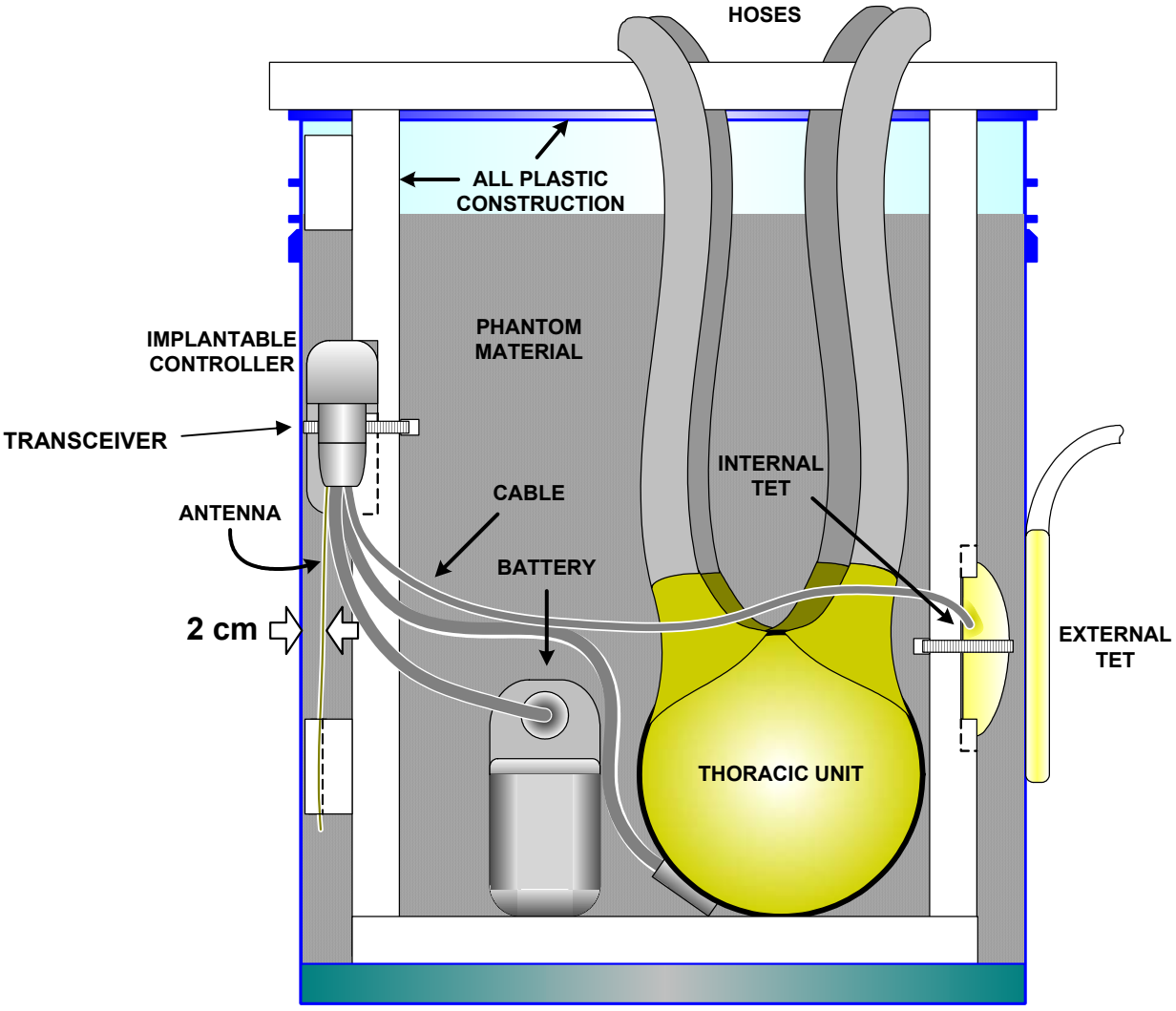
Andrew,

This email is in response to correspondence reference number 27728. Below is the response to your email, in order.

1. The setup of the of the implantable subsystem inside the container is shown in figures 1 and 2.

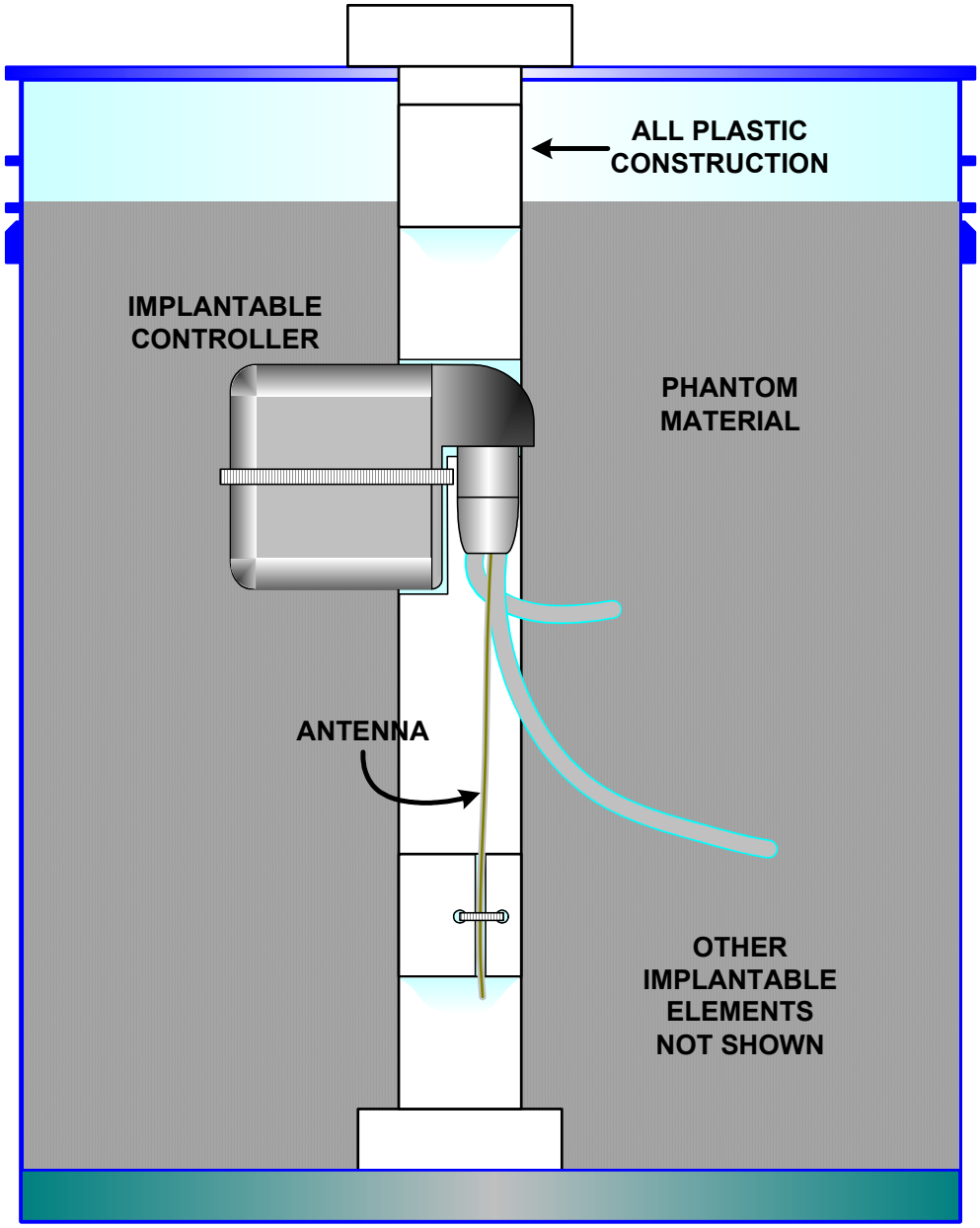
   The RF telemetry transceiver is housed within the Implantable Controller. The antenna is a 15cm wire with a carbothane jacket that exits the implantable controller via a hermetic multipin connector.

   The antenna was spaced 2cm from the wall of the enclosure as recommended by the FCC per the attached Lab Help Email below.



5 GALLON PLASTIC BUCKET CONTAINING PHANTOM MATERIAL.

Figure 1



5 GALLON PLASTIC BUCKET CONTAINING PHANTOM MATERIAL.

Figure 2

From: Phyllis Parrish [Phyllis.Parrish@fcc.gov]
Sent: Tuesday, March 30, 2004 7:06 AM
To: LabHelp
Cc: rdambrosio@abiomed.com
Subject: RE: Question

Question: The AbioCor implantable telemetry system uses an OOK modulated transceiver operating at 916.5 MHz and is designed to comply with 47 CFR 15.249.

Below is some of the information that Richard has requested:

The radiated output power of the device is approximately -8.0 dBm (158uW) at the implantable antenna. The transmitted data uses a bit-balancing scheme, similar to Manchester encoding, since the base band signal is AC coupled. The implantable transmitter is active about 90% of the time. During the remaining 10%, the implantable receiver is enabled to accept inbound commands.

Below are some facts to ease your concern regarding "Part 15 devices, which have no protection against harmful interference, to be used for life-saving/preserving devices" for this application.

1) The RF telemetry is not required to maintain operation of the device. (example: If the RF link is down for a day there will be no adverse
effect)
2) All of the inbound and outbound data use a CRC to maintain data integrity.
3) Commands required to disable the device require multiple messages.
4) The entire AbioCor system will undergo full immunity testing per EN60601-1-2 which include full testing of the EN61000-3 and EN61000-4 families of standards.
5) The AbioCor system has been undergoing clinical trials for the past
2-1/2 years using this telemetry system. Never has interference been interpreted as, or caused desired message to be interpreted as, something other than the intended message.

Please let me know if you require any additional information. Your prompt response is appreciated as we would like to commence testing next week.

You can reach me in the office at 978-646-1709. If you receive my voice mail, please dial "0" and have the operator page me, or you can try my cell phone at 978-314-6517.

Best Regards,

Ralph D'Ambrosio

rdambrosio@abiomed.com

Answer: We will allow testing in the open air or in a fluid that simulates body tissue on an open area test site. The choice is up to you. ANSI C63.4 requires testing in the open air, however, we have allowed other Part 15 transmitters to be tested in-situ or as-installed. A transmitter tested in air will be placed stand-alone on the tabletop. A transmitter tested in fluid must not be more than 2 cm inside the fluid on the tabletop. Be aware that a device tested in fluid will appear to have more power when compared side-by side to one tested in the open air. This could be advantageous to your future marketing plans. Supplement C to OET Bulletin 65 contains recipes for "phantom materials".

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2. The in-air testing was performed with the implantable subsystem located in the container, as shown in figures 1 and 2. The phantom material was not added for

this testing. Pictures of the actual test set-up can be found in the Intertek Test Report (Report number 3058793, Abiomed AbioCor Implantable Replacement Heart to FCC Part 15 Subpart C Section 15.249) on page 15 and 16. This report was previously uploaded. Table 1 on page 18 contains the radiated emissions levels in air and in the phantom material.

3. The transceiver hybrid located in the implantable controller is the RFM TR1000. The transmitter within this hybrid is capable of generating 1.5 dBm when the power is set to maximum. The power is set within the implantable controller, via a fixed resistor, to approximately –2 dBm.

If you have any additional questions, please contact me at 978-646-1709, or via email at rdambrosio@abiomed.com .

Best regards,
Ralph D'Ambrosio