

Comments on WHO Working Document QAS/.....

Title of the document : WHO Good xxxxxxx practices for yyyyyyyyy



World Health Organization

Comments submitted by : xxxxxx

Telephone number : xxxxxx

Address : xxxx

Email : x

Date : xxxxxxxx

Example for comments

Kindly complete the table without modifying the format of the document - thank you.

# section	# Paraph If more than one	Comment / Rationale	Proposed change / suggested text	Classification L= low M= medium H= high	Originator of the comments (for WHO use)
General comment(s) if any :					Originator of the comments
4.11	3	Manufacture of Sterile Preparations	There is a typo under point (b) – “lee” should be revised to “less”.	L	
10.7		Clause states the clothing required for each grade of the working area and the first sentence added to 3 rd paragraph Grades A/B (personnel should be excluded from Grade A) is related to a practice. New filling lines allow to comply with the exclusion of personnel from grade A.	Delete “personnel should be excluded from Grade A areas” in this clause and include a new one using a wording similar to US Food and Drug Administration’s 2004 Aseptic Processing Guidance “As operator activities increase in an aseptic processing operation, the risk to finished product sterility also increases.	H	
		<i>Box will increase automatically as you type</i>			
		<i>Please add rows as necessary (with "copy and paste" empty rows)</i>			