INVITATION FOR AN ISO INTERNATIONAL WORKSHOP AGREEMENT (IWA 15)

Specification and Method for the Determination of Performance Parameters of Automated Pipetting Systems

Kick-off meeting on 13 May 2014 in Frankfurt on Main/Germany

Agenda:

1. Opening of the meeting (10:30 a.m.)
2. Roll call of participants
3. Adoption of this draft agenda
4. Introduction to ISO and to the workshop concept
5. Background of the Workshop proposal (Dr. George Rodrigues, ARTEL)
6. Participation in the ISO Workshop
7. Discussion and approval of the draft Workshop Business Plan (see following pages)
   a) Confirmation of the Workshop Secretariat
   b) Confirmation of the time frame
   c) Reference language and translations
   d) Adoption of the Workshop's objectives
   e) Appointment of the Workshop's chairperson and vice-chairperson
   f) Formal approval of the draft Business Plan
8. Consideration of the future structure and contents of the CWA
9. Preparation of the next meeting(s)
10. Any other business
11. Closure of the meeting (approx. 4:00 p.m.)

Venue of the meeting (details see page 12):

DEHEMA e.V.
Theodor-Heuss-Allee 25, 60486 Frankfurt am Main/Germany

Please indicate your participation in the kick-off meeting by email to koerfer@dechema.de giving your full name, address and communication data.
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1. **Background to IWA 15**

Recent years have seen a steady growth in the usage of Automated Pipetting Systems (APS), which are implemented in an increasing number of laboratories. The functionality of these systems may range from simple dispensing systems to highly complex robotic systems, executing a wide range of liquid handling tasks, which are as diverse as the laboratories employing such technology. Simultaneously to the increased use of APS, assays which are being executed on these systems are trending toward smaller volumes and are increasing in their complexity. These developments require the users of APS to match the performance of their robotic systems to the requirements of their laboratory needs and then verify that each APS is working within its specifications.

Most laboratories who use an APS in their operations have developed some method (or a combination of methods) of verifying its performance. These methods are usually developed by each individual laboratory, and there is no standardized approach of ensuring that two different laboratories are using the same methods of verification. Unless extreme care is taken in the preparation of such laboratory-developed methods, the measurement results are not traceable to the International System of Units (SI). This issue is becoming more critical with the increasing globalization of the laboratory industry and market, and the need for coherent comparisons of data between individual laboratories, companies in different countries.

The increased performance demands of APS necessitate the development of an international standard for these instruments. An ISO standard will have a powerful effect on the application of APS, and on the business success of the companies who are manufacturing, selling and servicing these instruments. An ISO standard will also provide objective guidance to the end users of such instruments so they may match the performance of an APS to their laboratory needs.

The importance of providing a standardized way of classifying and evaluating the performance parameters of liquid transfer equipment was recognized as early as the 1970’s for handheld pipettes, and led to the development of DIN and BS standards, and eventually to ISO/CEN and ASTM standards for piston-operated pipettes.¹

This International Workshop Agreement (IWA) will begin to address this void of international standards for APS. Once the proposed IWA has been published, the proposers intend to develop this IWA into a full ISO standard following prescribed ISO procedures.

To the best knowledge of the proposers of this IWA, the only publicly available specifications addressing the performance evaluation of APS have been developed by Toolpoint² describing a photometric and gravimetric check procedure, but these do not fully address the needs of users, manufacturers, and their service organizations. These specifications do not classify or standardize the performance description of APS in a way that would allow a user or future user of an APS to make an informed decision on which robotic system will best match the laboratory’s performance needs. Additionally, these Toolpoint specifications are not widely known to end users, nor are they internationally recognized in the same way as an ISO standard or an IWA.
It is planned that the overall structure of the proposed IWA will be modeled upon the current ISO standard for handheld pipettes, ISO 8655. This standard forms a series with seven parts, which include parts for classification of equipment, with maximum error limits for each equipment class. Error limits apply to both systematic error and random error. Other parts in this ISO series define standard test methods for determining whether a particular piece of equipment meets specified performance requirements. ISO 8655 has become widely accepted in the handheld pipetting industry and among users. All major manufacturers now demonstrate that their pipettes meet ISO specifications. In addition, many users and third party testing houses now apply these ISO specifications or test methods as a basis for their own work. The efficiencies for both manufacturers and users of handheld pipettes due to the standardization of performance metrics and requirements, and the confidence in performance provided by ISO, are widely acknowledged. Similar benefits will occur when ISO standards and this IWA for APS are published.

2. IWA Proposers

The following organizations have proposed the development of this IWA and the launch of the IWA workshop:

   Artel, Inc.
   25 Bradley Drive
   Westbrook, Maine 04092
   USA

   Tecan Switzerland
   Seestrasse 103
   CH-8708 Männedorf
   Switzerland

3. Objective of this IWA

The objective of this project is to develop an international workshop agreement (IWA) for Automated Pipetting Systems, which will provide guidance in the classification and determination of performance parameters of said systems. This workshop agreement will benefit the manufacturers, users and service organizations of such pipetting systems.

The proposers of this IWA recognize that a wide variety of liquid delivery technologies are employed in APS currently available on the market. This variety necessitates distinguishing the types of APS technology for the purpose of classification, specifying allowed measurement uncertainties, and suitable testing methods of such systems. The herein proposed IWA will focus on the most widely used
technology of piston-operated APS. Other liquid handling technologies could be addressed in subsequent workshop agreements or standards.

It is proposed that initial development and publication will be in the form of an IWA, with the intent to develop this IWA further into a full ISO standard according to ISO procedures. It is expected that development and publication of this document would follow normal ISO scheduling for an IWA.

It is envisioned that this new IWA would initially consist of two parts:

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**Part 1** – The first part would describe a *Classification Scheme and Performance Requirements* (i.e. maximum error limits depending on equipment class and volume range).

The *Classification Scheme* for APS shall be appropriate and meaningful to the industry. Likewise, the maximum systematic and random error limits must be technically achievable by all reputable manufacturers and appropriate to users’ applications. One potential classification scheme might be based on liquid handling physics (e.g. a class for liquid filled syringe pump systems, and a separate class for air-displacement pipetting systems).

**Part 2** – The second part would describe *Standard Methods for Testing* conformity to the error limits.

The testing methodology should be readily implementable by manufacturers, field service technicians, as well as end-users. It should further provide standardized and traceable measurement results across APS platforms and testing sites.

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4. **Benefits of this IWA**

With APS having become increasingly commonplace in laboratories, a specification for expressing the performance of such systems is valuable for users as they specify and use their equipment. This is particularly true for laboratories working in conjunction with other labs across multiple sites, or worldwide.

By supplying a standardized methodology and language for specifying and describing the performance of APS, the ISO IWA will lubricate both purchase and use decisions by the market. It will allow manufacturers to focus on, and capitalize on, the differentiating features of their offerings, while allowing users to choose devices appropriate to their needs.

Benefits of an ISO IWA for APS would accrue to the manufacturers, the users, and the service organizations involved with the industry and market. Such a specification is a necessary ingredient to the growth of any industry or marketplace, allowing efficient commerce - design, manufacture, sales, service and use of a product.
5. The IWA Workshop Program

The fundamental basis of an IWA program is that organizations and key stakeholder, including manufacturers and users of the technology in question, work together to develop an internationally recognized guideline that serves the interests of this market.

This IWA will therefore be composed of key stakeholders from the manufacturers of APS, as well as users of such systems, and organizations concerned with servicing and independently verifying the performance of such instruments. These stakeholders will also represent an international community with participants from European and North American countries.

Following the ISO process for developing an IWA, this project will be broken down into five (5) distinct phases:

- Phase 1 – Presentation of the IWA Business Case (done)
- Phase 2 – Obtain ISO/TMB approval (done) and hold a Kick-Off Meeting (2014-05-13)
- Phase 3 – Development of the IWA-draft document and organizing the Workshop's Meeting(s)
- Phase 4 – Reaching consensus and preparation of the final IWA document
- Phase 5 – Publication of the final IWA document

These steps in the development process may be summarized as follows:

Presentation of the IWA Business Case
This proposal is designed to state the purpose and justification for this IWA to ANSI as supporting ISO member body, to DIN as potential secretariat and supporting member body, and to ISO/CS for approval of this IWA. This proposal has been developed with the support of interested manufacturers and users of APS.

Kick-Off Meeting
ISO/TMB has accepted this IWA proposal as a NP IWA 15 on 2013-12-03; Artel and Tecan together with the administrative partner (DIN) will arrange the kick-off meeting with all interested parties (scheduled to be in Frankfurt on Main/Germany on 2014-05-13). This first step in the overall workshop process serves to confirm the business plan, agree on the rules of the workshop, and agree on the chair, secretariat, and other key positions, e.g., technical author, advisors, etc. Participation fees (1.200,- Euro per stakeholder) will be established at this meeting and due on completion of the kick-off meeting.
Drafting the Workshop Agreement

After the kick-off meeting, the Chair will work with the Technical Author and the IWA participants on developing the full draft of this IWA proposal. Communications between the involved parties will be conducted via email and telephone conference calls.

The Workshop Meeting

The workshop meeting will be announced by ISO/CS to all ISO member bodies and any interested party is allowed to attend. The draft IWA document will be circulated prior to this workshop to the attendees. During the Workshop, the chair will seek to build consensus on the IWA document. It may be that more than one workshop meeting will be required to attain consensus. If necessary an additional workshop meeting will be scheduled.

Publication

Once consensus has been obtained among the participants of the workshop, the approved IWA document is then sent to ISO for publication. ISO will hold the copyright to this document and ISO member bodies may sell and distribute this IWA document.

The document presented in Appendix A summarizes the ISO IWA Development Process.

6. Timetable – Key Milestones

<table>
<thead>
<tr>
<th>Milestone</th>
<th>(Anticipated) Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation of IWA proposal to ISO/CS for approval</td>
<td>November 2013</td>
</tr>
<tr>
<td>Obtain ISO/TMB approval</td>
<td>03 December 2013</td>
</tr>
<tr>
<td>Hold kick-off meeting</td>
<td>13 May 2014</td>
</tr>
<tr>
<td>Develop full IWA draft document and hold workshop meeting</td>
<td>August to Oct. 2014</td>
</tr>
<tr>
<td>Final ratification of consensus document by workshop members</td>
<td>December 2014 to Feb. 2015</td>
</tr>
<tr>
<td>Publication of IWA by ISO</td>
<td>February to April 2015</td>
</tr>
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</table>
7. **IWA Organization**

The workshop will be chaired by Dr. George Rodrigues, to be appointed and confirmed at the Kick-Off meeting.

DIN will provide the secretariat under the guidance of Dr. Burkhard Winter (successor: Dr. Renata Koerfer).

Artel has conducted an initial investigation into relevant ISO committees and has identified the following committee as suitable for administering this IWA:

- ISO/TC 48 Laboratory Apparatus

It is anticipated that workshop participants will include manufacturers of APS, users of such systems, as well as organizations that service and verify proper functionality of such systems. The proposers of this IWA specifically encourage participation from representatives of the following stakeholder categories:

- Manufacturers of APS
- Users (automation engineers) of APS in a variety of markets, e.g.:
  - Pharmaceutical Industry
  - Forensic Sciences
  - Clinical Laboratories
- Service Organizations for APS
- Calibration Houses for laboratory instruments
- Government Regulatory Agencies (e.g., FDA, USP, NIST, and their international equivalents)

The workshop shall be open to any interested party accepting the Business Plan Objective and requesting to participate.

The working language of this workshop is English, and it is envisioned that the IWA will be published in English language only.

8. **Resources and Participation**

Participation in the workshop is open to any interested organization/company/person, who requests to participate and who pays the participation fee for the workshop. In addition to the workshop participation fee, each participant will have to cover his/her own expenses for attending this workshop.

Artel is proposing to lead this IWA program, including organization of the kick-off meeting, hosting the IWA workshop, and chairing the development of the draft document, bringing to bear its extensive experience and knowledge in liquid delivery metrology.
The workshop will be funded by participation fees of the participating parties. The exact fees for the participants will be determined together with the ISO administrative partner during the kick-off meeting when the plans for the workshop are finalized.

9. **Workshop Officials**

Chairman: Dr. George Rodrigues, Artel

Secretary: Dr. Burkhard Winter, DIN (Dr. Renata Koerfer, DIN)

Technical Editor: Dr. Bjoern Carle, Artel

10. **Contact Point**

Dr. George Rodrigues  
Senior Scientific Manager  
Artel  
25 Bradley Drive  
Westbrook, Maine 04092  
USA  
Tel: +1.207.591.6326  
Email: grodrigues@artel-usa.com

11. **References**

(b) BS 6018:1981, superseded by ISO 8655:2002  
(c) BS 7532: 1986, superseded by ISO 8655:2002  
(d) ASTM E1154:1989 (last re-approval: 2008)  
(e) ISO 8655:2002 (last re-approval in 2009)

[2] (a) URL to Toolpoint: http://www.toolpoint.ch  
(b) Toolpoint Photometric Volume Check Procedure, 2008  
(c) Toolpoint Gravimetric Volume Check Procedure, 2008

### ISO’s International Workshop Agreements (IWAs)

The IWA model is a quick way to obtain a recognized ISO document for your work. It is designed to be a flexible model so the format and content of the IWA, and the process to obtain it, are largely decided by the proposing organization.

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Step 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Make the proposal</strong></td>
<td><strong>Get ISO/TMB approval</strong></td>
<td><strong>ISO/CS circulates the details of the workshop</strong></td>
<td><strong>Hold the workshop and agree the document</strong></td>
<td><strong>Publish the IWA</strong></td>
</tr>
<tr>
<td>Approach ISO Central Secretariat or any ISO member with your proposal.</td>
<td>ISO/Cs then circulates your proposal to the ISO/TMB for approval (checking any proposed distribution arrangements with the ISO/Sec-Gen).</td>
<td>A notification – with the full details agreed at Step 2 – is circulated to all ISO members (by ISO/CS).</td>
<td>At the meeting the Chair (nominated in advance) will be confirmed.</td>
<td>The final draft of the IWA is sent by the Secretariat to ISO/CS.</td>
</tr>
<tr>
<td>Your proposal should include:</td>
<td>The TMB will also formally assign / confirm the ISO member body who will be your secretariat for the project.</td>
<td>ISO member bodies can then circulate the proposal as widely as possible in order to publicize it to potentially interested parties.</td>
<td>During the whole IWA process, the Chair must be impartial and seek to ensure the maximum amount of consensus possible has been achieved.</td>
<td>ISO/CS formats the document – giving it the relevant ISO cover page / logo.</td>
</tr>
<tr>
<td>✓ Purpose and justification</td>
<td>✓ The ISO member body works with the proposer to decide full details of the Workshop:</td>
<td>Note: Any organization or company or individual is allowed to attend.</td>
<td>Document is drafted and circulated to the workshop participants.</td>
<td>ISO/CS then supplies the document to all its member bodies who can supply it as they see fit.</td>
</tr>
<tr>
<td>✓ Relevant documents</td>
<td>✓ Price (if any fee)</td>
<td></td>
<td>This can be repeated until the Chair believes that the best possible consensus has been obtained.</td>
<td>Any special arrangements for the distribution of the IWA should be put in place here.</td>
</tr>
<tr>
<td>✓ List of organizations that may be interested</td>
<td>✓ Time/Date/Venue</td>
<td></td>
<td>Note: One possible mechanism is that the workshop participants work online on a dedicated Web site.</td>
<td></td>
</tr>
<tr>
<td>✓ Indications of any ISO member body willing to act as Secretariat</td>
<td>✓ Format</td>
<td></td>
<td>Note: Multiple meetings can take place if necessary.</td>
<td></td>
</tr>
<tr>
<td>✓ An estimate of the number of meetings if more than one is envisaged</td>
<td>✓ Background</td>
<td></td>
<td>This stage depends on the scope of the IWA. However, aim to finish in three months or less</td>
<td></td>
</tr>
<tr>
<td>✓ Details of any proposed special arrangements for distribution of the IWA</td>
<td>✓ Doc supply</td>
<td></td>
<td>One month</td>
<td></td>
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</tbody>
</table>

Start – ISO/CS will normally take less than one month to process your proposal.  
Maximum of three months  
Three months (90 days) advance notice is required before holding the workshop.  
This stage depends on the scope of the IWA. However, aim to finish in three months or less  
One month  

Should not take longer than 12 months – aim for less.
ISO's International Workshop Agreements (IWAs)

What is an IWA?
An IWA is an ISO document produced through a workshop meeting rather than through the full ISO technical committee process. Market players and other stakeholders directly participate in developing an IWA and do not have to go through a national delegation.

What subjects do they cover?
An IWA can be produced on any subject

Why should I choose the IWA?
An IWA will:
- Involve the main players from your target sector (public or private) and allow a sector to develop clear rules on an issue.
- Give visibility to your professional practices or reference documents (ISO is a highly recognized international body).
- Help you shape the future direction of the subject and influence any future ISO standard.
- Allow you to develop relationships within a profession or sector.
- Create understanding and co-ordination amongst your various stakeholders.
- Share best practice in a sector.
- Improve quality and interoperability.
- Lead to worldwide visibility due to ISO members' distribution networks.
- Help you to develop a members-only forum to communicate using, for example, a dedicated Web site.

Who will be involved?
Anyone can propose an IWA and anyone can participate in developing one. An ISO member body will be assigned to help you organize and run the workshop. This gives the project credibility by ensuring that the basic principles of international standardization (transparency, fairness and consensus) are applied.

How much will it cost?
There are different ways of financing the costs of the IWA – in particular the workshop meeting(s). In some cases, the participants are charged a fee to attend; in others, a charge is made for the resulting document. You can also cover the costs yourself as an organization. Whatever the mechanism, the costs can be decided by you and the ISO member body that acts as your secretariat.

How do I start?
The process of developing an IWA is detailed on the preceding page in five-steps. To start, you can approach ISO/CS or an ISO member body for an informal discussion of your proposal.

- E-mail tmb@iso.org to contact ISO Central Secretariat directly, or click on the URL below to find an ISO member body http://www.iso.org/isomembers
Venue of the kick-off meeting

By public transport:

From Frankfurt Airport

- approx. 20 min. by taxi
- S-Bahn: S 8, S 9 (line 8 or 9) to the main station (Hauptbahnhof), change to S 3, S 4, S 5 or S-6 (platform 104, underground) to the station Messe, exit Theodor-Heuss-Allee / Festhalle

From the main railway station (Hauptbahnhof)

- approx. 20 min. walk
- approx. 10 min. by taxi
• S-Bahn: S 3, S 4, S 5 or S 6 (platform 104, underground) to the station Messe, Exit Theodor-Heuss-Allee / Festhalle
• Underground: line U 4 (line 4) direction Bockenheimer Warte to the station Messe, Exit Festhalle and 10 min. walk
• Tram/streetcar line 16 or 17 to the stop Festhalle/Messe and 10 min. walk

By car:
Via Autobahn/Westkreuz to Frankfurt Stadtmitte, turn right at first traffic light after the railway bridge
From the city centre in direction Messe (exhibition grounds), on the Theodor-Heuss-Allee first left-hand turn-off lane before the railway bridge.
Entrance "Varrentrappstraße".
The area of DECHEMA is part of the low emission zone (Umweltzone) in Frankfurt. Only vehicles displaying an appropriate badge on their windscreen will be allowed to enter the low emission zone.
Parking spaces on DECHEMA site are available but limited. Please use, if necessary, the multistorey car parks along Theodor-Heuss-Allee; in direction city: Congress-Center-Messe (CMF) or Messeturm