



<b>DOC.ID:</b> WP-001	<b>WORKING PRACTICE TITLE:</b> SC DELIVERABLE REVIEW
<b>Version:</b> 1.0	<b>Effective Date:</b> 31DEC2017

<b>Purpose and Scope</b>	<ul style="list-style-type: none"> <li>This document describes the process for applying version control and review to PhUSE deliverables and documents identified by the Steering Committee. The PhUSE Project Coordinator, Technical Director or designee are responsible for ensuring this document is included in a tracking document named “Master List of Documents.xlsx”.</li> </ul>
<b>Policy Statements</b>	<ul style="list-style-type: none"> <li>The purpose of this Working Practice (WP) is to add further detail in support of SOP 001.</li> </ul>
<b>Terms, Acronyms and References</b>	<ul style="list-style-type: none"> <li>RACI – Step ownership matrix showing individuals who are (R)esponsible,(A)ccountable, give (C)onsent and who are (I)nformed per associated task.</li> <li>&lt;Link to process flowchart &gt;</li> <li>&lt;Link to SOP&gt;</li> </ul>
<b>Audience and Responsibilities</b>	<ul style="list-style-type: none"> <li>The PhUSE Technical Director or designee is responsible for the maintenance of this working practice.</li> <li>All PhUSE Office personnel, BoD, WG SC and WG Members and designees are responsible for adhering to this working practice.</li> </ul>

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<b>Task Matrix</b>	(Step#/RACI)	1	2	3	4	5	6	7	8	9	10	11	12	13	13.1	13.2	13.3	13.4	13.5	
	PhUSE Technical Director or designee			C	C	C								I	I	I	C	A		
	PhUSE Project Coordinator	I	I	I	I	I								I		R	R/A	I		
	Public																I	R		
	Project Team	R	R	R	R	R	R	R	R	C	I	I	I	I	I	I	I	I	I	R
	Project Team Leads	A	A	A	A	A	A	I	A	A	I	A	A	C	A	A	C	I	A	
	Steering Committee (SC)										I	R	R	R	R					
	Working Group Leads						I	A		A	A	I	I	I						

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<b>Task Matrix continued</b>	(Step#/RACI)	14A	14B	15	16	17	18	19	20	21	22	23
	PhUSE Technical Director or designee	I	C	I	I	I	I	I		I	I	A
	PhUSE Project Coordinator	I	I	I	I	I	I	I	I	I	I	I
	Public										I	
	Project Team	I	I	I					I	R	R	
	Project Team Leads	I	I	A	I	I	I	I	A	R	R	I
	Steering Committee	R/A	R/A	R	A	A	A	A	R	I	I	I
	Working Group Leads	I	I	I	I	I	I	I	I	A	A	R
	SDO Representative			I	R			R				
	FDA Representative			I		R		R				
	Other Review Representative			I			R	R				

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Perform the steps below to complete the process.

Step	Responsible Function	Action	Expected Result/Outcome
1.	Project Team	<ul style="list-style-type: none"> <li>Confirm with the Steering Committee (SC) that deliverable needs versioning and review, then start this process.</li> </ul>	Deliverable has been identified and is ready to go through process
2.	Project Team	<ul style="list-style-type: none"> <li>Determine the disposition of the deliverable.</li> </ul>	The deliverable required an Incremental version update, is New, or Final.
3.	Project Team	<ul style="list-style-type: none"> <li>If applicable, get incremental version number from PhUSE Project Coordinator, Technical Director or designee who will assign this number after recording it in the tracking document.</li> </ul>	The deliverable version has been assigned as the original number + 0.1
4.	Project Team	<ul style="list-style-type: none"> <li>If applicable, get new version number from PhUSE Project Coordinator, Technical Director or designee who will assign this number after recording it in the tracking document.</li> </ul>	The deliverable version has been assigned as version number 0.1
5.	Project Team	<ul style="list-style-type: none"> <li>If applicable, get final version number from PhUSE Project Coordinator, Technical Director or designee who will assign this number after recording it in the tracking document.</li> </ul>	The deliverable version has been rounded up to the next whole number increment; n.0
6.	Project Team	<ul style="list-style-type: none"> <li>Send the deliverable to Working Group Leads for review.</li> </ul>	Working Group Leads have received the deliverable
7.	Working Group	<ul style="list-style-type: none"> <li>Working group leads determine if further updates are required</li> <li>If so, feedback is sent to the Project Team who will incorporate it (Step 8).</li> </ul>	Deliverable goes through

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	Leads	<ul style="list-style-type: none"> <li>If no updates required, document is ready for SC, go to Step 9.</li> </ul>	feedback loop until ready for SC
8.	Project Team	<ul style="list-style-type: none"> <li>If necessary, manage the feedback from review and update the deliverable accordingly, go to Step 2.</li> </ul>	Deliverable has been updated per feedback
9.	Working Group Lead	<ul style="list-style-type: none"> <li>Send deliverable to PhUSE PC for Steering Committee review.</li> </ul>	Deliverable has been sent to the SC
10.	Steering Committee	<ul style="list-style-type: none"> <li>Confirm receipt of the deliverable.</li> </ul>	Deliverable has been received by the SC
11.	Steering Committee	<ul style="list-style-type: none"> <li>Review project deliverable and comments for any policy or sensitivity issues.</li> </ul>	Deliverable and comments policy or sensitivity issues identified
12.	Steering Committee	<ul style="list-style-type: none"> <li>Determine the next action for the deliverable.               <ul style="list-style-type: none"> <li>PhUSE Public Review (Step 13)</li> <li>Public Release (Step 14A)</li> <li>External Review (Step 14B)</li> </ul> </li> </ul>	Next action is identified
13.	Steering Committee	<ul style="list-style-type: none"> <li>If applicable, deliverable will go through PhUSE Public Review process (Steps 13.1 – 13.5).</li> <li>Else go to public release or external review (Steps 14A – 14B).</li> </ul>	PhUSE Public Review process is initiated or determination is needed for release or external review
13.1	Steering Committee	<ul style="list-style-type: none"> <li>Send recommendation to PC for PhUSE Public Review of deliverable.</li> </ul>	Public review recommendation is sent to PC
13.2	PhUSE Project Coordinator	<ul style="list-style-type: none"> <li>Post deliverable on the PhUSE Deliverables for Review Site (includes contacts).</li> </ul>	Deliverable posted to review site

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13.3	PhUSE Project Coordinator	<ul style="list-style-type: none"> <li>Initiate advertising availability of new deliverable for review.</li> </ul>	Deliverable is under public review
13.4	Public	<ul style="list-style-type: none"> <li>Review deliverable and send comments to Project Team contacts.</li> </ul>	Project Team contacts receive comments
13.5	Project Team	<ul style="list-style-type: none"> <li>Contacts collate and communicate comments to rest of Project Team.</li> </ul>	Public comments sent to Project Team following public review
14A	Steering Committee	<ul style="list-style-type: none"> <li>If ready for public release then go to Step 20 for marketing the deliverable and check to see if external review is needed in Step 14B. Marketing may be conducted even when deliverable is undergoing external review.</li> </ul>	Decision is made for marketing and/or external review.
14B	Steering Committee	<ul style="list-style-type: none"> <li>If external review is needed then go to step 15, else go to step 20 for marketing the deliverable. Please note that Step 14A public release may happen concurrently with external review.</li> </ul>	Deliverable is sent for marketing and/or external review.
15.	Steering Committee	<ul style="list-style-type: none"> <li>Primary Contact sends deliverable to External Organization for review. Please note, the deliverable should be pretty well final (ie, after PhUSE Public Review) before going out for external review.               <ul style="list-style-type: none"> <li>Deliverable sent to FDA Review Process – go to step 16.</li> <li>Deliverable sent to SDO Review Process – go to step 17.</li> <li>Deliverable sent to Other organization – go to step 18.</li> </ul> </li> </ul>	Deliverable sent to the appropriate external stakeholder for review
16.	FDA	<ul style="list-style-type: none"> <li>Deliverable is received and sent through FDA Review Process. Please note, this does not imply that FDA Working Group members cannot provide feedback during project team updates or PhUSE public reviews.</li> </ul>	Deliverable is reviewed externally
17.	SDO	<ul style="list-style-type: none"> <li>Deliverable is received and sent through SDO Review Process. Please note, this does not imply that SDO Working Group members cannot provide feedback during project team updates or PhUSE public reviews.</li> </ul>	Deliverable is reviewed externally

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18.	Other Review Process	<ul style="list-style-type: none"> <li>Deliverable is received and sent through Other Review Process. Please note, this does not imply that others involved in this process that may also be Working Group members cannot provide feedback during project team updates or PhUSE public reviews.</li> </ul>	Deliverable is reviewed externally
19.	FDO, SDO or Other Reviewer	<ul style="list-style-type: none"> <li>Send review feedback to appropriate Steering Committee Primary Contact and go to Step 12.</li> </ul>	Feedback received by SC PC
20.	Working Group Lead	<ul style="list-style-type: none"> <li>Send deliverable approval note to Project Team Lead.</li> </ul>	Working Group or Project Leads receive approval for marketing
21.	Project Team	<ul style="list-style-type: none"> <li>Create marketing information for the deliverable.</li> </ul>	Marketing information is created for deliverable
22.	Project Team	<ul style="list-style-type: none"> <li>Post deliverable and marketing information to the appropriate channel.</li> </ul>	Deliverable and information are available to all
23.	Project Team Lead	<ul style="list-style-type: none"> <li>Send note PhUSE Project Coordinator regarding final status and marking information for the deliverable.</li> </ul>	Communication Committee has been made aware of the deliverable and appropriate information
24.	Done	<ul style="list-style-type: none"> <li>This process is complete.</li> </ul>	Process is complete.

## Amendment Record

Version	Date	Description of Changes
1.0	31DEC2017	New Document Release

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## Review and Approval

The Document Owner is the PhUSE Technical Director or BoD designee who must sign along with the author. Both signatures are required for the document to be considered as approved.

<b>Identification</b>	<b>Document Author Approval</b>	<b>Document Owner Approval</b>
<b>Name:</b>	<b>Anup Patel</b>	<b>Stephen Bamford</b>
<b>Title:</b>	<b>PhUSE Technical Director</b>	<b>PhUSE Events Director</b>
<b>Signature:</b>		
<b>Date:</b>	<b>31<sup>st</sup> December 2017</b>	<b>31<sup>st</sup> December 2017</b>

## Document History

<b>Version</b>	<b>Author</b>	<b>Reason of change</b>	<b>Date</b>
1.00	Chris Hurley	Create this first version WP-001	December 31, 2017

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