

SOP Title	SOP No.	Version No.	Effective date
Initiating and Simulating a Recall	QA.SOP-007	00	YYYY/MM/DD

INITIATING AND SIMULATING A RECALL

Written by:	[Name]	Signature/Date	[YYYY/MM/DD]
Approved by:	[Name]	Signature/Date	[YYYY/MM/DD]

1. Purpose

- 1.1. This procedure describes the steps for initiating a recall of cannabis product sold, distributed or exported, in accordance with Part 2 – s.46 and Part 12 – s.247 of the *Cannabis Regulations*.
- 1.2. This SOP must be conducted prior to launching an actual recall (in accordance with **QA.SOP-008: Executing a Recall**).

2. Scope

- 2.1. This procedure applies to actual and simulated recalls.

3. Responsibilities

- 3.1. **Recall Team** : To participate in the urgent recall meeting, to contribute to the decision-making process relating to the Recall Plan, and to complete the recall tasks as assigned, within the established timeline. The Recall Team includes the QAP, the RP, and the Production Manager.
- 3.2. **Quality Assurance Person (QAP)** : To carry out the preparatory steps necessary for the execution of a real or simulated recall; to control the distribution and sale of the recalled product; to assign recall tasks to the Recall Team; to determine the most appropriate deadlines; to manage the recall meeting; and, to prepare the Recall Risk Assessment, and the Initial Recall Report.
- 3.3. **Responsible Person (RP)** : To gather the necessary inventory and distribution data concerning the recalled product; to organize the recall meeting; to inform Health Canada of the decision to initiate a recall; and, to monitor the progress of simulated recalls.

4. Acronyms and Definitions

- 4.1. **Recall Risk Level** : The numerical designation assigned to a recall that corresponds to the relative degree of risk posed by the cannabis product being recalled. There are three (3) types of Recall Levels (I, II, III), depending on the degree of risk to human health and safety :
 - 4.1.1. **Level 1 Recall (Serious, Imminent Danger)**: There is a reasonable probability that the use of, or exposure to, the affected cannabis will result in serious adverse health consequences or even death.

SOP TO BE CONTINUED...