NCMEP North Carolina Manufacturing Extension Partnership

PPE Regulatory Requirements for Re-Tooling: Regulatory Issues

Webinar Q&A

Expert Darren Reeves, invited guest speaker and president of DP Distribution and Consulting, discussed the COVID-19 state of emergency and how companies could potentially re-tool to keep their doors open and keep personnel employed.

Businesses facing a downturn in activity because of the economic slowdown following the state's stay-at-home order have a few choices for propping themselves up. One option is redefining themselves, taking advantage of their existing materials, machinery and talent to help manufacture personal protective equipment (PPE) and other critical supplies needed by the medical community, first responders and other businesses in which employees must interact frequently with the public.

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I understand there are regulations against marketing the efficiency of a mask, but can we make claims about the efficiency of the components of the mask? For instance, if the mask material has been lab tested to be efficient to 99% and 100% hydrophobic (fluid barrier), can we state that our mask uses a material with those properties?

Maybe. It is important to understand the context of the standards you are using in order to determine what claims you can make. If a material passes a particular test method then you can say that, but some standards were developed to test the entire device to make a certain claim. The reason they came up with different levels in some product specific standards was to be able to provide information to the healthcare providers to be able to determine what PPE is appropriate for which type of procedure. What we found in the past was that people would start testing the entire device, for example a mask or a gown, and they couldn't meet the overall requirements, so then they came up with these cute little tricks of, well, let's go ahead and use the same information but just testing the material. That's not really the way some of the standards are intended to be used. The standards were intended to be used on the entire finished medical device should not be confused with the testing of individual materials. So while there is nothing that specifically says you can't say that this material meets a particular test method, I'd be very careful how you word it. As long as you are not being misleading in any way and you are very clear that only the material meets a particular test method, but the overall finished device does not meet it, then you can use that test data.

What is the time frame for short-term and long-term? Months? Under a year?

I guess it's the same answer that the Governors, Senators and the President give every time they are asked this question. Nobody knows. At this point, everybody would like to think this whole thing is going to be over by the end of summer, but who knows what's going to happen. Is there going to be a second wave as everybody opens up? Are there going to be additional national cases or are there just going to be local outbreaks? What's going to happen when we get into flu season? Are we going to double the issues with both the flu and Covid? It seems to me like the majority of people are saying this isn't going to end until we get a vaccine for this particular virus. Everybody's probably heard they're not looking at that until probably the first quarter next year. I would say that would be a good guess. I think that's going to be probably the earliest they will get rid of the state of emergency, if you will, because that's when the EUAs and Enforcement Discretions will stop. So in reality, when I talk short term versus long term, the short term is until the end of the state of the emergency.

The long term is after that date. I've heard people say anything from literally the end of summer to four years from now. It could be anything in between, so the question for short term is "am I just doing this and I don't plan on doing it once my business comes back?" Long term would then mean "do I plan on making this a separate division once my business comes back because it's something we want to do and we realize we've got the opportunity to be profitable?" Obviously, we're here to do the right things and get protective equipment to the healthcare providers as quickly as possible, but if you're not going to make a profit at it, it's not a long term decision.

What if you use an overseas factory to manufacture PPE?

I deal with overseas manufacturers routinely, over and over. They've got to play by the same rules, so if you're using overseas manufacturers, there's nothing wrong with that, with the exception of the FDA has put out a warning. What we're seeing with the N95 respirators is that there's a lot of counterfeit going on and also specifically from China. If you have an N95 respirator from China, or even a KN95 they're allowed to use them, but there are some certain things that you've got to do as a manufacturer and you do need to let the FDA know what you are doing. You have to make them aware of what you're doing, so that they can make sure that the company is a valid company, As far as if you are producing a product in Mexico or India or Dominican Republic or anywhere like that, they have got the same rules as the US players.

Are fabric or cloth face masks and/or coverings considered Class I devices.

It depends on how you market it. That's really what the whole thing is about, how you are marketing it. The FDA enforcement guidance really talks about three different types of masks. They differentiate between four different options. One is a face mask. If you're just marketing it as a face mask and you do not have any other medical claims on there, then that is not regulated by the FDA at all. Period. The fabric or cloth masks generally fall into this category. A lot of the cloth masks that you are seeing companies re-tool to is because they are making those for the consumer market so that the consumer market doesn't use up the surgical masks or the respirators for healthcare providers. They want the normal consumer in the restaurant or at the gas station or in the grocery store to be wearing the non-medical masks, so that they are not utilizing the supply of the medical masks. If you have a medical mask, patient mask or isolation mask with no fluid barrier claims that would be a Class I, but as soon as you market it as a surgical mask with barrier claims that becomes a Class II device.

To make the PPE gown does it require a specific machine? Which machine is that and which company is making these seamless machines to select from?

There is no specific machine for PPE gowns. I have seen a lot of people out there doing cut and sew, but most of the gowns that were made during the pre-pandemic, if you will, have been disposable, polypropylene. In that case they will seal the seams using a heat sealer or a sonic welder. There's a bunch of different manufacturing ways to create those gowns. Normally, when I see a cut and sew operation they have difficulty getting the seams to pass the fluid barrier protection levels. Now, there is no requirement, really, to put those fluid barrier protection levels on your gowns. It's now common in the industry that people do that in order to notify the healthcare providers with the information. They need to know what procedures to use them in, but if we're talking about isolation gowns, or a patient gown, a lot of times they don't have any fluid barrier protection or they have the lowest which would be Class I. In cut and sew operations a lot of times I see people put an extra layer of tape like medical tape over the seams in order to get it to pass the tests, so there is no special machine to make these products.

FDA approval - how long does that take?

Normally, for the FDA 510(k) approval process, the FDA has 90 days legally to get information back to you once you submit it. What I was seeing pre-pandemic is that they were active and actually caught up. They were doing a really good job. They were getting information back to us, usually with a Refuse to Accept, or RTA, checklist. This is where they would go through and do a general checklist to see if your submission contains all the information that they require. If it does, you'll get information back within 45 to 60 days, saying that they need these things or that your submission has gone through. Normally they come back, at least with one round of questions. Once they send the questions back to you, then their 90 day clock stops and yours starts. You have a certain amount of time to get those questions answered. Once you get those questions answered back to them then their clock restarts at whatever time it stopped. 90 days is their goal from the time you make the submission to the time it is approved. The real question is how long will it take you to get the information to be able to make the submission. Again, all that was pre-pandemic. Right now, as you can imagine, the FDA is slammed with all kinds of requests and 510(k) and EUA submissions. It is my understanding that they are way behind. It is my guess that it is going to be much closer to the 90 days.

What if you're using an antimicrobial chemical that has been FDA approved through the chemical vendor, and you use that chemical in your mask? Can you claim your mask is an 'anti-microbial' mask?

In both the Enforcement Discretion and in the regulation, I would suggest if you've got that product, search the FDA database for antimicrobial medical devices. They consider an "antimicrobial" claim to be a different intended use, so you may have that material, you may have that chemical in your mask, but do not claim it right now because it will specifically say if it's a different intended use, then the Enforcement Discretion documents are NOT applicable. So be very careful about using the antimicrobial claims at this point because it makes the devices not fall within the Enforcement Discretion documents.

We manufacture/weave the PPE Class I material for PPE isolation gowns. This is a long term decision. Do we need to have FDA QSR plans in place?

To manufacture the material? No. The raw materials are not regulated by the FDA. Now with that said, I will elaborate just a hair more that if you are making the material for isolation gowns and you want to continue doing that long term, it would be helpful for you from a marketing standpoint to maybe do testing to AMMI PB 70 test requirements. If you can provide that test data to your customer, it is helpful from a marketing standpoint, but the FDA does not regulate raw materials.

Are you aware of a target price in this sector that manufacturers can reference when considering a pivot? Some manufacturers are not pivoting because they feel they can't hit the same prices that are coming out of China for instance.

I'm hesitating, because I don't have a specific product to which you are referring. As discussed if you are talking about face masks versus the surgical mask versus N95 masks or an isolation gown versus a surgical gown, they all have different price points. I don't have enough information to answer that question. I could give you some ballpark guesses from what I'm seeing, but I hesitate to do that for competitive reasons.

We are an overseas manufacturer. Will the FDA accept our product? Or do we need an overseas partner for the same?

The FDA technically does not care where the product comes from as long as you are following the rules. So the EUAs and the Enforcement Discretion documents are not just for US companies; therefore, any medical device manufacturing company or any company pivoting to

medical devices does not need a partner. After the pandemic, if you are a foreign manufacturer, you will need to have a US agent, which we can help provide that as well, in order to communicate with the FDA on certain issues. After the State of Emergency is over you will have to follow all of the normal medical device processes exactly as we talked about in this webinar. Now with that being said, I am seeing a switch in the consumers or the procurement departments going towards "made in America", so if you have customers and you have the market for your product, the FDA doesn't care where your factory is. The question really is "what's the market going to buy both tomorrow and next year?"

Can you make claims without regulation about the reuse of a mask for a certain period of time if you're making claims about the efficiency of the material used?

The reason I'm hesitating is we've got a couple different issues here. Number one is if you're saying you're making reference to the efficiency of the material that leads me to think that you're making claims of just the material and not the mask. So that's one red flag. The second one is the reuse. If you're making claims of any kind of reusable device that's fine, but you have to have the supporting data that it is still an acceptable claim and a valid claim at the end of the reuse period. So for example, if you say you can reuse this mask 25 times then any testing that you do would need to be on a product that was reused 25 times and then you would also be responsible for providing reuse instruction. Am I marketing it to use it and then clean it and then reuse it? What kind of cleaning process am I going to use? What is the cleaning material that we are going to use? There are a lot of things in that question that would need to be addressed in order to make valid claims, but YES, you can do it but NO, you can't do it without regulation.

What testing and certification is available and by whom for barrier masks? Is 5 micron a good target for non-medical masks?

For non-medical masks there is no requirement. ASTM standards are referenced by the Food and Drug Administration (FDA), as the endorsed standard in the United States for mask testing. The current standard ASTM F2100-11 (2011) specifies the performance requirements for Medical Face Masks with five basic criteria:

1. BFE (Bacterial Filtration Efficiency): BFE measures how well the medical face mask filters out bacteria when challenged with a bacteria-containing aerosol. ASTM specifies testing with a droplet size of 3.0 microns containing Staph. Aureus (average size 0.6-0.8 microns). In order to be called a medical/surgical mask, a minimum 95% filtration rate is required. Moderate and high protection masks must have bacterial filtration rates greater than 98%.

   Some manufacturers use the Modified Greene & Vesley method to determine the BFE rating. This method is NOT recommended by ASTM for product comparison or evaluating consistency.

2. PFE (Particulate Filtration Efficiency): PFE measures how well a hospital mask filters sub-micron particles with the expectation that viruses will be filtered in a similar manner. The higher the percentage, the better the mask filtration. Although testing is available using a particle size from 0.1 to 5.0 microns, ASTM F2100-11 specifies that a particle size of 0.1 micron be used.

   When comparing test results it is important to note the size of the test particles used, as use of a larger particle size will produce a misleading PFE rating.

3. Fluid Resistance: Fluid resistance reflects the surgical mask's ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer as the result of a splash or spray. ASTM specifies testing with synthetic blood at pressures of 80, 120, or 160 mm Hg to qualify for low, medium, or high fluid resistance. These pressures correlate to blood pressure: 80 mm Hg = venous pressure (Level 1), 120 mm Hg = arterial pressure (Level 2), and 160 mm Hg (Level 3) correlates to potential high pressures that may occur during trauma, or surgeries that include high pressure irrigation such as orthopedic procedures.

4. Delta P (Pressure Differential): Delta P measures the air flow resistance of the medical mask and is an objective measure of breathability. The Delta P is measured in units of mm H2O/cm2 and the lower the value the more breathable the mask feels. The ASTM standard requires that masks have a Delta P of less than 5.0 for moderate and high barrier masks, whereas low barrier masks must have a Delta P of less than 4.0.

5. Flame Spread: As hospitals contain sources of oxygen, heat, and fuel the ASTM F2100-11 standards include testing for flame resistance. Testing dictates that all hospital masks must withstand exposure to a burning flame (within a specified distance) for three seconds. All PRI·MED masks meet this requirement.

6. 5.5 ISO Certification: In addition to the above tests, all medical face masks must be tested to an international standard (ISO

10993-5, 10) for skin sensitivity and cytotoxic tests to ensure that no materials are harmful to the wearer. Tests are conducted on materials used in construction of the mask which come in contact with the user's skin. Most of the blue ear loop masks that you see people wearing on TV are Level 2 fluid barrier protection masks. I'll send that information. There's about four different tests that need to be performed, if you're going to make a certain claim on those.

I'm interested in hearing more about the patient enclosure.

I have had several people contact me on these. And it's interesting because I know they're used commonly in Europe and in the Asian nations. I don't know why they are not here, but those don't have a three letter code, they're pretty much I would consider a Class I device. They're simply placed over the patient who may be intubated to provide protection to the healthcare provider. They usually will have some sort of an opening that you can put your hands through. The FDA put out enforcement discretion documents on May 1st of this year, specifically for those units now. They're basically exempting companies from all of the registration listing and all the GPMs, but you have to have certain labeling. They're very specific on a bunch of labeling that has to be on that product because they have not approved any of those in the U.S. Here is the link to that document:

www.fda.gov/media/137584/download

Is any money or tax credit available for capital or expenses incurred by businesses that have started producing PPE?

There may be several options for assistance. Refer to NCMEP's COVID-19 Resource Page or contact NCMEP at (919) 513- 6119 or ncmep-information@ncsu.edu for more information.

www.ncmep.org/covid-19-update

Does Darren help companies related to FDA approval? Is his fee covered by government grants?

Darren does help companies with FDA approval. Contact NCMEP for more information regarding the availability of grant funding at (919) 513-6119 or ncmep-information@ncsu.edu.

What is meant by Class II "EXEMPT"?

Basically everything that we've talked about on the webinar is exactly what's going on with the FDA, but there are always exceptions. In general, a Class I device doesn't need any FDA approval. Class III devices need a PMA and Class II devices need a 510(k), but Class II is the biggest group and the FDA has gone through and said, there are some other requirements with Class II devices, one of the big ones is what we call design controls and we're getting into the deep waters here, but design controls are required for Class II and Class III devices, demonstrating that we have controls of the inputs, we have controls for the outputs and that we've verified and validated the design. This is something else that needs to be done, that doesn't need to be done with Class I devices, so that would be what's required for the 510(k). However, the FDA has gone through and said okay, we still believe you need to have the design controls in place, but it's a lower risk. I'll call this the low risk Class II to where the FDA says, as long as you've got your design controls in place, we don't need you to submit the 510(k) information to us, so it's 510(k) exempt. There are some very low risk Class I devices that are exempt from the good manufacturing practices as well. So again, everybody's different. You can contact the NCMEP and we can help walk you through what your particular devices requirements.

Our device is Class I and has passed AMTS F2100 testing. What are our company responsibilities related to FDA for Class I?

Right now, most of that is under the EUA, so you can put the product on the market quickly. In the future, once the pandemic is over, you're going to need to have the good manufacturing practices in place and also need to register your facility and list the device with the agency.

Is there an FDA product code for Class I barrier mask?

Class I barrier masks fall into the surgical apparel that is a non-surgical mask, FDA Product Code LYU. That's one of those gray animals. If you look at the enforcement discretion document that's out there, they would consider that to be either a non-medical mask or a non-fluid barrier claim mask.

Don't we still need to have NIOSH approval for non-medical respirators?

There's basically two different types of the N95. The whole purpose of the N is because of NIOSH, so if you're going to market it as an N95 respirator, you need to have the NIOSH certification and testing. If you're going to say it's a surgical N95 then you need to have the fluid barrier protection claim as well. Here is the link to the enforcement policy:

www.fda.gov/media/136449/download

Is there any assistance in terms of loans to finance the equipment/ raw materials ? And assurance of buy back of the production?

There may be several options for assistance. Refer to NCMEP's COVID-19 Resource Page or contact NCMEP at (919) 513- 6119 or ncmep-information@ncsu.edu for more information.

www.ncmep.org/covid-19-update

Can you define what it means to follow GMP guidelines?

The FDA Good Manufacturing Practices are called the Quality System Regulation (QSR) and are written in 21 CFR Part 820. It is implementing procedures that demonstrate how the organization meets the regulation. It is very similar to the ISO 9001 quality system standard.

What claims can be made for a barrier mask? We are a medical device company, normally making compression hosiery, so we know FDA does not "regulate" whether a product can or cannot be registered.

See the answer above on the testing that needs to be performed on masks. During the pandemic there are some very specific wording that must be on masks and are listed here:

www.fda.gov/media/136449/download

Are their MICRO Entity costs lower than $5,236? For very small businesses just starting?

Unfortunately, no. However, there is a small business discount for submitting a 510(k).

Can you explain differences between PPE Classes and Levels. Which Levels fall under which classes?

The FDA designates medical devices into Classes I, II, and III. This is to determine the level of oversight they believe they need to have over that device. Levels are determined by test methods to determine the efficacy of a product. Generally speaking, there is no correlation between the two.

Once PPE is produced and available, what is the best way to go about finding customers, especially those who are in urgent need?

NCMEP is working to make connections with manufacturers and organizations that need PPE. Contact NCMEP at (919) 513-6119 or ncmep-information@ncsu.edu for more information.

Any word on the seams on the Level 1 and 2 gowns?

AAMI PB70 documents exactly what testing needs to be done on gowns and the locations that need to be tested in order to make an AAMI Level 1, 2, 3 or 4 claim. This one is pretty straight forward.

What is the current requirement for medical face shields as it relates to certifications?

There are no certifications for face shields that I know of. See the following:

www.fda.gov/media/136842/download

Please could you provide ASTM F2100 testing lab names whose results are accepted by FDA.

Nelson Labs. WUXI Apptec.

I've been trying to get my mask material tested for some time now. Are there other labs out there that I could get my product tested?

NCMEP has partnered with a lab that might be able to help with testing masks. Contact NCMEP at (919) 513-6119 or ncmep-information@ncsu.edu for more information.

If face shields are considered Class I, are there FDA requirements post EUA?

The requirements post EUA are GMP implementation, registering the facility, listing the device and Unique Device Identification (UDI).

For reusable PPE like gown & mask textiles, is there a desired level of commercial launderability? 25 washes, 50 washes, etc.?

It is up to the manufacturer to validate whatever claim they make with respect to launderability. I do not know of a standard desired level.

Who do we contact for assistance in developing QMS documentation? Where can we find the templates?

NCMEP assists with developing QMS documentation for ISO 9001 and ISO 13485. NCMEP can provide you with a list of procedures that are required, training and implementation support. Contact NCMEP at (919) 513-6119 or ncmep-information@ncsu.edu for more information.

I'm manufacturing a Class II, N95 respirator which is a fluid barrier, but I'm unclear on what claims I can make about it because the FDA says it is regulated by NIOSH. I have test reports proving the efficiency of the material but I'm not sure if I can even convey that information to customers legally.

Great question and this one is a bit confusing. The Surgical Respirator, FDA Product Code MSH, is in fact 510(k) exempt by the FDA since it has to be approved by NIOSH; however, see the following as to when it is not exempt…

> "A surgical N95 respirator or N95 filtering face piece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering face piece respirators are exempt from the premarket notification procedures subject to 21 CFR 878.9 and the conditions for exemption identified in 21 CFR 878.4040(b)(1)."

So, any additional claims you make, like the fluid barrier protection level, can be made as long as you have the data and process controls to substantiate the claims.

As a thermoformer, we can supply clear face shields. Is there a certain spec for the clear shield? (PET RPET, PETG, Polycarbonate)?

There are no certain specs for face shields that we know of.

QKR Class I Mask Product Code

QKR is not a Class I FDA product code. It is the code the FDA came up with during the pandemic for importers to use to get the N95 respirators into the country and is the enforcement discretion code.

NCMEP is administered by NC State Industry Expansion Solutions (IES) and is joined by partners from the North Carolina Community College System, NCWorks Customized Training; the Economic Development Partnership of NC; the Polymers Center of Excellence; the Manufacturing Solutions Center; and North Carolina A&T State University.

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