Veroscan, Inc.
5085 W Park Boulevard, Suite 100
Plano, Texas 75093-2007
Tel (972) 690-9494
Fax (972) 690-9495

BY ELECTRONIC FILING

December 28, 2007

Federal Communications Commission
Attention: Julius Knapp
Office of Engineering and Technology
Washington, DC 20554

Re: ET Docket No. 07-257
Veroscan Request for Waiver of Section 15.247(b)
Reply to Comments

Dear Mr. Knapp:

Veroscan's Request for Waiver is being considered in the above-referenced Docket. Herein we reply to comments in the record.

BACKGROUND

The above-referenced waiver request[1] was filed to permit authorization of a system designed to answer an urgent need to ensure patient safety in surgical operating rooms. As discussed in our Petition, serious health complications are being created every day when surgical sponges or other surgical items are misplaced during surgery and left inside patients. In the United States alone, every year more than10,000 foreign objects are left in patients' bodies after surgery, 70-80 percent of which are surgical sponges. Current methods of tracking items have proven unreliable, and the most common method of locating a missing item in patients – using X-Rays – is only partially successful and creates levels of X-Ray exposure that are of concern.[2] At a minimum, lost items during surgery lead to longer hospital stays, increased patient stress, and increased cost. At worst, infection and death occur. The cost of such events exceeds $4 billion every year.

[1] *See* Veroscan Request for Waiver of Section 15.247(b), ET Docket No. 07-257, September 18, 2007 (Petition).
[2] Non-ionizing radiofrequency radiation is safer and faster detecting tagged items than the ionizing radiation of X-Ray systems that currently are used. Veroscan's system design ensures that even at its highest power and longest use, the amount of radiation absorbed by the patient fully complies with the FCC's radiation limits, 47 C.F.R. § 1.1310. *See* Letter from Veroscan filed in this proceeding on December 13, 2007.

Veroscan's innovative system is designed to significantly improve patient safety by electronically counting and tracking items that commonly enter and leave the operating room during surgery.[3] The entire system, except for its wand when used in the high-power mode, complies with existing FCC Part 15 limits. This one item, the wand, most often is used in the low-power (compliant) mode for scanning waste bags and the area around the patient that is external to the patient. Only if an item is not located using the entire system, including the wand in its low-power mode, would the wand be used in its high-power mode to scan the patient. The high-power mode itself consists of steps, beginning at low power and incrementally increasing over time until the item is found or the maximum power reached. Accordingly, in most instances the wand would not be activated in its high-power mode, but would be available if a tagged item cannot otherwise be located. The design of the high-power mode, in conjunction with its 25 percent duty cycle, limits the power used to the minimum required to find the missing item.

DISCUSSION

Two commenters, the Food and Drug Administration Center for Devices and Radiological Health (FDA), and Itron, Inc. (Itron), request additional information about the Veroscan system but do not oppose grant of the waiver. The FDA expresses concern with the electronic compatibility of our device with other medical devices typically used in operating rooms and therefore likely to be used in proximity to the Veroscan device, including pacemakers, defibrillators, and life-supporting and monitoring equipment. Veroscan has conferred directly with officials of the FDA and is undertaking to demonstrate the safety and compatibility of its device to the FDA. While the date for completing this work is uncertain, we expect that at worse it may take as long as six or more months to complete and be reviewed by the FDA. We will file in this docket a description of our work related to the FDA's concerns and the FDA's response when that work is complete. Accordingly, we respectfully request that action on our request for waiver be held in abeyance pending the results of our work with the FDA.

Itron expresses concern that the technical information submitted with our waiver request is "incomplete" because the pattern of the antenna was not disclosed. In the Petition, we identified the antenna as one having up to 8 dBi gain in the far field, and indicated that the radiation would always be directed downward toward the patient. Nevertheless, we have run an analysis of our prototype antenna and attach it to this Reply. As can be seen from the radiation pattern, substantial attenuation exists to the back and sides of the antenna. Our equipment is designed to direct as much radiation as possible toward the patient. It also is to be emphasized that only under the most

[3] *See* diagram attached to the Petition, *id.*

unusual circumstances would our requested maximum conducted power of 75 watts[4] ever be reached. Such power would be needed briefly for the body scan only if a missing tagged item remains undetected through use of all of the lower powers. Itron also requests that the "cumulative impact" on the RF environment of the Petition be considered. As we have disclosed, use of the wand in its high-power mode will be unusual in operating rooms equipped with the Veroscan system because the system itself without the wand is designed to accurately track all sponges and related items. Only if the system count differs would the wand be used to locate a missing item, and even then it would be used initially at low power to determine if the missing item is near the patient, as discussed above. Only if the item remains missing would the wand be manually placed in high-power mode, at which time it would start at low power and incrementally increase until the item is located or its power and time limits are met, at which time it is automatically disabled. Finally, we note that our device will be restricted to hospital and surgical center operating rooms, where medical equipment authorized under Part 18 of the Commission's Rules commonly operates with much more power in the same 902-928 MHz band.

A number of other informal comments were filed by individuals and generally address either the safety of RF levels or interference to amateur radio operators.[5] In our letter dated December 13, 2007, we submitted the results of testing that conclusively demonstrate compliance with the Commission's RF safety rules at 75 watts peak conducted power, as used in this application. With regard to concerns about interference to amateur radio operators, as stated above, the wand is used at high power very sparingly – only when a device that entered the operating room is unaccounted for through the system's normal tracking methods and searches conducted at low power. This will not occur very often, and even when it does, our tests indicate that in most cases the device will be located before the maximum power is reached. Further, this equipment can be operated only by trained personnel within the confines of an operating room located at a hospital or surgical center, because that is where the controller will be located. In such settings ISM equipment commonly is co-located and operates for continuous periods at far greater power than our wand device. Finally, the wand is always pointed downwards at the patient with an antenna exhibiting

[4] *See* Veroscan Letter of December 13, 2007, by which we amended our request to 75 watts due to detection testing, although except in rare instances we do not expect the maximum power to be reached during actual use. Our wand steps through various power levels, using only the minimum power required for detection and are turned off when the missing item is located.

[5] One informal commenter – Bill Beckman of Cleveland, Ohio – asserts that he was involved with testing our device at the Cleveland Clinic Foundation. He is mistaken. Our device has never been tested in Cleveland, and therefore his comments could not relate in any way to our device.

substantial attenuation to the sides and rear in the far field. Therefore the potential for interference to amateur or any other communications is remote.

CONCLUSION

In sum, after substantial testing (on cadavers and pigs, as is usual industry practice), we determined that 75 watts peak conducted power may be necessary in very rare situations to locate a tag, such as under a large patient, and therefore we amended our request to reflect this amount of power. For the reasons explained above, however, the wand will only be used at its maximum power in the rare circumstance that a device is missing in the operating room, must be found to ensure patient safety, and has not been located using lower powers (which are incrementally increased by the unit controlling the wand).

The FDA has expressed concern with the electronic compatibility of our device with other equipment commonly found in the operating room environment, and we have discussed this matter with them. While we have not experienced any problem during our tests, which have included using the highest powers in a typical operating room, we wish to remove any uncertainty and therefore request that our Request for Waiver temporarily be held in abeyance, as indicated above, while we work to address the concerns expressed by the FDA.

Sincerely,

John Volpi
Chief Technology Officer

Attachment: Wand Antenna Far Field Measurements

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Reply Comments of Veroscan Inc. was sent by first-class mail, postage prepaid, this 28th day of December, 2007, to the following:

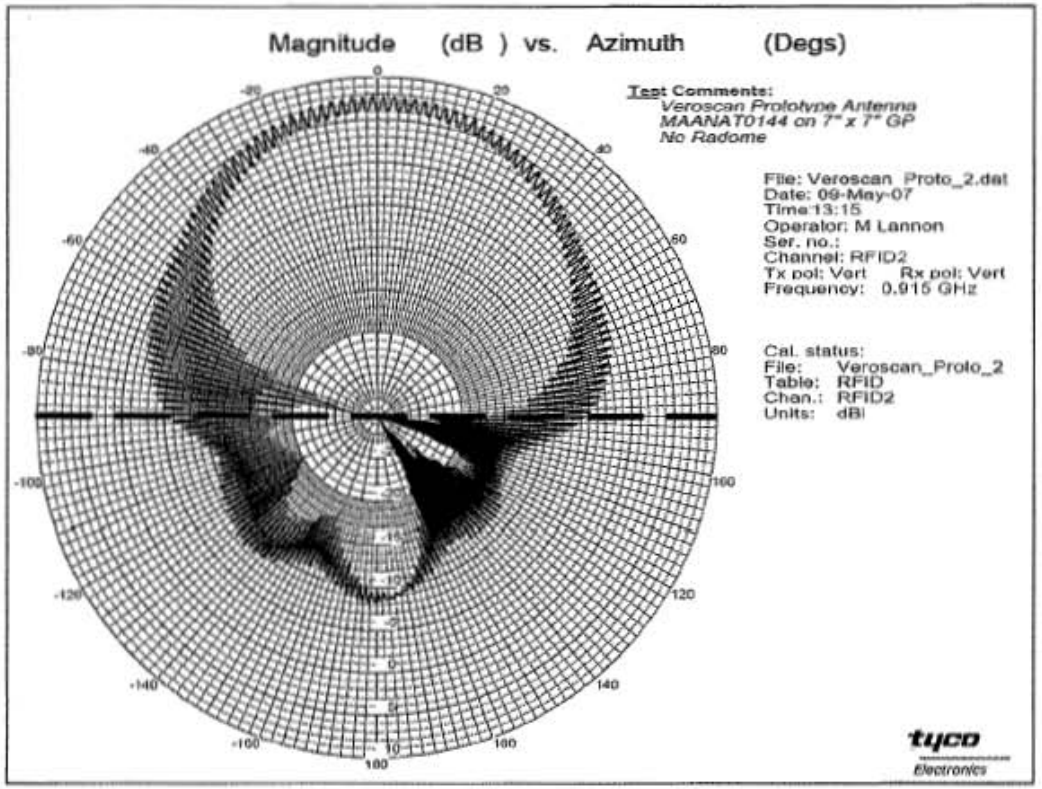
Joseph A. Godles
Laura A. Stefani
Goldberg, Godles, Wiener & Wright
1229 Nineteenth Street, N.W.
Washington, DC 20036
Counsel to Itron, Inc.

William A. Herman, Acting Director
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Miracle-D. Alston

Miracle-Dawn Alston

Wand Antenna



- The far field gain of this antenna, used for counting and Detect LO mode, is 8 dB
- Front to Back Ratio is >15 dB
- Antenna is symmetric in azimuth and elevation indicating a reasonable Front to Rear ratio

Copyright 2007, Veroscan Inc., All Rights Reserved