



Updated Storage and Shipping Guidance for Submission to CDC Infectious Disease Laboratories

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Meredith Korth, CQA (ASQ)

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U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Agenda

- Introduction
 - Today's Presenters
 - New/Featured OneLab Resources
- Updated Storage and Shipping Guidance for Submission to CDC Infectious Disease Laboratories
- Q&A
- Closing

Presenters

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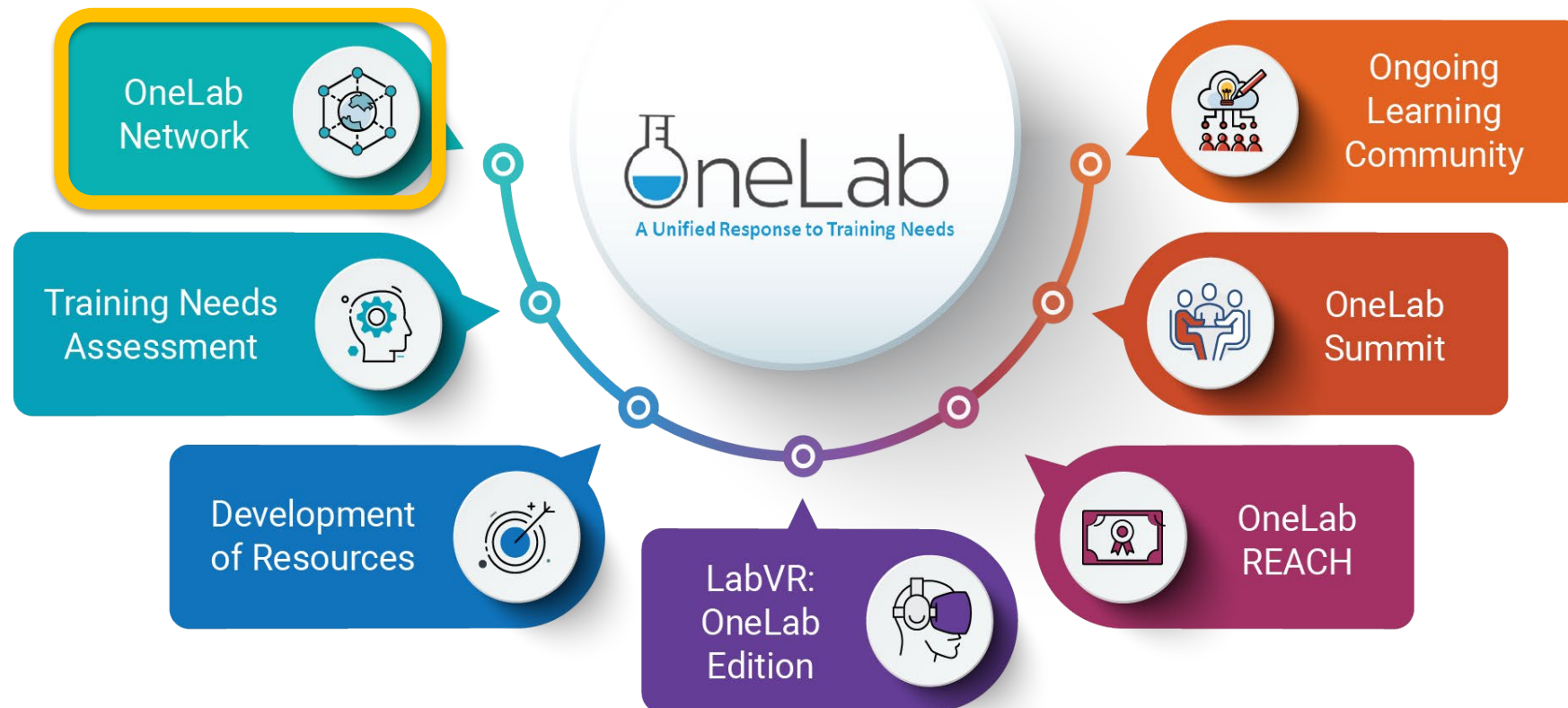


RECAP: WHAT IS THE ONELAB NETWORK?

OneLab: A Laboratory Capacity-Building Community

Bridge, train, and sustain

a capacity-building community among public health and clinical laboratory communities.





RELEVANT RESOURCES

Additional Packing and Shipping Resources

- eLearning: [Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know](#)
- Job Aids:
 - On our [Job Aids webpage](#)
 - SARS-CoV-2 Specimens: Packing and Shipping ([PDF](#) and [PowerPoint](#))

Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know

SARS-CoV-2 Specimens: Packing and Shipping

Step 2: DOT Job Aid

Use the decision tree below to help you classify your substance if shipping by motor vehicle courier/ground in accordance with Hazardous Materials Regulations (HMR). Use the IATA job aid for packages sent by air.

Substance for Classification

Is it known NOT to contain an infectious substance?

to humans and animals?
inactivated to they no longer pose a health risk?
(that is not considered to pose a significant health risk?
e.g., blood product, tissue, or organ) subject to US
Department of Agriculture regulation?

Is it a health care product that conforms to 29 CFR 1910.1030?
subject to local, or Indian tribal government regulations?
subject to the Federal Food, Drug, and Cosmetics Act?

Yes to any

Not subject to the requirements as
Division 6.2 material

Shipper
Consignee


UN3373

CDC

Specimen Shipping Job Aid

Maintaining proper specimen temperature during shipment helps ensure quality test results.



The background features a stylized globe with various colored dots (black, brown, green, yellow, grey) and lines connecting them, suggesting a global network or data flow. The globe is centered behind the main title text.

UPDATED STORAGE AND SHIPPING GUIDANCE FOR SUBMISSION TO CDC INFECTIOUS DISEASE LABORATORIES



Storage and Shipping Guidance for Submission to CDC Infectious Disease Laboratories

Dr. Atis Muehlenbachs, MD, PhD, FCAP

Laboratory Medical Director

Meredith Korth, CQA (ASQ) (Booz Allen Hamilton)

CLIA Compliance Program, ID Laboratories

January 28, 2022

Scope of this talk

- Packing and shipping overview
- CDC's standardized temperature definitions
- CDC's temperature monitoring process upon receipt

Disclaimer

This information is not a substitute for the required training to pack and ship infectious substances and is not intended to supersede federal regulatory standards.

Specimen Submission & Public Health Laboratories



Shipping and Packing Guidance- Overview

1. Determine the mode of transport for the package
2. Determine the classification of the package contents
3. Pack the specimen(s)
4. Label, mark, and document the package

Step 1

DETERMINE THE MODE OF TRANSPORT



Step 2

CLASSIFICATION



Step 3

PACK YOUR MATERIAL



Step 4

LABEL, MARK, AND DOCUMENT THE PACKAGE



Determine Mode of Transport

- The mode of transport will dictate the federal transport regulations that should be followed.
- Specimens should be shipped with overnight shipping when possible or if required for the specific testing requested.

Step
1



Determine the Classification

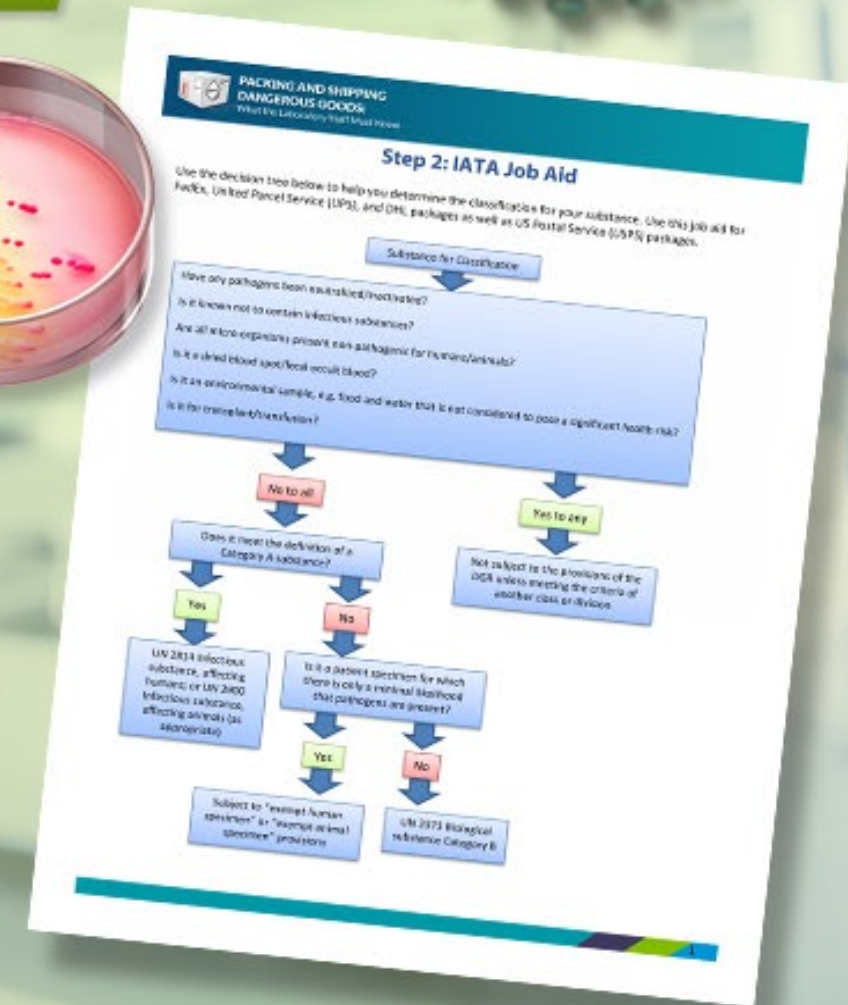
- For shipping by air:

https://www.cdc.gov/labtraining/docs/job_aids/packing_and_shipping/Step_2_IATA_Job_Aid_508.pdf

- For shipping by motor vehicle courier/ground:

https://www.cdc.gov/labtraining/docs/job_aids/packing_and_shipping/Step_2_DOT_Job_Aid_508.pdf

Step
2



Pack the Material

- The mode of transport and the specimen classification determine the packing requirements.
- Submitters should reference IATA's packing instructions (PI), which are followed by most submitting laboratories.
- Specimen shipments should be packed to maintain proper temperature control during transit.



Shipping Terminology

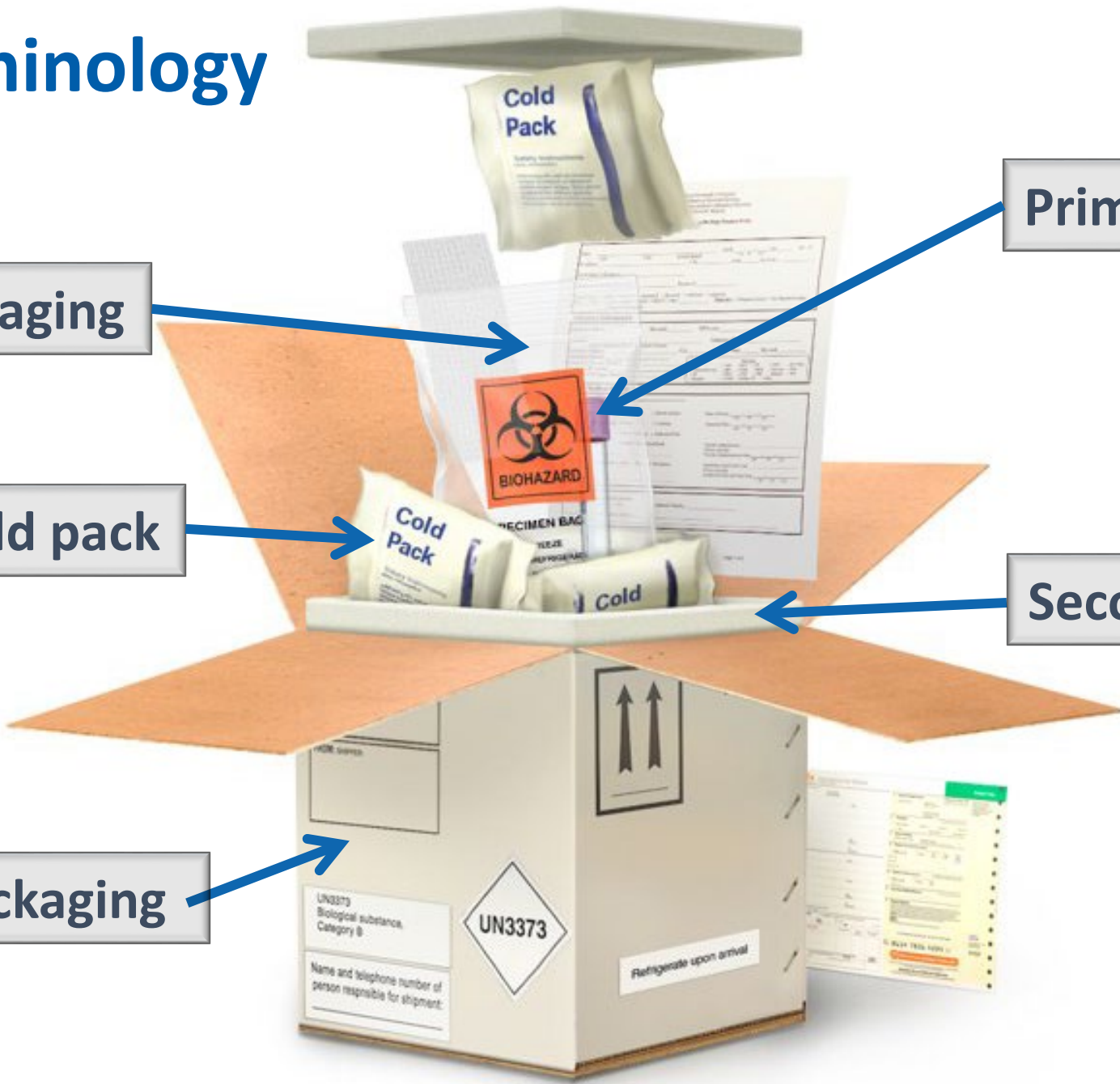
Secondary packaging

Primary Receptacle

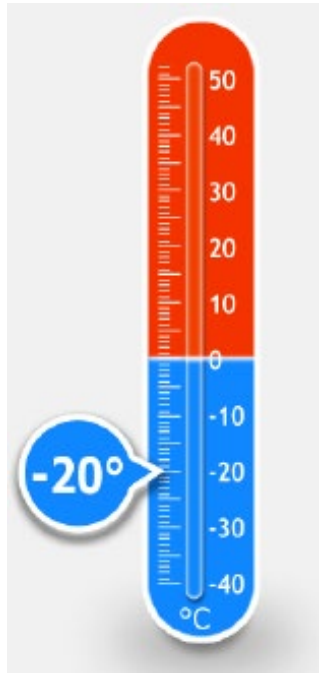
Cold pack

Secondary container

Rigid outer packaging



Standardized Temperature Definitions



- ***Frozen***: at or below -20°C
- ***Refrigerated***: within the range of $2\text{-}8^{\circ}\text{C}$
- ***Room-temperature***: within the range of $15\text{-}25^{\circ}\text{C}$
- ***Ambient***: equal to the surrounding environment

Shipping Frozen Specimens

- Specimens should be frozen at or below -20°C prior to packing.
- A sufficient amount of dry ice should be placed **within the secondary container and surrounding the secondary packaging.**
- Secondary packaging must be surrounded by a secondary container (i.e., a Styrofoam cooler) with walls that are, at minimum, two inches thick.



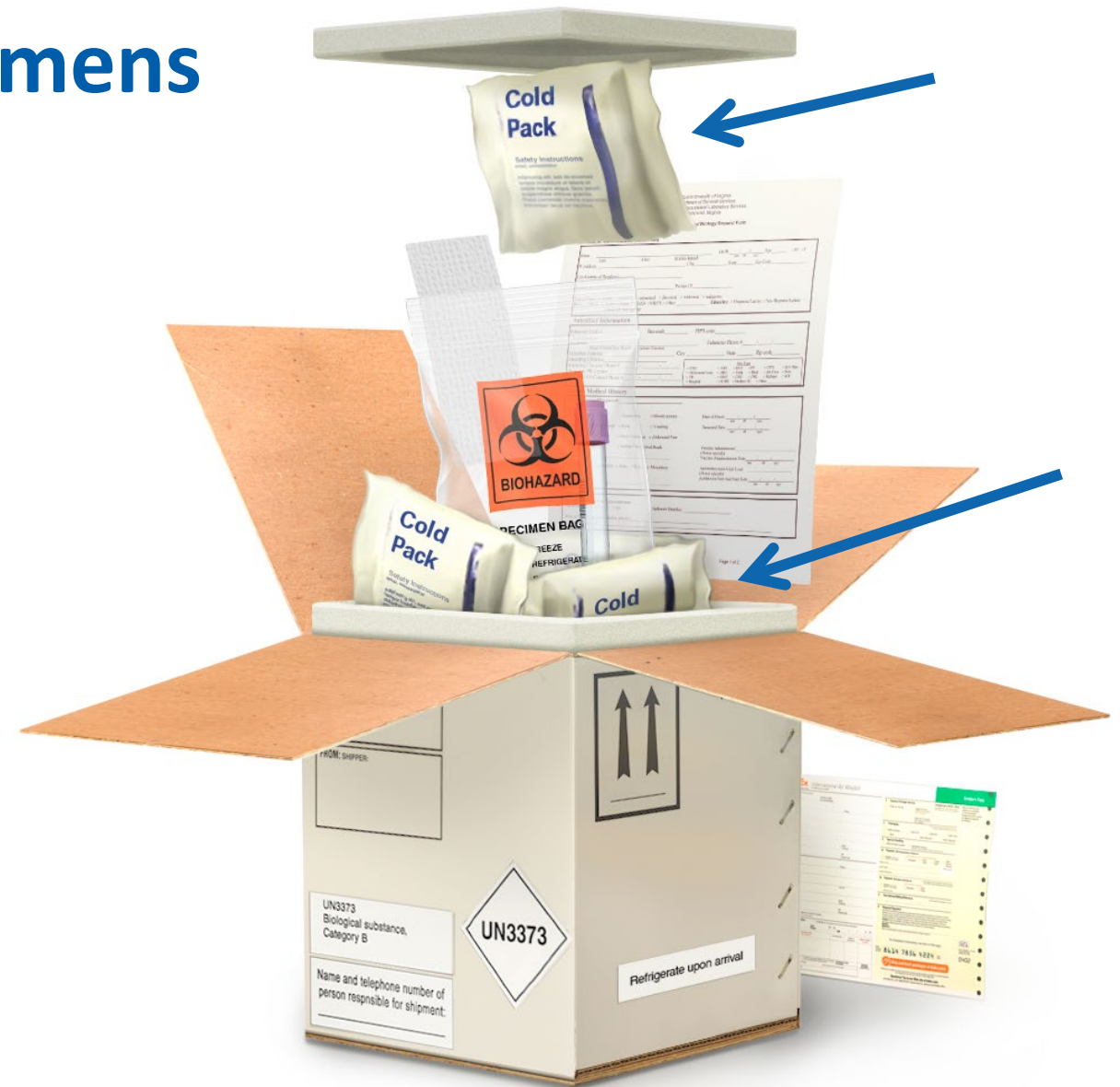
DRY ICE REMINDERS

- ✓ Should not come in contact with the primary receptacle
- ✓ Should not be used as a substitute for padding
- ✓ Shipping frozen must not adversely affect the specimen being shipped
- ✓ A minimum of 5-10 lbs required for overnight shipment



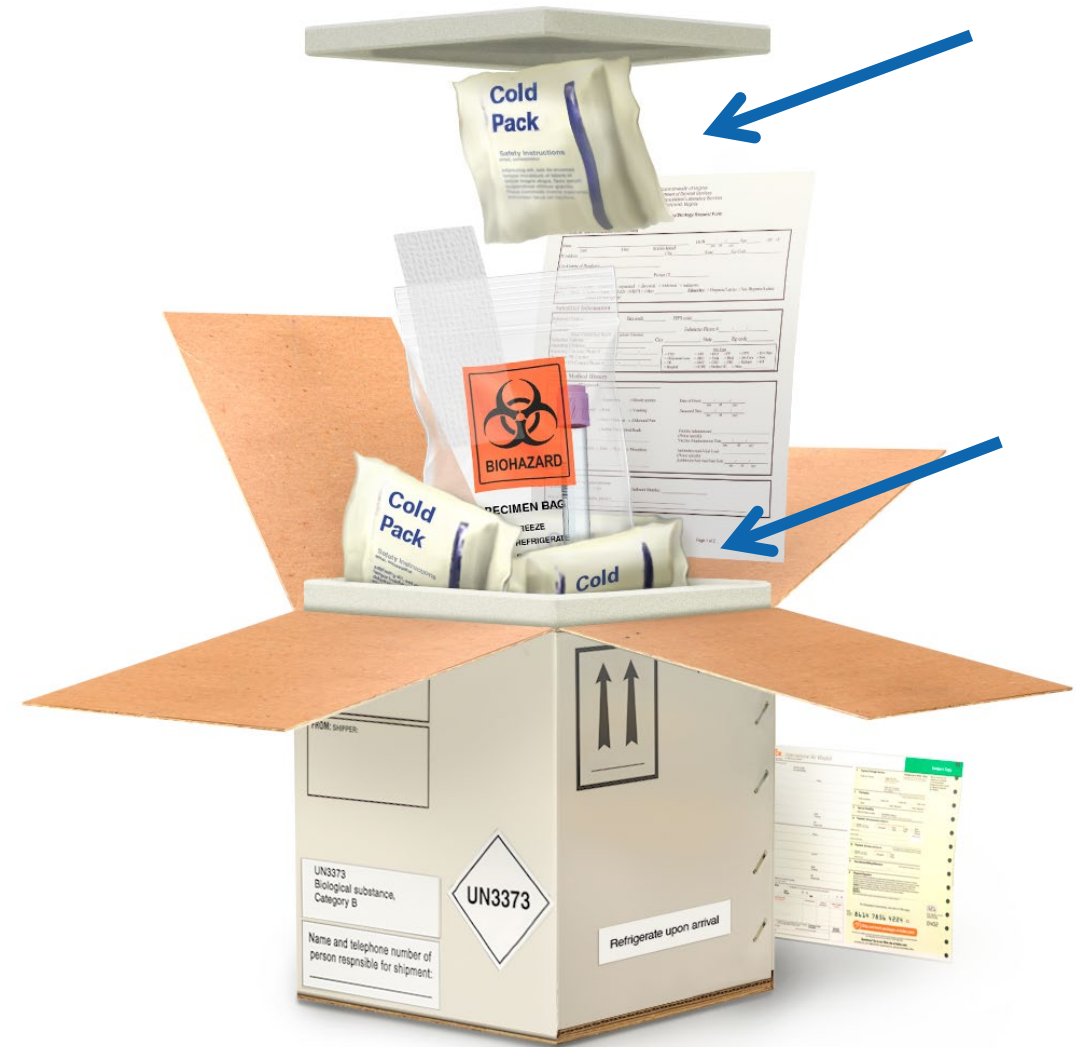
Shipping Refrigerated Specimens

- Ensure that the specimens are at 2-8°C prior to packing.
- Refrigerated or frozen cold packs should be placed **within the secondary container and surrounding the secondary packaging**
- Consider shipping distance, duration of travel, season, and external temperatures.



Shipping Room Temperature Specimens

- Ensure that the specimens are at room temperature (15-25°C) prior to packing.
- Use room-temperature cold packs **within the secondary container and surrounding the secondary packaging.**



Shipping Ambient Specimens

- Ensure that the specimens are at ambient temperature prior to packing.
- No temperature-maintaining materials are required.



Label, Mark, and Document

- The mode of transport and the classification, as determined in the previous steps, will determine the proper mode of labeling and marking, as well as documentation needed for the outer packaging.

Step
4



SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper	Air Waybill No.
Consignee	Page of Pages Shipper's Reference No. (optional)
This completed and signed copy of this Declaration must be handed to the operator.	
WARNING Failure to comply in all respects with Dangerous Goods Regulations may be in applicable law, subject to legal penalties.	
TRANSPORT DETAILS This shipment is within the limitations prescribed for: (delete non-applicable) PASSENGER AND CARGO AIRCRAFT <input checked="" type="checkbox"/> XXX Airport of Departure (optional): Airport of Destination (optional):	
NATURE AND QUANTITY OF DANGEROUS GOODS Failure to comply in all respects with Dangerous Goods Regulations may be in applicable law, subject to legal penalties. (Shipments type: (delete non-applicable)) NON-RADIOACTIVE <input checked="" type="checkbox"/> XXXXXXX	
Dangerous Goods Identification	Class or Division (Subsidiary hazard)
Packing Group	Quantity and Type of Packing

Temperature Monitoring at Accessioning

- Packages are received and sorted at CDC's centralized Specimen Triage and Tracking laboratory
- During the accessioning process, the package undergoes an audit where the condition of the containers and contents is recorded.
- **The temperature of the specimens is recorded using an infrared thermometer.**
- This temperature is used as a determining factor for specimen acceptance.



Conclusion

- Our mission is to work closely with our public health partners and to support the mission of public health with great laboratory science
- Specimen transport is a key component of the specimen life cycle. This guidance is intended to ensure that specimen integrity is maintained during transit. **The reliability and accuracy of a laboratory's tests are dependent on the quality of the samples it receives.**
- Specimens that do not meet the acceptance criteria upon arrival will be subject to rejection.

Acknowledgements

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 - Marla Petway


Thank you. Questions?

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The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention

The background features a complex network of lines, nodes, and gears in various shades of blue, grey, and yellow. The gears are of different sizes and orientations, some appearing to mesh together. The lines form paths and loops, suggesting a process or system. The overall aesthetic is technical and modern.

Q&A



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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