

*Appendix A*

**DISCUSSION**

Results, including a description of any problems that were encountered and how they were resolved, should be presented and discussed.

**SIGNATURE PAGE**

**Study Director:** Name, signature and date

## APPENDIX B

### Style Guide for LUMI-CELL<sup>®</sup> ER Validation Study Laboratory Reports and Documents

**STYLE GUIDE FOR LUMI-CELL<sup>®</sup> ER VALIDATION STUDY  
LABORATORY REPORTS AND DOCUMENTS**

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## 10.0 PURPOSE AND SCOPE

The purpose of this style guide is to specify stylistic conventions and formatting details for laboratory reports and documents for the LUMI-CELL® ER validation study. This guide applies to all draft documents produced for this validation effort.

## 11.0 GENERAL INFORMATION

For correct spelling of words or abbreviations, use the One-look Dictionary, found at:

<http://library.niehs.nih.gov/research/alphalist.htm>.

Documents should use default stylistic conventions per: 1997. *Franklin Covey Style Guide for Business and Technical Communication*, 3<sup>rd</sup> Ed., Salt Lake City: Franklin Covey Co.

Documents should use the default stylistic conventions per the *Instructions for Authors* for *Environmental Health Perspectives* (EHP) at

<http://www.ehponline.org/docs/admin/edpolicy.html>.

In case of a conflict, *EHP Instructions for Authors* supersedes *Franklin Covey Style Guide*.

Items listed in this guide supersede those in the *Franklin Covey Style Guide* and *EHP Instructions for Authors*.

## 12.0 STYLE AND FORMATTING RULES

### 12.1 Acknowledgements Section (see also Front Matter)

List the names and affiliations of persons who contributed to the preparation and publication of the document. Use the format:

**ACKNOWLEDGEMENTS** (bold, all caps, centered on the first line of the page)

*The following individuals are acknowledged for their contributions to <fill in project name>*

(italics, sentence case)

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List names and affiliations in double column format (column width 2.9 inches; 0.5 inches space between). Single column format may be used if there are not enough people to be listed to fill a page.

Use one of these formats for the names and affiliations:

**Affiliation** (Institute or Organization; bold, initial caps)

Name of first person, degrees

Name of second person, degrees (plain text, single spaced)

Use this format to list multiple people with the same affiliation.

or

**Name of Person, degrees** (bold, initial caps)

Affiliation

Geographic Location (e.g., Research Triangle Park, NC; plain text, single spaced)

Use this format to list individuals with different affiliations.

Always use an individual's preferred or published name.

## 12.2 Acronyms

Spell out an acronym the first time it is used in the following document sections: preface, executive summary, table, figure, and document body. In the text immediately following the spelled out acronym, insert the acronym in parenthesis, e.g., National Institutes of Health (NIH). Everywhere else in that section, use the acronym.

## 12.3 Appendices

Designate appendices by letter (e.g., Appendix A, Appendix B, etc).

If an appendix has multiple parts, designate the part by number (e.g., Appendix A1, Appendix A2, etc).

Each appendix must have a cover page that contains the appendix designation and the appendix title. If the appendix has multiple parts, a table of contents listing each sub-appendix designation,

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title and the beginning page number for the sub-appendix must appear on the cover page. See the **Table of Contents** entry for formatting.

Format appendix page numbers with the appendix designation, followed by a hyphen, followed by the page number (e.g., if Appendix A has 100 pages, number them A-1 through A-100, even if the appendix has multiple parts.)

#### 12.4 **Bold Text (see also Emphasis, Italics)**

Use bold text only for formatting textual elements as indicated in this guide (e.g., headings, table headings, etc.).

Use bold text for figure, table, or a cross-reference to a section within the text (e.g., see **Section 2.2**)

Do not use bold text for general emphasis.

#### 12.5 **Body Text (see also, Font)**

Body text is 12 pt. type, times new roman font.

#### 12.6 **Bulleted and Numbered Lists**

The approved bulleted and numbered list styles are shown below.

This is sample text. This is sample text. This is sample text. This is sample text. This is sample text.

- This is sample text. This is sample text. This is sample text. This is sample text. This is sample text.
- This is sample text. This is sample text. This is sample text. This is sample text. This is sample text.

1. This is sample text. This is sample text. This is sample text. This is sample text. This is sample text.

The level of a numbered list is indicated by the left indent.

The table below shows the approved indents for each bulleted and numbered list level.



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List Level	Left Indent <sup>1</sup>	Hanging Indent <sup>1</sup>	Tab Stop Position <sup>2</sup>
1	0.7"	0.3"	1.0"
2	1.0"	0.3"	1.3"
3	1.3"	0.3"	1.6"

<sup>1</sup> This setting is shown in the **Paragraph** window accessed via the **Format, Paragraph** command.

<sup>2</sup> This setting is shown in the **Tabs** window accessed via the **Format, Tabs** command.

Other rules for lists:

If list items are complete sentences, capitalize the first word and fully punctuate.

If list items are single words, phrases, or sentence fragments, capitalize the first word but do not use a punctuation mark at the end.

### 12.7 Captions (see also Figures, Tables)

A figure and table title precedes the figure or table it refers to. Captions are in 12 pt. type.

Figure titles are to be short sentences describing the contents of the figure or table, e.g., Table 1-1 Example Figure Titles for LUMI-CELL<sup>®</sup> ER

Use the format **Table 1-1 Title of Table** (bold, initial caps). Do not use a period after the table number.

Left justify the caption. Set the tab and the hanging indent at 0.7 inch.

The caption number is the chapter or section number followed by a hyphen and the sequential number of the table or figure in that chapter.

### 12.8 Citations within the Text

Use the format in *EHP Instructions for Authors* for citations within the text.

The use of *et al.* after the name of the first author is acceptable in a citation within the text.

### 12.9 Color (see also, Hyperlinks)

Use only black text in a document.

Do not use colored shading.

#### 12.10 Commas in a series

Use a comma to separate each item in a series consisting of three or more words or phrases, including the word or phrase that immediately precedes the final conjunction (e.g., This approach was modified by assuming that there are three homogeneous subgroups rather than two: strong irritants, weak irritants, and nonirritants.)

#### 12.11 Dates (see also Headers)

Write dates in the dd/month/yyyy format (e.g., 17 March 2006).

#### 12.12 Document Titles

Document titles are centered, bold and in all caps. They contain the report type, test method name, and phase (e.g., **DRAFT REPORT ON LUMI-CELL® ESTROGEN RECEPTOR TRANSCRIPTIONAL ACTIVATION TEST METHOD – PHASE I**)

#### 12.13 e.g.,

Use the format shown for the abbreviation for *for example*.

#### 12.14 Emphasis (see Italics)

#### 12.15 et al. (see also Citations within the Text)

In a citation within the text, do not italicize or underline et al. (e.g., Bantle et al., 1998).

#### 12.16 Figures (see also Captions, Tables)

Preferably, place a figure immediately after the paragraph that first cites the figure. If this is not possible, place the figure as near to this paragraph as possible.

Do not place a figure in the middle of a paragraph.

Format footnotes to figures similarly to table footnotes.

#### 12.17 Filenames

Limit filenames to *15 characters or less*.

Test phases are referenced as roman numerals, e.g., the third phase is Phase III).

Abbreviations to be used in file names:

Agonist = Ag

Antagonist = Ant

Comprehensive Testing = CT

Draft Report = DR

Final Report = FR

Range Finder Testing = RF

Files shall be named as follows:

Excel<sup>®</sup> Spreadsheets for *Range Finding* - Laboratory designator, phase of testing, type of test, agonist or antagonist testing, replicate number (e.g. for Laboratory A, phase IIb, range finder, agonist testing, replicate number 2 would be named *AIIbRFAG2*).

Excel<sup>®</sup> Spreadsheets for *Comprehensive Testing* - Laboratory designator, phase of testing, type of test, agonist or antagonist testing, replicate number (e.g. for Laboratory A, phase III, substance V0015, comprehensive testing, antagonist testing, replicate number 2 would be named *AIIIV0015CTAnt2*).

*Draft Reports* - Laboratory designator, type of report, phase of testing, report date, and version or revision number (e.g. for Laboratory A, draft report, phase IIb, 12 June 06, version 2 would be named *ADRIIb12Jun06v2*).

*Final Reports* - Laboratory designator, type of report, phase of testing, report date, and version or revision number (e.g. for Laboratory A, final report, phase III, 15 June 06, version 1 would be named *AFRIII15Jun06v1*).

#### **12.18 Font (see also Body Text)**

Use Times New Roman font.

#### **12.19 Footnotes**

Insert footnotes using the Microsoft Word **Insert, Footnote** command.

Footnote text is 10 pt. type.

The footnote text always appears on the page that contains the footnote mark.

Always indicate a footnote with a superscripted number.

See the **Tables** entry for formatting of footnotes in tables.

## **12.20 Front Matter (see also individual entries for parts)**

All documents that will be sent to the project coordinators and study management team must contain front matter.

Front matter always includes:

Title page

Table of Contents

Front matter may also include (in the following order):

List of Tables

List of Figures

List of Acronyms and Abbreviations

Acknowledgements

Preface

Executive Summary

The preface and executive summary are formatted similarly to body text sections.

Use continuous lowercase Roman numerals for page numbering in all front matter sections.

Page numbers are continuous throughout all front matter sections.

## **12.21 Headings**

Use 12-point type for section headings.

Format headings as follows:

**1.0 HEADING 1 (bold, all caps).**

**1.1 Heading 2** (bold, initial caps).

1.1.1 Heading 3 (underlined, initial caps).

1.1.1.1 *Heading 4* (italics, initial caps).

Do not use headings below fourth level.

Set heading numbers flush left.

Indent heading text at 0.7 inches from left margin.

## **12.22 Headers and Footers (see also Margins, Pagination)**

Include headers and footers in every document.

The headers for draft and final reports must include:

The laboratory designation, report type, and phase (e.g., *Laboratory A Draft Report – Phase I*)

The date of document preparation, editing, or other revision (italics) in dd/month/yyyy format (e.g., *17 March 2006*).

- On a portrait-oriented page, tab the date to 6.25 inches, right-aligned.
- On a landscape-oriented page, tab the date to 7.75 inches, right-aligned.

In an appendix, include the entire appendix designation in the header.

Use single spacing in the header.

Italicize all text in the header.

See the header of this style guide for an example.

The document footer contains only the page number. The page number is to be centered and in 1 point Times New Roman font.

## **12.23 Highlighting Text for a Reviewer**

When highlighting text for a reviewer, use only the **Highlight** tool (shown below).



Do not use colored shading (i.e., **Format, Borders and Shading**) for highlighting.

#### 12.24 i.e.,

Use the format shown for the abbreviation for *that is to say*.

#### 12.25 Initial Caps

Initial caps means capitalize all words except articles and prepositions. If an article or a proposition is the first word, capitalize it.

#### 12.26 Italics

Use italics for textual elements as indicated in this guide, and for general emphasis.

Specifically use italics for:

Words as words (e.g., The word *basically* is almost always unnecessary and should be avoided in concise writing.)

Publication titles

A word used in an unfamiliar way (e.g., These effects include *pitting* of corneal epithelial cells, *loosening* of epithelium, *roughening* of the corneal surface and *sticking* of the test substance to the cornea.)

To set off single letters from other text (e.g., samples *a* and *b* were tested...)

Foreign words

#### 12.27 Line Numbers

Use line numbers in all reports. Line numbers are continuous throughout the document.

Do not use line numbering on the title page. Begin line numbering in the table of contents.

#### 12.28 Line Spacing

Line spacing is 1.5 lines.

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**12.29** Format the list of tables and the list of figures similarly. Refer to the following example.

LIST OF TABLES		
Table 1.1	Summary of Current U.S. Legislation Related to Ocular Health	1.2
Table 1.2	<i>In Vivo</i> Ocular Irritancy Classification Systems	1.5
Table 3.2	Chemical Classes Tested in the ICE Test Method	3
Table 3.2	Product Classes Tested in the ICE Test Method	3.6
Table 4.1	Scale of Weighted Scores for Grading the Severity of Ocular Lesions	4.2
Table 4.2	Test Guidelines for <i>In Vivo</i> Ocular Irritation Test Methods	4.4
Table 4.3	Criteria Required for Classification of Animals into GHS Ocular Irritancy Categories	4.11
Table 4.4	Criteria for Classification of Substances According to the GHS Classification System (modified from U.N. 2003)	4.13
Table 4.5	Criteria Required for Classification of Animals into EPA Ocular Irritancy Categories (EPA, 1996)	4.14
Table 4.6	Criteria for Classification of Substances According to the EU Classification System (EU, 2001)	4.16
Table 6.1	Evaluation of the Performance of the ICE Test Method in Predicting Ocular Corrosives and Severe Irritants Compared to the <i>In Vivo</i> Rabbit Eye Test Method, as Defined by the GHS Classification System, by Study and Overall	6.5
Table 6.2	Evaluation of the Performance of the ICE Test Method in Predicting Ocular Corrosives and Severe Irritants Compared to the <i>In Vivo</i> Rabbit Eye Test Method, as Defined by the EPA Classification System, by Study and Overall	6.8
Table 6.3	Evaluation of the Performance of the ICE Test Method in Predicting Ocular Corrosives and Severe Irritants Compared to the <i>In Vivo</i> Rabbit Eye Test Method, as Defined by the EU Classification System, by Study and Overall	6.11
Table 6.4	Substances with Discrepant <i>In Vivo</i> versus <i>In Vivo</i> Classification Results According to the GHS	6.15

Align the figure or table number flush left.

Indent the figure or table title 1.0 inch.

Set a right-aligned tab at 6.25 inches with a dotted leader for the page number.

### 12.30 Justification

Use left justification for document text.

### 12.31 Margins

Set all page margins to 1 inch.

Set the header and footer to 0.5 inches from edge.

### 12.32 Numbers

When they occur in the text, spell out the numbers zero through nine, unless the number:

Is part of a date (see **Dates**)

Is used as a noun (e.g., Table 1, Sample 2, a value of 8)

Is a quantity followed by a metric unit (e.g., ...3 mL were used...)

Appears in a list containing numbers below and above 10 (e.g., 6, 10, and 12 rabbits)

Use numerals for any number greater than nine, unless the number begins a sentence.

For numbers greater than 999, use commas to separate three-digit groups (e.g., 1,000; 546,074; 2,000,000)

Write all decimal numbers as numerals and use a leading zero (e.g., 0.3).

Avoid sentences that begin with awkward constructions (e.g., 5 g of test substance was weighed out ...) *Rewrite* so the number does not occur at the beginning of the sentence (e.g., Each assay contained 5 g of test substance...).

### 12.33 Numbered Lists (see **Bulleted and Numbered Lists**)

### 12.34 Page Breaks

Because they often must be deleted and reset at each version, minimize the use of hard page breaks in a draft document.

### 12.35 Pagination

Include page numbers in all documents. Position in the footer and center justify.

Use 10 pt. type for page numbers.

### 12.36 Quotation Marks (see **Emphasis, Italics**)



Use quotation marks only for direct quotations.

Do not use quotation marks for emphasis.

Always place a period or a comma inside quotation marks.

Always place a colon or a semicolon outside quotation marks.

If a question is a direct quotation, place the question mark inside the quotation marks.

If a question is not a direct quotation, place the question mark outside the quotation marks.

Use only one ending punctuation mark in a sentence that contains quotation marks.

If a question occurs both outside and inside of a direct quotation, use only one question mark and place it inside the quotation mark.

If a direct quotation contains a spelling or grammar error or contains factually incorrect information, insert [*sic*] immediately after the questionable material to indicate that the error occurred in the source document. *Sic* is a Latin word meaning *thus* or *so*.

### **12.37 References Section**

Use the format in the EHP *Instructions for Authors*, found at <http://www.ehponline.org/docs/admin/edpolicy.html#refe>, for references.

Exception: EHP allows the use of et al. after the first six authors; this study will require that all authors be listed.

### **12.38 Spacing**

Separate sentences with one space.

Insert one space after a colon or semicolon.

Always put a space between a number and its unit.

When a symbol precedes a number, do not put a space between the symbol and the number. (e.g. \$2.00, quantity <1).

### 12.39 Section Numbering

Section numbering is in decimal format. See the **Headings** entry for an example.

### 12.40 Significant Digits

When entering numerical data or the results of calculations into body text or tables, follow the standard rules for significant digits. This may result in tabulated numbers with different numbers of digits after the decimal point.

### 12.41 Symbols

Use only symbols from the Symbol and normal text fonts.

### 12.42 Tables

Do not create a table that goes outside of the page margins.

Do not allow a table row to break across a page.

Left-justify all tables, even if the table does not fill the page horizontally.

Preferably, place a table immediately after the paragraph that first cites the table. If this is not possible, place the table as near to this paragraph as possible.

Do not place a table in the middle of a paragraph.

Use 11 point Times New Roman or smaller for table text.

Footnote text following a table is one size smaller than the table text.

For tables that occur in the body of a document, do not use a font size smaller than 8 pt.

Shade the table heading row 10% gray.

Note that column headings and row items may be aligned in table cells as desired, however, maintain consistency of alignment in individual tables or in groups of related tables (i.e., tables that show the same type of data or results.)

Indicate footnotes within a table with superscripted numbers; do not use letters to indicate footnotes. Superscripted symbols (e.g., \*, \*\*, #, @) may be used to indicate a footnote if the same symbol is applied repeatedly to different items within a table, or if a numerical footnote

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would cause confusion (e.g., with an exponent). For example, a \* symbol might be used in a table of chemical substances to indicate which substances are insoluble in water.

Definitions of abbreviations used in a table need not be numbered in a footnote. Multiple definitions, listed in alphabetical order and separated by semicolons, may be included in one footnote. (e.g., n=Number; SCNM=Study Criteria Not Met).

Place table footnotes in the following order:

Abbreviations

Footnotes indicated by symbols

Footnotes indicated by numbers

Other than noted above, format table footnotes like text footnotes (see **Footnotes**).

Always right justify CASRNs in a table.

Always left justify Substance Names in a table.

The following table is properly formatted.

Substance Name	CASRN	ER TA Agonist Activity <sup>1</sup>	Anticipated Difficulty
17- $\alpha$ ethinyl estradiol <sup>2</sup>	57-63-6	+++	
Butylbenzyl phthalate	85-68-7	++	
<i>p</i> - <i>n</i> -nonylphenol	104-40-5	++	
<i>o,p</i> -DDT <sup>2</sup>	789-02-6	+	Can potentially "stick" to plastic tissue cultureware
Flavone <sup>2</sup>	525-82-6	+	
Genistein	446-72-0	+	Relatively insoluble
Atrazine <sup>2</sup>	1912-24-9	-	Cytotoxic
Vinclozolin	50471-44-8	-	

Abbreviations: CASRN = Chemical Abstracts Service Registry Number

<sup>1</sup>+++ Indicates that the substance was strongly active (EC<sub>50</sub> value was <0.001  $\mu$ M);

++ indicates that the substance was moderately active (EC<sub>50</sub> value was between

0.001 and 0.1  $\mu$ M); + indicates that the substance was weakly active (EC<sub>50</sub> value

was >0.1  $\mu$ M), or a positive response was reported without an EC<sub>50</sub> value. The

EC<sub>50</sub> is the effective concentration that causes half-maximal activation of the receptor.

<sup>2</sup>Tested for agonism.

**12.43 Table of Contents (see also Front Matter)**

Any document may have a table of contents if the authors think it is necessary.

Any document that contains more than one chapter or section must have a table of contents.

An individual chapter or section may have its own table of contents if the authors think it is necessary; however, if this format is used, all chapters or sections must have a table of contents.

If a document is composed of multiple electronic files, Microsoft Word's automated table of contents feature cannot be used. The feature can be used if the document is a single electronic file.

Format the table of contents as in the following example (all text is Times New Roman, 12 pt.):

bold, all caps	→	<b>TABLE OF CONTENTS</b>	
		LIST OF TABLES .....	x
		LIST OF FIGURES .....	xiii
		LIST OF ACRONYMS AND ABBREVIATIONS .....	xiv
		ACKNOWLEDGEMENTS .....	xvii
		PREFACE .....	xviii
		EXECUTIVE SUMMARY .....	xxviii
bold, initial caps	→	<b>1 Introduction and Rationale for the Proposed Use of <i>In Vitro</i> Test Methods to Identify Ocular Corrosives and Severe Irritants</b> .....	1-1
		1.1 Introduction .....	1-1
		1.1.1 Historical Background of <i>In Vitro</i> Ocular Irritation/Corrosion Test Methods and Rationale for Their Development .....	1-1
		1.1.2 Ongoing or Planned Peer Reviews of the ICE Test Method .....	1-8
		1.2 Scientific Basis for the ICE Test Method.....	1-8
		1.2.1 Purpose and Mechanistic Basis of the ICE Test Method.....	1-8
		1.2.2 Similarities and Differences of Modes and Mechanisms of Action Between the ICE Test Method and Ocular Irritation in Humans and/or Rabbits.....	1-9
		1.2.2.1 The Mammalian Eye: Common Anatomy of the Human and Rabbit Eye.....	1-9
		1.2.2.2 Differences Between Human and Rabbit Eyes.....	1-11
		1.2.2.3 The <i>In Vivo</i> Rabbit Eye Test Method.....	1-12
		1.2.2.4 Differences Between the Chicken and Mammalian Eye.....	1-13
		1.2.2.5 Comparison of the ICE Test Method with the <i>In Vivo</i> Rabbit Eye Test Method.....	1-14
		1.2.3 Intended Range of Substances Amenable to the ICE Test Method and/or Limits of the ICE Test Method.....	1-14
		1.3 Regulatory Rationale and Applicability.....	1-15