AdeptGroup

ENGINEERING EXCELLENCE

A Guide to Choosing the Best ASTM 4169-22 Distribution Test

FOR YOUR PRODUCT

Context to Guide Your Decision

Determining which ASTM D4169-22 ***(Standard Practice for Performance Testing of Shipping Containers and Systems)*** distribution cycle (DC) test to use for a product and its packaging can be challenging. It can be an especially difficult decision for packaging that includes a medical device sterile barrier system in accordance with ISO 11607: 2019 standards.

With nearly 20 variations of the ASTM D4169 testing standard, the choice can seem overwhelming at first glance, but a thorough understanding of the product and its distribution environment elicits important context to guide the decision.

THE MAPPING PROCESS

The most useful method for narrowing the options is mapping out the manufacturing/sterilization/shipping/distribution path(s) for the product(s). This mapping process creates a rationale for the ASTM D4169 DC test used to demonstrate sterility and integrity during distribution of your product.

ASTM D4169

ASTM D4169 provides a guide for evaluating shipping units within a system using established test method equipment and testing levels representing various distribution channels. The standard tests different distribution conditions a product may face, allowing a packaging engineer to choose the most accurate simulation testing for the worst-case shipping environment within a distribution channel. This reduces the potential to over package or under package.

ISO 11607-1

The ISO 11607-1 document defines the sterile barrier system to be the ***"minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use."*** The sterile barrier system includes what we often call the primary package with any included labeling or additional components inside and the product. Protective packaging is defined in ISO 11607-1 as a ***"configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use."*** This means that protective packaging includes secondary and tertiary packaging when they're used, which may also include partitions, pallets, stretch wrap and more.

Distribution Testing

Distribution testing is required for all shipping containers (protective packaging) used to transport medical products.

It is critically important to protect the sterile barrier system because the distribution environment often includes hazards that can be detrimental, such as shock, vibration, compression, altitude, temperature and humidity. Though not a requirement, testing is also critically important for packaging of non-medical medical products, as it can help brands avoid unnecessary expenses related to over packaging or under packaging. Because ASTM D4169 has 18 DCs differentiated by transportation or distribution modes, the choice of which DC to use may not always be clear.

CHOOSING THE MOST APPROPRIATE DC MODE

While the number of options and the specific testing variations included in each DC may seem daunting at first glance, a series of simple steps can provide the clarity needed to make the right choice.

1) Determine the package destination

Account for all the destination stops the package is likely to encounter during transportation, including external sterilization sites, intermodal shipping locations, distribution centers, kitting operations and final customer centers.

2) Determine the mode of transportation the package is likely to experience

Account for all likely modes of transportation, including air, sea, truck, rail and others. In many cases, the package may experience a combination of several of these modes. It is important to note that ocean freight is not part of the ASTM D4169 standard, but other standards available from ISO can be used to supplement test selection options for packaging that will ship by sea.

For example, a common transport mode for many medical devices and pharmaceutical products is small parcel through UPS, FedEx, USPS or similar carriers. This transport option uses both air and truck as a routine part of transportation and directly correlates to DC 13 [Air (intercity) and motor freight (local, single package up to 150 pounds [61.8 kg])]. If a package weighs more than 150 pounds or is part of a unitized load (pallet or slip sheet) and shipped via air and truck, then DC 12 might be the best option. If the predesigned options do not fit an identified distribution transportation route, there is a user-defined cycle (DC 2) that allows a custom combination of simulated hazards that should be based on conditions the package may face in its distribution environment.

Distribution Testing Cont.

3) Develop a transportation distribution chart

A distribution chart may clearly identify the path(s) the product/package will take and provides a rationalization for what to test, how to conduct the test and why the test simulates the distribution channel the product will experience.The value of a transportation distribution chart becomes obvious when viewed through the lens of real-world examples:

EXAMPLE 1

A company did not develop a transportation distribution chart for palletized medical packaging shipped to hospitals in the interior of mainland China. Without the benefit of the valuable information represented by a transportation distribution chart, they chose the ASTM D4169 DC 12 simulated distribution testing standard. After the first few real-world shipments, the hospital's customers in the mainland China interior began to complain about breaches in the sterile barrier system. An evaluation of the damage showed the majority of transportation in this region was by single-parcel deliveries, specifically by bicycle couriers over very rough dirt roads. The single parcel/bicycle transportation mode had not been tested, leaving the company unaware that a sterile barrier system could be compromised and fail.

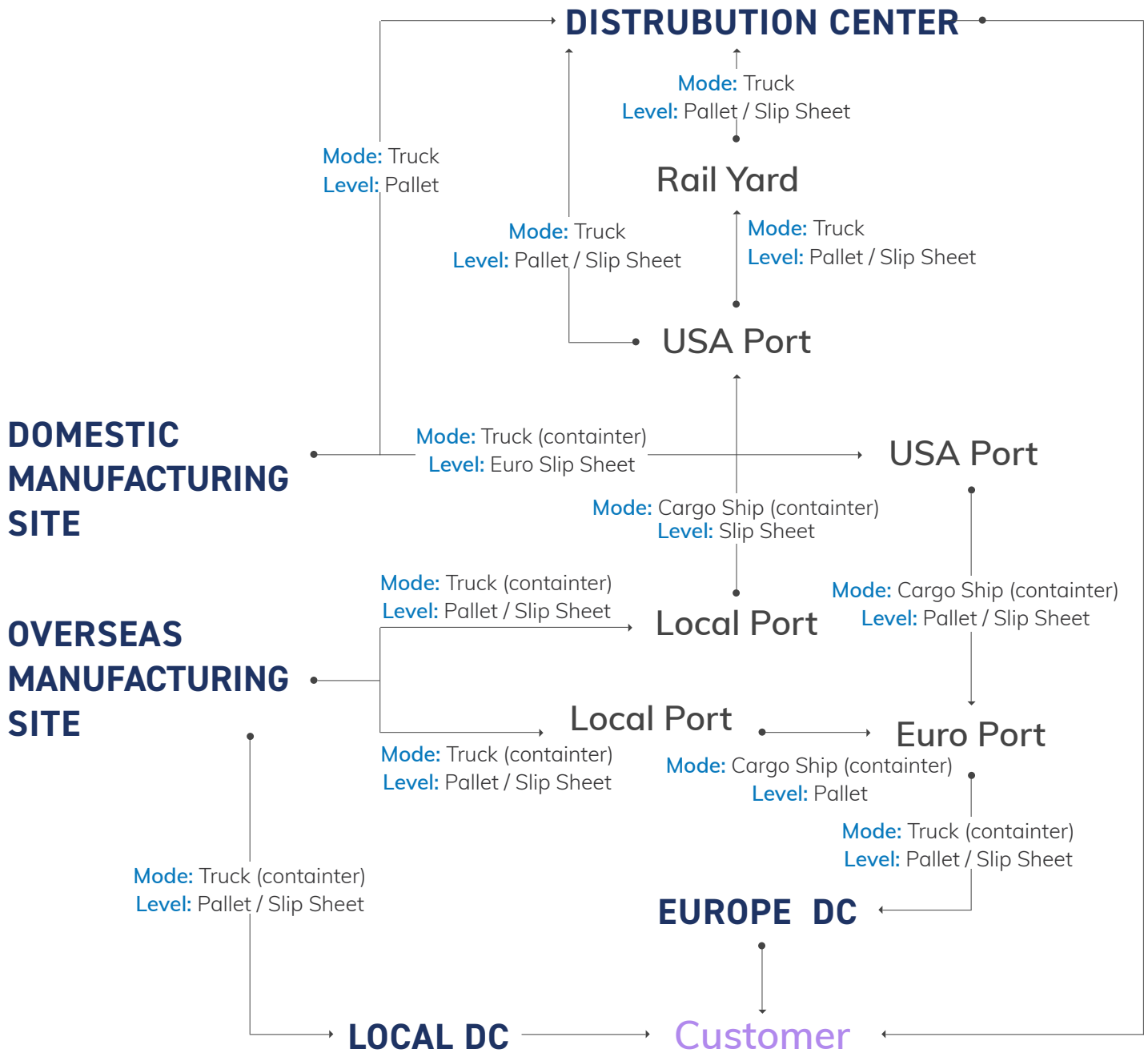
EXAMPLE 2

A successful example of a real-world situation that illustrates the value of a transportation distribution chart occurred when a company mapped out transportation by two-day air from Puerto Rico to Texas, then by truck to California. When the company's logistics team decided to go with ocean cargo shipping, a review of the transportation distribution chart revealed that the cases were not strong enough to withstand the humidity present in the new distribution channel. This realization led to development of new cases that were robust enough to survive ocean transportation.

EXAMPLE 3

A third example was sterilization of the finished pallet loads using EtO gas. The company mapped out the distribution correctly , but did not account for the humidity levels in the EtO chambers and the effects that this would have on the 32ECT corrugated shippers that were palletized in interlock patterns. After the EtO gas sterilization, the palletized loads were stored prior to release to the next leg of distribution, and each pallet load collapsed due to the humidity effects on the shippers, the interlock pallet pattern and the lack of internal structure to assist in supporting the shipping cases. This realization led to development of new cases in 200# test and column stacking of the case cartons on the pallet. These new cases and pallet pattern were now robust enough to survive the humidity environment in the EtO chambers.

Distribution Diagram Example



Once the transportation distribution diagram is complete and the most appropriate DC has been determined, the final step is to select an Assurance Level for testing.

Selection of the Assurance Level

The Assurance Level selection is based on the probability of occurrence for drop heights, compressive loads and vibration intensity.

Product costs and risk(s) to the customer are important factors to consider. Normally, the Assurance Level is determined by the product Risk Assessment, with a written rational providing justification for the choice.

Assurance Level I is the most conservative level and provides for the most severe test levels for consideration. It is used rarely and for very fragile, sensitive or expensive products that represent a big risk if damaged during shipping.

Assurance Level II is used most commonly and is recommended for most packaging that includes a sterile barrier system. This Assurance Level is used so frequently that it is essentially the default unless a product has special needs that call for one of the other levels.

Assurance Level III is the least conservative level and uses the least severe tests. It is used rarely and for items that represent a very low risk of damage during shipping.

The outcomes of completing the full determination process for distribution simulation testing are a Distribution Diagram, a DC for testing and an Assurance Level. Armed with these items, a packaging team can not only make the best testing decision for its product(s) and distribution environment, but can also back that decision up with documented evidence that supports the decision and provide assurance that testing accurately simulates conditions the package will face during distribution.

CONCLUSION

This organized process can be a powerful tool for a packaging team deciding which ASTM D4169 will best simulate the distribution environment its package will face, but there's no substitute for an experienced subject matter expert who can ensure the process is completed correctly and the results are accurate.

If you're looking for help with testing new packaging or any other packaging challenge, the Adept team is ready to help. Get in touch.