

The Critical Mission: Monitoring Critical Environments

By Kerri Lusk-Barnes

Vice President of Product
Management, ShockWatch

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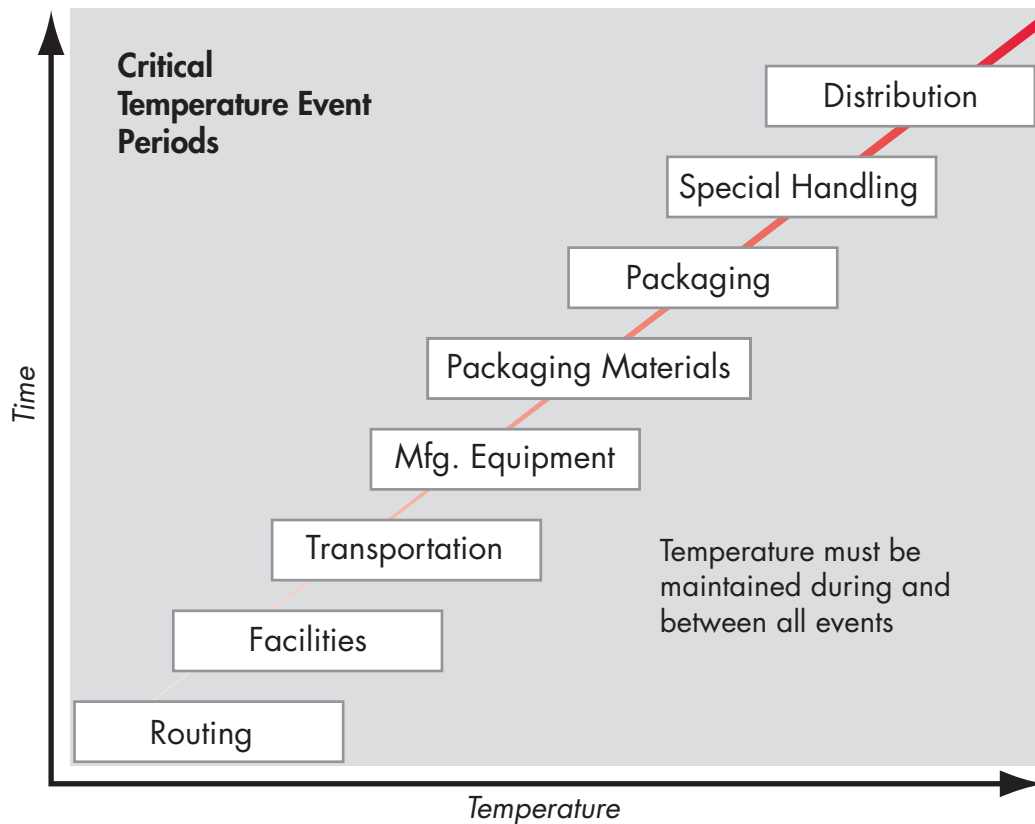
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Introduction

Every link in the supply chain is crucial — especially when products are sensitive to temperature or humidity levels. Properly controlling these variables in critical environments can mean the difference between a product that arrives at its final destination in perfect condition — and one that is rendered unusable.

Critical environments within the supply chain range from stationary units, such as display cases and freezers, to mobile units like refrigerated

trucks. The products that require these various environments are equally diverse. Anything from artwork and chemicals to food and drugs incurs damage if proper environmental conditions are not maintained at every stage — from the handling of raw materials through the production, shipping, and storage of final products. Ensuring proper conditions throughout the manufacturing, distribution, and storage process can be extremely challenging, but product quality, customer satisfaction, and safety depend on it.



Source: Cook, S., "Operational Considerations of Thermally Sensitive Healthcare Products," *Pharmaceutical Engineering*, July/August 2006

Types of Critical Environments

Critical environments generally have one of three purposes: to maintain product sterility, to preserve product freshness or safety, or to ensure product compliance. Product damage as a result of exposure to unacceptable environmental conditions can be extremely costly for manufacturers. The following are just a few examples of products and applications that require strict environmental control.

Art and Historical Documents

Artwork, including frescoes, paintings, and sculpture, deteriorate when subject to extreme or fluctuating temperatures and humidity levels. In its guide, “The Care and Preservation of Oil Paintings,” the Henry Ford Museum recommends that art collectors safeguard their oil paintings against cracking by using sensors to maintain acceptable conditions: from 65 to 75°F and 40 to 55 percent relative humidity, depending on the season. Similarly, the Library of Congress recommends that documents be stored in conditions no warmer than 72°F and at 35 percent relative humidity, with consistency being key. Controlling temperature and humidity within a library, museum, or archive is one matter, but maintaining these conditions during traveling exhibitions or displays can be challenging. The cost of art and artifact restoration can be extremely high — if the damage is repairable at all — not to mention that the loss or degradation of rare and original pieces causes immeasurable harm to society’s understanding of history and culture.

Food and Beverages

In the food and beverage industry, critical environments include everything from butcher shops and grain silos to shipping containers and freezers. Complete control of temperature and humidity levels is essential for preventing spoilage and contamination. The University of Florida’s Food Quality and Safety Design Team states, “At any point in shipping or storage, if vegetables are removed from a cold environment and warmed to a level where microbial growth may begin, pathogenic cells may begin to multiply and would not be eliminated by being returned to a cold

environment.” The guide recommends using a data logger to monitor and record temperatures during shipping and storage. Likewise, the U.S. Food and Drug Administration recommends “Installing, calibrating, and maintaining temperature measuring or recording devices as necessary to ensure accuracy” of freezers, refrigerators and other equipment.

Aside from the health risks, foods also deteriorate in quality when exposed to unacceptable environmental conditions. “Good management of temperature can reduce the physiological response of the tissue to bruising and control the appearance of bruising symptoms.” Optimal temperature for shipping and storage varies greatly by type of food.

Poultry Breeding

Precise environmental conditions are critical for animal breeding, which is most easily understood in the context of sperm banking and egg incubation in the poultry industry. A 2006 study of the Mississippi State University Poultry Science Department concluded that several factors, including storage temperature and storage duration, affect sperm quality index (SQI) values. Additionally, the University of Arkansas recently conducted a study of egg-holding temperatures on poultry farms specifically because that portion of the supply chain in the commercial broiler (breeding) industry is often overlooked — in spite of the fact that eggs may stay on farms for several days before being transported to hatcheries. The study found that the optimal on-farm egg-holding temperature varies with the age of the egg as well as the age of the hen that laid it, and that maintaining this optimal temperature could increase hatchability by as much as 5 percent. Where every successfully hatched egg yields revenue, it is clear how proper environmental conditions can directly impact the bottom line.

The list of industries requiring critical environments goes on and on. Perhaps the most critical applications are in the health care and pharmaceutical industries, where product damage is less apparent to the senses — and is potentially fatal.

A Focus on the Health Care and Pharmaceutical Industries

Recent estimates from the Healthcare Distribution Management Association, as published in *Pharmaceutical Commerce* magazine, show that about 10 percent of drugs are considered temperature-sensitive. The complex chemical nature of these products means that exposure to unacceptable environmental conditions may cause exceptional danger if such exposure goes unnoticed.

Probability of exposure is high, as there are more and more drugs on the market all the time. In a recent article on temperature-controlled packaging, thermal packaging expert Sanford Cook notes, “The rapid pace at which new medical products are being tested and coming to market has become a challenge that product managers, logistics and engineering professionals are confronted with at an accelerated rate.” To help monitor this influx, many regulations require strict adherence to recommended temperature levels and documentation to prove compliance. In recent years, government bodies from North America to Europe have begun stressing their requirements and guidelines in this area.

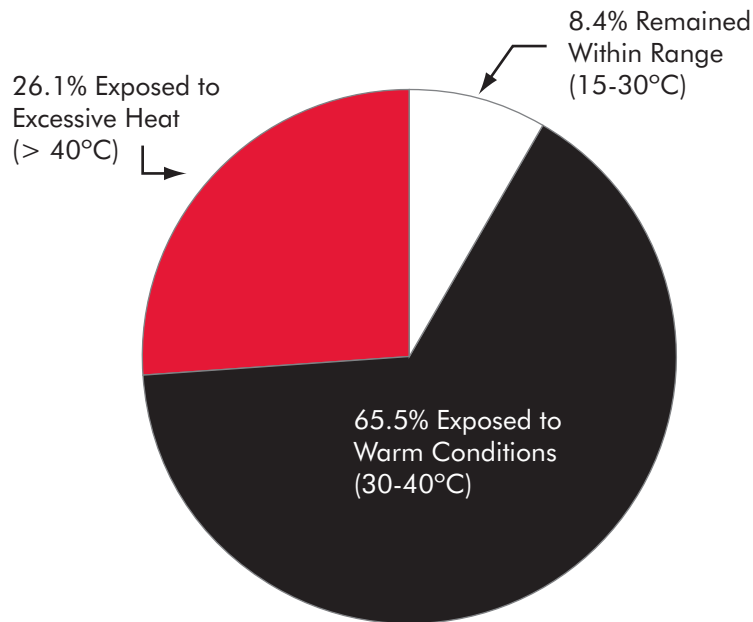
In 2000, the United States Pharmacopeia (USP) issued two new sets of guidelines that stipulate the need for room-temperature control during storage and distribution of medications, especially those deemed “labile” or especially sensitive, to prevent excessive heat or freezing from compromising drug quality. The broad application of these regulations is clear; the *American Pharmaceutical Association* article announcing the pending releases states, “These provisions could affect every link in the chain of distribution from manufacturer to patient.” USP recommends that storage-room temperature should be recorded and kept under 77°F, and that “labile products carry special time-temperature indicators (TTIs) throughout the distribution process.”

Medicines Control Agency Senior Inspector John Taylor reiterates the importance of temperature control for medications and the European Commission guidelines on this subject. He explains that in order to protect quality of medications and raw materials used in their development, “Temperature-monitoring devices should be used to demonstrate compliance with the designated temperature ranges.” As applicable throughout the cold chain, “records should be maintained to provide evidence of compliance with the labeled storage recommendations for those in whose care the product is at the time and to other parties who may seek this assurance.”

Putting the Supply Chain to the Test

Stability testing can indicate a drug’s susceptibility to degradation when exposed to extreme temperatures and humidity levels. According to an article in *Pharmaceutical Technology* magazine, “Stability testing provides evidence that the quality of a drug substance or drug product under the influence of various environmental factors changes with time.” The U.S. Food and Drug Administration provides guidelines for performing stability testing and labeling packages with specific required temperatures.

In response to inquiries about drug exposure to unacceptable temperatures during distribution, the United States Pharmacopeia (USP), an independent standards-setting organization, conducted its own test. According to the World Health Organization newsletter report, USP mailed packages containing temperature and humidity monitors across the country and found that only 8.4 percent stayed within acceptable condition ranges (15-30 °C total variation). Most (65.5 percent) were exposed to temperatures of 30 to 40°C, and the rest (26.1 percent) were exposed to temperatures above that range. In many of these cases (31.1 percent), the packages endured high humidity and temperatures above 40°C for as many as 19 to 21 days.



Source: WHO Pharmaceuticals Newsletter 1998, No. 01&02

Table I: Distribution of Medicines and Healthcare Products Regulatory Agency citations for 2002.

Area	Number
General storage: temperature control and monitoring	33
Cold chain: temperature control and monitoring	26
Lack of or inadequate written procedures	21
Returns: handling and records	15
Stock rotation and control	13
Quality system and duties of a responsible person	12
Premises, equipment, and calibration	10
Segregation of unsaleable goods	9
General transportation and delivery	7
Housekeeping and pest control	6

Source: Lucas, T., Bishara, R., SeEVERS, R., "A Stability Program for the Distribution of Drug Products," *Pharmaceutical Technology*, July 2004

Blood Storage and Transport

The U.S. Food and Drug Administration's guide to blood bank inspections stipulates that facilities must maintain proper temperatures — and provide supporting documentation of such — during shipping and storage. The guide states that

"The product storage temperature after drawing is 1—6°C unless room temperature platelets are to be prepared, in which case the blood should be held at 20—24°C. Temperatures outside this range damage the platelets."

According to the American Red Cross, a single blood donation can save up to three lives. But if exposure to unacceptable temperatures compromises the quality of blood, the results can be devastating.

Fertility and Cryopreservation

Temperature is critical in the growing human fertility industry for storing frozen sperm, eggs, and embryos. In recent years in the UK, several instances of sperm sample destruction due to malfunctioning storage equipment led the Human Fertilisation and Embryology Authority to require temperature monitoring of all storage containers. Now, alarms notify staff to take action when temperatures reach unacceptable levels. Because the number of sperm, eggs, and embryos may be extremely limited for some customers, it is vitally important to protect these assets under proper conditions.

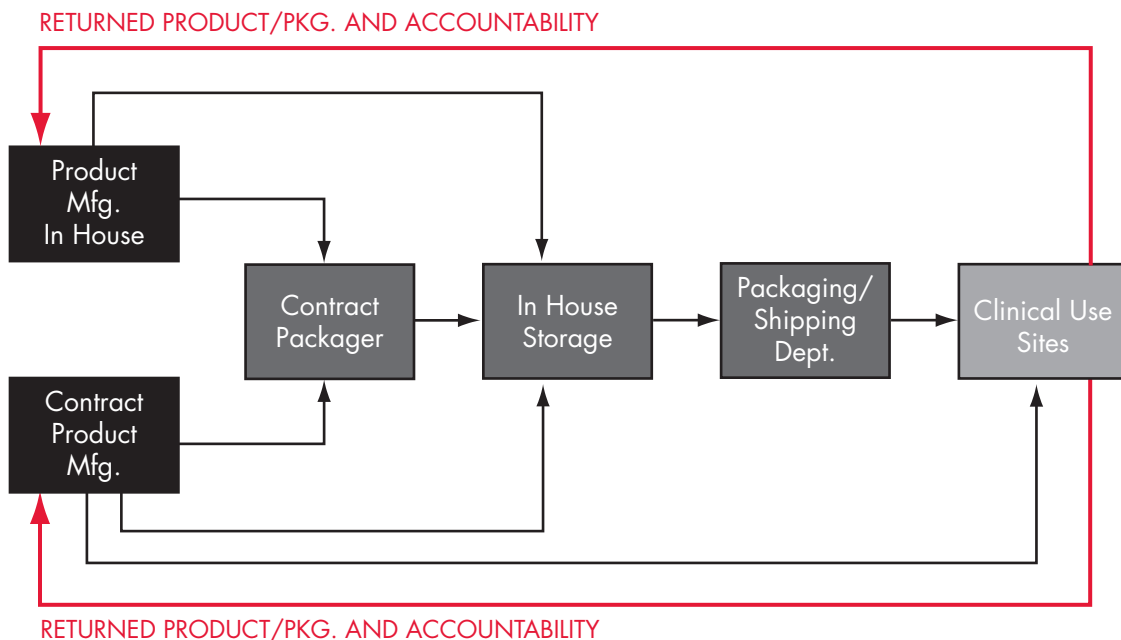
Controlling Environmental Variables in Shipping and Handling

The risks of exposure to unacceptable temperatures is clear across a variety of industries, but many manufacturers and distributors understandably struggle with knowing what happens to their products after they leave their facilities. Even if the supply chain is extremely short, unexpected delays and neglect at any stage of production or distribution can cause exposure to unacceptable conditions. This neglect can occur in storage, before the product leaves the facility, or after it arrives at its destination. Sanford Cook indicates that “equipment that generates heat is often overlooked” in the manufacturing facility, and this heat may accumulate and affect product quality. Manufacturers and distributors alike should use caution when leaving product near equipment or exposed to other sources of heat for any length of time.

The shipping and handling phase of the supply chain subjects temperature-sensitive products to an extremely high level of risk for damage,

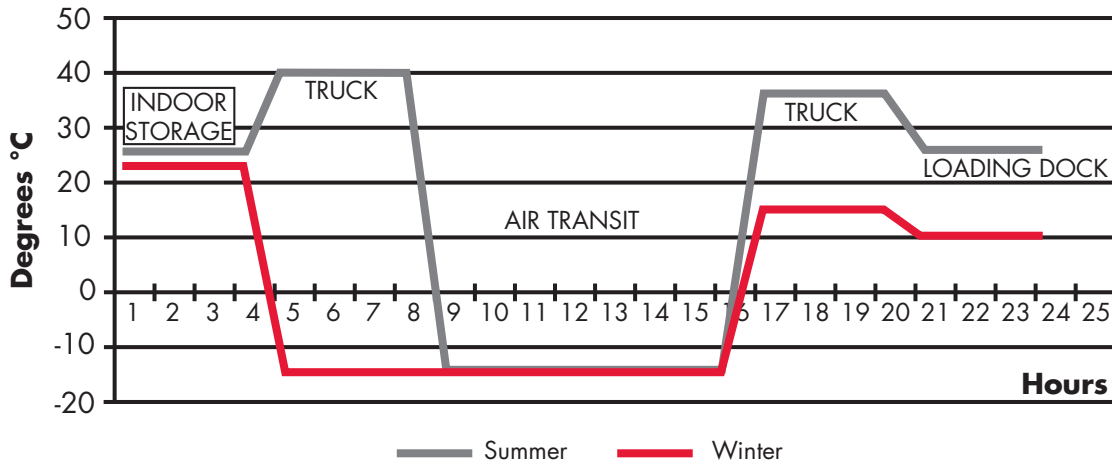
especially when travelling through extreme climates or seasons. Cook suggests that packaging often provides a false sense of security. He states, “There are many types of protective shipping systems that are available from specialty suppliers. However, any system used must be validated to ensure the protection of the product from environmental damage.” Prevalidated packaging materials are not necessarily reliable until tested and proven for a specific application. For example, Cook explains, sealed, insulated containers that incorporate refrigerants or phase change materials (PCMs) sometimes function like independent atmospheres with their own weather systems. As interior temperatures change, condensation forms much like rain and poses a threat to the product inside. Furthering this point, a recent Pharmaceutical Commerce article on cold chain management in the pharmaceutical industry states, “Even the best packaging technology can be undermined, as the failure range is roughly 5 to 9%, according to industry estimates.”

Clinical Product Distribution Chain



Source: Cook, S., “Operational Considerations of Thermally Sensitive Healthcare Products,” *Pharmaceutical Engineering*, July/August 2006

24-Hour Shipping Profile



Source: Cook, S., "Operational Considerations of Thermally Sensitive Healthcare Products," *Pharmaceutical Engineering*, July/August 2006

It is important to note that, according to the online Disaster Resource Guide, "Today's warehouse is the truck on the road." As more companies employ a "just-in-time supply chain methodology" to keep product moving, protecting these products becomes more challenging. The conditions surrounding products in transit are arguably much more difficult to control than those in a

stationary facility — especially if these products are incorporated or sold directly upon arrival with little opportunity for thorough quality checks.

Products that do spend some time in warehouses or distribution centers must be closely monitored. Power outages and shelf life pose a significant threat to product quality at this stage.

Solutions for Monitoring Critical Environments

Because packaging and temperature-controlled environments are not fail-proof, manufacturers need a reliable method for monitoring the condition of their products. As previously mentioned, temperature monitoring devices are recommended for this purpose, but there are several options available in the market. Manufacturers must consider the type of product and the conditions of distribution in order to select the right device for their specific application.

RF Technology

Some companies use radio frequency (RF) technology to collect temperature and humidity readings in the supply chain, but a recent *Manufacturing & Logistics IT* magazine article points out that freezing temperatures drain batteries. Plus, RF devices tend to be quite costly and therefore impractical for widespread usage, especially if real-time monitoring is not necessary. The technology may also prove inadequate to monitor conditions across a large container or refrigerated truck because RF devices cannot detect variations within the space. Medicines Control Agency Senior Inspector John Taylor states, “The number of temperature monitors will depend on the size of the load and they must be located carefully to provide assurance that temperatures in all parts of the load remain acceptable.” Using multiple devices within a large truckload, for example, may not be cost-effective.

Environmental Indicators

Environmental indicators are simpler and much more cost-effective solution for monitoring temperature of multiple product shipments or throughout containers, especially for short distribution cycles. The indicators adhere to individual containers or products to closely monitor conditions throughout the supply chain

Kerri Lusk-Barnes

Vice President of Product Management, ShockWatch

Kerri Lusk-Barnes manages U.S. and international marketing for ShockWatch® Equipment Monitors and Shipping & Handling Monitors. She oversees product management initiatives and new product and service development across the complete ShockWatch product line. Previously, Lusk-Barnes served as president of her own business management consulting firm and spent 15 years in a variety of management positions with Nortel Networks. She received her bachelor’s degree in marketing at Texas A&M University and earned an MBA at Brunel University in England.

— from the loading dock to the retail display case. Because the devices monitor temperatures inside the packaging, they provide more accurate information than devices that only monitor the temperature on one side of a storage room or truck trailer. Environmental indicators are easy to use and provide indisputable evidence of exposure to unacceptable temperatures, ensuring compliance with regulatory requirements.

Environmental Recorders

As the middle-of-the-road option, environmental recorders monitor temperature as well as humidity, but are much more affordable than RF devices. Environmental recorders feature an extended memory and battery life to allow for long-term data recording of temperature and humidity levels, as well as length of exposure. When continuous, real-time monitoring is unnecessary but comprehensive data is still required, environmental recorders provide the best solution for monitoring long-term distribution cycles or storage. Programmable to begin recording data at any time, these devices follow products from point A to point B and beyond, plus all stops in between.

Conclusion

Controlling critical environments is essential to the quality of temperature- and humidity-sensitive products. Regardless of industry, evidence shows that temperature-controlled storage units and specially developed packaging solutions are never completely reliable for keeping products at required temperatures. When a company’s bottom line and customers’ safety depend on the integrity of a product, environmental indicators and recorders or RF technology can provide the means for monitoring these environmental variables. With these devices in place, companies know if their products arrive at optimal condition.

Sources:

Fahey, Mary. "The Care and Preservation of Oil Paintings." Henry Ford Museum. 2007. <http://www.thehenryford.org/explore/artifacts/paint.asp#1b>

"Preserving Works on Paper: Manuscripts, Drawings, Prints, Posters, Maps, Documents." The Library of Congress. October 18, 2006. <http://www.loc.gov/preserv/care/paper.html>

M. Mahovic, J. Brecht, S. Sargent, M. Ritenour, K. Schneider, A. Simonne, J. Bartz; "Fresh Produce Handling, Sanitation, and Safety Measures: Beans, Cucumbers, Eggplants, Squash, Peppers, Sweetcorn." University of Florida IFAS Extension. <http://edis.ifas.ufl.edu/FS094>

"Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables." U.S. Food and Drug Administration. March 2007. <http://www.cfsan.fda.gov/~dms/prodgui3.html>

Olusola Lamikanra, Syed H. Imam; Dike Ukuku. Produce Degradation: Pathways and Prevention. 2005. <http://books.google.com/books?id=9C-okJUucPMC&pg=PA100&lpg=PA100&dq=food+bruising+temperature+fluctuation&source=web&ots=zOPfQTzgHc&sig=Y8B6eIAY6cmshbzkIg2Kwnkq35s>

P.R. Dumpala, H.M. Parker and C.D. McDaniel. "The Effect of Semen Storage Temperature and Diluent Type on the Sperm Quality Index of Broiler Breeder Semen." 2006. <http://www.pjbs.org/ijps/fin707.pdf>

Savannah Henderson, Doug E. Yoho and R. Keith Bramwell. "On-Farm Egg-Holding Temperatures for Commercial Broiler Breeders." 2006. <http://www.thepoultrysite.com/articles/621/onfarm-eggholding-temperatures-for-commercial-broiler-breeders>

Quinn, F.J., "The Stakes Rise for Cold Chain Management," Pharmaceutical Commerce, October 30, 2007

Cook, S., "Operational Considerations of Thermally Sensitive Healthcare Products," Pharmaceutical Engineering, July/August 2006

Otto, A., "USP To Issue New Storage/Distribution Guidelines," Pharmacy Today, 2000.

Taylor, J., "Recommendations on the Control and Monitoring of Storage and Transportation Temperatures of Medicinal Products," The Pharmaceutical Journal, July 28, 2001.

Lucas, T., Bishara, R., Seevers, R., "A Stability Program for the Distribution of Drug Products," Pharmaceutical Technology, July 2004

"Medication errors: cisplatin overdose – special alert," WHO Pharmaceuticals Newsletter 1998, No. 01&02

"Blood Bank Inspections." U.S. Food and Drug Administration. http://www.fda.gov/ora/inspect_ref/igs/blood.html#PART%20C%20-%20RED%20BLOOD

"FAQs About Blood and Blood Needs." American Red Cross. <http://www.givelife2.org/aboutblood/faq.asp>

Horsey, Kirsty. "New Storage Guidelines Issued for UK Fertility Clinics." Progress Educational Trust. 2008. http://www.ivf.net/ivf/new_storage_guidelines_issued_for_uk_fertility_clinics-o315-en.html

Porier, M., Zawada B., "Risky Business, Failing to Assess Supply Chain Continuity," Disaster-Resource.com

Scott, A., "Food traceability is still top of mind," Concerning the food and beverage supply chain, Manhattan Associates.