

Title: Good Documentation Practices

Document No: 730000523

Version No: 03

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1. PURPOSE

The purpose of this document is to establish a standard procedure within Waters, based upon generally accepted practices, for all documentation retained as records required by a Quality Management System.

2. SCOPE

The scope of this procedure is quality records [e.g. project documents, production records and other quality system records] including those that require hand written entries which are maintained to support Quality System requirements.

Additional record completion requirements specific to process, department or site, will be detailed within the individual procedure/work instructions as required.

Note: When completing customer provided documentation then the customer provided instruction takes precedence.

This procedure applies to all Waters personnel.

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition / Abbreviation
E.O.D	End of Data
GDocP or GDP	Good Documentation Practice The acronyms are used interchangeably, with GDP being used more historically and GDocP more recently [as GDP can also be used to signify Good Distribution Practice]. Within Waters, GDP is used to signify Good Documentation Practice unless otherwise stated.
Production records	Record that is created as a result of manufacturing, test, assembly or repair of Waters products, e.g. test reports, assembly logs, inspection results
Project document	Document created as result of design control activities, i.e. product development process
P.P. / PP	by proxy. Latin = per procuracionem
Quality record	Record that is created to support and provide evidence of implementation of the quality system
N/A	Not applicable
Transcription	Process of taking data entries and transferring them to another record

4. ROLES AND RESPONSIBILITIES

Roles	Responsibilities
All employees	All persons who make manual entries to records are responsible for ensuring that those records are completed in compliance with the requirements of this procedure and that training to this procedure is documented.

5. REFERENCES / RELATED DOCUMENTS

Doc No;	Document Title
730000295MP	Quality System Document Control
WAT000050MP	Waters Record Retention Corporate Policy
730000483	Global WI/Operating Procedure Template

6. FORMS

Not Applicable

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7. HEALTH & SAFETY

No Health & Safety specific considerations

7.1. Equipment/Materials of use Required

Not Applicable

8. PROCEDURE

All sections are applicable to records with hand written entries except section 8.2 which is specific to computer based records.

See Appendix 1 for examples.

8.1. General Requirements

Roles	Tasks/Instructions
All employees	8.1.1. All entries must be made directly onto the record in a timely manner as the operation occurs, i.e. record the data at the time of performing the task. Note: It is prohibited to photocopy forms with pre-populated entries to generate additional records. 8.1.2. All manual entries must be made in blue or black indelible ink. Pencil or red pen is not permitted. 8.1.3. All manual entries must be clear and legible. Use block capital letters if necessary. 8.1.4. A record is to contain the signature of person[s] making manual entry[s] and date of signature. Signature may take the form of initials or full signature; initials/signature must be traceable to the individual. 8.1.5. When entering repetitive data, ditto marks are not to be used. It is permissible to line through a complete area/section and denote the line with a value for the whole area/sections if the value is the same in each section, this should be signed and dated. If data points are being recorded manually over time, the data should be recorded in line with section 8.1.1, even if the data has the same value. 8.1.6. All records should be paginated (e.g. page 1 of 10). 8.1.7. Attachments must contain reference to parent document and be paginated (e.g. page 1 of 10). It is acceptable to reference the parent document on the initial page only if the pages are permanently fixed together (e.g. stapled) 8.1.8. Recording of measurements must include the correct unit of measurement, e.g. if a weight is expressed in grams, the entry must include an indication of the unit: "g". 8.1.9. When comments or additional information are added to a document, the extra information must be signed and dated by the person entering the comments. 8.1.10. If a designee is to be used, then that person signs his/her name and print name against the original printed name [P.P./PP prefix maybe used to identify delegation] . There must be a documented record that proves the person is a designee, e.g. designee list, job description, designation authorization, unless direct supervisor of original named person. Designee must have evidence of training in the relevant procedure that governs activity being designated.

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8.2. Computer based records

Roles	Tasks/Instructions
All employees	8.2.1. Primary (raw data) records such as: - Approval of Policies / Procedures - Pre approval and post approval of Change Controls - Approval of Non conformances shall be completed using a "date stamped" entry. 8.2.2. Typed dates and names entered in the system to record completion of actions for which the primary record (raw data) is elsewhere (for example recording completion dates of actions) shall reference the primary data source and match the date entries in that raw data.

8.3. Date & Time Requirements

Roles	Tasks/Instructions
All employees	8.3.1. Date format must use alpha characters to designate the month to avoid confusion from differing dating conventions. Any of the following formats are acceptable. Dots or dashes can be added between the elements as required. Superscript th and st can be appended to day. • 05 Apr 2017; • 05 Apr 17; • 05 April 2017; • 05 April 17; • April 05, 2017. 8.3.2. Back dating or post dating is not permitted. 8.3.3. When time information is required, entry is to be in 24 hour clock format (e.g. 16:30 or 16.30).

8.4. Corrections of errors are made as follows:

Roles	Tasks/Instructions
All employees	Note: No handwritten changes or corrections can be made to printed text of an approved controlled document. Changes to pre-defined content are performed via document control processes. 8.4.1. Draw a single line through the incorrect entry without obscuring the original information (over writing is not permitted). 8.4.2. Write the correct information as close to the original entry as the document will allow. If space is limited the use of annotation symbols may be used to link correction to original entry e.g. asterisks, numbering. 8.4.3. Sign/initial and date the correction. The date of correction is the date the correction was made, not the date the error was made. 8.4.4. An explanation for the correction should be included if it is not obvious why the correction was made. 8.4.5. The use of correction fluid/tape, e.g. Whiteout or Tippex, is not permitted. 8.4.6. Manual corrections that impact the intent or decision/results of a record can be made only by the author of a document or department Supervisor/Manager in absence of author. Administration/minor changes that do not impact the intent of the record can be made by the author, reviewer, approver or Quality e.g. corrections to spelling or clarification.

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8.5. Blank Spaces

Roles	Tasks/Instructions
All employees	8.5.1. When completing a record make sure spaces or fields which do not require any information are denoted as Not Applicable (N/A), sign and date the entry. 8.5.2. It is permissible to line through an area and denote the line with Not Applicable (N/A), sign and date; this indicates that section of the document is not applicable. If subsequent data is required to be recorded, the N/A should be crossed through, signed and dated. 8.5.3. E.O.D may be used to denote End Of Data with signature and date, indicating that further sections of the record are Not Applicable. If subsequent data is required to be recorded, the EOD should be crossed through, signed and dated. 8.5.4. Records may also contain specific options to complete only applicable sections of the process. e.g. an instruction may advise the employee to continue from specific sections leaving other sections unused. This needs to be clearly indicated and instructed within the governing document and/or record.

8.6. Rounding and Reporting of Data:

Roles	Tasks/Instructions										
All employees	8.6.1. All raw data will be recorded exactly as observed in the manner defined in the governing procedure and/or specification. 8.6.2. If the procedure or specification requires that the measurements are to be recorded to a specific number of significant digits, the results should be rounded. If the extra digit is 5 or greater, round up. If 4 or less, round down per the example below: <table> <tr> <th>Reading (raw data)...</th><th>Reported as ...</th></tr> <tr> <td>20.15 -----></td><td>20.2</td></tr> <tr> <td>20.19 -----></td><td>20.2</td></tr> <tr> <td>20.14 -----></td><td>20.1</td></tr> <tr> <td>20.12 -----></td><td>20.1</td></tr> </table>	Reading (raw data)...	Reported as ...	20.15 ----->	20.2	20.19 ----->	20.2	20.14 ----->	20.1	20.12 ----->	20.1
Reading (raw data)...	Reported as ...										
20.15 ----->	20.2										
20.19 ----->	20.2										
20.14 ----->	20.1										
20.12 ----->	20.1										

8.7. Transcription of data

Roles	Tasks/Instructions
All employees	Applicable to transcription not specified within governing procedure/work instruction. e.g. rewrite for clarity, rewrite due to damage of original record. 8.7.1. If manual entries made at the time of operation (original) required transcription to a new record, the original must be kept and appended to new record. 8.7.2. Transcribed entries must be identified detailing 'original' record, reason for transcription, name of person performing transcription, signature and date (ref 8.1.4).

8.8. Meaning of Signatures

Roles	Tasks/Instructions
All employees	8.8.1. Signatures/Initials on quality documents mean the following, unless otherwise stated: 8.8.1.1. I did the work as required by the procedure/work instruction. 8.8.1.2. I have checked that the data/information is accurate, complete and correct based on my review.
All employees	8.8.2. The format of the signature and initials used should be in the same format as recorded on the personnel register/signature log, if applicable. 8.8.3. If a personnel register is not maintained then ensure that where there is more than one person with the same initials working in the same area that they are distinguished by the addition of a middle initial or employee number. e.g. Larry Hann [LH], Linda Sarah Hall [LSH]

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9. APPENDICES / ATTACHMENTS

Appendix 1

GDocP Quick Reference Guide

Date Formats	Acceptable	Date Formats	Acceptable	Reason																																							
05 Dec 17		5th Dec 2017		The zero is missing, this could be modified to 15 or 25																																							
05 Dec 2017		06/05/17		Incorrect month format, this could be interpreted as 05 June or 06 May																																							
05 December 17				Incorrect month format, this could be interpreted as 05 June or 06 May																																							
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<table><tr><th>Weight (g)</th><th>Completed By</th><th>Date</th></tr><tr><td>13.2</td><td>J. Bloggs</td><td>02-Jul-13</td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td></td><td></td></tr><tr><td></td><td>N/A JB</td><td>02/Jul/13</td></tr></table>	Weight (g)	Completed By	Date	13.2	J. Bloggs	02-Jul-13								N/A JB	02/Jul/13		<table><tr><th>Time</th><th>Weight (g)</th><th>Completed By</th><th>Date</th></tr><tr><td>9.00</td><td>13.2</td><td>J. Bloggs</td><td>02-Jul-13</td></tr><tr><td>9.15</td><td>"</td><td>"</td><td>"</td></tr><tr><td>9.30</td><td>"</td><td>"</td><td>"</td></tr><tr><td>9.45</td><td>"</td><td>"</td><td>"</td></tr><tr><td>10.00</td><td>12.3</td><td>C. Smith</td><td>02-Jul-13</td></tr></table>	Time	Weight (g)	Completed By	Date	9.00	13.2	J. Bloggs	02-Jul-13	9.15	"	"	"	9.30	"	"	"	9.45	"	"	"	10.00	12.3	C. Smith	02-Jul-13		Ditto marks are not acceptable. It is not clear who filled in the data.
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DOCUMENT HISTORY

VERSION:	03	ORIGINATOR:	Wendy Baker	Change ID:	N/A
SUMMARY OF CHANGE: Clarify purpose and scope, remove reference to Waters Division as no longer exists. Add definitions of GDocP and Transcription. GDP acronym changed to GDocP throughout document now commonly used to represent Good Distribution Practice and statement added to definitions. Update role to All employees and state training on procedure must be documented. Remove references to site specific documents. General requirements – specify that photocopying of partially completed records to generate other records is not permitted. Add permitted method as substitute to ditto marks. Change use of PP to denote designee as optional. Addition of computer based records section. Date requirements – update examples to 2017 Corrections – Clarify date of correction. Add that minor administration changes that do not impact intent record can be made by author, reviewer, approver or Quality. Blank spaces – add option that record and/or governing document can instruct to leave section blank. Clarify how to cancel N/A or EOD annotation. Rounding – specify that data is to be recorded as detailed within governing procedure. Meaning of signatures – clarify the check on accuracy is based on review. Clarify distinguishing initials example Appendix 1 – update examples to reflect procedure updates. All delta signs removed as all sections have been updated					
VERSION:	02	ORIGINATOR:	N/A	Change ID:	N/A
SUMMARY OF CHANGE: Change abandoned.					
VERSION:	01	ORIGINATOR:	C Spalding/L Hogan	Change ID:	N/A
SUMMARY OF CHANGE: Update to template 730000483 version 06, addition of requirements when transcribing data, clarification of when manual corrections can be executed. Addition of Appendix 1 GDP Quick Reference Guide. Addition of requirement to have a designee documented record. Addition of section on meaning of signatures					