經濟部標準檢驗局 產品驗證生產廠場品質管理系統查核表

Inspection Checklist for Quality Management System of Product Certification Production Premise Registered by the Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs, R.O.C.

	基本資料 ^I Basic Information ^I		
品質管理驗證機構 Quality Management Certification Body	查核日期 Inspection Date		
受查核生產廠場 Production Premise to be inspected	廠名/Name: 廠址/Address:		
品質管理系統驗證之 稽核類型 ² Audit Type of Quality Management System Certification ²	□重新驗證/Re-Certification □追查/Surveillance □其他/Others:		
登錄產品驗證類別 ³ Registered Product Certification Category ³	□商品驗證登錄 Registration of Product Certification (RPC) RPC 證書名義人及識別碼: RPC Certificate Holder and Identification No. of RPC: 登錄產品名稱: Name of the Paristanad Products		
	Name of the Registered Product: □ 自願性產品驗證 Voluntary Product Certification (VPC) VPC 證書名義人及識別碼: VPC Certificate Holder and Identification No. of VPC:		
	登錄產品名稱: Name of the Registered Product:		

查核項目	觀察結果		
Inspection Items		Observation	Results
1. 生產廠場(以下簡稱該廠)是否營運中			
或已經主管機關登記為歇業?4			
Is the production premise in operation or is			
it registered as closed by the competent			
authority? ⁴			
2. 該廠是否知道自己已被登錄為 BSMI RPC	□否/No		
或 VPC 之生產廠場? ⁵			
Does the production premise realize that it			
is registered as the production premise of	□是/Yes		
RPC or VPC by the BSMI? ⁵	RPC/VPC 證:	書名義人:	
		tificate Holder:	
(1)如果不知道,請說明該廠與 RPC 或 VPC 證書名義人間業務往來情形?			
If no, please explain business dealings		h . e mb .	
between the production premise and the	RPC/VPC 證:	-	
RPC/VPC certificate holder?	RPC/VPC Cer	tificate No.:	
(2)如果知道,請說明 RPC 或 VPC 的證書			
名義人是誰?與自己相關的 RPC 或			
VPC 證書號碼有那些?			
If yes, please explain who is the RPC or			
VPC certificate holder and what are the			
RPC or VPC certificate numbers?			
3.1 該廠是否持續滿足 ISO 9001 標準要求?	□是/Yes		
Does the production premise continuously	□否/No		
meet the requirements of ISO 9001?			
3.2 有無不符合事項,不符合對應條款及內		/In conformity	
容為何?6	□不符合/Nonce		
Is there any non-conformity? Please	條款/clause	:	內 容/ content
specify the nonconformity and its			
corresponding clause in the requirements. 6			
	□相符/consiste	 nf	
RPC/VPC 證書之產品範圍相符? ⁷	□ 不相符/incons		
Does the manufacturing equipment or		sistent .	
activity of the production premise comply			
with the scope of the registered products	│ │□無異動/No Cl	anga	
covered in the RPC/VPC certificate? ⁷	□無共動/No Ci □有異動/Chang	0	
_		/Items	台田/Description
4.2 本次稽核 ISO 9001 證書內容是否異動?	N. 1. 2.	/Items	說明/Description
如有異動,請說明異動後之資訊為何?			
Has the content of ISO 9001 certificate	廠址/Addres		
been changed during the audit? If there is	登錄範圍/So	cope	
any change, please note the changed	驗證標準/	G. 1 1	
information. ⁸	Certification		
		ertificate No.	
	證書效期/E	_	
	其他事項/O	thers	

查核項目	觀察結果
Inspection Items	Observation Results
5. 該廠產製過程所依據規範為何,以使產品能持續滿足 RPC 或 VPC 證書上所適用之法規、法令及檢驗標準要求? What specification does the production premise abide by to make the products in keeping with the applicable regulations and inspection standards covered in RPC or VPC certificate? 9	
6. 該廠如何管理產製過程,以使後續產製產品能與 RPC 或 VPC 所登錄之型式一致? ¹⁰ How does the production premise manage the manufacturing processes to ensure the subsequently manufactured products are in compliance with the product type registered in the RPC or VPC certificate? ¹⁰	
7.1 已登錄為 RPC 或 VPC 產品是否能依規定於本體或外包裝上標示【商品安全標 → +識別號碼 Rxxxxx】或自願性產品驗證標誌【	
查核人員簽章: Signature of Inspector:	受查核生產廠場代表簽章: Signature of Representative of Inspected Production Premise:

填表說明/Directions

- 1. 基本資料應於赴生產廠場<u>前</u>完成,以便於查核過程抽樣。
 The basic information should be completed **before** going to the production premise to conduct sampling during the inspection process.
- 本表各查核事項應於稽核生產廠場時確認,如於生產廠場重新驗證稽核時執行,請勾選重新驗證;如於後續維持驗證稽核時執行,請勾選追查;如於其他作業時執行,請勾選其他,並請說明之。

To fill in the form when auditing a production premise, please confirm and click on "re-certification" in case it is to do the re-certification and click on "surveillance" for maintaining the certification. Click on "others" and describe it if none of the above matches.

- 3. 請於查核前至 BSMI「品管驗證機構系統」(https://rpconline.bsmi.gov.tw/app/loginqmi.jsp)或至 BSMI 官網「首頁/資訊與服務/查詢業務總覽」查詢該生產廠場取得本局商品驗證登錄(RPC) (https://civil.bsmi.gov.tw/bsmi_pqn/pqn/uqi2102f.do) 或 自 願 性 產 品 驗 證 (VPC) (https://civil.bsmi.gov.tw/bsmi_pqn/pqn/uqi2108f.do)之相關資訊,包含證書名義人及識別號碼及登錄產品名稱,以利查核時確認,倘資料量多時,得另附加清冊。
 - Before the inspection, you may need your agent's help to go online for the BSMI "Quality Management Certification Body System" page (https://rpconline.bsmi.gov.tw/app/loginqmi.jsp, Chinese only) or go to the Chinese homepage of BSMI official website to search for the related information (including the certificate holder, identification number of RPC/VPC, and the name of the registered products applied by the inspected production premise) about the registration of product certification (RPC) (https://civil.bsmi.gov.tw/bsmi_pqn/pqn/uqi2102f.do) or voluntary product certification (VPC) (https://civil.bsmi.gov.tw/bsmi_pqn/pqn/uqi2108f.do) so as to make confirmation during the inspection process. List it in the form of an inventory in the case of massive amount of data.
- 4. 查核項目第 1 項:請確認生產廠場是否為營運中的工廠,倘該廠呈停工狀態,請說明是否已向 貴機構報備,停工期為何。無論生產廠場的營運狀態為何,皆應至主管機關公示資料查明最新 的 登 記 資 訊 (國 內 廠 商 登 記 資 訊 請 至 下 述 網 站 查 詢 (https://findbiz.nat.gov.tw/fts/query/QueryBar/queryInit.do)。 Inspection item 1: Please identify if the inspected production premise is in operation at present. If it has come to a standstill, please specify if it has reported the status with the downtime duration until resumption already. The inspector(or with the help of the agent) should find the latest registration

information on the competent authority's public disclosure site.

- 5. 查核項目第 2 項:請向生產廠場確認是否知道自己已被登錄為 BSMI 產品驗證之生產廠場。如生產廠場表示不知道時,應進一步詢問其與 RPC 或 VPC 證書名義人間是否有業務往來,倘生產廠場表示沒有時,請立即通知 BSMI (TEL: 02-23431805,Email: lingju.huang@bsmi.gov.tw)。如生產廠場表示知道時,請其說明所掌握的 BSMI 產品驗證現況,並據實填寫。 Inspection item 2: Please confirm with the inspected production premise whether it knows that it is registered as the production premise of RPC/VPC by the BSMI or not? If no, continue to inquire if there are business dealings with the RPC/VPC certificate holder and inform the BSMI immediately if there are none (Email: lingju.huang@bsmi.gov.tw). If the production premise is aware of being registered, demand it to specify the BSMI current certification status of the registered RPC/VPC products as far as it knows and write down according to that.
- 6. 查核項目第 3.2 項: 稽核時如發現有不符合 ISO 9001 事項,請簡要描述不符合依據條款及內容 (如 4.1 XXXX)。

Inspection item 3.2: If the production premise is found any non-conformity to the requirements of

ISO 9001 during the audit process, please indicate the non-conformity and its corresponding clause briefly.

- 7. 查核項目第 4.1 項: 請確認當年度生產廠場現場設備或生產活動與 RPC/VPC 證書登錄產品範圍 之相符程度,倘有不一致情形,應說明不一致的情形及後續處理方式。
 - Inspection item 4.1: Please check if the manufacturing equipment or activities on the field of the production premise for the current year are in compliance with the scope of the registered products covered in the RPC/VPC certificates. Describe the situation and the follow-up processing if any inconsistency occurs.
- 8. 查核項目第 4.2 項:請說明經該次稽核是否異動 ISO 9001 證書內容,如有異動時,應描述異動項目之資訊。
 - Inspection item 4.2: Please indicate if there are any changed contents in the ISO 9001 certificate through the audit and specify the changed information if any.
- 9. 查核項目第 5 項:請說明生產廠場於產製過程中使用 BSMI 公告之法規、法令或檢驗標準現況,倘該廠未採用時,請描述該廠實際所依循其他規範情形(如 ISO/IEC 國際標準、國家標準等)。
 - Inspection item 5: Please specify the current status of which the regulations, rules, or inspection standards that announced by the BSMI are applied in the production processes. If none of the above are applied, please describe the actual situation of which the specifications are abided by (e.g. ISO/IEC standards, national standards and so on).
- 10. 查核項目第 6 項:請說明生產廠場是否取得登錄於 BSMI 之型式試驗報告或技術文件資料,倘該廠未取得時,請描述該廠產製過程實際管理情形(如規格依據、生產計畫等)。 Inspection item 6: Please confirm if the production premise has received the type-testing reports or technical documents registered by the BSMI or not. If the answer is negative, please describe its practical condition of manufacturing processes management (such as the basis/source of specification and manufacturing plans).
- 11. 查核項目第 7.1 項:請至少抽查 1 件取得本局登錄之產品,並說明商品安全標章或自願性產品 驗證標誌(含識別號碼)實際使用情形。倘該廠表示非由該廠執行標示作業時,請向該廠確認後續 作業流程並記錄。
 - Inspection item 7.1: Please sample at least one of the products registered by the BSMI from the production premise and specify the practical condition of labeling the product safety mark with identification numbers or VPC mark with identification numbers. If the production premise express that it is not responsible for the mark labeling, please check the follow-up operation procedure with the production premise and make a record of it.
- 12. 查核項目第 7.2 項:請至少抽查 1 件非登錄於本局之產品,觀察是否有誤用或違規使用標章或標誌之情形。
 - Inspection item 7.2: Please sample at least one of the products not registered by the BSMI and see if there is any misuse or illegal use of the aforementioned marks.
- 13. 查核項目第8項:當有其他重要發現與生產廠場相關時,請於本項說明。
 - Inspection item 8: Please note or specify here in this item if there are other important findings related to the production premise.