# FDA Tests RFID's Effect on Insulin

The U.S. Food and Drug Administration reports that extended exposure to UHF RF transmissions raises the temperature of insulin in vials.

By Mark Roberti

Oct. 31, 2005—The U.S. Food and Drug Administration (FDA) has evaluated the effects of electromagnetic energy from a UHF radio frequency identification interrogator (reader) on vials of insulin. The FDA's tests have determined that extensive exposure can increase the temperature of the insulin by a few degrees.

Insulin and other pharmaceuticals can lose their effectiveness if exposed to high temperatures, but the FDA didn't test the effect of UHF RFID systems on the potency of the drug. The aim of the tests was to determine what effect, if any, UHF readers might have on pharmaceuticals that need to be maintained at a certain temperature range. The concern is that the 915 MHz radio waves could heat up liquid drugs, just as a microwave oven uses 2.45 GHz radio waves to cook food.

Using an unidentified commercially available stationary 915 MHz RFID interrogator and antenna, the FDA placed 14.4-centimeter-long (5.7-inch) vials of insulin no further than 40 centimeters (15.7 inches) from the antenna and exposed them to 1 watt of RF power. Although insulin most often comes in much smaller vials, 14.4-centimeter vials were chosen because they capture the most energy possible and, therefore, represent the worst-case scenario. The agency measured the rise in temperature of the insulin, used a computer to model the experiment and compared the temperature change observed in the lab with that predicted by the computer model.

By using computer models, the agency could study many shapes and sizes of drug containers—as well as types of RFID antennas—that it could not obtain, according to Howard Bassen, leader of the FDA's Electromagnetics and Wireless Laboratory Division of Physics, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, who wrote the FDA's report on the test.

"Good agreement between measurements and computer modeling was achieved," Bassen's report indicates. "This modeling allowed learning the relationship of the heating and electric field at all points in the liquid as we varied the size, shape and location of one or more vials with respect to the reader antenna."

In the supply chain, vials of medicine would typically be interrogated quickly, and the brief dose of RF energy needed to read an RFID tag's unique number would cause very little impact. But it is possible that someone could leave vials of drugs in front of an antenna emitting energy for several minutes or even longer. Therefore, the FDA performed a "worst-case analysis" to see how much the temperature of the insulin would rise in an insulated box containing one or more vials of liquid insulin when left in front of an antenna for an hour. The agency is currently carrying out longer-term thermal modeling and experiments, Bassen notes.

"For a one-hour exposure, our estimates based on the rate of heating [observed through computer modeling and experiments] indicated a temperature rise of 1.7 degrees Celsius," the report says. "However, preliminary lab measurements [for a one-hour exposure] revealed a 1.1-degree temperature rise."

Insulin is shipped in insulated packages, Bassen explains, but in boxes used for the FDA study, less-than-perfect insulation allowed some cooling to occur.

"Exposing this vial in a well-insulated box would result in heating of 1.7 degrees in one hour based on computer modeling," the report says. "We also determined that the microwave electric field strength of 32 volts per meter would be induced [in insulin] instantaneously in our worst-case situation."

Acording to the report, the agency does not know of any studies that have evaluated the effects of electric fields on the potency of pharmaceuticals.

Researchers at the Massachusetts Institute of Technology (MIT) have been studying the possible effects electromagnetic radio waves from UHF RFID systems might have on drug potency. The FDA believes the data in this current report can help guide drug future potency studies by providing objective data on the increase in temperature and the effects of EM radiation on vials of temperature-sensitive liquid pharmaceuticals.

The full report, "Liquid Pharmaceuticals and 915 MHz Radio Frequency Identification Systems, Worst-Case Heating and Induced Electric Fields," can be downloaded from the RFID Journal White Paper Library.