

The following are Sanyo's comments related to the questions that came up during the Stakeholder's meeting on September 24th as well as our response to some of the comments that were made during the meeting.

Q1- We feel that that definition 1.1 adequately describes the market segment for refrigerators. There were comments made during the meeting on this that explosion proof units should be included as a subcategory as well. Explosion proof units tend to be a small segment of the market and typically don't fall under the definition of pharmaceutical grade product in our opinion and should not be included.

Q2- We feel the table adequately describes the market.

Q4- The range of volume appears to be representative of the market. There was one unit submitted that way way out on the edge at 70 cu ft, but as long as it has doors and is a standalone unit (not a walk in room) then it meets the criteria.

Q5-Standard deviation is getting more complicated than we need to get and the data means very little in the real world of pharmaceutical product. Keep in mind our goal here is to provide an environment where ALL product inside the unit it kept within parameters at all points in the unit. Standard deviation calculation simply creates more data than necessary. Adding data for evaluation helps to answer questions we have not thought of yet, but clouds the data that most end users need to make informed decisions.

Q6-Both magnitude and duration of temperature variances have an impact on product. Since it is product specific, based on mass, it's better to give the customer data showing this information at all points so they can make an informed opinion. Customers who are concerned about the product integrity will perform what's called a PQ, (beyond the scope of this program since loads will vary) The PQ is intended to measure temperature variances specific to product loading. This is the reason why we requested unloaded mapping in the first place as it puts every product on the same level playing field. It is also common knowledge that the freeze/thaw rate of any product is significantly slower to that of cooling and warming air temperature. Any unit which meets specification for air temperatures will thus not be deemed unsuitable for product.

Q7- There is significant impact on the above characteristics on energy consumption, which when you get back to the reason for pharmaceutical grade product in the first place. It separates the good performers from the poor performers. Typically you have to cycle the compressors more to meet pharmaceutical grade requirements, which will consume more energy. The need for proper pharmaceutical grade product in the market is very clear for those of us working in the market. We have seen many cases in the news and from customers where vaccine was improperly stored and vaccine has been spoiled. The CDC and California Dept of Health and others produce guidelines to this effect that product needs to be properly stored in true pharmaceutical grade units.

Q8- Other product characteristics that significantly impact performance are related to product loading and the environment that the unit is being used in. Manufacturers of true pharmaceutical grade products

typically advise customers in their manuals and customer training on the proper use of the equipment.

Q9- As we mentioned in the meeting, true pharmaceutical grade products have glass doors that are well insulated to avoid temperature fluctuations, so there is likely to be very little difference as we move forward, but this will be borne out during further testing and submission of more results.

Q10- All our equipment has either glass or solid doors. There may be units out there with air curtains like food service equipment, but these don't tend to be used in this application.

Q11- In our designs, we use triple pane doors in most applications to create better temperature uniformity and energy consumption. This is specific to pharmaceutical grade product but is not always the case. Keep in mind that the product is designed first and foremost to meet pharmaceutical grade applications and is not a converted food service refrigerator (in most cases)

Q12- solid vs glass door is typically a user preference as many products stored in these units can be photo sensitive. Customers will often request opaque tinting even on glass door units if solid doors are not available

Q13- often defrost cycles on pharmaceutical grade products are microprocessor controlled and not based simply on time. Manufacturers recognize the need to control temperature variances so refrigeration evaporator coils are not allowed to warm up too much. They often have sensors integrated into the coil to terminate the defrost cycle and only initiate the cycle when necessary.

Q14 - Manual defrost unit require an education process. In our case many of our units have simple physical indicators located in the areas where frost typically accumulates first. The indicators contrast with the frost (they're red). if you can't see them anymore it's time to defrost. These were designed based on typical results where the insulating frost build-up will affect performance.

Q15- There are applications that can be serviced by either automatic or manual. it typically comes down to product requirements and to a lesser degree, user requirements. Manual defrost typically provides the best storage temperature uniformity at the expense of convenience as customers with manual defrost units require alternate storage locations while the unit is being defrosted. As always with these units, end user education and knowledge of their particular product storage requirements are key factors.

Q16- Like question 15, this is an education process for the end users. It all depends on the storage requirements of the products.

Q17- Relative market share all depends on what units will be considered pharmaceutical grade. Manual and continuous seem to be the market leaders in pharmaceutical grade. Likely in equal amounts. Keep in mind that storage requirements for specific product can always be in a state of flux. So what's true today, may not be true tomorrow as new pharmaceutical products with differing storage requirements are developed.

Q18- Manual defrost does tend to provide the best results, but as stated earlier there are disadvantages to this method as well as defrosting these units typically requires an alternative storage location. Provided we are only talking about refrigerators...The FDA, ICH, WHO, CDC and many other regulatory bodies insist on automatic defrost cycles to help eliminate unit failure and wasted or spoiled product. The nature

of the defrost is varied by manufacturers for "best case" performance and reliability. Evaluating them individually is less necessary than presenting the data with footnotes as to the subtle differences in specification.

Q19- Both continuous and automatic defrosts have their own benefits and short comings. The method is going to be dependent on customer preference related to the perceived impact on the product during the cycle. This question may be better answered as more manufacturers submit product.

Regards:

Joe LaPorte  
Service Manager  
SANYO North America  
Biomedical Solutions Division  
1300 Michael Dr, Suite A  
Wood Dale, IL 60191  
630-694-8214 office  
847-924-1751 cell  
E-Mail: [jlaporte@sna.sanyo.com](mailto:jlaporte@sna.sanyo.com)