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Reason for Revision

Revisions resulting from the Q2 2016 BSA review.

R.J. Reynolds Tobacco Company Tobacco Product Integrity Plan

This documented plan demonstrates the Company's current processes and controls, which continue to evolve and will also be updated as regulations are promulgated.

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Background and Introduction

Passage of the Family Smoking Prevention and Tobacco Control Act ("FSPTCA") in 2009 granted the United States Food and Drug Administration ("FDA") with the authority to regulate the development, manufacture, marketing, and distribution of tobacco products. As of this writing, FDA has exercised its jurisdiction only as to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products.

Tobacco Product Integrity Plan Introduction

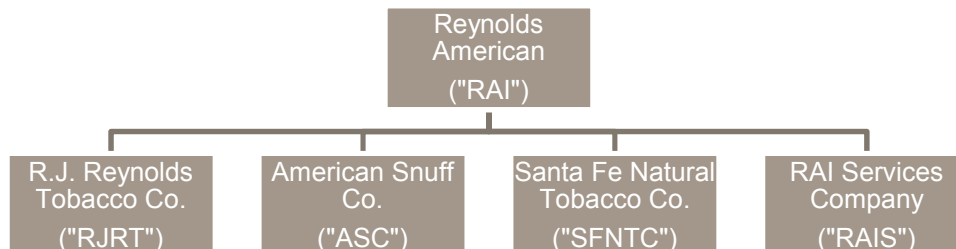
R.J. Reynolds Tobacco Company ("RJRT") has created the Tobacco Product Integrity Plan ("TPIP" or "Plan") to provide a road map that lays out the approach to the regulatory environment and to provide a holistic overview of the key programs and control activities that demonstrate three main goals: not increasing the inherent risk of its tobacco products; manufacturing its products according to specifications; and complying with applicable laws and regulations.

TPIP discusses control programs, activities, and processes that start during the tobacco product development process and continue throughout the supply chain from the tobacco leaf growers and other suppliers of ingredients and materials, to incoming material receipt and storage at the manufacturing facility, through manufacturing, storage and distribution. The Plan also includes other activities that span the organization and support multiple functions.

Company Overview

RJRT is a subsidiary of Reynolds American Inc. ("RAI"). RAI's other tobacco-manufacturing operating companies currently regulated by the FDA include American Snuff Company LLC ("ASC") and Santa Fe Natural Tobacco Company ("SFNTC").

This document is specific to RJRT and its tobacco products that fall within the FDA's jurisdiction. RAI Services Company ("RAIS") is a subsidiary of RAI that performs certain functions and activities on behalf of RJRT pursuant to service level agreements. The types of activities included in service level agreements may include, but are not limited to, information management, training, scientific and regulatory affairs, and legal. For purposes of this document, RJRT is referred to as "the Company."



Regulatory Governance

RAIS bears primary responsibility for coordinating regulatory compliance for RAI's FDA-regulated tobacco-manufacturing operating companies. The RAIS Scientific & Regulatory Affairs ("S&RA") department, reporting to the RAIS Executive Vice President – Scientific and Regulatory Affairs ("RAIS EVP S&RA ") provides interpretation, guidance, direction, and oversight on regulatory compliance.

The Regulatory Oversight Committee ("ROC"), led by the Senior Vice President ("SVP") S&RA and with representatives such as the Quality Directors from each of the aforementioned tobacco-manufacturing operating companies and RAIS, is responsible for monitoring and reporting FDA regulatory compliance risks using FDA regulatory key performance indicators. The ROC serves as a point of linkage on FDA regulatory matters between the tobacco-manufacturing operating companies and is responsible for reporting FDA-related matters through Fast Forward, the Company's Integrated Business Management process.

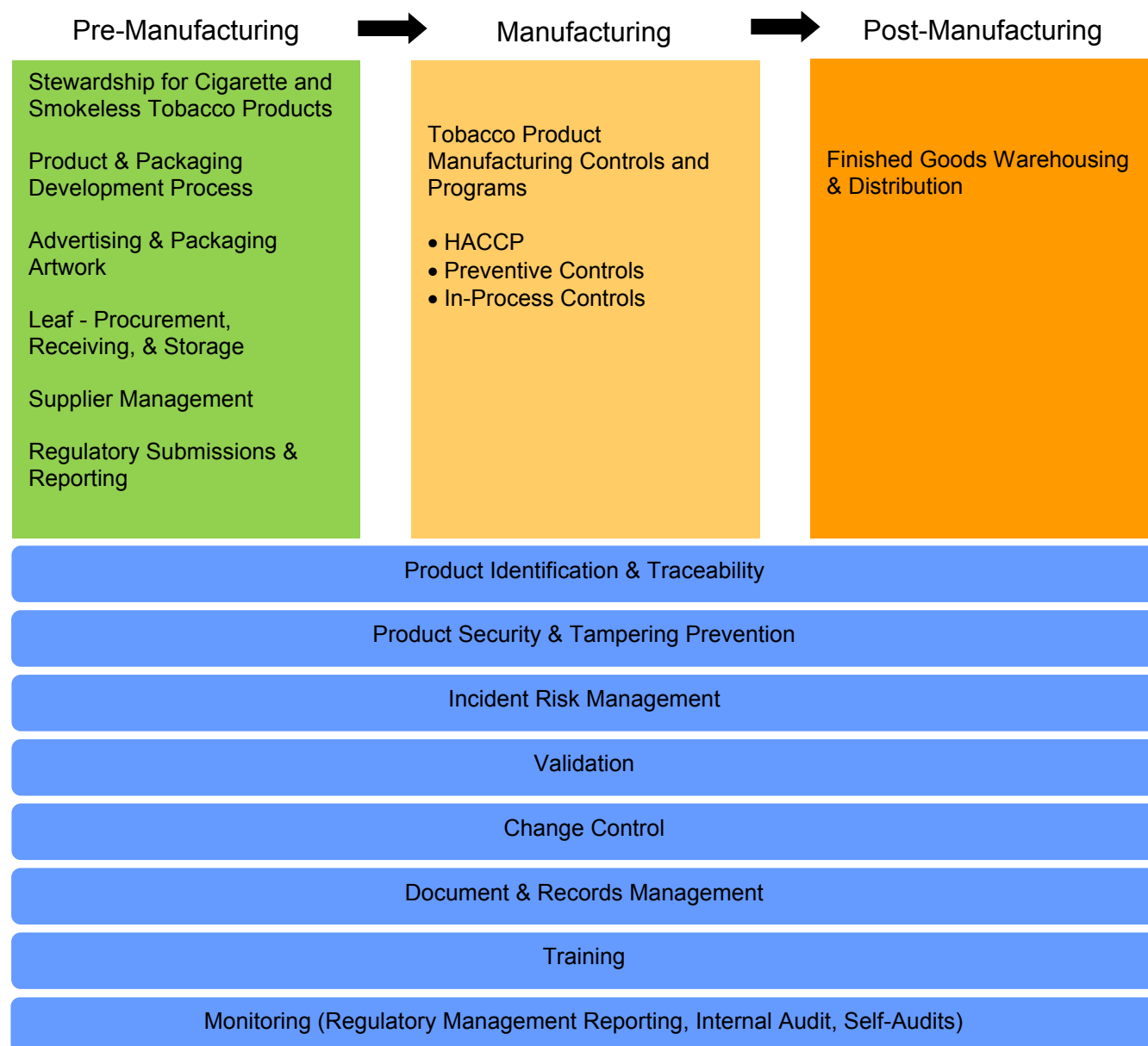
FDA compliance has been integrated into the Fast Forward process through its monthly cycle for communication, review, and/or decision-making regarding key issues and initiatives. As a final step in the Fast Forward cycle, FDA

regulatory key performance indicators are reviewed and overall FDA compliance governance and oversight is provided by the Regulatory Management Review ("RMR") committee, which is led by the RAIS EVP S&RA and includes representatives from S&RA, Law, R&D, Operations, Consumer Marketing, Information Management and Internal Audit.

Additionally, the RAIS EVP S&RA provides periodic updates on FDA compliance and related risks at the Leadership Team and RAI Board of Directors meetings.

TPIP Document Structure

The following diagram provides an overview of how the TPIP document is structured and organized:



The Plan has been structured to begin with Pre-manufacturing, which includes those activities that typically occur before a tobacco product is introduced into commercial production. It is important to note that while the Plan was written from the point of developing a new product, TPIP applies not only to new tobacco products but also to changes

to the Company's current tobacco products. The Pre-manufacturing section includes, but is not limited to, activities such as product and packaging development, product stewardship, supplier qualification, and regulatory submissions. The controls and processes described in this first section of TPIP serve as the fundamental foundation to ensuring that nothing the Company does or adds to its products will increase the inherent risks associated with tobacco products.

The Manufacturing section includes preventive controls and programs associated with tobacco product production such as personnel practices, in-process controls, and Hazard Analysis and Critical Control Point ("HACCP") methodology. The controls described in the Manufacturing section have been designed to address potential risks related to product contamination and non-conformances that may occur during the manufacturing process. These control programs also help ensure that tobacco products are produced in accordance with the product specifications.

The third TPIP section, Post-manufacturing, focuses on the Company's control environment that extends beyond manufacturing. It includes shipment and distribution processes and the controls implemented to maintain the integrity of the products that have not left company control.

The Plan also includes an overarching section designated as Supporting Activities & Processes which supports the various functions described within the Pre-manufacturing, Manufacturing, and Post-manufacturing sections. These other supporting programs include controls such as the Company's risk management process for handling incidents that may occur at any point during manufacturing or may arise Post-manufacturing through the complaint process. Supporting activities also include training, change control, and monitoring, which are essential control components for the activities described in TPIP.

Roles and Responsibilities

Roles and responsibilities for the activities outlined in TPIP have been defined and documented. Individuals who assume these roles are knowledgeable and qualified for their respective roles and have been trained on applicable laws, regulations, policies, and procedures relevant to their job function.

Business Process Owners ("BPO") and Business Process Managers ("BPM") have been identified from the business to provide leadership and oversight for individual processes associated with regulated activities. The BPO's accountabilities include, but are not limited to, ensuring the processes meet regulatory requirements, consistency, timeliness, and change management. Communications, recommendations and decisions related to FDA activities are incorporated into the Fast Forward process through the guidance of the BPO. The BPM is responsible for the execution of the items for which the BPO is accountable.

Additionally, third party contractors are utilized for certain activities included in TPIP. Third parties are bound by contract to comply with Company requirements/expectations and any applicable laws/regulations and undergo appropriate training.

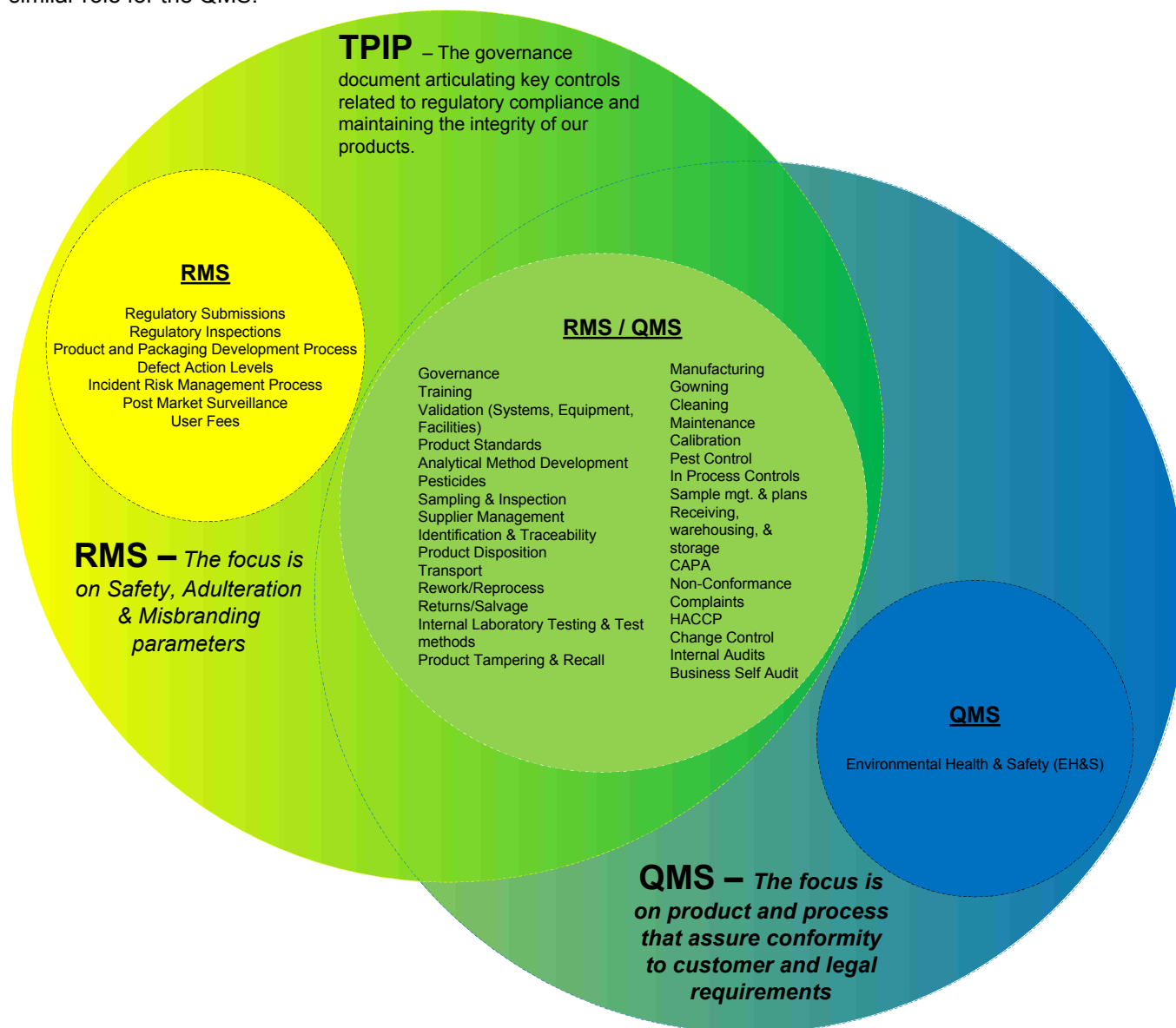
Regulatory / Quality Framework

As depicted below, there are a number of overlapping system elements within the Regulatory Management System (“RMS”) and the Quality Management System (“QMS”) with the primary difference relating to focus.

The RMS is the structure established to ensure holistic planning and implementation of all FDA regulatory compliance initiatives. The RMS scope is focused on FDA compliance. RMS includes end-state Business Process Owners that are ultimately accountable for on-going compliance.

The QMS is the structure in place to ensure the organization can provide product that meets customer and applicable statutory and regulatory requirements.

The TPIP is the governance document articulating the key controls related to the RMS. The quality manual plays a similar role for the QMS.



I. Pre-manufacturing

Stewardship for Cigarette and Smokeless Tobacco Products

Overview

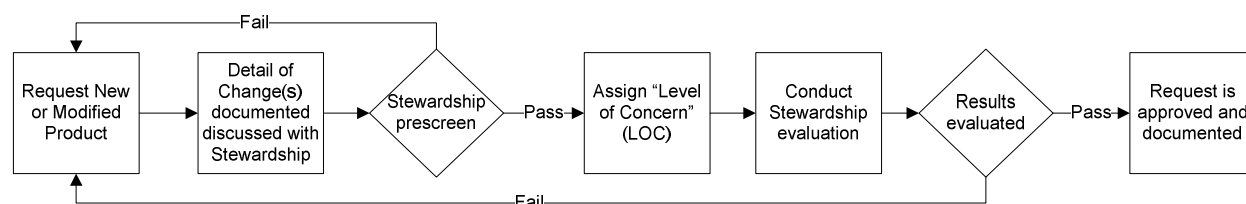
Cigarettes and smokeless tobacco products will continue to evolve to incorporate new blends, processes, ingredients, materials, technologies, and designs. Product Stewardship is founded on the principle that nothing is to be done or added to tobacco products that will increase their inherent risk. With every new product or change in a blend, process, ingredient, material, technology and/or design of an existing tobacco product, the potential effect of that change is evaluated using a framework that is based on the information available concerning the product and the proposed change.

The Stewardship Process for evaluating cigarettes and smokeless tobacco products is performed by Product Integrity, a department within S&RA. The process has evolved over many years and entails product review by qualified staff and assignment of a "Level of Concern" ("LOC") ranging from "I" (low) to "V" (high). The LOC is a relative measure of the extent to which a product modification may present the potential to alter the inherent risk. Any LOC greater than LOC I requires chemical and/or biological testing in an escalating tiered testing strategy. This tiered testing paradigm is based on the assumption that the degree of effort expended to reduce the uncertainty surrounding the safety of a product modification should relate logically to the likelihood that the modification might pose an increased risk to the consumer.

In summary, product changes are scientifically evaluated prior to implementation and no proposed change is made until the evaluation reasonably determines that it will not increase the inherent risk of the tobacco product and before receipt of any applicable FDA approval.

The Stewardship Process

The Stewardship Process is conducted when a new or modified product is being evaluated. The evaluation is conducted on the basis of a rigorous set of guidelines to assess the potential for blends, processes, ingredients, materials, technologies, and designs to alter the chemical constituents or biological activity of product(s) to reasonably determine that the inherent risks associated with the use of the product are not increased. The steps in the Stewardship Process are illustrated by the diagram below.



Documentation of Guidance and Procedures

The Stewardship Process is supported by guidance documents and standard procedures. Internal Stewardship Guidance Documents for Cigarettes and Smokeless Tobacco Products establish the framework of the Stewardship Process. The premise of the Stewardship Process is the assignment of LOC. The LOC framework is described in detail in the Stewardship Guidance Documents including a discussion of the testing strategy based on LOC and the evaluation criteria for Stewardship test data. The product and/or process change categories are also addressed in detail in the internal Stewardship Guidance Documents. Standard procedures with associated process flows have been documented to establish the manner in which the Stewardship Process is implemented for the various categories of product and process changes.

Change categories include the following:

- *Tobacco Blends and Processes*
- *Ingredients Added to Tobacco*
- *Structural Materials*
- *Product Designs*

Additional Stewardship Scope

The stewardship scope extends to Agrochemical Residue Evaluation, Stewardship of Manufacturing Materials, and Stewardship of Packaging Materials. The testing and review process is tailored to the data requirements and review criteria for each of these areas. Changes to manufacturing and packaging materials are evaluated prior to implementation and no proposed change is made until the evaluation reasonably determines that it will not increase the inherent risk of the tobacco product.

Communication and Documentation of Stewardship Decisions

Upon completion of any required testing and evaluation of the test results, Stewardship makes a determination regarding the impact of the modification on the inherent risk of the tobacco product. As stated previously, no proposed change is made until the evaluation reasonably determines that it will not increase the inherent risk of the tobacco product. The Stewardship recommendation is documented and communicated to the relevant stakeholders. Information documented may include, as applicable, the rationale for the assignment of LOC, the testing conducted as prescribed by the LOC, the test data and evaluation thereof, and a final determination to approve or reject the proposed new or modified product. The Stewardship Memorandum along with all supporting documentation is retained as appropriate based on established standard procedures. S&RA considers the Stewardship analysis in assessing whether and/or which regulatory reporting requirements are applicable as a result of the modification reviewed.

Product and Packaging Development Process ("PPDP")

Overview

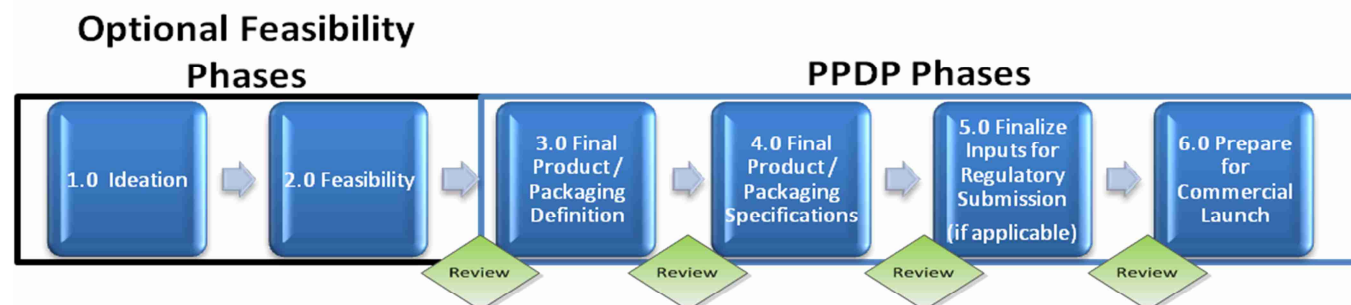
The Product and Packaging Development Process ("PPDP") governs the development of new tobacco products and/or packaging, from line extensions to new product platforms, as well as changes that impact the design parameters of existing tobacco products and/or packaging. The PPDP consists of a series of interrelated development phases, each with specific objectives, deliverables, and requirements. The process ensures that tobacco products and packaging are developed such that designs meet consumer expectations with related activities being documented and controlled. Contractors working on behalf of the Company may also be subject to specific, designated PPDP requirements.

Changes that do not impact the design of the tobacco product and/or packaging may be qualified using change control procedures applicable to non-design changes for Material/Supplier; Machine/Process; and New Packaging and Printed Products qualification. When PPDP is warranted, the applicable elements of the process that must be documented, reviewed, and approved are identified in a PPDP Project Plan.

Responsibilities within PPDP are shared among the Project Leader and Team, Management, and the Fast Forward Product Coordinator. Management representatives are identified for the purpose of providing approval at specified points throughout the process. The Fast Forward Product Coordinator provides general oversight, process expertise for PPDP, and governance of the process through management reviews of key metrics.

The Product and Packaging Development Process

The PPDP procedure is based on a rigorous set of guidelines that govern the phases of PPDP. The PPDP phases are illustrated by the diagram below.



Optional Feasibility Phases (1-2)

The focus of Phase 1 is the development of ideas. Phase 2 is intended to gather information to determine if an idea or concept is feasible from a technical and business perspective. If an idea is deemed to be feasible, this phase will be used to determine the development approach and basic characteristics of the proposed tobacco product and/or package.

PPDP Phases (3-6)

Phase 3 signals the beginning of PPDP documentation requirements. From Phase 3 forward, PPDP documentation requirements are clearly delineated. Phase 3 is focused on finalizing and documenting the tobacco product and/or packaging definition of the single design that will be evaluated through the subsequent steps of the process. Phase 3 is also when the Quality Plan would be created or initiated. The Quality Plan identifies requirements and associated procedures for material/vendor and/or machine/process qualification as well as for establishing quality metrics, if required.

During Phase 4, transition testing is conducted to ensure that product and/or package design is correctly translated into production specifications. Tobacco product and/or packaging specifications are reviewed, finalized and documented, and ultimately included in the regulatory submission, if applicable, which occurs in Phase 5. Phase 5 concludes with a review of the PPDP Project File which is updated and completed in Phase 6 with the confirmation of the operational requirements for commercial launch. If a regulatory submission is required, Phase 6 activities will be

initiated after the regulatory response is received. When PPDP is complete, the tobacco product and/or packaging will be prepared for potential commercial launch and the project file closed. After each phase of PPDP, management reviews are documented.

PPDP Framework for Risk Management

PPDP relies on the Stewardship Process for the purpose of ensuring that the development of new tobacco products and/or packaging does not increase the inherent risk of the product. For additional detail, refer to the TPIP section on Stewardship for Cigarette and Smokeless Tobacco Products.

PPDP Documentation Approach

The PPDP Project File either serves as the repository for relevant documents and records, or contains references to documents and records housed in other systems. The Project Leader initiates and maintains a project file ensuring that each file contains required documents, records and approvals.

Advertising and Packaging Artwork

Overview

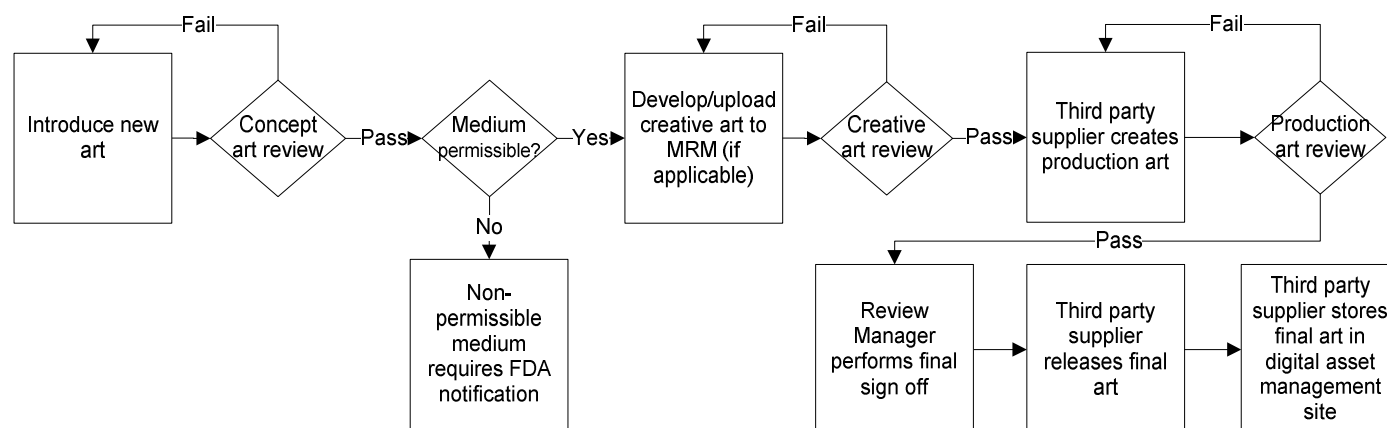
The provisions set forth in the FSPTCA serve as a framework for the evaluation of proposed marketing initiatives. Advertising and packaging artwork (i.e., packaging labels) must meet the defined criteria for warning labels, fonts, size, and other formatting requirements set forth in the FSPTCA and subsequently issued regulations by the FDA.

RJRT utilizes third party contractors for certain advertising and packaging artwork development activities. RJRT is responsible for ensuring work performed by third parties is in compliance with FDA requirements.

Advertising Approval Process

Advertising can only be published on FDA permissible mediums; otherwise, written notification must first be provided to the FDA. The advertising review and approval process is the Company's primary control to ensure all advertising conforms to FDA requirements.

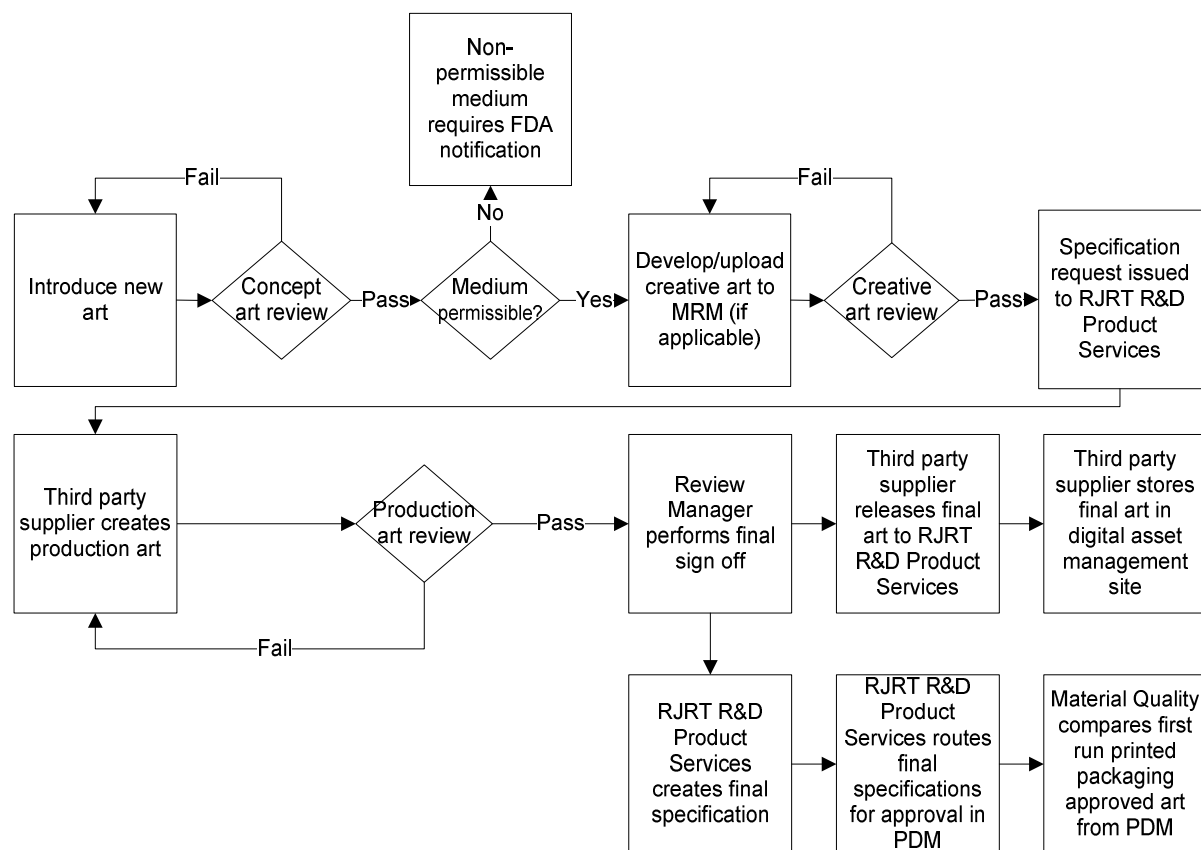
The advertising review and approval process is initiated when new or modified advertising art is introduced. The review is based on a rigorous set of guidelines that assess the content, format, health warning rotation schedule and permissibility of the art medium. RJRT uses Marketing Resource Management ("MRM") software as the system to manage art review workflows and as a repository for documentation relating to specific marketing and packaging activities. MRM allows RJRT to manage the advertising and packaging material creation work flow processes to ensure all reviews occur as needed. The diagram below provides an overview of the steps involved in the review and approval process for all new or modified advertising.



Packaging Artwork Approval Process

Packaging artwork refers to labels and other written, printed, or graphic matters on or accompanying any product or its containers or wrappers. The packaging review and approval process discussed below and other controls within production ensure labels associated with the packaging conform to FDA requirements.

New or modified packaging artwork is reviewed and approved through a process similar to the advertising review process but for packaging, a specification request must be initiated. RJRT R&D Product Services assigns a new Material ID for the art and creates a final specification within Product Data Management ("PDM"), the system that houses all product information and specifications. The diagram below illustrates the key steps involved in the packaging review and approval process.



Packaging Verification during Production

When a production run is initiated, the current version of the product specification, including the bill of materials related to the specific product, is posted from PDM to SAP, the integrated information system used to support multiple departments. At the beginning of the production run, the Production Scheduler responsible for the run confirms that the specification is the correct version. The specification is then sent to the production floor Manufacturing Execution System ("MES"). Manufacturing personnel scan the incoming packaging materials against the bill of materials in MES to confirm that the correct packaging materials are used for the specific product associated with the production run.

In some instances, packaging of the finished tobacco product is performed by contract manufacturers. All contract manufacturers are required to comply with supplier contract requirements, which include conforming to RJRT packaging specifications and periodically providing RJRT with samples of the packaged finished tobacco product for inspection.

Leaf - Procurement, Receiving, and Storage

Overview

Leaf procurement and supplier management includes purchasing, receiving, inspecting, and inventory management activities associated with tobacco materials and tobacco material services managed by the Leaf Department. Tobacco materials include, but are not limited to, stemmed leaf, scrap, and stems. Tobacco material services include transportation and receiving station agents.

Supplier Qualification Process

Tobacco materials and related service suppliers are qualified and approved based on their ability to consistently meet company specified requirements. Company specified requirements for the supplier may include evidence of financial viability, appropriate business process and regulatory compliance requirements, and adequate resources and facilities to consistently produce and deliver the product or service as required. Once the supplier is qualified, the approved supplier list is updated and the supplier is added as an approved supplier within SAP or the Contract Growing System. SAP is used for purchasing tobacco from third party tobacco material providers and the Contract Growing System is used for domestic purchases made directly from leaf growers. If a supplier does not consistently meet company specified requirements and the decision is made to disqualify the supplier, the supplier is blocked within the purchasing system to prevent future purchases.

Purchasing and Receiving

Leaf Growers

Domestically, RJRT purchases and receives leaf directly from approved suppliers (i.e., leaf growers) at third party receiving stations. All growers are required to sign seasonal growing contracts that outline RJRT standards and expectations. Once leaf is delivered to the receiving stations, Leaf Buyers inspect each bale before purchasing for ripeness, color, stalk position and other factors that determine grade. The Leaf Buyers then assign a unique bar code to the tobacco material so the bales can then be tracked electronically within the Contract Growing System. Leaf can only be purchased from approved suppliers that have been set up within the Contract Growing System. Purchased domestic leaf is then sent to a third party to be stemmed. At this point, the Contract Growing System interfaces with the Green Leaf System. The Green Leaf System is utilized throughout the stemming process to track inventory movements based on unique bar code labels.

Third Party Tobacco Material Suppliers

Internationally, RJRT purchases tobacco materials from third party tobacco material suppliers who purchase directly from growers in the country of origin. In some cases, domestic tobacco materials may also be purchased from third party tobacco material suppliers rather than direct from the grower. RJRT requires that tobacco material suppliers and the stemmeries they operate meet the standards and expectations outlined in the RJRT Stemming Manuals, which includes processes for how to sample and test the leaf to ensure it meets RJRT leaf grade expectations.

Once stemmed, the leaf, whether purchased offshore or domestically, is transported to an RJRT storage facility, where it is stored until it is approved for release.

Inventory and Quality Management

Leaf Stemmeries

Leaf materials are sampled for moisture levels during the stemming process. Composite samples of all leaf materials are prepared from the moisture samples and are evaluated by contract laboratories for agrochemical residues. RJRT and third party stemmeries also have programs in place to prevent material and product contamination. Stemmeries are required to have process and controls for the removal of non-tobacco related materials that may include searchers, mechanical separation, and metal detectors throughout the stemming process.

Warehouses and Transportation

RJRT warehouse facilities are managed by a third party that is required to meet RJRT expectations to preserve the integrity of the tobacco materials. Third party warehousing manuals include defined SOPs and work instruction guidelines and policies related to the storage and control of tobacco materials. The warehousing manuals include, but are not limited to, procedures that address sanitation, pest control, personal hygiene, product handling, product identification, and traceability to ensure that tobacco materials are properly controlled throughout the storage process.

Receipts of stemmed leaf are systematically matched against orders within SAP to ensure only approved orders are received from approved suppliers. Delivery containers and individual packages are inspected for damage. When received into storage, leaf is also inspected as a final receipt confirmation to ascertain that the material meets specified requirements.

Inbound and outbound transportation of tobacco materials to and from warehouse facilities is conducted by a third party that is required to meet RJRT expectations and specifications.

Supplier Management**Leaf Growers**

Domestic leaf growers are evaluated to ensure they have the ability to meet contracted volumes and provide tobacco leaf in accordance with RJRT specified requirements, including compliance with practices outlined in the Good Agricultural Practices ("GAP") for Tobacco Growers manual. The GAP manual is a summary of guidelines that are required for the production of a good quality tobacco crop. Components of the GAP program for tobacco growers include, but are not limited to, environmental, occupational health and safety standards, variety integrity and suitability, pest control, agrochemical management, and worker training programs. Grower deliveries are monitored prior to purchase through random inspections, rotational/pre-selected agrochemical testing, and verification of contract requirements. Domestic growers are also subject to random farm visits, which are tailored accordingly to each grower and entail reviews for compliance with supplier contract requirements.

Third Party Tobacco Material Suppliers

Tobacco material suppliers are monitored and evaluated on performance at least annually to assess their capability to provide the specified tobacco material. Tobacco material supplier evaluations include multiple measures of performance such as visual grade standard evaluations, agrochemical residue sampling, and container infestation reporting. Leaf stemmeries used for de-stemming, drying, and packing tobacco leaf for storage are reviewed against site specific supplier agreements, which include requirements for facility operations, security, and other specific controls and requirements.

Tobacco Material Service Providers

Tobacco material service providers are formally evaluated annually and continuously monitored to ensure compliance with RJRT requirements.

Supplier Management

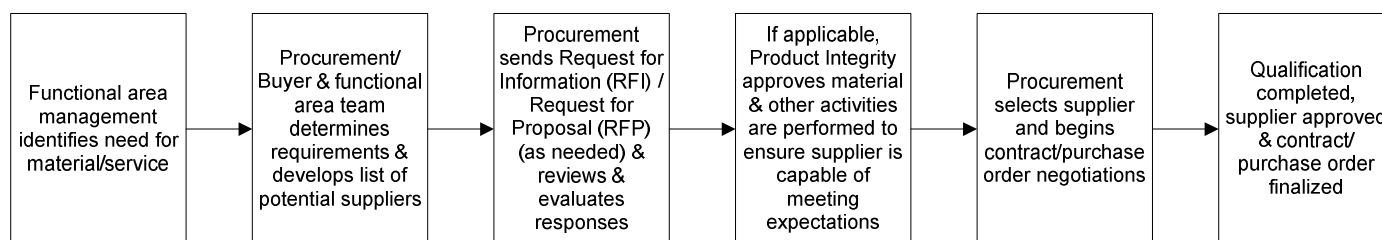
Overview

Supplier management is fundamental to ensuring that materials and services that impact finished tobacco products conform to specified requirements, comply with relevant FDA regulations, and do not increase the inherent risks associated with tobacco products.

As discussed in the previous section, tobacco materials and its related services are managed by the Leaf Department. The remainder of RJRT's supply base consists of suppliers that provide direct materials and indirect materials/services. Direct materials consist of those materials, other than tobacco, that comprise the tobacco product and its corresponding packaging (e.g., ingredients, packaging, filters, paper, etc.). All other materials and services fall under the indirect materials/services bucket (e.g., professional services, capital equipment, maintenance, repair and operations spare parts, etc.).

Supplier Selection and Qualification Process

Suppliers are evaluated, selected, and qualified, as appropriate, on the basis of their ability to consistently meet company specified requirements and relevant regulatory requirements. Company specified requirements for the supplier may include evidence of financial viability, ability to meet specifications, business process and regulatory compliance controls, and adequate resources to consistently produce and deliver the material or service as required. The basic steps in the supplier evaluation and selection process are illustrated in the diagram below. The steps may vary and may not apply in all cases depending on the type of supplier and the material or service they provide; however, the diagram represents the general process for supplier selection.



During qualification, the supplier is assessed to ensure it is qualified to meet the specific requirements associated with the material or service. If the supplier is providing a new material to be used in production, Product Integrity, a department in S&RA, must provide approval of the new material during qualification and prior to use. As part of the qualification process, a business and regulatory risk assessment is performed and controls for the specific supplier and/or material are established and documented in a control activity matrix. Once the supplier is qualified, the supplier is added to a list of qualified, approved suppliers. Only suppliers on the approved supplier list may supply materials and services.

If a supplier does not conform to company specified requirements and the decision is made to disqualify the supplier, the supplier is blocked to prevent future purchases. In some cases, a supplier may be subject to requalification activities.

Procurement Process

The procurement process ensures that suppliers are provided all information necessary to supply the product or service required. The process consists of negotiating and establishing procurement contracts, capturing supplier information, preparing purchase orders, and managing the supply base performance. Contractual arrangements are provided for the protection of proprietary information and intellectual property as well as state or reference the requirements associated with the material or service. The procurement process is structured so that materials or services are clearly identified and, as appropriate, may only be procured from approved suppliers against approved specifications. For materials or services impacting product, suppliers are required to notify the Company of planned changes to materials and/or processes so that the Company may assess and approve the change prior to

implementation. During the supplier audit process, specific questions are asked and document/process reviews are conducted to detect potential changes and to confirm there was proper notification and prior approval of the change.

PDM is used to store material specifications and capture approvals that occur as part of the Product Stewardship process related to the qualification of materials used in the finished tobacco product (i.e., direct materials). To the extent RJRT provides specifications to the supplier, formal agreement is obtained for supplier to make to specification, including confirmation by signing and returning specifications or by approval of specification via PDM.

Receiving Process

Upon receipt, a systematic process is used to match incoming receipts of direct and indirect materials against purchase orders. This systematic control confirms order accuracy and completeness and also ensures that only approved purchased materials are received and used in the production process.

Incoming materials are evaluated or inspected per the applicable activities listed in the control activity matrix for each supplier of a material type. These activities may include, but are not limited to, sampling and testing, reviewing Certificates of Analysis or Certificates of Compliance, and receipt inspections.

Monitoring Supplier Performance

Supplier performance is regularly monitored to ensure adherence to all Company standards and requirements. The Company uses a risk-based approach to determine and establish monitoring procedures, supplier controls, expectations, and requirements. Business and regulatory risk assessments are performed to determine the frequency and extent of supplier monitoring.

Performance information is reviewed against expectations and requirements. Periodic review of supplier performance provides the opportunity to identify and recommend improvements to supplier deliverables relating to materials, equipment, processes, systems, and services. Supplier metrics and key performance indicators are used to provide meaningful and actionable indicators of opportunities for improvement.

Information used to evaluate suppliers includes performance against specifications, audits/assessments conducted by RAIS Supplier Compliance, RAIS Supplier Quality Assurance, and/or a third party, performance against business requirements, delivery performance, supplier scorecards, continuous improvement initiatives, total cost reduction initiatives, and other information obtained during supplier reviews.

In the event that suppliers do not conform to specified requirements, action is taken to properly handle non-conformances. The supplier may be required to create a Supplier Corrective Action Request ("SCAR") which is recorded according to the requirements specified by the Company's non-conformance process.

Regulatory Submissions and Reporting

Overview

Among its many provisions, the FSPTCA has specific requirements related to regulatory reporting, which includes, but is not limited to, submissions, notifications, pre-market approvals, and post market surveillance of Modified Risk Tobacco Products ("MRTTP"). It is the Company's responsibility to understand and interpret the implications of the reporting provisions and ensure that regulatory reporting to the FDA is accurate, complete, and timely.

Provisions included in the FSPTCA and FDA guidance that relate to regulatory submissions and other types of reporting to the FDA include, but are not limited to, the following:

- Registration of facilities and product listings - facilities registration includes the names of owners/operators, place of business and other relevant business-related information, and establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products; product listings include all tobacco products which are being manufactured, prepared, compounded, or processed for domestic commercial distribution as well as all labeling and consumer information and representative advertising.
- Ingredient reporting - For products in the market prior to June 2010, a baseline ingredient submission is required which includes tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and sub-brand. For all new tobacco products, a baseline ingredient report is required 90 days prior to commercial launch in addition to other pre-market submission reporting requirements. Finally, whenever any tobacco additive is newly incorporated or eliminated, or the amount of an existing tobacco additive is changed, a 90-day pre / 60-day post change notification is submitted.
- Harmful and Potentially Harmful Constituent Reporting – For products in market on or before June 2012, a baseline constituent report is required for each brand and sub-brand, listing the amount of each constituent in the tobacco and, as applicable, the smoke of the product, that the FDA has determined to be harmful or potentially harmful to health. For all new tobacco products, a baseline constituent report is required 90 days prior to commercial launch in addition to other pre-market submission reporting requirements.
- Submission of health-related documents - includes documents that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents, ingredients, components, and additives.
- Substantial equivalence ("SE") submission or exemption request - includes appropriate and sufficient product-specific data and information to demonstrate that the product (1) is substantially the same as the predicate product(s) to which it is being compared; (2) presents different characteristics but does not raise different questions of public health; or (3) should be deemed exempt from SE requirements.
- Pre-market approval applications - includes pre-market tobacco product applications ("PMTA") and MRTTP applications.
- Post Market Surveillance and Studies of Modified Risk Tobacco Products - includes MRTTP application and if application approved, submission of post market studies and surveillance on an annual basis.

As needed, S&RA provides an interpretation on the specific reporting requirements included in the FSPTCA and any FDA-issued guidance. S&RA also provides direction to guide compliance activities and implementation to ensure consistent compliance with FDA regulations and requirements by RAI's tobacco-manufacturing operating companies.

Other ad-hoc reporting may occur upon request by the FDA. S&RA will provide guidance as needed when ad-hoc reporting requests arise.

The Submissions & Reporting Process

S&RA is responsible for managing the submissions and reporting process. The data collection and submission process is conducted by S&RA, in conjunction with appropriate operating company stakeholders who have the necessary background and knowledge to provide and compile required information. Additionally, S&RA provides final review and approval for all submissions, reports or notifications prior to their being submitted to the FDA. Key controls are built into the review process to ensure accuracy, completeness, and timeliness.

In summary, the Company is committed to ensuring it provides accurate, complete, and reliable information to the FDA in an effort to support science-based Agency decisions and actions.

II. Manufacturing

Tobacco Product Manufacturing Controls and Programs

Overview

Throughout its manufacturing processes, RJRT has various controls and programs to help achieve the Company's goals of not increasing the inherent risk of its tobacco products, to comply with applicable laws and regulations, and to achieve consumer quality expectations. The controls and programs discussed in this section are focused on manufacturing products to specifications, preventing tobacco product contamination and mitigating other potential risks that could lead to non-compliance.

HACCP/Preventive Controls

The Company has adopted the Hazard Analysis and Critical Control Point ("HACCP") methodology as a component of its preventive risk management program in which risk assessments are performed to determine potential biological, chemical, and physical hazards that could be associated with the Company's tobacco products or its manufacturing processes. In HACCP, the focus of the hazard analysis is on potential short-term acute safety risks and the goal is to identify any critical control points. A critical control point is a process step at which control can be applied and is essential to prevent or eliminate a potential safety risk or reduce it to an acceptable level. To date, the Company has not identified any hazards that warrant critical control points. HACCP plans for new product platforms are initiated during the Product and Packaging Development Process.

Preventive controls are also identified and documented as part of the HACCP plan. Preventive controls are risk-based procedures, practices, and processes that minimize or prevent the potential hazards identified and that are consistent with the current and historical scientific understanding of the intended use of the product. Preventive controls are foundational to an effective HACCP system and help provide the conditions necessary to protect the product while it is under Company control. The preventive controls summarized in this section were identified through the HACCP analyses that have been conducted across the Company for each product platform. Collectively, the preventive control programs address all areas of the manufacturing process; the employee, the environment, the facility, and the product.

Preventive controls that the Company currently relies on include, but are not limited to, the following:

- Good Manufacturing Practice ("GMP") Personnel Practices - RJRT operates according to established processes and controls that will prepare the Company for future Tobacco Product Manufacturing Practice ("TPMP") regulations. The Company complies with GMP Personnel Practices for personnel, including visitors, in processing and packaging areas. These practices were established to prepare for future TPMP regulations and address personnel restrictions and requirements. GMP Personnel Practices also address the types of materials or personal items that are restricted from processing and packaging areas within the manufacturing facilities. These practices outline specific guidelines, which include, but are not limited to, Non-Tobacco Related Material (NTRM)/Accidental Product Contamination, Illnesses, and Workplace Attire.
- Product Stewardship - Product Stewardship is founded on the principle that nothing is to be done or added to tobacco products that will increase their inherent risk. Every new product or change in a blend, process, ingredient, material, technology and/or design of an existing tobacco product is scientifically evaluated prior to implementation. No proposed change or introduction of new product is made until the evaluation reasonably determines that it will not increase the inherent risk of the tobacco product.
- Internal standards for materials, equipment, parts, and cleaning agents - Prior to introduction into an RJRT facility, materials, equipment parts, and cleaning agents that may come in contact with the product are pre-approved based on reviews conducted by Product Integrity, a department in S&RA. Once in the facility, internal standards exist for the preventive maintenance, repair, and cleaning of the parts and equipment. The standards, which may be in the form of SOPs, work instructions, or other documentation such as maintenance schedules or equipment manufacturer manuals include, but are not limited to, equipment calibration, equipment inspection, proper installation of machine parts, and cleaning procedures. These standards help ensure that only approved materials

enter the facility and are properly maintained once inside. Cleaning agents and other chemicals are controlled via the Chemical Hygiene Plan.

- Supplier/Material controls - Suppliers are thoroughly assessed and pre-approved. The Company assesses the risk associated with each supplier to determine the appropriate level of supplier monitoring and oversight. Incoming materials are verified at the time of receipt to ensure only pre-approved materials are received into the facilities and conform to requirements established in the supplier control matrix. Tobacco and non-tobacco materials are stored in a manner to prevent contamination and/or degradation.
- Pest control - The guiding principle of the Company's pest control program is to prevent pests from contaminating products through integrated pest management. The Company uses a variety of tools throughout the supply chain to control pests including monitoring of pest populations via visual inspections and pheromone traps, fumigation of tobacco leaf storage facilities, and cleaning.
- Training - Personnel, including employees and any third-party contractors, are trained on procedures and control programs to adequately perform assigned functions and work responsibilities.

Additional details on these preventive controls can be found in the following TPIP sections: Stewardship for Cigarette and Smokeless Tobacco Products, Supplier Management, and Training.

Monitoring is performed for preventive controls to ensure conformance to procedures and specifications throughout the manufacturing process. Monitoring includes, but is not limited to quality control check points, checklists, internal audits, business self-audits, and continuous monitoring of the manufacturing process.

In-Process Controls

In-line and off-line in-process controls exist throughout the manufacturing processes at RJRT. Automated, in-line controls are built into the manufacturing process to systematically adjust the processing based on predetermined parameters. These controls include, but are not limited to, various meters, scales, and gauges to ensure the product is processed in accordance with the product specification. In-line controls are monitored and maintained through calibration and preventive maintenance and include alerts and alarms (where applicable) for operators responsible for monitoring the system.

Off-line in-process controls measure and test attributes of the product that cannot easily or accurately be measured or controlled via in-line controls. Testing results are used to inform the process of any necessary adjustments. Testing is performed by the operator or laboratory personnel throughout the manufacturing process where sampling points have been identified for process control and to ensure the product is adhering to the specification. Laboratories are held to laboratory compliance standards and are either in-house or outsourced to a third party provider. SOPs and work instructions document where the sampling should take place, how often to sample, how to perform the test and how to adjust the process, if necessary, based on the testing results. Records of samples and testing results are maintained.

Non-conforming Product

Product that does not meet the specification may be discarded, reworked, reprocessed, or used under authorized concession. This decision is based on the attribute tested and the location of the product in the manufacturing process. There is a protocol for non-conforming product that outlines the disposition decision process for any out-of-specification product and who is responsible for the decision.

III. Post-manufacturing

Finished Goods Warehousing and Distribution

Overview

RJRT's finished goods warehousing and distribution processes include transporting finished goods from manufacturing facilities to Distribution Centers ("DCs") where they are stored and then transported to customers via common carriers. To control and maintain the integrity of tobacco products throughout the supply chain, RJRT has developed the R.J. Reynolds Tobacco Company Warehousing Supplier Expectations manual to outline requirements, policies, and procedures related to the finished goods warehousing and distribution processes.

RJRT partners with third party logistics providers ("3PLs") via contractual agreements to handle warehousing, storage, and transportation of finished goods. RJRT Supply Planning and Logistics provides oversight of the 3PLs and the distribution network and related activities from when the finished goods leave the manufacturing facility to when they are delivered to the customer.

Warehousing / Storage Process

When finished goods arrive at the DC, the arrival is documented and relevant information is recorded upon receipt. Warehouse personnel perform inbound load inspections to reconcile inventory and identify any potential contamination and/or damaged product. Any exceptions identified during the inspection process are handled in accordance with established procedures.

All finished goods are stored in a clean, dry, well-ventilated area to prevent potential contamination or degradation. Stock rotation and shipping guidelines are used and warehouses provide reports to RJRT Supply Planning and Logistics to assist in complying with rotation requirements.

The DCs are required to follow a comprehensive sanitation program, which includes procedures and schedules for cleaning, to ensure warehouses are maintained in sanitary condition. Each DC also has a pest control program to minimize the risk of pests in the facility and protect against potential contamination. These programs require periodic inspections, documentation of any failures or findings, and resolutions when applicable.

Physical security controls of the grounds and facility, which include access control, alarm systems, and pre-screening of applicants, provide additional safeguards of the Company's stored finished goods.

Distribution / Transportation Process

Trailers/containers used for transport of finished goods must be clean, dry and free of odors, leaks, contamination and infestation. As an additional physical security precaution, a trailer/container inspection process has been established to ensure proper equipment is utilized. Trailers/containers that fail inspection are rejected according to this procedure. Trailer/container inspection logs, including rejections, are kept in either manual or electronic format.

Returns and Reclaim

Returned products that have remained in the 3PL control are assessed to determine if the product should be re-boxed, reclaimed, or destroyed. Any products that are returned from any source outside of the Company's control (i.e., returns from wholesalers, retailers, consumers) are destroyed.

Monitoring

Warehouses and associated transportation services are periodically audited for operational and security compliance by representatives from RJRT Supply Planning and Logistics and the 3PLs. The audits assess compliance with operating requirements and identify opportunities for improvement. An audit checklist is utilized during the operational audit to verify compliance with established policies and requirements.

The audits include reviews and/or assessments of the following:

- Physical inventory
- Stock condition stored at the facility
- Operating procedures
- Compliance with the R.J. Reynolds Tobacco Company Warehousing Supplier Expectations manual
- Compliance with established security processes and procedures

Documentation

Applicable documentation or records for warehousing and distribution including bills of lading, proof of deliveries, inspection logs, reconciliations, and inventory count sheets are stored on site in accordance with established procedures and guidelines.

IV. Supporting Activities & Processes

Product Identification and Traceability

Overview

RJRT uses a variety of systems to track and trace finished tobacco products and all related tobacco materials and direct materials, including leaf, ingredients, components, and packaging, through the supply chain from the leaf grower or supplier through production, processing, storage and distribution. Product identification is integral to effective and efficient traceability systems and is critical for customer complaint investigation or removing product from the market. Product identification and traceability systems and controls enable the Company to track and trace tobacco materials, direct materials, and finished goods from a specified time frame, location, or production run to the first recipient post Central Distribution Centers.

RJRT utilizes third parties for warehousing and distribution services. In some cases, third party contract manufacturers are used for manufacturing and/or packaging of finished tobacco products. Suppliers of direct materials are required to comply with RJRT labeling requirements, which include unique identifiers that allow for traceability back to individual lot and container information.

Leaf

Leaf that is purchased domestically is tracked electronically within the Contract Growing System and the Green Leaf System beginning at the point when the Leaf Buyer assigns a unique bar code to the purchased tobacco material bales. The Contract Growing System and the Green Leaf System are RAIS-managed systems that include grower contract information which allows each bale to be traced back to the grower from which the leaf was purchased. Purchased leaf is then sent to a third party stemmery and shipment information, including bill of lading and unique barcode information, is passed electronically to the third party stemmery, and the deliveries are confirmed to the Green Leaf System.

As leaf is fed into the stemming process, the bar coded label is scanned as consumed against a specific production run, and the unique barcode information for each run is passed to the Green Leaf System. Following the production run, a unique bar coded label is applied to the stemmed tobacco materials, which includes information identifying the production run and any required unique identifiers, which allow for traceability back to a group of growers. Stemmed leaf is shipped to an RJRT storage facility and, upon receipt, bale coupons are scanned and the leaf inventory information is transferred to SAP.

Internationally and domestically from third party tobacco material suppliers, RJRT purchases tobacco from tobacco materials suppliers who purchase directly from growers in the country of origin. Traceability begins at the time of receipt into SAP at the RJRT storage facility.

SAP assigns unique batch identification ("ID") upon receipt into storage and this ID is used to trace tobacco materials throughout the production process.

Direct Materials

Incoming direct materials are assigned unique identifiers using various inventory control systems upon receipt to allow for traceability during production. The material item ID is also verified upon receipt and is used to trace the incoming material to its vendor information, including manufacturing date, production order number, pallet/container number, and other relevant information. All direct materials, as well as tobacco materials, are entered into the Manufacturing Execution System ("MES") using bar code scanning technology, where available. MES is used to track the consumption of materials and manage resulting product information throughout the manufacturing process. Item IDs are verified and materials are inspected periodically throughout the production process.

Each facility maintains work instructions which explain the processes for collection of batch data that includes required information necessary to properly trace direct materials.

Finished Goods

When finished tobacco products are ready for shipment, manufacturing data, including the quantities of ingredients, tobacco materials, and direct materials and the production order number, are transferred to SAP and inventory records are updated accordingly. Finished goods are then noted as shipped within SAP and the appropriate data is transferred to the third party distribution center.

Upon receipt from manufacturing at the central distribution center, applicable finished goods information, such as pallet numbers, item numbers, quantities, manufacturing date and time, and machine complex, is entered and tracked within the third party's Warehousing Management System. The third party warehouse is responsible for maintenance of documentation for traceability of all product receipts and shipments. Shipment documentation includes a product Stock-Keeping Unit ("SKU") and the description, quantity, date of product shipment to a customer or other warehouse location, and other required information.

Product Security and Tampering Prevention

Overview

RJRT uses preventive measures to help mitigate the potential risk of product tampering or other acts that could result in product and/or material contamination. RAI's tobacco-manufacturing operating companies developed the RJRT Product Security and Tampering Prevention (PSTP) documentation to outline the minimum requirements for each tobacco-manufacturing operating company's security controls, preventative measures, and practices to help ensure product security and mitigate the risk of product tampering. On-going reviews are conducted to assess RJRT's compliance with the minimum requirements of Product Security and Tampering Prevention. PSTP security measures and practices include, but are not limited to, the items described below which are defined in greater detail in the PSTP documentation.

Facility Security

Access to facilities and certain specified locations within the facilities is restricted to authorized personnel. Entrances to facilities are controlled by card readers and/or security officers. A guard service is used for monitoring incoming personnel, performing regular security inspections, and periodically conducting security breach testing. The guard service is required to advise RAIS Corporate Security of any suspicious behavior, security breaches, or violations of security policy. Visitors are required to register prior to entry into a facility and must be escorted by an employee and remain under their supervision at all times while on the premises.

Added security controls may be in effect in certain restricted areas within the manufacturing facilities. Additionally, video surveillance is used at entrances/exits and security cameras are strategically placed throughout the manufacturing facilities to track and monitor access to those facilities.

Personnel Security

Personnel, including employees and any third party contractors that perform work on Company premises, are screened and background checks are conducted as appropriate to their position. Personnel are trained on applicable Human Resources policies and any security awareness and response training relevant to their job function.

Only items required for work or to maintain personal well-being are permitted in the manufacturing facilities and material and product storage areas. Company provided lockers and any personal storage facilities, including personal packages or bags, are subject to search. Protocols are in place for random searches by security personnel of those entering manufacturing facilities.

Transportation, Receiving, & Material Security

Vehicles that transport both materials and/or finished tobacco products are inspected for purposes of confirming acceptability of the product (e.g., damage) as well as for detecting any indication of possible contamination or unauthorized access. Evidence of possible tampering noted during the inspection process is escalated to management and Corporate Security. Receiving personnel are required to verify trailer seal integrity and trailer seal identification against delivery documentation when receiving shipments that require the use of seals. Additionally, security guards at the facility entrance/exit gates inspect trailers and seals (when seals are required) and the results of their inspections are documented.

Any specific packaging or labeling requirements to provide additional security of purchased materials are included in the supplier requirements documentation. Incoming material item identification and purchase order information is verified prior to unloading the delivery vehicle. The Company's chemical security program provides additional security measures to help ensure that only approved chemicals are stored and used within the facilities, including material and product storage areas. The program also restricts access to chemicals to authorized personnel.

Access to Computer Systems

Access to computer process control systems and critical data systems is restricted to those with appropriate clearance in accordance with the logical security controls established through RAIS's Information Management function.

Tampering / Sabotage Incident Investigation & Response

Personnel are required to be alert to any signs of tampering or other suspicious actions and to report any unusual behavior or potential security issues to management and/or Corporate Security in accordance with established communication protocols. Investigations of threats or information about signs of tampering or other security problems are conducted as necessary, and, if warranted, law enforcement authorities or regulatory agencies are contacted.

Internal Security Inspections

Internal security inspections and third party security audits are periodically conducted to monitor compliance with Product Security and Tampering Prevention requirements.

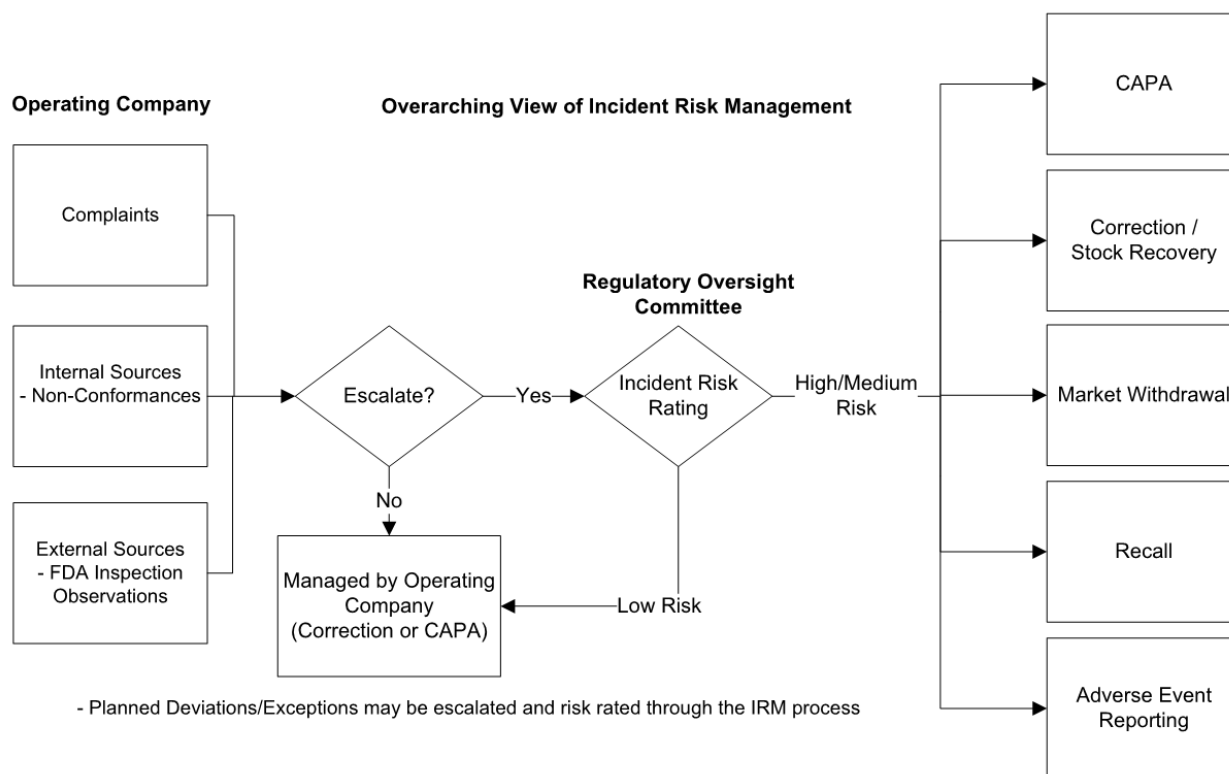
Incident Risk Management

Overview

S&RA has established a risk-based approach for the oversight and management of incidents that may impact the Company's compliance with the FSPTCA. This Incident Risk Management ("IRM") process allows for governance, including multiple levels of review, and control of various types of incidents throughout the life of the incident, from issue identification through incident closure. Incidents may arise from multiple sources including consumer/customer complaints, non-conformances, and external sources such as FDA inspection observations. Planned Deviations/Exceptions may also be escalated and risk rated. Through the IRM process, a level of risk is assigned to each incident, which determines the appropriate level of escalation to management for review and decision-making. Potential outputs of the IRM process may include, but are not limited to, corrections; stock recovery; corrective action, preventive action ("CAPA"); market withdrawal; recall; or adverse event reporting.

SmartSolve is a software tool used to integrate multiple FDA regulatory components and facilitate the IRM process by managing workflows and retaining documentation related to IRM and its associated processes.

The following diagram represents an overview of the IRM process and the related inputs and outputs of the process:



Roles and Responsibilities

Regulatory Oversight Committee

The Regulatory Oversight Committee ("ROC") is responsible for ensuring proper governance and oversight of escalated incidents, determining incident risk ratings, if applicable, and approving recommendations on required actions that are necessary for risk mitigation.

Incident Coordinators

Each IRM incident source has a designated Incident Coordinator to manage the incident process, which includes ensuring relevant incidents and information are entered into the SmartSolve system, ensuring proper approvals, escalation, reporting, monitoring, and conducting follow-up activities, as needed. Incident Coordinators are trained in the IRM process.

Incident Sources

Complaints

Complaints include any written, electronic, or oral communication received that alleges a deficiency related to the quality of a finished tobacco product. Consumer Relations facilitates the collection of complaints information. Complaints may arise from a variety of sources including consumers, customers, and field sales representatives. They have access to several points of contact for submitting complaints related to tobacco products, including phone numbers and email addresses.

Complaints are received by a third party contact center or Consumer Relations and assessed against established criteria. Complaint categorization and definitions have been approved by S&RA in conjunction with the Quality Director. Based on the complaint category selected, a response level is assigned and reviewed by the RJRT Complaint Coordinator. Certain categories may prompt a request that the complainant return the alleged defective product to RJRT quality department. The response level determines whether further action is required, including escalation and review. Per the IRM process, depending on the response level, a complaint is either escalated for review through IRM, or the complaint is documented and closed, when appropriate, for trending and periodic reporting. Complaint records that require further investigation or escalation are reviewed by the Quality Director or designee to confirm or reassign the response level. During this review, the Quality Director or designee will confer with S&RA, as needed. If warranted, an investigation is conducted at the direction of the Quality Director or designee. The investigation is approved, closed, and when applicable, a CAPA may be initiated. Consumer Relations will respond as necessary to the complainant.

Non-Conformances

Non-conformances result from failing to meet a specified requirement. A specified requirement includes either a stated expectation, which if not met, requires a disposition decision and the disposition of the impacted product or documented processes or procedures that must be followed in order to ensure consistent and repeatable outcomes.

The non-conformance management ("NCM") process includes suppliers, service providers, and all personnel who participate in the identification and management of non-conformances. Sources of non-conformances may include, but are not limited to, product, tobacco materials, direct materials, indirect materials, services, and processes.

When a non-conformance is identified, management is notified and any non-conforming items or products are identified, labeled, and isolated, as appropriate. A non-conformance record is initiated and categorized by assigning a level based on established criteria and escalated in accordance with IRM procedures. Non-conformances are reviewed and trended per Company defined guidelines and are escalated as needed based on the level of risk or if trending warrants escalation through the IRM process. A CAPA, Supplier Corrective Action Request ("SCAR"), change control and/or disposition of product or materials are possible outcomes that may result through the NCM process.

Planned Deviations/Exceptions

Planned deviations/exceptions ("PDE") include planned, temporary deviations/exceptions from established procedures, processes, methodologies, and/or suppliers/service providers. The process for managing PDE includes,

but is not limited to, deviations/exceptions related to areas such as specifications, manufacturing equipment, training requirements, and process documentation.

When the need to deviate from an established procedure, process, methodology, material and/or supplier/service provider is identified, personnel are notified and a review is performed to understand the need and urgency to deviate. Information is gathered, including a risk and impact mitigation plan, as needed, to submit a deviation request to S&RA for review and agreement. If necessary, the deviation request including the risk and mitigation plan may be escalated through the IRM process. The authorized PDE reviewer then approves the deviation to proceed as planned. If the PDE warrants the need for a permanent change, appropriate personnel are notified to initiate the relevant change control process.

Incident Triage and Escalation

Incident Relevance Assessment

A relevance assessment is performed within the complaints, non-conformances, and planned deviations/exceptions processes described above to determine whether the incident could potentially have an impact on product safety, adulteration, or misbranding.

An incident classified as Level III may, on its own, represent an issue that impacts product safety, adulteration, or misbranding. Level III incidents are escalated to the ROC for further review, governance and oversight. Level II incidents could represent an issue impacting product safety, adulteration, or misbranding depending on the trend of the same type of incidents. Level II incidents are trended and escalated to the ROC if the established threshold is broken or as deemed appropriate by S&RA and the Quality Director. Level I incidents are not considered to have a potential impact on product safety, adulteration, or misbranding and therefore, are not escalated to the ROC.

For escalation purposes, Level II and/or Level III incidents may be escalated to ROC when certain conditions are met (refer to the IRM SOP for further details) and only when agreed by S&RA.

Incident Risk Assessment

Escalated incidents that are supported with corroborating information are assigned an overall priority risk rating by the ROC based on probability of future recurrence and impact on product safety, adulteration, and misbranding. The priority risk rating determines required actions and the level of monitoring and oversight by the ROC. The risk rating drives the need for a CAPA and other activities such as review and agreement of action plans to mitigate potential risk and monthly status reporting to the ROC.

Potential Incident Outcomes

Corrective Action, Preventive Action ("CAPA")

A CAPA is initiated, if required, based on the incident's risk rating. The CAPA is a closed loop process, from initiation to verification of effectiveness. The CAPA process is used to collect and analyze information, investigate the incident, identify the root cause, and take appropriate action to eliminate or reduce the likelihood of recurrence. If a CAPA is required, an investigation is conducted to determine potential root cause(s) and an action plan is developed, which must be approved by appropriate RJRT management prior to execution. Once approved, the action plan is implemented to eliminate or mitigate the issue.

The action plan shall include a review of similar equipment, products and/or processes to determine whether the application of the proposed corrective action can eliminate further potential non-conformances in these similar areas. Method for verifying effectiveness of corrective action to be taken will be identified and supporting evidence of the action plan's effectiveness is documented and provided to RJRT management for approval.

Correction, Stock Recovery, Market Withdrawal, and Recall

In the event of non-conforming products, product contamination, product tampering, or other incidents that are significant enough to potentially cause products to be in violation of the FSPTCA, appropriate individuals within RJRT are authorized to make the determination that the incident warrants a market withdrawal or recall based on the recommendation of and the overall risk priority rating provided by the ROC. Certain incidents, where products or materials have not left company control, may be resolved through a stock recovery, during which a correction can be

made. In certain instances involving product in the marketplace, corrections may be made without requiring a recall. Once a decision is made to initiate a stock recovery, market withdrawal or recall, the Company follows a consistent, defined process to locate and correct, or if necessary, remove tobacco products from the market. Involved parties are notified as needed and actions taken by the Company are communicated accordingly. Recalls additionally require notification to and communication with the FDA throughout the recall process.

Adverse Event Reporting

Certain incidents may be related to an adverse experience associated with the use of a tobacco product. While specific regulations have not yet been promulgated by the FDA, serious unexpected adverse experiences may require reporting to the FDA if the Company becomes aware of any information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to an unexpected adverse experience or any significant increase in the frequency of an expected adverse product experience. S&RA maintains written records of adverse event reporting to the FDA, and any related correspondence or records of investigations and evaluations; and S&RA will develop processes to fulfill these reporting requirements once the regulations are promulgated.

Incident Closure

Incidents may be closed once all required actions are complete and the appropriate management reviews have been performed to ensure that actions taken were effective in eliminating or mitigating the risk of recurrence. Incidents are formally closed along with supporting evidence of management approval of the closure and mitigation activities associated with the incident.

Validation

Overview

S&RA oversees validation activities on behalf of RJRT pursuant to service level agreements. Validation is a documented process performed to ensure the reliability and consistent intended performance of a system in scope per the S&RA Validation Strategy. Validation is used to demonstrate control over FDA relevant systems and their functionality.

The validation approach, change control, and roles are documented in the Validation Strategy, Validation Master Plan, and related validation SOPs.

The Validation Process

S&RA uses a top-down risk-based approach to effectively manage validation. Systems are assessed for validation relevance in accordance with the Validation Strategy and related SOPs. The relevance assessment focuses on key FDA compliance areas, criticality and business need. Validation relevant systems are validated per the Validation Master Plan. A risk assessment is conducted as part of validation as required by related validation SOPs.

Periodic Review

Validated systems are reviewed on a periodic basis to verify the systems and the associated documentation are maintained in a validated state. The frequency of review is determined during the initial validation of the system. The review frequency and due date are documented in the Periodic Review Schedule.

Change Control

Overview

RJRT is required to execute changes in accordance with the Enterprise Change Control process, established by S&RA to appropriately control and document changes within relevant business processes and systems. The Enterprise Change Control process helps ensure that relevant executed changes that affect the production of tobacco products are managed, communicated, approved, and documented. Other existing business processes and supporting applications such as PDM, MRM, and Document Management are considered part of the Enterprise Change Control Process. Change Control is facilitated by using these applications as well as the Change Control module within the SmartSolve system. The change control process also enhances communication among stakeholders and builds a consensus regarding the change request prior to beginning change control.

Enterprise Change Control Process

The Enterprise Change Control process consists of five steps that are common across all change processes used for documenting and managing in-scope changes. The five steps are as follows:

1. Initiate change request - Changes must be initiated by documenting a baseline set of information pertinent to the change being proposed.
2. Change request approval - All changes must be approved by designated approvers prior to implementing any proposed change.
3. Implement change - Execute and provide evidence of completion of tasks necessary for implementation of the change, including training.
4. Document change - Documentation to confirm change implementation tasks have been completed is reviewed and evaluated.
5. Close change - Changes are marked closed for record keeping purposes.

Additional details related to these five steps are outlined in the Enterprise Change Control SOP. The Enterprise Change Control model referenced in the SOP provides an overview of the core elements of the change control framework and the applicability of change control to relevant business processes and systems used to bring tobacco products to market. Unique business processes for managing change exist within functional areas and operate in accordance with the Enterprise Change Control framework.

Document and Records Management

Overview

RAIS is responsible for managing the document and records management processes on behalf of RJRT pursuant to service level agreements. RAIS has a Records Management Policy to ensure documents and records are properly controlled through systems and processes. Fundamental controls for documents and records include security, restricted access, approval, and accessibility.

Document Management Process

Functional business departments within RJRT have designated managers and/or coordinators who are responsible for identification and maintenance of documents based upon the approved SOPs and schedules.

RAIS, in coordination with RJRT, utilizes various systems to help ensure the accuracy, completeness, and availability of the Company's controlled documents. Pilgrim SmartDoc is an application tool implemented to assist with delivering and managing processes to appropriately achieve these objectives for the organization. Access to systems maintaining company documents is restricted to authorized personnel to ensure accessibility to appropriate stakeholders for viewing and/or editing.

RAIS has established document management processes that help ensure a consistent approach is followed by using templates for document creation, numbering schemes for version control, and review and approval protocols for document creation and/or revisions. The document management system and process also allow for documents to be searchable and easily accessible to relevant stakeholders.

Records Management Process

Functional business departments within RJRT have designated managers and/or coordinators who are responsible for identification, retention and disposition of records based upon the approved policy and schedules.

RAIS, in coordination with RJRT, utilizes various systems to help ensure the availability, retention, and disposition of the Company's records. OpenText Content Server is an application tool implemented to assist with delivering and managing processes to appropriately achieve these objectives for the organization. System access to company records is restricted to authorized personnel to ensure accessibility to appropriate stakeholders for viewing.

The RAIS Records Management Policy outlines requirements for record retention and disposition. Hard copy records are subject to the same disposition and retention requirements included in the Records Management Policy and are maintained in controlled locations.

Training

Overview

RJRT is committed to ensuring personnel are qualified with the necessary education, background, training, and experience to adequately perform their assigned responsibilities. To support this commitment, a comprehensive training program has been established to define roles, responsibilities, and procedures for assessing, designing, developing, implementing, evaluating, and documenting training activities.

Training Process

Management identifies training requirements and creates a training plan to ensure personnel are qualified to complete assigned work responsibilities. For purposes of this section, "Management" may include, but is not limited, to the following: Business Process Owners/Business Process Managers, project managers, department or functional leaders, or any other manager of personnel. Human Resources Talent Development ("HRTD"), a department of RAIS, and Management collaborate to develop training content, delivery methodology (e.g., computer based training, instructor led training, on the job training), and resources required for course delivery. Management approves designated timelines associated with the development and delivery of all required training as well as course curriculum. Management and HRTD collaborate to approve all instructors who will deliver training. Approved instructors must meet required education, background, training, and experience qualifications. RJRT employees are responsible for completing required training within the approved timeline as well as acknowledging their completion of training requirements for record keeping purposes. Management is responsible for reviewing employee training records to ensure training plans are current and training requirements have been completed.

Electronic training records are maintained within a learning management system ("LMS"), which is a system that maintains current training related qualifications, documentation, and records. Access to the LMS is restricted to designated personnel to preserve the integrity of all training records. HRTD updates training records and applicable qualifications within the LMS and is responsible for providing guidance and oversight of training record retention policies. HRTD is also accountable for maintaining training records that are compiled and submitted via hard copy in a secure location with limited access.

HRTD conducts training course evaluations to assess the effectiveness of the training programs, instructors, and delivery methodology. HRTD provides training effectiveness and completion reporting to Management for its review.

RJRT uses contract manufacturers and other third parties for various activities that support business processes related to FDA compliance. Supplier contracts require contract manufacturers to train personnel in accordance with RJRT requirements and produce training records, if requested.

Periodic Review

Management periodically reviews and identifies personnel required to participate in on-going training activities, including new personnel and employees that have changed roles or responsibilities.

Monitoring

Overview

Various monitoring activities are in place to help ensure that control activities and programs designed to comply with the FSPTCA are operating as intended. Monitoring includes, but is not limited to, the Regulatory Oversight Committee ("ROC") monitoring and reporting, Regulatory Management Review ("RMR"), Internal Audit Department ("IAD") assurance activities, and Business Self-Audit ("BSA"). Each of these activities provides an effective means for governance and communication of any significant issues that are identified through the various monitoring functions.

Regulatory Oversight Committee

The Regulatory Oversight Committee is responsible for monitoring, trending, and reporting on FDA regulatory key performance indicators ("KPIs"). The ROC reports FDA-related matters through Fast Forward, the Company's Integrated Business Management process.

Regulatory Management Review

The Regulatory Management Review committee includes representatives from S&RA, IAD, Law, R&D, Operations, Information Management and Consumer Marketing. The RMR committee is responsible for providing appropriate governance, oversight, and guidance to ensure that the Company complies with FDA's regulatory requirements. RMR occurs at least on a monthly basis to monitor key Company FDA-related programs and initiatives and to ensure the regulatory framework is evaluated for continuous process and efficiency improvement goals. RMR includes reviews of Internal Audit findings and FDA inspection results, including management's actions to correct control gaps. RMR also sets direction for, provides oversight to, and monitors FDA regulatory KPIs. The FDA regulatory KPIs include a review of IRM escalated incidents; FDA actions; non-conformances; the CAPAs from escalated incidents; planned deviations/exceptions; and trends in complaints. The FDA regulatory KPI dashboard is also reported through Fast Forward on a monthly basis. Periodic updates are given to the Leadership Team by the RAIS EVP S&RA.

Internal Audit Department

RAI's IAD is an independent, objective, assurance and consulting function designed to add value and improve the organization's operations. The IAD assists the Audit and Finance Committee of the RAI Board of Directors in fulfilling its oversight responsibilities by serving as an integral component of the Company's risk management, internal control, and governance processes by providing an independent and objective internal monitoring function. Utilizing the Company's Enterprise Risk Management ("ERM") process, Strategic and Business Process Risk Assessments are performed, inclusive of FDA related risks. The risks identified through these assessments provide the basis for the IAD's Annual Audit Plan, which focuses on the highest risk areas. The IAD works closely with the functional business owners to ensure proper understanding of the risk and control environment and accuracy in reporting. Functional area management is responsible for providing management actions for each finding. Any management actions, specific to FDA, that are not resolved by the due date are reported to the RAIS EVP S&RA. The General Auditor issues a quarterly General Auditor's Report, which lists audits with significant findings to members of the Audit and Finance Committee of the RAI Board of Directors and to executive management.

Business Self-Audits

BSAs are used to evaluate the effectiveness of the key controls and processes outlined in TPIP. Per a defined schedule, designated representatives from each functional area included in TPIP are required to complete a BSA questionnaire to acknowledge their responsibility and accountability for ensuring controls are in place to effectively manage key FDA risks associated with the activity. For certain areas, BSA detailed testing is also conducted periodically. BSA detailed testing requires the functional business owner to provide supporting evidence that key controls are in place. The results of the BSAs are reviewed by a representative from the IAD / ERM function and any issues identified are escalated and communicated as necessary to ensure appropriate mitigation steps are taken to address any potential risks.

Glossary

The definitions and interpretations of terms in the FSPTCA apply to such terms when used in the TPIP. For the purpose of TPIP, the following definitions apply:

Business Process Manager (“BPM”) means the personnel identified from the business to provide leadership and oversight for FDA processes. The BPM is responsible for the execution of the items for which the BPO is accountable.

Business Process Owner (“BPO”) means the personnel identified from the business to provide leadership and oversight for FDA processes. The BPO is accountable for ensuring their processes meet regulatory requirements and ensuring consistency, timeliness and appropriate change management among other things.

Company control includes products that are in Company facilities or in the possession of distribution centers, transportation providers, external agencies, and external entities acting on behalf of the Company through contracts including, but not limited to, distribution and storage.

Complaint means any written, electronic, or oral communication received by the tobacco product manufacturer that alleges a deficiency related to the quality of a tobacco product.

Consumer means someone of an age to legally purchase tobacco products.

Contamination refers to any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products.

Corrective Action, Preventive Action (“CAPA”) means the process used to collect and analyze information, investigate an incident and identify the root cause, and take appropriate action to eliminate or reduce the likelihood of recurrence.

Customer means someone who purchases products directly from the Company (e.g., wholesaler).

Direct Material (Material) means any ingredient, additive, or other substance other than tobacco incorporated into or added to a tobacco product during manufacturing (e.g., ingredients, packaging, filters, paper, etc.).

Distribution Centers (“DC”) means the warehouses where finished goods are received from manufacturing facilities. Finished goods are stored at the DC and then transported to customers via common carriers.

Document means a discrete work of writing which stores or communicates information and is typically managed by a specific set of regulatory or corporate rules and requirements with approvals and audit trails (e.g., Standard Operating Procedures, work instructions, policies, etc.).

Enterprise is inclusive of all tobacco-manufacturing operating companies of RAI.

Enterprise Risk Management (“ERM”) means the process designed to identify potential events that may affect the Company, manage risk to be within the organization's risk appetite, and provide management and the Board of Directors reasonable assurance regarding achievement of the organizational objectives. ERM enables management to identify, assess, and manage risks in the face of uncertainty, and is integral to value creation and preservation.

Fast Forward means the Company's Integrated Business Management process. It is a cross-functional process for communication, integration and decision-making.

Finished tobacco product means any tobacco product that has completed the manufacturing and packaging process and is intended for commercial distribution. Finished tobacco products may also be called finished goods.

Good Manufacturing Practice ("GMP") Personnel Practices means the internal processes and controls established by the Company to prepare for future Tobacco Product Manufacturing Practice regulations and address personnel restrictions and requirements.

Hazard Analysis and Critical Control Point ("HACCP") means the risk-based management system in which product safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw materials production, procurement and handling, to manufacturing, distribution, and use of the finished product.

Incident Risk Management ("IRM") means the process which allows for governance, including multiple levels of review, and control of various types of incidents throughout the life of the incident, from issue identification through incident closure.

Indirect material means any other material or service that is not a direct material (e.g., professional services, capital equipment, maintenance, repair and operations spare parts, etc.).

In-process controls means controls used to verify that products are manufactured according to the product specifications (e.g., meters, scales, gauges, testing/sampling product, etc.).

In-process tobacco product means any tobacco product that is fabricated, compounded, blended, ground, extracted, sifted, or processed in any other way by a tobacco product manufacturer for use in the manufacture of a finished tobacco product.

Internal Audit Department ("IAD") means the department that functions as an independent, objective, assurance and consulting activity designed to add value and improve an organization's operations.

Level of Concern ("LOC") means a relative measure of the extent to which a proposed product modification may present the potential to alter the inherent risk of a tobacco product.

Manufacturing Execution System ("MES") means the system used to manage materials and quality processes and execute production orders in most of the Manufacturing Sites. The data includes batch and production order records; material lot identification, history and genealogy; shipping and receiving documents; at line quality records and equipment process performance data.

Marketing Resource Management ("MRM") means a web-based system used to manage the work flow process and review of advertising and packaging / labeling creative. MRM is part of the Aprimo Marketing Studio® software suite.

Non-conformance means the result from failing to meet a specified requirement. A specified requirement is a stated expectation, which if not met, requires a disposition decision related to the applicable product (e.g., raw materials, work-in-process, finished tobacco products, point-of-sale materials, advertising, or submissions).

NTRM is the company's acronym for Non-Tobacco Related Material

Pest means any objectionable insect or other animal including birds, rodents, flies, and beetles.

Planned deviations/exceptions ("PDE") means planned, temporary deviations from established procedures, processes, methodologies, and/or suppliers/service providers.

Product and Packaging Development Process ("PPDP") means the established process to govern the development of new tobacco products and/or packaging and changes that impact the design parameters of existing tobacco products and/or packaging.

Product Data Management (“PDM”) is the Siemens SIMATIC IT Interspec software used to manage product life cycle data in support of RAI Operating Companies.

Product Stewardship means the principle that nothing is to be done or added to tobacco products that will increase their inherent risk. With every new product or change in a blend, process, ingredient, material, technology and/or design of an existing tobacco product, the potential effect of that change is evaluated using a framework that is based on the information available concerning the product and the proposed change.

Record means any data or information which provides evidence of a business activity and represents the outcome/results of actions taken within our business processes (e.g., completed forms, batch records, controlled compilation records, archives and/or research reports that provide official company reporting activities and require retention rules, etc.).

Regulatory Management Review (“RMR”) means the monthly review of key FDA programs and initiatives by management.

Regulatory Oversight Committee (“ROC”) means the enterprise-wide, cross-functional committee responsible for ensuring proper governance and oversight of escalated incidents, determining incident risk ratings, if applicable, and approving recommendations on required actions that are necessary for risk mitigation.

Retailer means someone who sells product to consumers for consumption.

Rework means action taken on a non-conforming tobacco product so that it is suitable for use before it is released for further processing or distribution. Tobacco products to be reworked require an evaluation and disposition prior to use.

Safety incident means there is a reasonable probability that a tobacco product may contain a manufacturing or other defect not ordinarily contained in tobacco products that would cause serious, adverse health consequences or death. A marketed tobacco product may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or there is a significant increase in the frequency of a serious expected adverse product experience.

SAP is the company name and is the common term used to reference the software suite of tools utilized for ERP (Enterprise Resource Planning).

Specification means any requirement by a tobacco product manufacturer to which a finished or in-process tobacco product or manufacturing process must conform.

Standard Operating Procedures (“SOPs”) are the documents that define the objectives, scope and responsibilities by which personnel perform tasks and activities, in alignment with established policies.

Tobacco-manufacturing operating companies mean the following RAI operating companies: R.J. Reynolds Tobacco Company (“RJRT”), American Snuff Company (“ASC”) and Santa Fe Natural Tobacco Company (“SFNTC”).

Tobacco material means materials derived from tobacco (e.g., leaf, stems, etc.).

Tobacco material service providers mean suppliers managed by the Leaf Department that provide services other than tobacco materials (e.g., transportation, receiving station agents, etc.).

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing of a component, part, or accessory of a tobacco product) that FDA has authority over pursuant to Section 901(b), 21 U.S.C. § 387a(b), of the FSPTCA.

Tobacco Product Manufacturing Practices ("TPMP") means the regulations for the manufacture, labeling, packing, and storage of tobacco products that will be promulgated by FDA pursuant to Section 906(e) of the FSPTCA.

Work Instructions means the documents that detail how to implement Standard Operating Procedures and communicate "what" to do and "how" to do it for a specific activity.