plate was published in the Journal of AOAC and can be accessed on the AOAC website.[9] (This method has no Performance Tested Method [PTM] data because the method was fully validated prior to creation of the AOAC PTM program.)

ISO 16140-2:2016 validation data

Neogen Petrifilm EB Plate was also validated via NF VALIDATION by AFNOR Certification per the ISO 16140-2:2016 protocol. The AFNOR Certificate 3M 01/06-09/97 and summarized validation study report can be found on the AFNOR Certification website.

Food item for implementation verification. This laboratory will need to select one (food) item within the scope of the validation, which also is within the scope of laboratory application of the user laboratory. For verification of this method, the laboratory chose vanilla ice cream, because it is easily homogenized for dividing into test portions.

Food items for (food) item verification. This laboratory will need to choose one challenging (food) item from each of the three identified (food) Categories, and the one non-food item Category to complete verification of this method. For this example, the laboratory chose vanilla ice cream with chocolate pieces and almonds; dehydrated milk powder; and ready-to-cook spinach and cheese tortellini to verify each of the three (food) categories in the validated method claim; the laboratory chose swabs with Letheen broth for verification of the one non-food category.

(Food) items chosen for both implementation and (food) item verification are highlighted in Figure 4.

STEP 3: IMPLEMENTATION VERIFICATION – INTRA-LABORATORY REPRODUCIBILITY STANDARD DEVIATION (sIR)

Implementation verification for quantitative methods is achieved by determining the Intra-laboratory reproducibility standard deviation, expressed as sIR (Intra—meaning within one lab, versus Inter—meaning between several labs, as is conducted during a full method validation).

For this study, the laboratory will choose one (food) item within the scope of the method validation, which also falls within the scope of laboratory application. In this instance vanilla ice cream was chosen. The

Figure 4. The "User" Laboratory (food) items – Quantitative method

THE USER LABORATORY – (FOOD) CATEGORIES				
Heat Processed Dairy	**Infant Formula**	**Multi-Component/Composite Foods**		**Environmental Samples**
Vanilla ice cream	Infant cereal with wheat, oats, sugar, rice	Frozen cheese pizza	Ready-to-cook pasta	Sponges with Letheen broth
Vanilla ice cream with chocolate swirls	Dehydrated milk powder	Frozen supreme pizza	Ready-to-cook spinach and cheese tortellini	Swabs with Letheen broth
Vanilla ice cream with chocolate pieces and almonds	Whey-based dairy infant formula	Frozen sausage and anchovy pizza	Ready-to-cook cheese tortellini	

laboratory must collect a minimum of 10 different kinds of samples of vanilla ice cream to ensure a variety representative of what would typically be received by the laboratory. These samples may include ice creams from different batches (lots), manufacturers, production days, etc. Collecting more than 10 samples is advisable to ensure an adequate variety.

Overnight, a culture of *Enterobacteriaceae* is grown, followed by serial dilutions and plating to determine inoculation levels. Each of the 10 (or more) test portions of vanilla ice cream undergoes thorough homogenization and is then divided into two test portions: A and B. Each set of test portions is then inoculated with a range of contamination levels typically found in samples routinely analyzed in the laboratory (between 30 cfu/g – 30,000 cfu/g). Since this study is conducted within one laboratory, it is crucial to ensure that the analysis of the test portions A and B differs in as many ways as possible: using different technicians, incubators, batches of culture media (different preparations from the same batch of media powder), etc.

Each test portion is then analyzed using the Neogen Petrifilm *Enterobacteriaceae* Count Plate method. Results are recorded and used to calculate the intra-laboratory reproducibility standard deviation (sIR) using the formula provided in the standard or using the Excel®-based program (workbook) available on the ISO TC34/SC9 website.

Within the validation study report for the Neogen Petrifilm *Enterobacteriaceae* Count Plate method, locate the lowest Inter-laboratory reproducibility standard deviation (sIR) mean value of the (food) items used in the validation study and compare this to the calculated sIR obtained in the verification study. In Figure 5, the lowest sIR mean value in the validation study for this method was found to be 0.125 (0.126 [low] + 0.122 [medium]+ 0.126 [high]) = 0.374 [total]) / 3 = mean value = 0.125).

Figure 5. Lowest Inter-laboratory reproducibility standard deviation (sR) mean value validation study.

Accuracy profile			
Study Name	3M Petrifilm *Enterobacteriaceae*		
Date			
Coordinator			
Tolerance probability (beta)	80%	80%	80%
Acceptability limit in log (lambda)	0,50	0,50	0,50
	Alternative method		
Levels	Low	Medium	High
Target value	2,274	3,238	4,191
Number of participants (K)	14	14	14
Average for alternative method	2,224	3,244	4,223
Repeatability standard deviation (sr)	0,122	0,110	0,104
Between-labs standard deviation (sL)	0,031	0,052	0,071
Reproducibility standard deviation (sR)	0,126	0,122	0,126
Corrected number of dof	26,745	25,758	23,978
Coverage factor	1,339	1,343	1,349
Interpolated Student t	1,314	1,315	1,318
Tolerance interval standard deviation	0,1283	0,1245	0,1291
Lower TI limit	2,056	3,080	4,053
Upper TI limit	2,393	3,408	4,393
Bias	**-0,050**	**0,006**	**0,032**
Relative Lower TI limit (beta = 80%)	**-0,218**	**-0,158**	**-0,138**
Relative Upper TI limit (beta = 80%)	**0,119**	**0,169**	**0,203**
Lower Acceptability Limit	**-0,50**	**-0,50**	**-0,50**
Upper Acceptability Limit	**0,50**	**0,50**	**0,50**

The sIR must be ≤ 2 x the lowest sIR to meet the implementation verification Acceptability Limits (again, per Table 16 in the standard). The result obtained in the study for sIR was 0.17, which is ≤ 2 x 0.125 sR, successfully completing the implementation verification of this method. Figure 6 illustrates the results using the Excel®-based program (workbook) from the ISO TC34/SC9 website, after inputting all the evaluation data.

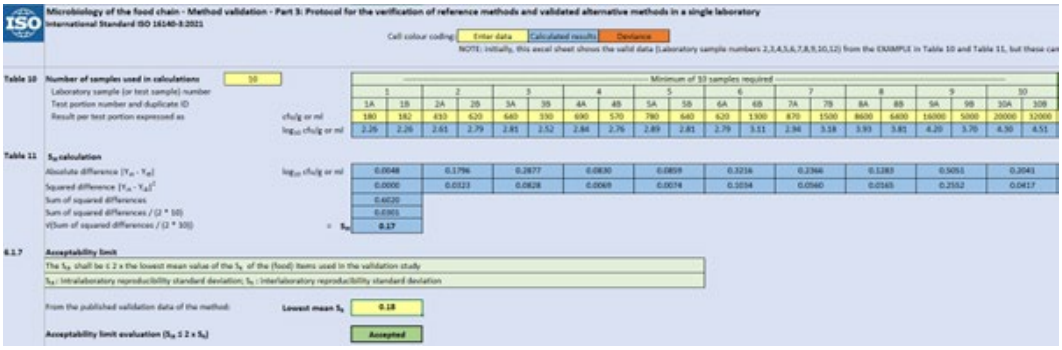

Figure 6. Quantitative implementation verification results: sIR using the Excel®-based program on ISO TC34/SC9 website

STEP 4: (FOOD) ITEM VERIFICATION USING eBIAS

(Food) item verification for quantitative methods is achieved by determining the estimated Bias (eBias), which is another unique definition within this standard. An accurate determination of the bias (as conducted in validation studies) is not feasible due to the small number of samples tested in the verification study. Therefore, the term *eBias* is utilized for the verification study.

To conduct (food) item verification, the laboratory will use the three challenging (food) items and one non-food item (swabs with Letheen broth) chosen from the review of the categories in the scope of the laboratory application.

Each (food) item will be artificially contaminated at three inoculation levels that cover the range of use of the method as it is routinely used by the laboratory (for example: 30-300, 300-3,000 and 3,000-30,000 cfu/g). Each of these three levels will be performed in duplicate.

A culture of *Enterobacteriaceae* is grown overnight, and then serial dilutions are made and plated to determine the correct inoculation levels. When diluting the inoculation suspension to prepare for inoculation in the (food) item duplicates, consider including additional dilutions that may be needed to achieve counts within the countable range of the method for each of the three levels. As illustrated in Figure 7, the inoculum requires further dilution to achieve the correct dilution/counting levels for the high, intermediate, and low levels. The inoculum, when mixed with the volume of the (food) item, requires less dilution.

To calculate the eBias, enumeration is conducted and recorded for:

- The **inoculum** at three levels.
- The **(food) item *with*** inoculum at three levels.
- The **(food) item *without*** inoculum in duplicate (as a negative control) to determine the background microbiota level (if any) in the (food) item.

For each of the three levels, the counts of the (food) item duplicates are averaged and a log10 transformation is done to determine $\log_{10}$ cfu/g for each level. These results are then expressed in $\log_{10}$ cfu/test portion for each level and compared to the log transformation on the count of that *same* inoculum level determined for each level *without* the (food) item. The eBias is the absolute difference in results between the inoculated (food) item and the inoculum.

To meet the Acceptability Limits for eBias per the standard (found in Table 16), the absolute difference for each level must be ≤ 0.5 $\log_{10}$/ml. Again, the Excel®-based program (workbook) is also available on the ISO TC34/SC9 website for you to insert your data and help complete all calculations.

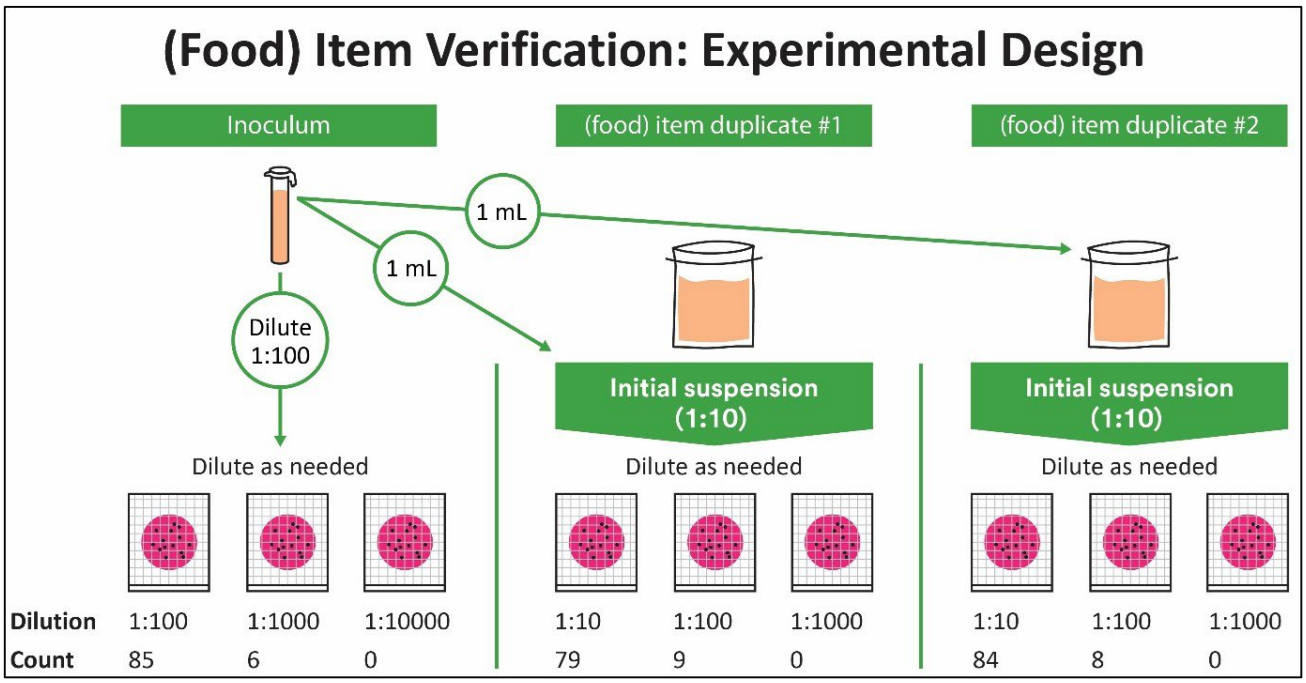

Figure 7. Quantitative (food) item verification protocol with three levels of inoculum

Conclusion

Laboratories must demonstrate (verify) they can properly use methods before implementing in their facility. The publication of ISO 16140-3:2021 now provides an internationally recognized standard for method verification that can be used to meet the methods verification requirement of the ISO 17025:2017 standard. In this article, examples of qualitative and quantitative methods were provided using both AOAC and ISO validated methods to get you started, and it is highly recommended that you also check out additional sources of training to deepen your understanding and application of the ISO 16140-3:2017 standard. On the ISO TC34/SC9 website,[10] you can find a number of materials available to help you with the use and application of this standard, including a recording of a webinar delivered on 2 March 2020 by ISO members shortly after the publication of the standard, and several PowerPoint® training presentations that were developed for your use. The slide presentations have the script for each slide written in the slide notes to help you properly deliver their content. The presentations are available in both PDF and in PowerPoint format so that you have the ability to translate the content into your local language to help with presentation and understanding.

- Presentation: Overview of the ISO 16140 series – standards for validation and verification of microbiology methods (PDF or PowerPoint)
- Presentation: Overview of ISO 16140-3 'Method verification' – improving confidence in laboratory results (PDF or PowerPoint)
- Presentation: "Deep dive" into ISO 16140-3 'Method verification' – an extended training for improving confidence in laboratory results (PDF or PowerPoint)
- Excel-calculation tool ISO 16140-3:2021 for assistance on statistics (link)
- Recording of the Webinar on 2 March 2021: Publication ISO 16140-3 'Method verification' in English (link)
- Webinar in French on 1 April 2022: Publication ISO 16140-3 'Method verification' (Presentation mainly in English and Recording)
- Frequently Asked Questions for ISO 16140-3:2021 'Method verification' (link)

NOTE

3M's former Food Safety business and product portfolio, including Petrifilm Plates and Molecular Detection Assays, are now part of Neogen.

For additional questions and support regarding the application of ISO 16140-3 in your laboratory, please contact Neogen at www.neogen.com

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Author Biography

DeAnn Benesh recently retired from Neogen where she was a Global Regulatory Manager providing leadership to global teams to engage in strategic local regulatory activities to drive recognition and acceptance of methods, and partner with government and non-government organizations in the development of standards and methods. She was a Past President and Fellow of AOAC, active in ISO IC34/SC9 as an expert participating in several ISO 34/SC9 Working Groups, Co-leader of the ISO 16140-3 (Method Verification) drafting committing, a member of the Microval General Council, past Chair of the IAFP Food Law and of the IAFP International Food Protection Issues Professional Development Groups, and recipient of the IAFP President's Recognition Award. DeAnn holds a Bachelor of Science degree in Medical Technology from the College of Pathology, University of Minnesota, Minneapolis, MN; a Mini master's in international business from the University of St. Thomas, St. Paul, MN; and a Certificate in International Food Law through Michigan State University, East Lansing, MI.

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