Guide to Water Bath Alternatives in the United States

Purpose and Scope of this Guide

This guide intends to inform users in the United States what alternative methods to the hot water bath test are allowed in the United States without the need for a Special Permit from the U.S. Department of Transportation (DOT) and explain how to implement the methods and documentation necessary to meet the DOT requirements.

This guide also provides information on various technologies from equipment manufacturers that may be used to meet the conditions of the alternative methodologies. Users of this guide will need to work with an equipment supplier to ensure compatibility with their production facility and products. This guide is not an endorsement of any particular equipment manufacturer or their technology and will be updated as the U.S. aerosol industry becomes aware of new technology and/or suppliers.

Should a user seek to use an alternative method to the water bath test and not follow one of the alternatives listed in the 49 C.F.R. § 173.306 and meet its conditions, a Special Permit must be obtained.

This guide has been developed for users in the United States. While it is suspected that much of the information within this guide can be used in other parts of the world, non-U.S. users need to be aware of all applicable laws, regulations and other obligations.

Background

In order to ship aerosol products as a limited quantity and avoid the requirements and cost of shipping them as hazardous products, the U.S. Department of Transportation (DOT) requires each aerosol product unit undergo the hot water bath test. However, in lieu of the hot water bath test, DOT allows aerosol manufacturers to use one of four alternative methods, provided certain conditions are met. DOT does not provide input on the applicability or implementation of these methods.

The hot water bath test has served as an integral part of aerosol production since the 1950s. The original purpose of the test was to check for container integrity but provides an additional benefit of detecting leaks and over pressurized containers. The hot water bath test fulfills a confirmatory process to assure that the aerosol products placed on the market are safe for storage, transport, and consumer use.

However, since the 1950s, much has changed in the production of aerosol products. First, the quality of aerosol containers has significantly improved. Second, modern line speeds are considerably faster, and it is far more challenging for workers to visually identify leaking units.

As aerosol manufacturers look to become more sustainable, it is important to recognize that the hot water bath test demands a large footprint on the production line, requires a significant amount of water, compressed air, and energy, spreads any contamination on the container to other units, and has the potential of causing corrosion. Due to this, aerosol manufacturers must expend a considerable amount of resources to keep the water bath operational as designed.

Equipment manufacturers have developed alternative technologies to verify that aerosol products will not deform or rupture under high temperatures or leak. These technologies may be used in part to comply with the alternative methods allowed by DOT to replace the hot water bath test.

Motivations to Eliminate the Hot Water Bath Test

There are many reasons why an aerosol manufacturer would want to look at alternative methodologies to the hot water bath test when building a new aerosol production line or renovating an existing line.

These reasons may include:

- Increasing operational efficiency with faster line speeds when the water bath limits the rate of unit production.
- Improving quality controls with faster line speeds.
- Ability to detect microleaks that may be missed in a water bath test.
- Poor visibility into water bath through safety plexiglass.
- Obstructed views of containers in certain water bath designs causing difficulty in identifying and removing leaking product.
- Difficulty in **safely** removing defective containers from the water bath, especially the containers that have domed and are at risk of rupture.
- Enhance global trade opportunities with alignment of FEA (European Aerosol Federation) alternative test method guidance.
- New product innovation and development is limited by the capabilities of the water bath (e.g., unable to fill taller containers for which the water bath was not designed).
- Contamination of the water bath, which can lead to a poor appearance of finished product.
- Interference with the labeling process of the aerosol product; there is less flexibility of the location of labeling containers since it is necessary to label product following the water bath test (near the end of the line). There is also an increased potential in the corrosion of the container when water is trapped under the label and residue from contaminated water may impact label adhesion.
- Initial and maintenance cost of the water bath.
- Cost of modifying and upgrading the water bath design.
- Cost of the boilers for heating the water bath.
- Cost of the gas or electricity to operate the water bath at appropriate temperatures.
- Cost of the water and chemicals used to treat the water in order to prevent corrosion and disperse contaminants.

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- Cost of blow off heads and air capacity to run them.
- Cost of cleaning products after the water bath test and avoiding their poor appearance in the event of contamination.
- Cost of the disposal of contaminated water.
- Cost of having an employee(s) watch and monitor the water bath for potential leaks.
- Avoiding the difficulty in placing observers (location) around the water bath test.
- Floor space considerations.
- Improve Scope 2 emissions.
- Inclusion in environmental, social, and governance (ESG) reporting.
- Marketing of sustainability improvements.
- Reduce carbon footprint.
- The use of machine intelligence allows collaboration across unit operations for better quality control.

Definitions

"Automated checkweigher" means a machine that checks the weight of the commodity after filling.

"Bag-on-Valve" means a type of compartmentalized aerosol dispenser, featuring a bag that separates the product from propellant.

"Crimp" means creating a permanent, hermetic seal between the valve and the container.

"Crimp head" means a component of the crimping equipment that utilizes a mechanical process to form the permanent, hermetic seal.

"Crimping Equipment" means a machine that creates a permanent, hermetic seal between the aerosol valve and container.

"Female Valve" means a valve not having a stem permanently affixed within the valve body.

"Male Valve" means a valve having a stem permanently affixed within the valve body.

"Piston" means a type of compartmentalized aerosol dispenser, featuring a piston that separates the product from the propellant.

"Propellant Charging Head" means a component of the propellant filling equipment that injects propellant into the aerosol dispenser. Injection may be through the aerosol valve, around the valve, or through a bottom orifice that is then plugged.

"Propellant Filling Equipment" means a machine used to inject propellant into aerosol dispensers.

"Statistical Process Control" means a quality assurance process that ensures the integrity of the finished aerosol product.

Alternative Method Implementation

This section provides the requirements from DOT for each alternative methodology as well as notes from aerosol industry experts as to how to implement.

Alternative Method A – Alternative Water Bath Test
Requirements of Alternative Method A:

(1) One filled container in a lot of 2,000 must be subjected to a test performed in a hot water bath. The temperature of the bath and the duration of the test must be such that the internal pressure reaches that which would be reached at 55°C (131°F). If the container shows evidence of leakage or permanent deformation, the lot of 2,000 containers must be rejected;
(2) A second filled container in the lot of 2,000 must be weighed and compared to the weight specification for the containers as documented in the operating procedures for the weight test. Failure of the container to meet the weight specification is evidence of leakage or overfilling the lot of 2,000 must be rejected;
(3) The remainder of the containers in the lot of 2,000 must be visually inspected (e.g., examination of the seams). Containers showing evidence of leakage or overfilling must not be transported; and,
(4) Each person employing this test must maintain a copy of the operating procedures (or an electronic file thereof) that is accessible, or through, its principal place of business and must make the procedures available upon request, at a reasonable time and location, to an authorized official of the Department.

Notes on Implementation of Alternative Method A:

a) At today's line speeds, the aerosol manufacturer would only be able to collect the containers. Users of this method have to quarantine production and test samples after the fact, only releasing product for shipment after testing is completed and the lot passes.
b) One or more visual observers need to be trained on inspection and documentation of this process.
c) Closure specification compliance must be demonstrated by maintaining records throughout the production run for each closing head. Statistical Process Control is one of the best methods to maintain dimensions within specification and generate documentation to show compliance.
d) A verified checklist should be maintained to confirm that the correct propellant is being used for the production run. In addition, Statistical Process Control should be used to

show that each propellant charging head remains within specification tolerances throughout the production run.

e) An automated checkweigher shall be located on the line to ensure that there are no under or overfilled containers. It shall be equipped with an automatic rejection station.

Additional Safeguards for Consideration of Implementing Alternative Method A:

a) An appropriate leak detection system can be located on the line that is sensitive to the propellant/product being run along with a reject system.
b) A sensor, along with a physical obstruction, can be mounted along the line to verify that the bottom/top of the container has not deformed out of specification and be capable of rejecting deformed containers.
c) Production personnel along the line should be trained to recognize deformed containers and gross leakers so that they can be removed if seen and stop the line if necessary.
d) A record should be kept for each production run that details the number of container rejections at each station within the process. This information should be analyzed for root cause and corrections made where needed.

Alternative Method B – Automated Pressure Test

Requirements of Alternative Method B:

Each person employing an automated process for pressure testing of filled containers must develop procedures for implementation of the test. Each person must maintain a copy of the procedures (or an electronic file thereof) that is accessible at, or through, its principal place of business and must make the procedures available upon request, at a reasonable time and location, to an authorized official of the Department. The procedures must, at a minimum, include instruction on the following:

(1) Pressure specifications. Each person must specify pressure standard(s) (e.g., a pressure limit or range) for a container respective of the design and/or contents. Each container, after it is filled, must be pressure checked and compared to the standards. For a pressure limit, any container exceeding the pressure limit must be rejected. For a pressure range, any container outside of the set range must be rejected. The instruments used to determine the pressure must be properly calibrated before a production run to an accuracy of ± or better.
(2) Periodic inspection. At designated intervals, a randomly selected container must be inspected for proper closure and verification of filling pressure. If a container shows signs of improper closure or over-filling, five (5) additional randomly selected containers must be inspected. If any of the additional containers show signs of improper closure or over-filling, all containers produced since the last inspection must be rejected.

Notes on Implementation of Alternative Method B:

a) In order to establish safe pressure standards for every new product developed, final product samples shall be allowed to come to equilibrium and then heated thoroughly to 55°C if the product is filled above 95% of the container capacity. If the product is filled to less than 95% of the container capacity, then the product only needs to be heated to 50°C. In either case, the conditions shall be recorded, and the pressure measured. The pressure cannot exceed two-thirds of the design pressure of the container (e.g., non-spec maximum pressure is 140 psig, 2P maximum pressure is 160 psig, 2Q maximum pressure is 180 psig, 2S maximum pressure is 160 psig).

b) Final samples of every new product shall be allowed to come to equilibrium at ambient temperatures expected in the production plan and the temperature and pressure recorded. This data can be used to determine the correct pressure range for the automated production pressure checker. Some adjustment may be needed to account for products that do not reach equilibrium by the time they reach the pressure checker on the line. The pressure range ensures that the product will not exceed the specified pressure at 50°C or 55°C.
c) The online pressure check equipment shall be capable of testing the pressure in each container and rejecting containers that are outside of the specified pressure range for the product being run.
d) Equipment currently available works on both male and female valves with buttons off. Some of the equipment use pre-pressurized heads that do not allow product to escape during the test.
e) Less frequent periodic inspection may suffice as long as closure specifications are monitored throughout the run and the 100% pressure tester is functioning reliably. The frequency should be determined based on the reliability of the pressure tester. At the designated intervals, a randomly selected container shall be inspected for proper closure and verification of filling pressure.
f) Closure specification compliance shall be demonstrated by maintaining records throughout the production run for each closing head. Statistical Process control is one of the best methods to maintain dimensions within specification and generate documentation to show compliance.
g) A verified checklist should be maintained to confirm that the correct propellant is being used for the production run. In addition, Statistical Process Control should be used to show that each propellant charging head remains within specification tolerances throughout the production run.
h) An automated checkweigher shall be located on the line to ensure that there are no under or overfilled containers. It shall be equipped with an automatic rejection station.

Additional Safeguards for Consideration of Implementing Alternative Method B:

a) An appropriate leak detection system can be located on the line that is sensitive to the propellant/product being run along with a reject system.
b) A sensor, along with a physical obstruction, can be mounted along the line to verify that the bottom/top of the container has not deformed out of specification and be capable of rejecting deformed containers.
c) Production personnel along the line should be trained to recognize deformed containers and gross leakers so that they can be removed if seen and stop the line if necessary.

d) A record should be kept for each production run that details the number of container rejections at each station within the process. This information should be analyzed for root cause and corrections made where needed.

<u>Alternative Method C – Weight Test</u>

Requirements of Alternative Method C:

Each person employing a weight test of filled containers must develop procedures for implementation of the test. Each person must maintain a copy of the procedures (or an electronic file thereof) that is accessible at, or through, its principal place of business and must make the procedures available upon request, at a reasonable time and location, to an authorized official of the Department. The procedures must, at a minimum, include instruction on the following:

(1) Weight specifications. Each person must specify target weight specifications for a particular container. Each container, after it is filled, must be weighed and compared to the target weight specification for the container. Any container outside the target weight specification is an indication of leakage or overfilling and must be rejected. The instruments used to determine the weight must be properly calibrated before a testing run and be sufficiently sensitive to measure within 0.10g of the true weight of the container;
(2) Heat testing and pressure limits. One container out of each lot of successfully filled containers must be heat tested by raising the internal pressure until it reaches that which would be reached at 55°C (131°F). The lot size should be no greater than 2,000. If the pressure in the container exceeds the maximum pressure allowed for the container type or if the container shows signs of leakage or permanent deformation, the lot must be rejected. Alternatively, five (5) additional randomly selected containers from the lot may be tested to qualify the lot but if any of the five containers fail the test, the entire lot must be rejected;
(3) Periodic inspection. At intervals of not more than 10 minutes, a randomly selected container must be inspected for proper closure and verification of filling pressure. If a container shows signs of improper closure or over-filling, five (5) additional randomly selected containers must be inspected. If any of the additional containers show signs of improper closure or over-filling, all containers produced since the last inspection must be rejected; and
(4) Visual inspection. Each container must be visually inspected prior to being packed. Any container showing signs of leakage or permanent deformation must be rejected.

Notes on Implementation of Alternative Method C:

a) At today's line speeds, the aerosol manufacturer would only be able to collect the containers. Users of this method have to quarantine production and test samples after the fact, only releasing product for shipment after testing is completed and the lot passes.

b) One or more visual observers need to be trained on inspection and documentation of this process.
c) Closure specification compliance shall be demonstrated by maintaining records throughout the production run for each closing head. Statistical Process Control is one of the best methods to maintain dimensions within specification and generate documentation to show compliance.
d) A verified checklist should be maintained to confirm that the correct propellant is being used for the production run. In addition, Statistical Process Control should be used to show that each propellant charging head remains within specification tolerances throughout the production run.
e) An automated checkweigher shall be located on the line to ensure that there are no under or overfilled containers. It shall be equipped with an automatic rejection station.

Additional Safeguards for Consideration of Implementing Alternative Method C:

a) An appropriate leak detection system can be located on the line that is sensitive to the propellant/product being run along with a reject system.
b) A sensor, along with a physical obstruction, can be mounted along the line to verify that the bottom/top of the container has not deformed out of specification and be capable of rejecting deformed containers.
c) Production personnel along the line should be trained to recognize deformed containers and gross leakers so that they can be removed if seen and stop the line if necessary.
d) A record should be kept for each production run that details the number of container rejections at each station within the process. This information should be analyzed for root cause and corrections made where needed.

<u>Alternative Method D – Leakage Test</u>
Requirements of Alternative Method D:

(1) Pressure and leak testing before filling. Each empty container must be subjected to a pressure equal to or in excess of the maximum expected in the filled containers at 55°C (131°F) or 50°C (122°F) if the liquid phase does not exceed 95% of the capacity of the container at 50°C (122°F). This must be at least two-thirds of the design pressure of the container. If any container shows evidence of leakage at a rate equal to or greater than 3.3×10^{-2} mbar L/s at the test pressure, distortion or other defect, it must be rejected; and
(2) Testing after filling. The person filling each container must ensure that the crimping equipment is set appropriately, and the specified propellant is used before filling a container. Once filled, each container must be weighed and leak tested. The leak detection equipment must be sufficiently sensitive to detect at least a leak rate of 2.0×10^{-3} mbar L/s at 20°C (68°F). Any filled container which shows evidence of leakage, deformation, or overfilling must be rejected.

Notes on Implementation of Alternative Method D:

a) There are two methods of complying with the first part of this alternative method regarding the pressure and leak testing before filling:
    a. Have an agreement with aerosol container supplier(s) to have 100% of the containers tested to the design pressure. If any containers show evidence of leakage at a rate equal to or greater than 3.3×10^{-2} mbar L/s at the test pressure, distortion or other defect, it shall be rejected. The container manufacturer shall supply records to the aerosol product manufacturer to verify compliance with the pressure testing requirements.
        i. The aerosol product manufacturer shall maintain lot traceability so that they can identify which containers are used for each product.
    b. An aerosol product manufacturer can purchase the equipment to pressure check each container before filling.
        i. Should the aerosol product manufacturer pressure and leak test themselves, they shall maintain the results with the production records for each product.

b) As part of the product development process, every product developed shall be allowed to come to equilibrium and then heated thoroughly to 55°C if the product is filled above 95% of the container capacity. If the product is filled to less than 95% of the container capacity, then the product only needs to be heated to 50°C. In either case, the conditions shall be recorded, and the pressure measured. The pressure cannot exceed two-thirds of the design pressure of the container (e.g., non-spec maximum pressure is 140 psig, 2P maximum pressure is 160 psig, 2Q maximum pressure is 180 psig, 2S maximum pressure is 160 psig).

c) Closure specification compliance shall be demonstrated by maintaining records throughout the production run for each closing head. Statistical Process Control is one of the best methods to maintain dimensions within specification and generate documentation to show compliance.

d) A verified checklist should be maintained to confirm that the correct propellant is being used for the production run. In addition, Statistical Process Control should be used to show that each propellant charging head remains within specification tolerances throughout the production run.

e) An automated checkweigher shall be located on the line to ensure that there are no under or overfilled containers. It shall be equipped with an automatic rejection station.

f) An appropriate leak detection system shall be located on the line that is sensitive to the propellant/product being run along with a reject system.

g) An automated system should be mounted along the line to verify that the bottom/top of the container has not deformed and be capable of rejecting deformed containers.

h) There needs to be documentation for all of these notes on implementation as DOT will want these records to verify that the aerosol product manufacturer has complied with Alternative Method D upon inspection.

Additional Safeguards for Consideration of Implementing Alternative Method D:

a) The number of container rejections at each station within the process should be analyzed for root cause and corrections made where needed.

Decision Matrix (Generic for Aerosol Industry)

Product Characteristics	Alt. Method A	Alt. Method B	Alt. Method C	Alt. Method D
Steel Container	Yes	Yes	Yes	Yes
Aluminum Container	Yes	Yes	Yes	No
Plastic Container	Yes	Yes	Yes	Yes
Male Valve	Yes	Yes	Yes	Yes
Female Valve	Yes	Yes	Yes	Yes
Bag-on-Valve (BOV)	Yes	Unable to measure pressure by pushing propellant through the valve	Yes	Yes
Piston	Yes	Yes	Yes	Yes
Button on Valve	Yes, but buttons must be removed from test containers	No	Yes, but buttons must be removed from test containers	Yes
Propellant – Hydrocarbon	Yes	Yes	Yes	Yes
Propellant – Dimethyl Ether	Yes	Yes	Yes	Yes
Propellant – Hydrofluorocarbon	Yes	Yes	Yes	Yes
Propellant – Hydrofluoroolefin	Yes	Yes	Yes	Yes
Propellant – Nitrogen	Yes	Yes	No	Yes (with pressure differential leak test)
Propellant – Carbon Dioxide	Yes	Yes	No	Yes (with certain methods)
Propellant – Compressed Air	Yes	Yes	No	Yes (with pressure differential leak test)

Positive and Negative Attributes	Alt. Method A	Alt. Method B	Alt. Method C	Alt. Method D
Test 55°C pressure for one container per 2000	Required	N/A	Required	N/A
Test one container per 2000 for correct weight fill	Required	N/A	Recommended	N/A
100% visually inspected for leakage and deformation	Required	N/A	Required	N/A
100% of containers tested to confirm within target weight	N/A, but online checkweigher recommended	N/A, but online checkweigher recommended	Required	N/A, but online checkweigher recommended

Every 10 minutes or less, a container must be inspected for proper closure and verification of filling pressure within specification	Recommended	Recommended	Required	Recommended
Periodic (unspecified period) inspection of container for proper closure and pressure	N/A	Required	N/A	N/A
Pressure and leak testing of container before filing	N/A	N/A	N/A	Required, container manufacturer certification necessary unless aerosol product manufacturer completes step
Each product pass online leak detection	N/A	N/A	N/A	Required
Method requirements limit line speed	Yes	No	Yes	No
Tracking of production lots within production runs required	Yes	No	Yes	No
Add to line setup requirements between product runs	No	Yes	No	Yes
Beneficial for products that are heat sensitive	Yes	Yes	Yes	Yes
Labor intensive	Yes	No	Yes	No
Not very practical for high-speed lines	Yes	No	Yes	No
Requires additional equipment	No	Yes	No	Yes
Each container must be visually inspected	Yes	No	Yes	No