

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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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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