TOPICAL FEATURE



The Making of the International Standard for Writing in Plain Language ISO 24495-1: Its Usefulness, Content, and How It Came into Existence

Thomas M. Schindler / Lay & Regulatory Writing, Biberach, and BioNTech SE, Mainz, Germany

There is ample evidence across many domains that writing in plain language saves time or money or both for readers and organizations. Communication in plain language is generally more effective and produces better outcomes than traditional writing. In many contexts, readers prefer plain language over traditional writing styles, and use of plain language fosters the building of trust. Finally, the process of translating is usually more efficient for plain language documents.

In July 2023, after many years of development, discussion, and alignment, the International Organization for Standardization (ISO) published a standard for plain language.¹ This publication makes an internationally developed and agreed-upon standard available to all people interested in the use of plain language. It is an authoritative source developed by plain language practitioners, linguists, technical writers, designers, and text creators from many different countries. The standard will help all writers (authors) to make their texts (documents, web pages, etc.) most useful for the intended audiences (readers, users). It applies to most written languages and reflects the most recent research on plain language and the experience of plain language experts.

ADVANTAGES OF HAVING A PLAIN LANGUAGE STANDARD

We all benefit from the availability of technical standards in our everyday lives. They ensure that a plug bought in New York will fit a socket in Alaska and San Diego. International standards ensure that a product has the same specifications, regardless of where it is manufactured and used. Standardization fosters economic activity and growth. "Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators."²

Medical writers appreciate the usefulness of standards in the realm of drug development. The many activities of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)³ "All industries and sectors benefit from improved communication. Readers benefit when they can understand and use information. And organizations gain improved branding, efficiency, and effectiveness of communications products. A plain language standard provides all sectors, in nearly all languages, with a set of guidelines and strategies to make information more accessible and effective."⁴

have led to a large set of standards that cover many aspects of drug development, including the definition of requirements on content and format of clinical documents, eg, structure and content of clinical study reports ICH E3 or the study protocol and investigator's brochure in ICH E6 on Good Clinical Practice. Many of these standards are subsequently transferred to company standard operating procedures and associated working instructions and hence have a direct impact on the work of medical writers. Also, the plain language standard provides a whole host of advantages:

Interoperability: The standard fosters the mutual understanding of what constitutes plain language. It provides a basis for discussion and serves as a basis for the use of plain language in special domains. The common standard allows integration of the various components developed in specialized domains.

Clarity and consistency: The standard provides clear guidance on how to develop texts in plain language that are easily understood by users. This reduces ambiguity and enhances the reliability of communication.

Cost efficiency and compliance: The standard will help streamline the processes of writing in plain language and thereby reduce costs. Both the generation of plain language texts and their efficiency can be evaluated against compliance with the guidelines, creating a useful measure for writers (authors) and readers (consumers). **Collaboration and development:** The availability of the standard facilitates collaboration among practitioners, allowing them to work in a common framework. This will accelerate development processes and exchange in the community of practitioners across languages.

Portability: The standard will enable the transfer of texts across different environments and languages. Texts and documents developed in compliance with the standard can be more easily translated without major modifications.

Structure of the plain language standard

- Foreword
- Introduction
- Scope
- Normative references
- Terms and definitions
- Governing principles
- Guidelines
- Annex A: Overview of principles and guidelines
- Annex B: Sample checklist

THE CONTENT OF THE STANDARD

At the center of the standard is the definition of plain language. It is characterized as communication in which wording, structure, and design are so clear that intended readers can easily

- find what they need,
- understand what they find, and
- use that information.

Consequently, the standard evolves around 4 principles that are elaborated on in separate subchapters:

Principle 1: Readers get what they need (relevant)

- O Identify the readers
- Identify the readers' purpose
- Identify the context in which readers will read the document
- Select the document type or types
- Select content that readers need

Principle 2: Readers can easily find what they need (findable)

- Structure the document for readers
- Use information design techniques that enable readers to find information
- Use headings to help readers predict what comes next
- Keep supplementary information separate

Principle 3: Readers can easily understand what they find (understandable)

- Choose familiar words
- Write clear sentences
- Write concise sentences
- Write clear and concise paragraphs
- Consider including images and multimedia
- Project a respectful tone
- Ensure that the document is cohesive

Principle 4: Readers can easily use the information (usable)

- Evaluate the document continually as it is developed
- Evaluate the document further with readers
- O Continue to evaluate readers' use of the document

For each principle, detailed guidelines are presented each with a small number of examples. Together with the definition of terms and 2 annexes, the standard provides comprehensive coverage of the key considerations for writing plain language texts that are useful for their audiences.

"Plain language ensures readers can find what they need, understand it and use it. Thus, plain language focuses on how successfully readers can use the document rather than on mechanical measures such as readability formulas."¹

AVAILABILITY OF THE STANDARD

The standards developed under the auspices of ISO or any national standard body are not free. They are therefore not freely available on the internet. They must be bought from ISO for a small fee; in the case of the plain language standard, the fee is 96 Swiss Francs (around \$110). Clearly, this is a comparatively small sum that could be afforded by most. If the standard is used for professional purposes, this expense is usually tax-deductible. The money that is generated by selling the standards ensures that ISO remains independent of economic and political influences and can give full freedom to its communities of volunteers. Charging for standards allows ISO to "ensure that they are developed in an impartial environment and therefore meet the needs of all stakeholders for which the standard is relevant."⁵

THE MAKING OF THE STANDARD

Looking back, it is difficult to determine who exactly it was who came up with the idea for creating a universal definition of plain language and a standard across regions, let alone finding out when and where it happened. However, the initiators and the people who over many years devoted their time and efforts to nurture the idea are still around. That said, they are usually too modest to brag about their involvement in the development of the plain language standard.

To fully appreciate this achievement, it is important to understand that all the definitory and alignment work in the field of plain language has been done by volunteers who are enthusiastic plain language practitioners and advocates. There was no institutional support from academia and no monetary support from governments for this initiative. However, some Northern European countries such as Norway have supported the cause by sending official delegates. Even so, the international plain language standard was developed by people who were prepared to spend many evenings and weekends discussing ideas and fine-tuning text proposals.⁶⁻⁹

It is difficult enough to develop a definition in a community of practitioners and to internationally align it. It is even more challenging to get a standard developed and adopted by the International Organization of Standards (ISO). It's not ISO that prompts the development of a certain standard. Rather, someone, usually industry or other groups of practitioners, approaches a national member organization of ISO which—if they see value in the proposal—brings it into the ISO system of expert groups. These groups are organized in larger groups called technical committees, or TC for short (there are about 250 TCs in ISO). These groups of experts negotiate and align on all aspects of the standard.¹⁰

The strength of the ISO process relies on its global scope, its representation of developing countries and consumer groups, and the principle of consensus. The latter ensures that all comments of all stakeholders are considered. Experts representing national standard development organizations need to be nominated by their countries' committee to work in an ISO working group.

Overall, it has taken some 16 years from the first public appearances of the idea of a plain language standard in 2007 to the release of the ISO standard in 2023.¹¹ The first 7 years, until 2014, were spent developing and discussing a definition of plain language. The definition was formally adopted by the International Plain Language Federation (IPLF) in 2014. Then, in 2017, the IPLF set up a committee to develop a plain language standard.

As is so often the case, it was the initiative of a small group of people, in this case, from the IPLF, led by Christopher Balmford, a lawyer by training, to approach Standards Australia and probe their willingness to take up the topic. He cold-called the relevant person at Standards Australia and met with him. Christopher's enthusiasm overcame the initially profound skepticism, and he convinced Standard Australia to take up the topic. Apparently, his cause was greatly helped by the fact that he incidentally mentioned that he and a friend had paddled a sea kayak the 150 miles from mainland Australia to Tasmania, island hopping on a 16-day trip. This demonstrated his tenacity, endurance, and dedication—all very much needed for bringing an idea to an adopted standard.

Standard Australia quickly realized that a plain language standard would be more effectively developed internationally, rather than nationally, and proposed the project to ISO. In 2019, ISO Technical Committee 37 (Language and Terminology) approved Standards Australia's initiative to develop a plain language standard globally. This was an enormous success because the standard could now be developed in alignment with all 35 national standard organizations that are members of the technical committee.

Subsequently, ISO TC 37 set up a working group (WG 11) to do the groundwork. The working group appointed a "drafting committee" of 8 members to do the initial writing of the many drafts and to discuss the feedback from both the national standard committees and other professional organizations such as Clarity, the Center for Plain Language, PLAIN (Plain Language Association International), the International Institute for Information Design, and the European Parliament.

The proposals of the drafting committee were then discussed and decided in the wider working group (WG 11), which comprised the delegates of the national standard bodies that had decided to become involved. Christopher Balmford was appointed Convenor and was tasked to lead the development and to ensure that the principles of ISO such as fairness, freedom of speech, equality, and consensus in all decisions were followed. The working group usually had some 30 delegates from 18 countries—from every continent except Antarctica—representing about 20 languages.

On a personal level, Christopher, being located in Australia, had to chair meetings starting at 11 PM and often continuing until 1 AM so as to accommodate the different time zones of the experts around the globe. Over some 4 years, there were many intense phases, particularly when revised drafts were due and when comments to drafts needed to be evaluated. Often, several hundred comments needed to be read, discussed, and decided upon. Each comment that had been made had to be responded to in writing!

LEADERSHIP, DEDICATION, AND COLLABORATION

Being a global endeavor, both the working group and the drafting committee comprised a wide range of different characters, all being experts in the field, each one of them enthusiastic about the topic, but each one with a well-formed and well-articulated opinion. It was the task of the Convenor to ensure that everybody was heard, every contribution was discussed, and, most importantly, a solution was found to which everybody could agree (in line with ISO's consensus principle). The role was also administrative, ie, calling for the meetings and, very often, writing the minutes.

To successfully perform at the helm of such a diverse and lively group of experts, it takes a well-balanced, patient, and emphatic character with a detailed understanding of the topic. Most helpful was Christopher Balmford's ability to thoughtfully guide discussions to a fulfilling conclusion.

The majority of the conceptual work was done by the drafting committee, which, during the many very intense phases, often had several meetings a week. Although the composition of the drafting committee changed over time, key members who contributed over extended periods of time were Annetta Cheek (USA), Vera Gergely (Hungary), Angelika Vaasa, (Belgium), David Lipscomb (USA), Susan Kleimann (USA), Torunn Reksten (Norway), Machiko Asai (Japan), Rosa Margarita Galán Vélez (Mexico), and Andreas Baumert (Germany; also, the author of this article was a member of this group for several months in 2022, substituting for Andreas Baumert). Furthermore, editing was handled by Gael Spivak (Canada). Many of them are involved in one of the plain language organizations.

Although good leadership was of great importance, the development of the plain language standard was successful because of the collaborative, inclusive, sharing attitude of both the members of the drafting committee and the WG 11 over some 4 intense years!

ALL'S WELL THAT ENDS WELL?

Before the standard could be finally published, it had to undergo various steps of approval and discussion in ISO. One of them was approval by ISO TC 37. In preparation of the final vote, all national standard bodies represented in TC 37 were given the opportunity to review and comment on the final draft. This alone took several months because the national standard bodies needed to be given enough time for their review. However, after approval by TC 37, the final standard was published in June 2023. It is now available at the ISO website (see above). The IPLF has also developed a detailed list of frequently asked questions about the standard.¹²

Although the standard is adopted on international level, national standard bodies with their respective committees are working on the localization of the standard to their language and territory. The IPLF offers a guideline and a checklist for all those plain language practitioners who want to engage in the adoption of the standard by their national standard body.¹³

Building on ISO plain language standard part 1, there are 2 initiatives underway that aim to expand the standard into the realm of

- legal writing and drafting¹⁴ and
- science writing (ISO/AWI 24495-3, *Plain Language* Part 3: *Science Writing*).

Furthermore, because ISO is re-evaluating every standard in 5-year intervals, the preparations for the next update have already begun.

Christopher Balmford has meanwhile stepped down and Angelika Vaasa, from the European Parliament, has

been appointed Convenor. However, given Christopher's enthusiasm for plain language, he will continue supporting the cause.

The ISO plain language standard was initiated and developed by an international group of experts and enthusiasts over 4 years in a process that was based on



Christopher Balmford

respect and equality. The standard will help authors to write documents in which readers find what they need, understand what they find, and use that information.

Author declaration and disclosures: The author notes no commercial associations that may pose a conflict of interest in relation to this article.

Author contact: thomas.schindler@biontech.de

References

- International Organization for Standardization. *Plain Language*, *Part 1: Governing Principles and Guidelines*, ISO 24495-1:2023; 2023. Accessed September 23, 2023. https://www.iso.org/ standard/78907.html
- 2. Standards. International Organization for Standardization. Accessed January 3, 2024. https://www.iso.org/standards.html
- 3. ICH Official web site. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Accessed January 3, 2024. https://www.ich.org/
- 4. The ISO plain language standard. International Plain Language Federation. Accessed December 20, 2023. https://www. iplfederation.org/iso-standard/
- Frequently asked questions: why is there a charge for standards? International Organization for Standardization. Accessed January 3, 2024. https://www.iso.org/footer-links/frequently-askedquestions-faqs/general-faqs.html
- Balmford C. An ISO standard for plain language: the back story and the next steps. 2018;79:6-10. Accessed January 3, 2024. https://www.clarity-international.org/wp-content/ uploads/2020/06/Clarity_79.pdf
- 7. Balmford C, Cheek A, Kleimann S, Harris L, Schriver K. Plain language standards. A way forward. *The Clarity Journal*

2018;79:11-16. Accessed January 3, 2024. https://www.clarityinternational.org/wp-content/uploads/2020/06/Clarity_79.pdf

- 8. Balmford C. An ISO plain language standard. International Plain Language Federation. Published September 7, 2020. Accessed January 3, 2024. https://www.iplfederation.org/an-iso-plainlanguage-standard/
- Balmford C. A language-neutral plain language standard a tool for us all. *PLAIN eJournal* 2021;3(2):6-7. Accessed January 3, 2024. https://plainlanguagenetwork.org/wp-content/uploads/2022/08/ pl_2021_e-journal_vol3_no2.pdf
- Developing standards: key principles in ISO standard development. International Organization for Standardization. Accessed January 3, 2024. https://www.iso.org/developingstandards.html
- International Plain Language Federation. Timeline of developing the ISO Plain Language Standard. GoogleDocs. Accessed January 3, 2024. https://docs.google.com/document/d/10vfmI55yXnikMC Jwp9NIDtdOpLcfXX5RyeVf4ZpHzjg/edit
- 12. Complete list of FAQs. International Plain Language Federation. Accessed January 3, 2024. https://www.iplfederation.org/1163-2/
- 13. Adopting and localizing the standard. International Plain Language Federation. Accessed January 3, 2024. https://www. iplfederation.org/adopting-and-localizing-the-standard/
- 14. International Organization for Standardization. *Plain Language, Part 2: Legal Writing and Drafting*, ISO/AWI 24495-2. Accessed January 3, 2024. https://www.iso.org/standard/85774.html

