REGULATORY TECHNICAL WRITING

LABOR ERGO SCRIBO!

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« … Compliance documents are critical documents covering a broad scope of objectives. They may be the permanent record of a compliance effort correcting a regulatory deficiency; justification for an approach utilized in product manufacturing required for new product approval; Annual Product Quality Review ….

Compliance documents may be consulted during the entire lifetime of a product, process, utility, *etc*., potentially spanning calendar years of time.

Quality and Compliance professionals must strive for excellence in the preparation of these documents as these documents must convey excellence for the personal credibility of the author, the reputation of the organization, and the success of the site Quality and Compliance functions…»

P.L. Pluta, Technical Writing for Compliance Part 1, IVT Network (2019)

INDEX

Background

- **Technical Report**

  Also known as *"scientific report"* is a document designed to convey technical information in a clear and easily accessible format.

« Technical reports are the documents in which engineers, scientists, and managers transmit the results of their research, field work, and other activities to people in their organization …
The importance of being able to write a good report cannot be emphasized too strongly …
Often, a written report is the only tangible product of hundreds of hours of work. Rightly or wrongly, the quality and worth of that work are judged by the quality of the written report – its clarity, organization and content. Therefore, it pays to take time to write a good report »

G. Blake, R.W. Bly, The Elements of Technical Writing, Macmillan (1993)

Background *(cont.)*

Blake and *Bly*, in their book, identify several types of reports:

- **Periodic report (⇔ *APQR*)**

  Report submitted at regular intervals to provide information on the activities or status of the organization. Bank statements, annual reports, and call reports are examples of periodic reports.

- **Progress report**

  Update on an ongoing activity as it is being carried out. The activity may be construction, expansion, research and development, production, or other projects.

G. Blake, R.W. Bly, The Elements of Technical Writing, Macmillan (1993)

Background *(cont.)*

- **Research report (⇔ *Validation report or Investigation report*)**

  Results of research, studies, and experiments conducted in the lab or in the field.

- **Field report (⇔ *Audit report*)**

  Results of an on-site inspection or evaluation of some field activity, which might be construction, pilot-plant tests, or equipment installation and setup.

G. Blake, R.W. Bly, The Elements of Technical Writing, Macmillan (1993)

Background *(cont.)*

- **Recommendation report**

  Report submitted to management as the basis for decisions or actions. It makes recommendations on such subjects as whether to fund a research program, launch a project, develop a new product, buy a piece of capital equipment, or acquire a company or technology.

- **Feasibility report**

  Report that explores the feasibility of undertaking a particular project, venture or commitment. It examines and compares alternatives, analyzes the pros and cons, and suggests which, if any, of the alternatives are feasible.

G. Blake, R.W. Bly, The Elements of Technical Writing, Macmillan (1993)

Background *(cont.)*

A type of technical report which is a little bit difficult to categorize because of its nature is the:

- **Executive Summary**

  It is a short document produced, in general, for business purposes. It summarizes a longer report or proposal or a group of related reports in such a way that readers can rapidly become acquainted with a large body of material without having to read it all.
  Unlike an abstract, is a document in miniature that may be read in place of the longer document.

In all cases it deals of technical documents divided into sections which allow different readers to access different levels of information.

Background (*cont.*)

- We all write for many different reasons: to inform, to explain, to teach, but also to remember, to tell, *etc*.
- « At least one third of an executive's time is spent writing »
- « Rarely are school-leavers or graduates capable of producing the kind of writing that their organizations desire »

R. Petelin and M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Background (*cont.*)

- «…Writing is at center of all disciplines and professions…»
- «…Writing is a process in which thinking and learning take place…»
- «…When people write about something, they understand and learn it better. That's why it's called the writing-thinking-learning connection…».
- «.. Writing creates ideas. … We write to find out we want to say. Writing is epistemic: it constructs / creates knowledge ...»

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Background (*cont.*)

- In 1970's it was established a "plain language movement" (PLAIN) in the US to encourage the use of a less bureaucratic language by regulators.
- In 2010, the use of plain English became a federal requirement, after President Obama's signing of the "Plain Writing Act". Similar initiatives have been launched in the UK and Ireland
- https://plainlanguage.gov is an official website of the United States government
- In 2006 the European Commission has created a guide for writing clearly in several languages (https://op.europa.eu/en/publication-detail/-/publication/725b7eb0-d92e-11e5-8fea-01aa75ed71a1/language-en)

Background (*cont.*)

Why writing business documents ?

« When writing business documents, one aim is usually to complete a task….

- provide answers to specific questions
- keep others informed about major activities
- help plan and co-ordinate activities (individual and organizational)
- analyze the elements and interrelationships of a situation
- instruct others
- establish accountability

R. Petelin and M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Background (*cont.*)

- But what does exactly writing mean?

WRITING MEANS PLANNING !

- **«** Like a house, a text needs a good design, solid foundations, an elevation, multiple entrances, and a roof that closes it. If it is airy it is better. Moving inside and finding the way must be simple. An original facade, but not bizarre. Finally, it must be appropriate for its function of use.»

L. Carrada, Lavoro, dunque scrivo!, Zanichelli (2012)

Background (*cont.*)

- From a general point of view, the writing process can be divided into three main phases:

- Let’s now get into the writing process in more detail

Background (*cont.*)

- «…Writing is often a rather invisible activity in organizations. Untrained writers think that because they can talk they can write. That's not necessarily so…»

- «…Writing well is a complex skill that develops slowly over time and not necessarily in a linear fashion…».

- «.. Experienced writers know that **writing is a difficult, complex, time-consuming, recursive process**. ... Put another way, they write with the intention of revising. They write knowing that it's easier to correct than to create...»

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Background (*cont.*)

If you cannot write well, you cannot think well;

if you cannot think well, others will do your thinking for you.

Oscar Wilde

I never travel without my diary.

One should always have something sensational to read in the train.

Oscar Wilde, The Importance of Being Earnest

Background (*cont.*)

Want to be an outstanding leader? Keep a journal

N. Adler, Harvard Business Review (2016)

- « Writing online doesn't provide the same benefits as writing by hand »
- « Pursuing an idea through writing requires us to think in a focused way… allows us to move beyond the trivial and immediate to the more complex and significant »
- « Rewriting demands an internal monologue on the ideas under consideration about phrasing, connections, "signposts", inclusions, exclusions, and structure »

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Background (*cont.*)

In summary:

Writing is not just getting things down on paper;

it's getting things into the minds of other people !

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

How can this be achieved ?

Simply looking at good writers !

Reading

What characterizes good writers?

« They:

- Know why they are writing and what their readers hope to find
- Prefer simple, direct expression of ideas
- Satisfy the reader's need for information, not their own need for self-expression
- Know the rules, but also know when to break them for effect
- Exhibit syntactic clarity and rhetorical sensitivity and sophistication
- Present work that has been meticulously edited and proofread »

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Reading (*cont.*)

Beside all this, what mostly characterizes good writers is that they are

GOOD READERS !

and therefore:

« If you want to learn to write well, immerse yourself in reading ! »

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Reading (*cont.*)

Why?

- Reading expands your vocabulary
- Reading exposes you to different writing styles
- Reading helps you subconsciously absorb the rules of syntax, grammar, style, and punctuation
- Reading helps you subconsciously absorb genre conventions, and the principles of effective structure and document design
- Reading gives you increased insight and inspiration

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Reading *(cont.)*

What does it mean that a text is "readable" ?

- Legible for the reader
- Aesthetically attractive to the reader
- Interesting to the reader
- Understandable to the reader

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Reading *(cont.)*

To achieve this target, in professional contexts you'll need to consider your readers':

- **education level**, field of study, theoretical, practical and/or technical knowledge
- **experience** academic, professional organizational, managerial, technical
- **familiarity with the subject**
- **expectations and needs of the document**
- **motivation to read**
- **urgency**, *i.e.*, how pressing is the need for information
- **context** in which the document will be read

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Reading Critically

What just said addresses a key issue:

« … As a writer, you'll need to try to be the best reader of your own documents … »

Since this is very difficult there is just one way of doing it:

READ CRITICALLY

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Reading Critically *(cont.)*

What does this mean Critically Reading?

- What is the aim of this document ?
- Why are you reading this document ?
- Who are the key intended readers of this document ?
- Is the approach to the subject matter appropriate for the readership ?
- What kind of reading does this document invite ? Chronological reading ? Skim reading ? Close reading?
- How is the document organized/structured ?

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Reading Critically *(cont.)*

- How is the document designed/presented ?
- Have you read similar documents ? If you have, how does this document compare with them ?
- How do you intend to use the information in this document ?
- Who do you think the writer is ? What kind of "voice" comes through ?
- Is the writer an authority on the topic, with an appropriate background and qualifications ?
- What perspective / framework informs the writer ?

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Reading Critically *(cont.)*

- Is there any evidence of bias in this document ?
- Is the content trustworthy, fair and sufficient ?
- Is the reasoning sounding?
- How practical or useful is this document ?
- Does the document have an index ?
- Is the material in the document up to date ?

It is useless to say that all these considerations are valid when reading a book too !

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

R.P. Clark, The Art of X-ray Reading, 1st Edition, Little, Brown and Co. (2016)

Structuring a document

After all these preliminary, but fundamental, consideration it is time to move to the core of this part, *i.e.*,:

STRUCTURING A DOCUMENT

Structuring a document *(cont.)*

From a very general standpoint the words of a famous writer, Rudyard Kipling, can be of help in this respect:

I keep six honest serving-men
(They taught me all I knew);
Their names are What and Why and When
And How and Where and Who.

Rudyard Kipling

Structuring a document *(cont.)*

- ***Who:*** will write the report ? On her/his behalf ? On the superior's behalf ?
- ***To whom ?*** who is the reader?
- ***What*** do your readers want to know? What do they need to know?
- ***Why*** does the report need to be written?
- ***Where*** the material comes from ? Where will you get your information?
- ***How*** the report will be organized, formatted, designed, checked, signed off, printed, and distributed ?
- ***When*** is the deadline?

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Structuring a document *(cont.)*

Producing coherent, well-structured writing in the academy and the workplace is achieved by:

1. using **TEXTUAL FEATURES** such as a foreword or preface, a table of contents, a title, an abstract or summary, and headings and subheadings that preview and clarify the structure of the document

2. providing an **ADVANCE ORGANIZER**, for example, *This report deals with ….*

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Structuring a document *(cont.)*

3. structuring coherent, well-punctuated, and unambiguous sentences

4. structuring coherent and cohesive paragraphs with a *topic sentence* to introduce a paragraph (where appropriate), and a *summary sentence* to conclude a paragraph (where appropriate)

5. presenting an appropriate sequence of ideas (when are you editing, check this against a retrospective outline)

6. using different levels of headings (major and minor headings) as signposts/cues to indicate the level of significance

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Structuring a document *(cont.)*

7. using distinct, repeated patterns

8. making it as easy on the reader as possible by linking different sections of a text using connecting words/ transitional expressions/ « cohesive ties »

9. providing useful redundancy, for example, repeating the same information in summary, introduction and conclusion of an essay or paper

10. anticipating and addressing potential pitfalls and areas of confusion for readers

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Structuring a document *(cont.)*

11. including visual representations such as pictures, graphs, tables, and infographic to illustrate complex concepts and phenomena….. readers can process graphic communication more quickly than words !

12. using appropriate typography and layout to enhance the text

13. concluding the document by summarizing and making recommendations, where appropriate.

R. Petelin, How Writing Works, 1st Edition, Allen & Unwin (2016)

Style

A well structured document is not enough !

Of fundamental importance is also:

STYLE

***i.e.*, rules of usage and principles of composition of plain English style.**

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

Style *(cont.)*

A list of reminders:

1. **Place yourself on the background**

   Write in a way that draws the reader's attention to the sense and substance of the writing, rather than to the mood and temper of the author.

2. **Write in a way that comes naturally**

   Use words and phrases that come readily to hand.

3. **Work from a suitable design**

   Gauge the nature and the extent of the work from a suitable design.

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

Style *(cont.)*

4. Write with nouns and verbs

Write with nouns and verbs, not with adjectives and adverbs, *e.g.*

- *Software-programmable modular information system* NO
- *A modular informative system with programmable software* YES

5. Use past tense to describe your experimental work and results

In this case the present tense would be inappropriate.

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

G. Blake, R.W. Bly, The Elements of Technical Writing, Macmillan (1993)

Style *(cont.)*

6. In most other writing, use the present tense

Hypothesis, principles, theories, facts and other general truths are expressed in the present tense. Avoid using the conditional could or would and invoking the future tense needlessly, because these uses add an unnecessary sense of indefiniteness to a definite statement.

7. Revise and rewrite

Revising is part of writing….. Save both the original and the revised version!

G. Blake, R.W. Bly, The Elements of Technical Writing, Macmillan (1993)

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

Style *(cont.)*

8. Do not overwrite

Rich, ornate prose is hard to digest!

9. Do not overstate

Do not describe something in a way that makes it seem more important than it really is. Do not use a big word when a smaller one will do !
abbreviate ⇔ *shorten*, *beverage* ⇔ *drink*, *concept* ⇔ *idea*, *currently* ⇔ *now*, *etc.*

10. Avoid the use of qualifiers

Avoid: *rather, very, little, pretty, etc.*

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)
G. Blake, R.W. Bly, The Elements of Technical Writing, Macmillan (1993)

Style *(cont.)*

11. Do not affect a breezy manner

Cut rhetoric. Be compact, informative and unpretentious.

12. Opt for an informal rather than a formal style

NO	YES
For the purpose of breaking up a beam of sunlight into the seven visible colors of the spectrum, a glass prism was procured.	I used a prism to break up sunlight into a rainbow.

Instead of *hitherto, inasmuch as, thereby, etc.* use: *so far, since, thus, etc.*

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

G. Blake, R.W. Bly, The Elements of Technical Writing, Macmillan (1993)

Style *(cont.)*

13. Use orthodox spelling

Do not write *nite* for *night*, *thru* for *through*, *pleez* for *please*, *etc.*

14. Do not explain too much

It is seldom advisable to tell all. Be sparing, for instance, in the use of adverbs after "he said", "she replied", *etc.* In other words: ***be plain !***

15. Do not construct awkward (= difficult) adverbs

Words that are not used orally are seldom the ones to put on paper. Once again: ***be plain !***

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

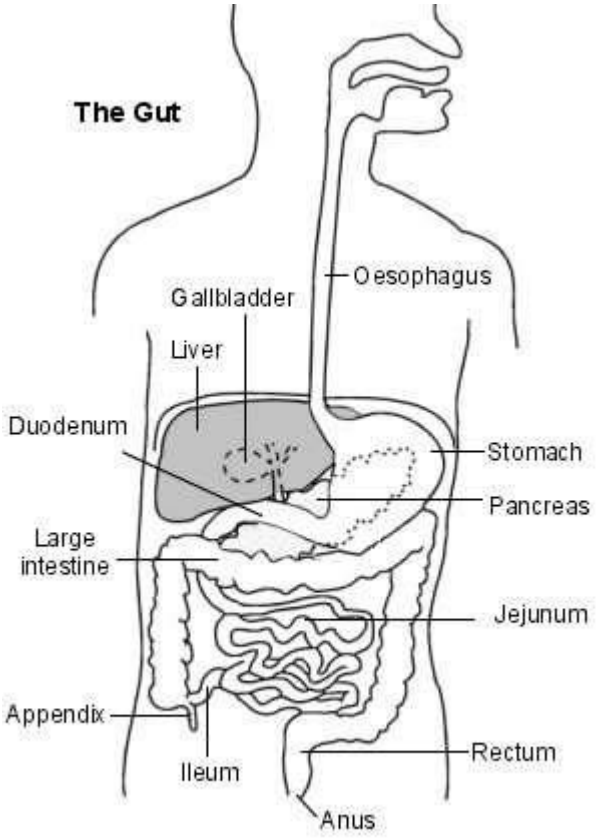
Style *(cont.)*

16. **Make sure the reader knows who is speaking**

    Dialogue is a total loss unless you indicate who the speaker is.

17. **Avoid fancy words**

    Prefer Anglo-Saxon words and use them properly: for example *gut* and *intestine* are not interchangeable …Never call a *stomach* a *tummy* (or *belly*) without good reason 😉



W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

Style *(cont.)*

18. Do not use dialect / slang / jargon

It is also advisable to avoid *legalese*, *computerese* or other specialized languages unless the report is intended specifically for that audience.

e.g., *drone*

- for military personnel ⇒ remote-control aircraft
- for biologists ⇒ male honeybee
- for Scotsmen ⇒ the continuously sounding pipes in their bagpipes ☺

Style *(cont.)*

19. Be clear

Since writing is communication, clarity can only be a virtue... When you become hopelessly mired in a sentence, it is best to start fresh.

20. Do not inject opinion

Try to keep things straight !

21. Avoid figures of speech

A “figure of speech” is a word or phrase that possesses a separate meaning from its literal definition (metaphor or simile) and it should be avoided. Once again, try to keep things clear preventing misunderstandings.

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

Style *(cont.)*

22. Do not take shortcuts at the cost of clarity

Do not use acronyms unless you are sure they will be easily understood.
A good rule is to start by writing out names in full, and then, later, to shorten them.

ESA stands for	European Space Agency
	Euratom Supply Agency
	European System of Accounts
	Endangered Species Act
	Environmentally Sensitive Area
	Eastern and Southern Africa
	Electron-Stimulated Adsorption
	and several other alternatives.

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

Style *(cont.)*

23. Avoid foreign languages

Write in English !

24. Prefer the standard to the offbeat

Avoid euphemisms and eccentricities typical of young writers like: *psyched*, *nerd*, *dude*, *geek*, *etc.*

W. Strunk, E.B. White, The Elements of Style, 4th Edition, Pearson (2000)

Style *(cont.)*

To conclude, two last points:

DON'T MISSPELL !

In fact:

« Erroneous spelling is a mark of illiteracy or at least carelessness ….. poor spelling may lead the reader to conclude that our reported results were obtained with equal careless ness. Needless to say, this detracts from the credibility of our findings »

ALWAYS USE THE ELECTRONIC SPELL CHECKER BEFORE RELEASING A DOCUMENT !

S.M. Rogers, Mastering Scientific and Medical Writing, 2nd Edition, Springer (2014)

Style *(cont.)*

PREFER ACTIVE STYLE INSTEAD OF PASSIVE !

- The investigation of the cytochrome P450-dependent drug metabolism *was carried out using* a microsomal preparation.
- *We investigated* the cytochrome P450-dependent drug metabolism in a microsomal preparation.

Active statements are shorter and avoid unnecessary guessing as to who is responsible for the work reported.

The passive style of writing was favored in the past, today is preferred the active voice !

S.M. Rogers, Mastering Scientific and Medical Writing, 2nd Edition, Springer (2014)

Style: a checklist

- ☐ **Prefer active style instead of passive**
- ☐ **Write in a way that comes naturally**
- ☐ **Place yourself on the background**
- ☐ **Write with nouns and verbs**
- ☐ **Use past tense to describe your experimental work and results**
- ☐ **In most other writing, use the present tense**
- ☐ **Revise and rewrite**
- ☐ **Do not overwrite**
- ☐ **Do not overstate**
- ☐ **Avoid the use of qualifiers**
- ☐ **Cut rhetoric. Be compact, informative and unpretentious**
- ☐ **Opt for an informal rather than formal style**

Style: a checklist (*cont.*)

- ☐ **Use orthodox spelling**
- ☐ **Do not explain too much**
- ☐ **Make sure the reader knows who is speaking**
- ☐ **Avoid fancy words and do not use dialect / slang / jargon**
- ☐ **Be clear**
- ☐ **Do not inject opinion**
- ☐ **Avoid figures of speech**
- ☐ **Do not take shortcuts at the cost of clarity**
- ☐ **Avoid foreign languages**
- ☐ **Prefer the standard to the offbeat**
- ☐ **Always use the electronic spell checker before releasing a document !**

Types of Documents *(cont.)*

- **Title / Cover page**

  This page must include:

  - Title of the report, date of issue, document number, revision number
  - Authors' and Reviewers' names, titles, signatures and dates
  - Descriptive Summary with Conclusions: purpose of the study, results, conclusions and recommendations /follow-up/ further actions if applicable.

  It is highly recommended to have the summary on the first page. This allows the reader to immediately grasp the meaning of the document and therefore decide whether to read the report or not. This aspect is particularly appreciated during audits where the amount of material to be viewed is usually a lot. 😉

Types of Documents *(cont.)*

- **Table of contents (or Index)**

  It is a list of all sections and subsections forming the document with page numbers.
  It is usually in the page immediately after the Title / Cover page.

- **Introduction / Purpose**

  This paragraph identifies the purpose and the scope of the document and « introduce the main message ».
  It should be written in a neutral way as the rest of the document, but there are also different opinions about it.

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Types of Documents *(cont.)*

- **Introduction / Purpose** *(cont.)*

  « It is conventional for the introduction to have a straightforward lead-in: “This report describes the activities of…and suggest that…” »

  Other types of lead-ins are possible, but, after reading the introduction, the reader must have anyway a clear understanding of the document's topic and its purposes.

  If it deals of a report following a study protocol, the reference to the protocol should be added and at the end of this section.

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Types of Documents *(cont.)*

- **Background / Preliminary Remarks**

  This paragraph is very important as it

  summarizes the knowledge available prior to the study in a chronological order clarifying the need and the meaning of the study reported in the document.

  As for the rest, it must be written clearly and concisely, illustrating the facts for what they are.

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Types of Documents *(cont.)*

- **Body of the document**

  This part of the document is the core of the report.

  In fact, the body of the document « develops the main message, as the writer provides evidence; explains; gives details and examples; defines terms and ideas; explores reasons, causes, effects, and points out similarities and differences »

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Types of Documents *(cont.)*

- **Body of the document** *(cont.)*

  This part of the document is divided into numbered and headed sections that separate different sub-sections in a logical order. For example, the body of an analytical technical report usually includes the following paragraphs:

  - Experimental Section
    - Materials and Methods
    - Analytical Procedures
  - Results and Discussion

  The structural correspondence with a scientific article is quite evident here more than elsewhere in the document.

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Types of Documents *(cont.)*

- **Conclusions**

  A short, logical summing up of the theme(s) developed in the main text.

  « Conclusions are usually considered weak if totally new or irrelevant ideas are introduced; a sudden reversal negates all previous information; impossible claims or promises are made; or the report ends on an apology or complaint.
  To write a powerful conclusion, end with a significant, relevant idea, for example, the greatest consequence or implication of the report's information. Some writers repeat a key term used in the introduction to tie together the whole report »
  In this paragraph is where recommendations are usually made.

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Types of Documents *(cont.)*

- **References (Bibliography)**

  Details of published sources of material referred to or quoted in the text (including any lecture notes and URL addresses of any websites used).
  Bibliographical references should be listed in the order in which they are cited.

- **Appendices (if appropriate)**

  Any further material which is essential for full understanding of your report (*e.g.*, large scale diagrams, computer code, raw data, specifications) but not required by a casual reader

- **List of Enclosures**

  A list of graphs, tables, *etc.* enclosed to the document as separated printed pages or included in the body of the document itself.

Types of Documents *(cont.)*

A bad example of cover page taken from the net: too messy !

THIS PAGE TO BE REPLACED WITH *XXXX* (IMPLEMENTATION SIGN-OFF FORM) FOR IMPLEMENTATION PHASE OF VALIDATIONS

Recommendations/Comments: Validation Team Leader

Name ..... Signature: ..... Date: .....

Recommendations/Comments: Change Manager

Name ..... Signature: ..... Date: .....

Recommendations/Comments: on behalf of Review Board

<Title of Process Owner>..... Name ..... Signature: .....

QA Representative: Name ..... Signature: ..... Date: .....

<File Name and CCR Reference Number:>

Validation Title	Validation of Automated grouping analyser using *xxx* software.	Validation Phase	Operational qualification

Change Control Reference Number: CC/05/133	Hospital/Trust:	Change Manager:

Validation Team	< 1 > Manager	< 2 > Manager	< 3 > Manager	QA Manager
Name				

Validation Start Date		Validation Finish Date:	

Short description of equipment or process being validated.

Testing of Automated grouping analyser using *xxx* operating software on Windows 2003 platform with a range of challenges to ensure system operability:

Security

Level and clot detection.

Probe failure rescue.

Barcodes interpretation.

Reagent Identification.

Serology resolution and interpretation.

Details of equipment used in the validation.

Automated grouping analyser using *xxx* operating software on Windows 2003 platform

Automated grouping analyser using *xxx* operating software on Windows 2000 platform

Name of IT system data interface and host system

ABD/ABD ref:5005 grouping cards

ABDDAB ref:5009 grouping cards

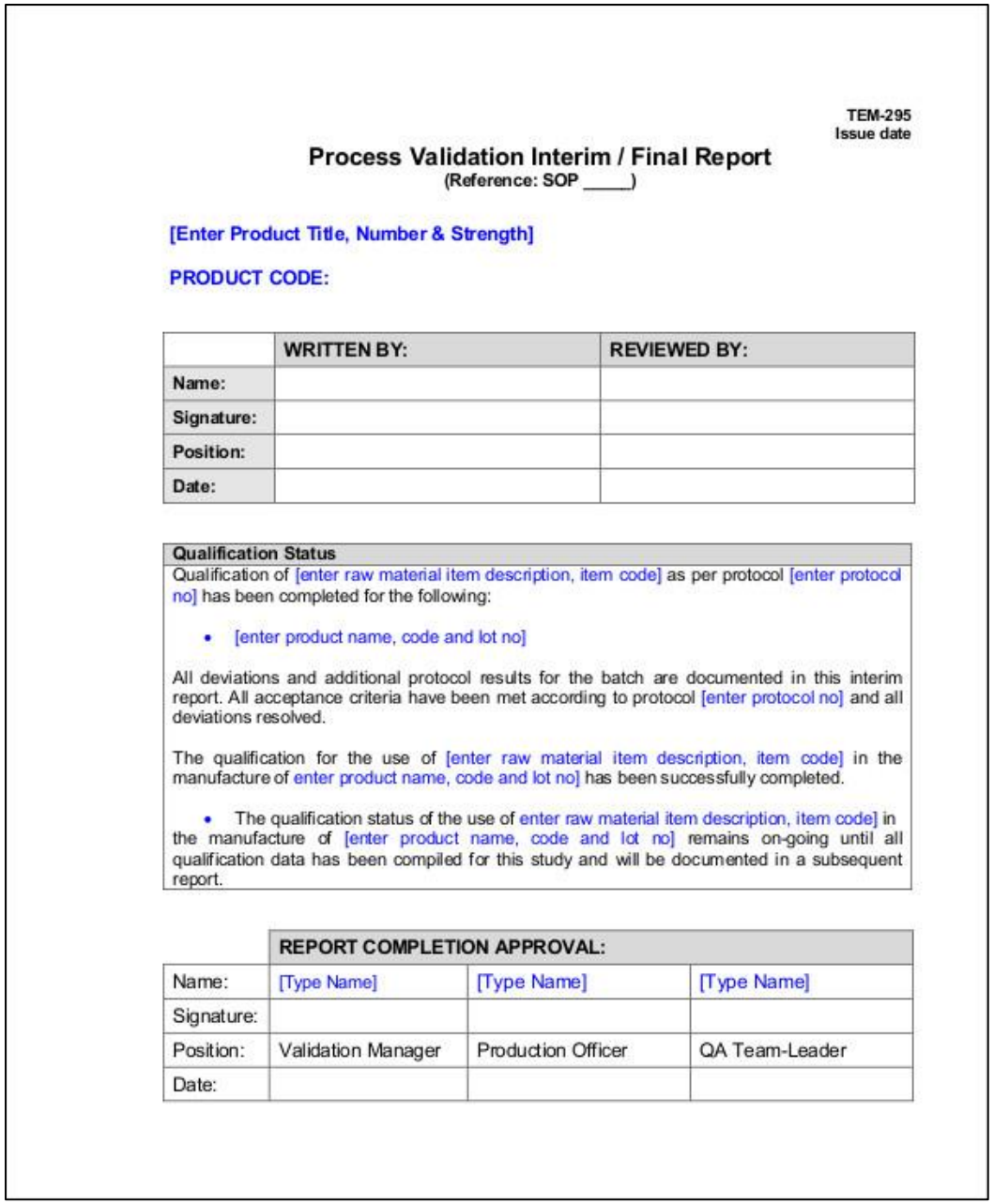
Rh/K ref:5011 phenotyping cards

LISS IAT ref:**** IAT cards.

Types of Documents *(cont.)*

Another bad example from the net !

Better than the previous one, but still messy !



TEM-295
Issue date

Process Validation Interim / Final Report
(Reference: SOP _____)

[Enter Product Title, Number & Strength]

PRODUCT CODE:

	WRITTEN BY:	REVIEWED BY:
Name:		
Signature:		
Position:		
Date:		

Qualification Status
Qualification of [enter raw material item description, item code] as per protocol [enter protocol no] has been completed for the following: • [enter product name, code and lot no] All deviations and additional protocol results for the batch are documented in this interim report. All acceptance criteria have been met according to protocol [enter protocol no] and all deviations resolved. The qualification for the use of [enter raw material item description, item code] in the manufacture of enter product name, code and lot no] has been successfully completed. • The qualification status of the use of enter raw material item description, item code] in the manufacture of [enter product name, code and lot no] remains on-going until all qualification data has been compiled for this study and will be documented in a subsequent report.

	REPORT COMPLETION APPROVAL:		
Name:	[Type Name]	[Type Name]	[Type Name]
Signature:			
Position:	Validation Manager	Production Officer	QA Team-Leader
Date:			

Types of Documents *(cont.)*

A possible cover page template!

ACME S.r.L. ANALYTICAL VALIDATION REPORT	
Report Title /No.: *Acetyl Salicylic acid: HPLC assay validation / 01 -2020*	
Pages in full Report: 10 + 12 Enclosures	**Issue date:** *xxxxx*
Author's Last name and initials: *xxxxx*	
Lisa Murray, *Head Quality Control*	**Signature** **Date**
Reviewer's/Supervisor's Name:	**Reviewer's/Supervisor's Signature /Date:**
Tim Robbins, *Quality Assurance*	**Signature** **Date**
Anna Brown, *Head Quality Assurance*	**Signature** **Date**

Descriptive Summary with Conclusions

This report deals with….

……..

In light of the experimental findings the validation of the HPLC method for Acetyl salicylic Acid can be considered successfully completed.

According to ACME SOP No…. , a periodic revalidation of the method must be undertaken by the end of 2025.

And now, what happens ?
The work continues ☺

Proofreading

« Proofreading is the final stage of the writing process and the one that, if neglected, can damage your professional image and cancel out all your efforts to produce a perfect document »

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

Proofreading *(cont.)*

There are several strategies for an efficient proofreading:

- « Limit proofreading to the final stage of your writing process… premature proofreading … is time wasted »
- « Allow time to elapse between writing and proofreading the document »
- **Print the document !**

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

L. Carrada, Lavoro, dunque scrivo!, Zanichelli (2012)

Proofreading *(cont.)*

- Use a pen or a pencil to look at each letter / word /punctuation or use a ruler and move it down the page line by line.
- **Read aloud !** Oral reading requires attention and it reveals not only the major errors (*e.g.*, complicated syntax) but also the more subtle ones such as repetitions, lack of smoothness, rigidity of style, *etc.*

A good rule of thumb is: don't write anything that you can't even decently pronounce!

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

L. Carrada, Lavoro, dunque scrivo!, Zanichelli (2012)

Proofreading *(cont.)*

- **Check the contents and their organization.** Has everything been said or has something escaped? Are connections between sentences logical and fluids? Headings are still consistent? Conclusions are still convincing ?
- **Grammar check !** Are tenses correct? And the prepositions?
- **Style improvement !** At this level it is necessary to cut as much as possible. Useless words, redundant sentences and unnecessarily complicated sentences must be eliminated. Let’s check if we can say the same things with fewer words !

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

L. Carrada, Lavoro, dunque scrivo!, Zanichelli (2012)

Proofreading *(cont.)*

- **Carefully check the sources of information !**

  Are names and dates correct?

  Quote the words of others in quotes or make a paraphrase. Do not attribute to yourself the merits of others !

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

L. Carrada, Lavoro, dunque scrivo!, Zanichelli (2012)

Proofreading *(cont.)*

- **Control of document formatting because form is substance !**

  The first impact with a text is visual**.**
  Are the paragraphs well spaced?
  Are the bold ones too many and are likely to confuse?
  Is the line spacing the right one for good readability?
  Is the font chosen the most suitable? Current trend is to use *Sans serif* for headings and *serif* for the body text.

R. Petelin, M. Durham, The Professional Writing Guide, Allen & Unwin (2003)

L. Carrada, Lavoro, dunque scrivo!, Zanichelli (2012)

Proofreading: a checklist

- ☐ **Limit proofreading to the final stage of your writing process**
- ☐ **Allow time to elapse between writing and proofreading the document**
- ☐ **Print the document**
- ☐ **With a pen look at each letter / word /punctuation moving down line by line.**
- ☐ **Read aloud and don't write anything that you can't even decently pronounce!**
- ☐ **Check the contents and their organization. Do not overstate.**
- ☐ **Check grammar**
- ☐ **Improve style ≡ Cut as much as possible**
- ☐ **Check the sources of information**
- ☐ **Control of document formatting because form is substance !**

Final Review

In summary, a well written technical document should meet the following standards:

- **TECHNICALLY & GRAMMATICALLY ACCURATE :** All information and data provided must be accurate. The wording must be grammatically correct, concise, and precise.
- **USEFUL :** The document must inform.
- **CONCISE:** Tell the whole story using the fewest possible words ! Conciseness ≠ Brevity !
- **COMPLETE:** Nothing essential is left out.
- **CLEAR :** Short and simple, no jargon, logically ordered in one step at a time

G. Blake , R. W. Bly, The Elements of Technical Writing, Macmillan (1993)

Final Review *(cont.)*

- **CONSISTENT:** The manuscript should be a " story " with a clear message based on a logical train of thought.
- **CORRECT:** In spelling, punctuation and grammar.
- **TARGETED :** Written for the majority, but also nontechnical should be able to get the gist!
- **WELL ORGANIZED:** A logical structure + well balanced mixture of text and visuals + high-quality data, all clearly presented without duplications.
- **INTERESTING:** People in the technical fields are human too !

G. Blake , R. W. Bly, The Elements of Technical Writing, Macmillan (1993)

CONCLUSIVE SUMMARY

CONCLUSIVE SUMMARY

- Each written document must be designed, drawn up and carefully reviewed
- Writing is a difficult, complex, time-consuming and recursive process
- There is just one main rule, but very difficult to follow: ***write simply and clearly !***
- Improving writing skills requires training, but above all practice. Critical reading of written texts helps
- « … Never consider excessive fussiness and accuracy when the texts must represent ourselves, our Company or our Customer … »

L. Carrada, Lavoro, dunque scrivo!, Zanichelli (2012)