

# Standard Operating Procedure

## Title: Classification of Defects for Incoming Packaging Components

Department	Warehouse	Document no	WAR-110		
Title	Classification of Defects for Incoming Packaging Components				
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### 1.0 DOCUMENT OWNER

Warehouse / Quality Manager

### 2.0 PURPOSE

Define the classification of defects found during the inspection of incoming packaging components.

### 3.0 SCOPE

This SOP explains the Acceptable Quality Limit (AQL) levels and categories of defects for all incoming packaging components received and tested at a GMP site.

It also determines the responsibility levels for the acceptance or rejection when an Out of Specification (OOS) result occurs.

### 4.0 RESPONSIBILITY

It is the responsibility of the Incoming Goods Inspectors to identify and evaluate the extent of a defect when inspecting a packaging component.

It is the responsibility of the Quality Assurance Manager to accept or reject the defective packaging component that falls outside its AQL level.

### 5.0 PROCEDURE

All deliveries of packaging components undergo thorough sampling and inspection against artwork and the Packaging Material Specification (PMS).

When a defect is found during the inspection:

**5.1 Determine the type of problem, defects or failure** for any characteristics of the component whether it's related to the delivery, appearance, dimension, printing, assembly, weight or material.

**5.2 Refer** to the Tables of Defects (**Appendix A**) and find the listed defect that corresponds to the type of problem determined.

**5.3** If the defect is listed in:

**5.3.1 Appendix 1** – It is a **Critical** defect: a defect that would result in hazardous or unsafe conditions for individual using, maintaining or depending upon the product. **(AQL of 0.0%)**.

**5.3.2 Appendix 2** – It is a **Major** defect: a defect that is likely to result in failure or that would materially reduce the usability of the product for its intended purpose. **(AQL of 0.4%)**.

**5.3.3 Appendix 3** – It is a **Minor** defect: a defect that is not likely to materially reduce the usability of the product for its intended purpose. **(AQL of 1.5%)**.

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## **Table of Contents Hotels Engineering Standard Operating Procedures Bing**

1. Understanding the eBook Hotels Engineering Standard Operating Procedures Bing
  - The Rise of Digital Reading Hotels Engineering Standard Operating Procedures Bing
  - Advantages of eBooks Over Traditional Books
2. Identifying Hotels Engineering Standard Operating Procedures Bing
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Hotels Engineering Standard Operating Procedures Bing
  - User-Friendly Interface
4. Exploring eBook Recommendations from Hotels Engineering Standard Operating Procedures Bing
  - Personalized Recommendations

- Hotels Engineering Standard Operating Procedures Bing User Reviews and Ratings
- Hotels Engineering Standard Operating Procedures Bing and Bestseller Lists
- 5. Accessing Hotels Engineering Standard Operating Procedures Bing Free and Paid eBooks
  - Hotels Engineering Standard Operating Procedures Bing Public Domain eBooks
  - Hotels Engineering Standard Operating Procedures Bing eBook Subscription Services
  - Hotels Engineering Standard Operating Procedures Bing Budget-Friendly Options
- 6. Navigating Hotels Engineering Standard Operating Procedures Bing eBook Formats
  - ePub, PDF, MOBI, and More
  - Hotels Engineering Standard Operating Procedures Bing Compatibility with Devices
  - Hotels Engineering Standard Operating Procedures Bing Enhanced eBook Features
- 7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Hotels Engineering Standard Operating Procedures Bing
  - Highlighting and Note-Taking Hotels Engineering Standard Operating Procedures Bing
  - Interactive Elements Hotels Engineering Standard Operating Procedures Bing
- 8. Staying Engaged with Hotels Engineering Standard Operating Procedures Bing
  - Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Hotels Engineering Standard Operating Procedures Bing
- 9. Balancing eBooks and Physical Books Hotels Engineering Standard Operating Procedures Bing
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Hotels Engineering Standard Operating Procedures Bing
- 10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
- 11. Cultivating a Reading Routine Hotels Engineering Standard Operating Procedures Bing
  - Setting Reading Goals Hotels Engineering Standard Operating Procedures Bing
  - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Hotels Engineering Standard Operating Procedures Bing
  - Fact-Checking eBook Content of Hotels Engineering Standard Operating Procedures Bing

- Distinguishing Credible Sources
13. Promoting Lifelong Learning
- Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
- Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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