Module 3: Product Description

3.3.3 Standard Operating Procedures (SOPs)

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On the following pages, please find an overview of the currently valid Directives, Standard Operating Procedures (SOPs) and Working Instructions (WKIs), which are employed by the PMP S.A. for below mentioned processes. The current versions of the Quality Documentation is available at PMP S.A. upon requested.

1. CORPORATE PROCESS DOCUMENTATION

Process	QMS Documents
Manufacturing and production activities, including a description of facilities and all production steps	Directive: • **PMI-RRP-DIR-114284 Commercial Manufacturing (RRPCE):** This document describes the minimum requirements and responsibilities to manufacture PMI RRPs for commercial purpose. Standard Operating Procedures: • **PMI-RRP-SOP-113902 Identification and Traceability (RRPCE):** This document describes key elements and general requirements for the traceability of RRPs consumables. • **PMI-RRP-SOP-110795 Batch Control of Semi & Finished Products for RRPs (RRPCE):** This document describes the process for batch sampling, testing and assessing at laboratories the acceptability of RRPs semi & finished products for batch release according to the relevant quality control strategy. • **PMI-RRP-SOP-110792 Production Batch Record Management (RRPCE):** This document describes the process to manage production batch records from the time they are issued to the time they are archived. • **PMI-RRP-SOP-110793 Batch Disposition for Commercial Manufacturing (RRPCE):** This document describes the batch disposition process for the commercial batches of RRPs to certify that each batch meets the established specifications. • **PMI-RRP-SOP-110800 In-Process Control Management for RRPs (RRPCE):** This document describes the general approach for the development, validation and operation of in-process control instruments/systems intended for monitoring and/or control of RRPs during commercial production.

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	• **PMI-RRP-SOP-110790 Master Batch Record Creation and Maintenance (RRPCE):** This document describes how master batch record are created, reviewed and updated for a semi-finished product, or in case of a change (recipe, process, or specifications modification), in order to ensure traceability and conformity of the manufacturing records completed during production.
Managerial oversight and employee training	Directives: • **PMI-RRP-DIR-112740 Quality Management Review (CC-RRPCE):** This document describes the requirements for the quality management review process to ensure that the Quality Management System (QMS) remains suitable, adequate, effective, and aligned with PMI strategies and quality objectives. • **PMI-RRP-DIR-112836 Competence and Training Management (CC-RRPCE):** This document describes the requirements for the management of QMS related competence and training in order to ensure that individuals are competent/qualified to fulfill their assigned tasks, and to ensure that the qualification status of employees is continuously maintained. Standard Operating Procedures: • **PMI-RRP-SOP-112742 Quality Management Review Process (CC-RRPCE):** This document describes how to perform Quality Management Review (QMR) to ensure that the QMS remains suitable, effective, and aligned with PMI strategies and quality objectives. • **PMI-RRP-SOP-114287 Training Management (CC-RRPCE):** This document describes how to manage QMS related training in PMI organization to ensure that the employees are competent/ qualified to fulfill their assigned tasks, and to ensure that the qualification status of employees is continuously maintained.
Manufacturing processes and controls for product design risk and any mitigations for identified hazards that have been implemented	Directive: • **PMI-RRP-DIR-112834 Risk Management (RRPCE):** This document establishes the requirements, roles and responsibilities, as well as a guidance for executing quality risk management related to RRPs. • **PMI-RRP-DIR-112837 Change Management (CC-RRPCE):** This document describes the requirement for the management of changes. Standard Operating Procedures:

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	• **PMI-RRP-SOP-110729 Process Risk Management pFMEA (RRPCE):** This document establishes the requirements for the risk management of the RRP QMS related to facility and process. • **PMI-RRP-SOP-111979 Change Management Board (RRPCE):** This document describes the review and approval process of the escalated RRP changes, and the roles and responsibilities of the Change Management Board (CMB) for RRPs. • **PMI-RRP-SOP-110777 Process Characterization (RRPCE):** This document describes the key elements of the process characterization that is the methodology to define the appropriate manufacturing control strategy and establishes the process controls required to ensure that the delivered products consistently meet the expected quality and requirements.
Activities related to identifying and monitoring suppliers and the products supplied (including, for example, purchase controls and materials acceptance activities)	<u>Directives:</u> • **PMI-RRP-DIR-114254 Supplier Quality (RRPCE):** This document defines the requirements related to the supplier quality management process. • **PMI-RRP-DIR-113699 Material Management (RRPCE):** This document defines the requirement to establish a sustainable material management process, by ensuring the full integrity and traceability of materials during the entire lifecycle of PMI products. • **PMI-RRP-DIR-112381 Product Stewardship (RDNEU):** This document describes the requirements of product stewardship activities for the RRPs and conventional products. <u>Standard Operating Procedures:</u> • **PMI-RRP-SOP-114255 Qualification and Monitoring of RRP Suppliers (RRPCE):** This document describes the process of qualification, monitoring and re-qualification of suppliers providing goods or services to PMI. • **PMI-RRP-SOP-113457 Shelf Life Management of RRP Materials (RRPCE):** This document describes the shelf life management of materials used for assessment and commercialization of RRPs and defines the process to establish and maintain the shelf life of materials, and extend the shelf life date of material batches. • **PMI-RRP-SOP-113459 Incoming Material Inspection for RRPs (RRPCE):**

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	This document defines incoming material inspection process, to assure the quality of materials delivered by suppliers fulfils PMI requirements and therefore can be used in production. • **PMI-RRP-SOP-113461 Materials Suppliers Final Inspection Strategy (RRPCE):** This document describes the criteria and the laboratory control inspection process to be followed by materials suppliers, to ensure that the material/component delivered to any PMI manufacturing centers fulfils the PMI quality requirements and consequently can be used for the production of RRPs and/or their related semi-finished products. • **PMI-RRP-SOP-114053 Source Inspection of RRP Devices (RRPCE):** This document defines the process for inspecting RRP devices produced, tested and released by Electronic Manufacturing Services (EMS) in order to verify their functionalities during the different phases of the product lifecycles. • **PMI-RRP-SOP-112375 Regulatory Toxicology and Compliance of Reduced Risk Products (RRPCE):** This document identifies the process for the evaluation of Direct Materials (DIM) and of new/revised design used in Heated Tobacco Products (HTP) and Nicotine Containing Products (NCP) for their specific intended use, and identifies the outcome provided to a requestor. This document describes the process of regulatory and toxicological compliance assessment of products intended for human exposure, and also the requirements for the release of an item in PLM by product stewardship from a regulatory and compliance perspective.
Validation and verification activities used to ensure the tobacco product matches specifications	<u>Directive:</u> • **PMI-RRP-DIR-111873 Product and Process Development & Maintenance (CC-RRPCE):** This document defines the requirements for the development, commercialization and maintenance of all PMI products as well as their manufacturing process. <u>Standard Operating Procedures :</u> • **PMI-RRP-SOP-114971 Process Qualification and Validation (RRPCE):** This document describes the qualification, validation and hyper care approach for the manufacturing process of RRPs consumables. • **PMI-RRP-SOP-114964 Continued Verification (RRPCE):**

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	This document describes the activities to perform in order to confirm that the manufacturing processes for the production of RRPs are maintained at the same level of control compared to initial validation.
Testing procedures conducted before the products released for sale and distribution in the U.S. including information such as the concentration of the standard solution as well as a description of acceptance activities with protocol and acceptance criteria	Directive: • **PMI-RRP-DIR-113525 Testing Laboratories (RRPCE):** This document specifies the general requirements to carry out tests on RRPs in the PMI testing laboratories to ensure the integrity and traceability of the product data. Standard Operating Procedures: • **PMI-RRP-SOP-110793 Batch Disposition for Commercial Manufacturing (RRPCE):** This document describes the batch disposition process for the commercial batches of RRPs to certify that each batch meets the established specifications.
Handling of complaints, nonconforming products and processes, and corrective and preventative actions	Directives: • **PMI-RRP-DIR-110809 Customer Care (RRPCE):** This document defines a set of guidelines to setup the customer care function for RRPs. • **PMI-RRP-DIR-112835 Nonconformity (NC) & Corrective and Preventive Action (CAPA) (CC-RRPCE):** This document defines the requirements for the management of Nonconformities (NCs) and Corrective and Preventive Actions (CAPAs). Standard Operating Procedures: • **PMI-RRP-SOP-110811 Customer Care Management (RRPCE):** This document describes the customer facing processes for RRPs covering customer management and incident management. • **PMI-RRP-SOP-110810 Post-Market Surveillance for RRPs (RRPCE):** This document describes the passive Post-Market Surveillance (PMS) processes and activities for all RRPs for which PMI is the legal manufacturer. • **PMI-RRP-SOP-114285 Nonconformity Management (CC-RRPCE):** This document describes the process for the management of NCs related to products and processes including material, equipment, data services and systems.

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	• **PMI-RRP-SOP-114289 CAPA Management (CC-RRPCE):** This document describes the process to manage Corrective and Preventive Actions (CAPAs).

2. DEVICE MANUFACTURING PROCESS DOCUMENTATION

Process	QMS Documents (PMI only)
Manufacturing and production activities, including a description of facilities and all production steps	-
Managerial oversight and employee training	-
Manufacturing processes and controls for product design including a hazard analysis that detail the correlation of the product design attributes with public health risk and any mitigations for identified hazards that have been implemented	Directives: • **PMI-RRP-DIR-111873 Product and Process Development & Maintenance (CC-RRPCE):** This document defines the requirements for the development, commercialization and maintenance of all PMI products as well as their manufacturing process. • **PMI-RRP-DIR-112834 Risk Management (RRPCE):** This document establishes the requirements, roles and responsibilities as well as a guidance for executing quality risk management related to RRPs. Standard Operating Procedures: • **PMI-RRP-SOP-118559 RRP Firmware Development (RDNEU):** This document describes the process for the development and release of firmware for RRPs devices and accessories. • **PMI-RRP-SOP-111909 RRP Design Change (RRPCE):** This document describes the procedure for initiating, assessing, authorizing, implementing and closing design changes to the RRPs during their development and commercialization. • **PMI-RRP-SOP-111916 How to Perform Design Failure Mode and Effect Analysis (dFMEA) (RDNEU):** This document describes the process for the initiation, approval and maintenance of Design Failure Mode & Effect Analysis (dFMEA) to address design-related failures for RRPs.

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Process	QMS Documents (PMI only)
Activities related to identifying and monitoring suppliers and the products supplied (including, for example, purchase controls and materials acceptance activities	Standard Operating Procedure: • **PMI-RRP-SOP-114227 Audit Process Management (CC-RRPCE):** This document describes the process of preparing, conducting, reporting and following-up an audit within PMI organization. The audit process is designed to monitor and verify whether the PMI organization conforms to the requirements of the QMS of PMI and the applicable international standard(s) and regulations.
Testing procedures conducted before the products released for sale and distribution in the U.S.	Standard Operating Procedures: • **PMI-RRP-SOP-114053 Source Inspection of RRP Devices (RRPCE):** This document defines the process for inspecting RRP devices produced, tested and released by Electronic Manufacturing Services (EMS) in order to verify their functionalities during the different phases of the product lifecycle. Working Instructions: • **PMI-RRP-WKI-114043 iQOS Holder Source Inspection Protocol (RRPCE):** This document describes and defines the inspection activities of the iQOS Holder, which consists of sampling plan, testing equipment, visual inspection and functional testing steps. • **PMI-RRP-WKI-114050 iQOS Pocket Charger Source Inspection Protocol (RRPCE):** This document describes and defines the inspection activities of the iQOS Pocket Charger, which consists of sampling plan, testing equipment, visual inspection and functional testing steps. • **PMI-RRP-WKI-114151 iQOS Inspection Results Recording in GOLD (RRPCE):** This document describes the step of recording the data of source inspection into GOLD. This work instruction covers the creation of a batch, the reception of the sample, the test results entering, the release of those results, the test approval and the different ways to review the batches. • **PMI-RRP-WKI-114152 iQOS Battery AQL-Testing (RRPCE):** This document describes and defines the Acceptable Quality Limit (AQL) testing method of iQOS battery by specifying the sampling plan, list of equipment and operating method.

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Process	QMS Documents (PMI only)
	• **PMI-RRP-WKI-114155 iQOS Ongoing Reliability Testing (RRPCE):** This document defines the Ongoing Reliability Test (ORT) method of iQOS Holder and Pocket Charger by specifying the sampling plan, list of equipment and testing method.
Handling of complaints, nonconforming products and processes, and corrective and preventative actions	Directives: • **PMI-RRP-DIR-112835 Nonconformity (NC) & Corrective and Preventive Action (CAPA) (CC-RRPCE):** This document defines the requirements for the management of Nonconformities (NCs) and Corrective and Preventive Actions (CAPAs). Standard Operating Procedures: • **PMI-RRP-SOP-110826 Management of Product Related Special Situations (RRPCE):** This document defines / describes the process for managing Product Related Special Situations (PR-SS) at all levels of PMI which pose a potential safety exposure for adult consumer if used as intended. • **PMI-RRP-SOP-114285 Nonconformity Management (CC-RRPCE):** This document describes the process for the management of NCs related to products and processes including material, equipment, data services and systems. Working Instructions: • **PMI-RRP-WKI-110832 iQOS System Non-Conformities, CAPA, and Fault Catalogue Management in PLM (RRPCE):** This document describes how to use PLM for defect, non-conformity, CAPA, and fault management. • **PMI-RRP-WKI-110833 Returned RRP Device Investigation (RRPCE):** This document describes the PMI recurring process of investigation of returned RRP device. • **PMI-RRP-WKI-110834 Level 0 Returned RRP Device Investigation (RRPCE):** This document describes the process to perform Level 0 returned RRP device investigation for potentially returned RRP devices returned from end-users in the markets to Points of Sales (POS). • **PMI-RRP-WKI-110835 Level 1 Returned RRP Device Investigation (RRPCE):**

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Process	QMS Documents (PMI only)
	This document describes the process to perform Level 1 returned RRP device investigation for the returned devices which were already assessed in the markets during execution of Level 0 returned RRP device investigation and sent further for deeper investigation. • **PMI-RRP-SOP-114289 CAPA Management (CC-RRPCE):** This document describes the process to manage Corrective and Preventive Actions (CAPAs).

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