

TITLE: Submitting Internal Quality Alerts					
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Procedure Owner:	Process Author:	Final Approved By:	Approval Date:		
Quality	Samantha Stephen	Ryan Milligan	2/6/2024		
	Author Signature:	Approver Signature:			

# Process – Submitting Quality Alerts

### 1. Purpose:

1.1. The purpose of this procedure is to provide a written process of submitting internal quality alerts from retail utilizing Odoo.

## 2. Scope:

2.1. This applies to all retail staff submitting quality alerts for internal flagged quality-concerns.

## 3. Responsible Parties:

- 3.1. Quality is responsible for the update, maintenance, overall document control of this procedure, and tracking trending data for submitted quality alerts.
- 3.2. Retail leadership is responsible for ensuring that retail staff adhere to this policy and train staff accordingly.
- 3.3. Retail staff, once trained are responsible for following this procedure and ensuring that all internal quality concerns are reported via Odoo.
- 3.4. Any assigned teams or individuals are responsible for adhering to this procedure

#### 4. References:

4.1. N/A

#### 5. Definitions:

- **5.1. Quality Alert-** An alert submitted utilizing Odoo's quality functionality to notify Quality of quality-related concerns at the store level.
- **5.2.** Newly Created
- **5.3. Confirmed-** Quality alert has been received by the responsible person
- **5.4.** Action Proposed- Remediation plan has been set by the responsible team
- **5.5. Solved-** Corrective action has been completed and teams have been trained on the preventative action.

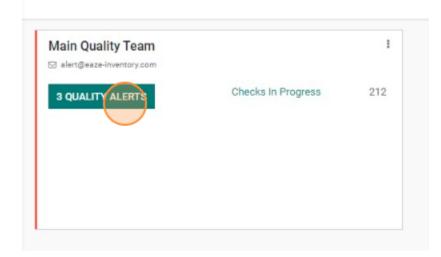


## 6. Procedure:



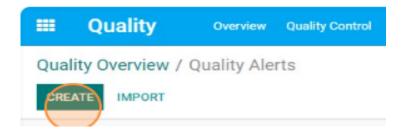
## 6.1. Creating a Quality Alert

- 6.1.1. Navigate to the Odoo webpage and select the Quality module.
- 6.1.2. Select "Quality Alerts" under Main Quality Team

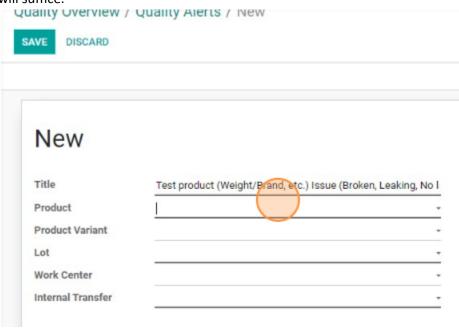


6.1.3. In the top right-hand corner, select "Create"





- 6.1.4. A new internal tab will appear within Odoo for a New Quality Alert, within this alert begin to fill out each section starting with the Title.
  - 6.1.4.1. The title should reflect what the quality alert is about, a short description with the product name will suffice.



- 6.1.5. **Product**-The product name can either be typed in or easily selected through the dropdown functionality.
  - 6.1.5.1. **Product Variant-** will automatically fill in based on what the product is.
- 6.1.6. **Lot-**field will be reflective of the lot or box, the affected product(s) came from.
  - 6.1.6.1. The lot code can be found on the external package, below the barcode.
  - 6.1.6.2. If there are multiple lots, list them in the description tab.
  - 6.1.6.3. You will only be able to see lots associated with the company and product
- 6.1.7. Work Center- is not required.
- 6.1.8. **Internal Transfer-** Ensure the selected choice is to transfer the unit(s) out and from where the products were moved from stock to Quality Control. You may also create the transfer from within the QA module.
- 6.1.9. **Team** This will represent who will be responsible for addressing the concern.
- 6.1.10. **Responsible-** Select the responsible user
- 6.1.11. Tags- Select based on issue and may be created if issue(s) do not already available
- 6.1.12. **Root Cause** Dependant on issue



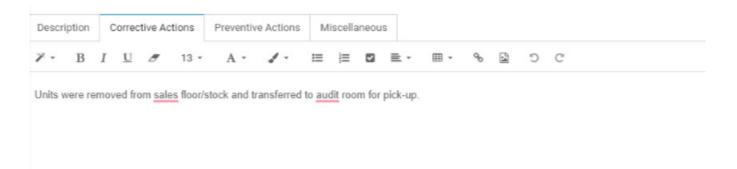
6.1.13. **Priority-** Select based on level of concern, issue, or quantity.

#### 6.2. Detailing a Quality Alert

- 6.2.1. Once the primary information has been provided for the Quality Alert, it is important to provide a description of the issue.
- 6.2.2. Then provide the below required information:
  - 6.2.2.1. Product Name:
  - 6.2.2.2. Weight:
  - 6.2.2.3. Production Batch
  - 6.2.2.4. Date Issue Occurred:
  - 6.2.2.5. Quantity Affected:
  - 6.2.2.6. Initials of individual identifying concern:
  - 6.2.2.7. Initials of management verifying:
  - 6.2.2.8. Additional notes or photos, **photos are required**. Notes are not.

#### 6.3. Detailing Corrective Actions and Submitting an Alert

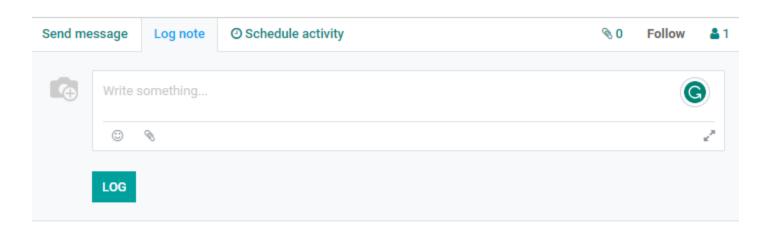
- 6.3.1. Once the Description portion has been completed, move onto the Corrective Actions section.
- 6.3.2. This section may be completed by inputting what has been done already to mitigate the issue or to prevent affected units from reaching a patient. However, further Corrective Actions will be created by the assigned team.
- 6.3.3. Once the alert has been completed, select "Save" in the top left corner which will submit the Quality



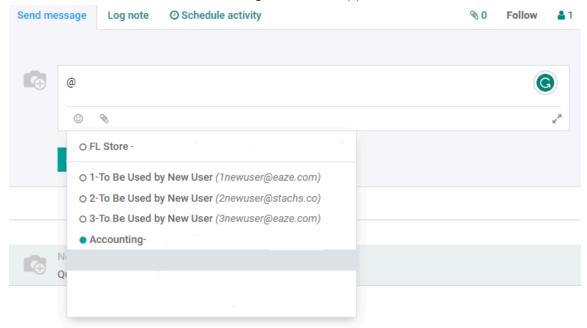
Alert.

6.3.4. For any additional notes, the "Log Notes" tab may be used to log related but not required notes once the Quality Alert is completed.





6.3.5. The "Send Messages" tab may be used to communicate with the assigned team or others related to the issue by utilizing the "@" symbol and typing in the individual(s) or store(s) name, this functionality will send a direct email notification to the assigned individual(s).



- 6.3.6. Preventative Actions, Miscellaneous, and the actions at the top right "Confirmed, Action Proposed, More" are all used by the assigned team
- 6.3.7. Proceed with the physical inventory by adhering to the Return To Inventory (RTI) SOP.

### 6.4. Resolving Quality Alerts Using Corrective Actions

6.4.1. Corrective actions are to be completed by assessing the root cause of the concern through an investigation using multiple members of an affected team so different ideas may be gathered as to the root or direct cause for the concern.





General: Submitting Internal Quality Alerts QP-SOP-012, Current Version 1.0

- 6.4.2. Before a Quality alert can be fully resolved it must have all of the required information from the retail team and receive corrective and preventative actions.
  - 6.4.2.1. Preventative actions may not apply to every concern as there are special circumstances where a random event can occur resulting in little to no traceable data to take action and identify root cause.
  - 6.4.2.2. Preventative actions are to act in such a way to ensure that the same corrective action does not need to be repeated and responsible teams must be informed of both the corrective and preventative actions to ensure a corrective action plan is rolled out effectively.

#### 7. Attachments:

7.1. N/A

# 8. Revision History:

REVISION NUMBER	STEPS REVISED	REASON FOR REVISION	INITIALS	EFFECTIVE DATE
1.0	All	Creation of SOP	SNS	2/6/2023