

Standard Operating Procedure (SOP): Incident Response and Reporting for Allergen-Related Events

This SOP defines the procedures for **incident response and reporting for allergen-related events**, ensuring timely identification, management, and documentation of allergen exposure or reactions. It covers initial incident recognition, immediate medical intervention, containment measures, communication protocols, and detailed reporting to prevent recurrence and enhance overall safety in environments handling allergens.

1. Purpose

To establish a clear and effective process for responding to and reporting allergen-related incidents in order to minimize health risks, ensure regulatory compliance, and promote a safe environment.

2. Scope

This SOP applies to all staff, contractors, and personnel involved in the handling, preparation, distribution, or service of allergen-containing products.

3. Definitions

- **Allergen-Related Incident:** Any unintentional exposure, contamination, cross-contact, or allergic reaction suspected or confirmed to be caused by an allergen.
- **Allergen:** Any substance recognized as capable of causing an allergic reaction (e.g., peanuts, gluten, dairy, etc.).
- **Incident Report:** A documented record of the event, actions taken, and outcomes.

4. Responsibilities

- **All Staff:** Must promptly report and respond to potential allergen-related incidents as outlined in this SOP.
- **Supervisors/Managers:** Oversee the implementation of this SOP, ensure incidents are properly managed and documented.
- **Designated First Responders:** Provide immediate medical assistance as required.

5. Procedure

1. **Incident Recognition**
 - Identify signs/symptoms of allergic reaction (e.g., hives, swelling, difficulty breathing).
 - Recognize potential or confirmed allergen contamination events.
2. **Immediate Medical Response**
 - Call emergency medical services if severe symptoms (anaphylaxis) are present.
 - Administer epinephrine auto-injector or other prescribed medication, if available and trained to do so.
 - Stay with the affected individual until medical help arrives.
3. **Containment and Control**
 - Isolate the area/product implicated in the exposure.
 - Cease operations in the affected area, if necessary, to prevent further exposure.
4. **Notification and Communication**
 - Notify management, supervisors, and Health and Safety Officer immediately.
 - Inform all relevant personnel and departments (e.g., kitchen, quality assurance, HR).
5. **Documentation and Reporting**
 - Complete an Incident Report Form with details on the event, response actions, and outcomes.
 - Submit the report to management and retain records according to policy.
6. **Investigation and Corrective Actions**
 - Conduct a root cause analysis to identify factors leading to the incident.
 - Develop and implement corrective and preventive actions (CAPA) to avoid recurrence.
 - Review and update allergen control protocols, training, and labeling as needed.

6. Training

All relevant staff must receive training on allergen identification, incident response procedures, and use of emergency

medications. Refresher training is to be conducted regularly.

7. Review and Revision

This SOP must be reviewed annually or after any allergen-related incident. Revisions should incorporate lessons learned and regulatory updates.

8. Attachments/Forms

- Allergen Incident Report Form (template attached or linked)
- Emergency Contact List
- Allergen Control Plan