

**FDA Webinar: FDA Innovation Challenges: Identify Sterilization
Alternatives and Reduce Ethylene Oxide Emissions**

**Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants will be on a listen-only mode until the question-and-answer session. At that time please press Star followed by number 1, unmute your line and record your name clearly to be introduced. Today's conference is being recorded and if you have any objections you may disconnect. I'd like to introduce Irene Aihie. Ma'am you may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I'm Irene Aihie of CDRH's Office of Communication and Education. In response to the February 2019 closure of a large device elevation facility the FDA is taking steps to ensure that hospitals, healthcare providers and patients have access to medical devices that are safely and effectively sterilized. On July 15, 2019, the FDA announced the launch of two public innovation challenges to encourage innovation in medical device sterilization.

Challenge one focuses on identifying alternatives to ethylene oxide sterilization methods. And challenge two is focused on developing strategies to reduce ethylene oxide emissions. The FDA Center for Devices and

Radiological Health will accept applications for both of these challenges through October 15, 2019. The FDA encourages participation in these challenges from organizations such as medical device companies or distributors, technology manufacturers including startup companies or labs, academic and research institutions, healthcare facilities, professional societies, foundations and other nonprofits.

Today Chris Dugard and Steven Elliott both from the Office of Surgical and Infection Control Devices here in CDRH will discuss both innovation challenges. Following the presentation we will open the line for your questions related to the information provided during the presentation. Additionally there are other subject matter experts here to assist with the Q&A portion of our Webinar. Now I give you Chris.

Chris Dugard: All right thank you and good afternoon everyone. This is Chris Dugard. And as Irene mentioned I'm a reviewer in the (sterilization) devices team in the Office of Health Technology. And I'm joined by Steve Elliott who is also a reviewer in the same team. And today we're going to be talking about FDA's innovation challenges to identify sterilization alternatives to ethylene oxide and reduce ethylene oxide emissions.

So here's an overview of the agenda. I'm going to start with an overview of ethylene oxide sterilization in general. Then I'll go into FDA's efforts to address issues associated with ethylene oxide sterilization. Then I'll provide an overview of the innovation challenges, tips for potential applicants and then we have a page of resources and we'll have time for questions at the end.

Sterilization is defined as a process intended to render devices free of viable microorganisms in order to prevent patient exposure to pathogenic microorganisms. Sterilization is a binary consideration, the device is sterile or

it is not. But there is no way to prove with 100% certainty that a product is sterile. Since microbial activation is expected to be exponential we express how thorough a cycle is through probability in what we call the sterility assurance level or SAL. For example a typical SAL for medical devices is expressed as an SAL of ten to the minus 6 or a probability that only one in 1 million devices is contaminated following exposure to the cycle. This is calculated by exposing either bioburden that's been characterized or biological indicators which I will refer to as BIs from now on with a known population and resistance to the intended cycle determining the SAL based on whether the BIs or bioburden are successfully inactivated or killed.

There are several common types of sterilization modalities used to process medical devices and these are thermal which includes steam sterilization and dry heat sterilization, chemical which includes ethylene oxide gas, vaporized hydrogen peroxide, chlorine dioxide, et cetera and irradiation which includes gamma, x-ray and E-beam. Sterilized medical devices are critical to our healthcare system and patient safety to prevent infections through the use of these devices. As you all probably can tell the focus on this talk will be on ethylene oxide.

Ethylene oxide is a common if not the most common sterilant used for medical devices. Discovered in the 1800s it was originally used for fumigation until the military began using it as a sterilant in the 1940s. It was eventually patented for sterilization of medical devices in the late 1950s and since then it has achieved roughly 50% of the market share for medical devices provided sterile to healthcare. The reason for this is its great material compatibility as it is compatible with most common medical device materials, its ability to penetrate multiple layers of packaging with only metal and glass really providing any sort of effective barrier against it and scalability on an industrial

scale that is large quantity of devices and mixed loads can be sterilized at once.

Liquids would be one of the primary kinds of products that are not suitable for ethylene oxide sterilization. EO mode of action is alkylation of microbial DNA preventing further division. An ethylene oxide cycle involves exposure of product to ethylene oxide gas under vacuum in a sealed chamber with defined temperature and humidity conditions. And despite EO's effectiveness for sterilizing medical devices it also has its disadvantages. There are more variables that are critical parameters such as time, temperature, ethylene oxide gas concentration and relative humidity that need to be addressed to ensure a reproducible cycle. As ethylene oxide concentration goes up the more lethality there is in the cycle but this may impact material compatibility. The longer the cycle the more lethality but again this may impact throughput and material compatibility.

The higher the temperature the more lethality but ethylene oxide is a low temperature process ideal for temperature sensitive products. So this may be a limiting factor. Humidity adds moisture to hydrate spores which makes them more susceptible to the lethal effects of ethylene oxide but this may require preconditioning to ensure consistent lethality. Aeration of devices post sterilization to remove ethylene oxide residuals adds even more time. Compare this to irradiation where the only critical parameter is the dose of radiation delivered.

So those are considerations on cycle design but in terms of safety there are also disadvantages as ethylene oxide is highly flammable and explosive. Ethylene oxide emissions during the sterilization process can be both an environmental and worker health concern as ethylene oxide is identified as a hazardous air pollutant and is classified as a carcinogen. To date we are aware

of one industry ethylene oxide sterilization facility that has been closed on the basis of emissions. As a result there are concerns associated with manufacturing and processing of devices historically sterilized with ethylene oxide not just in terms of safety but also in terms of finding a suitable alternative to EO if more facilities are closed. If more were to be closed this may severely impact availability of devices typically sterilized with ethylene oxide.

While these safety concerns present challenges that need to be mitigated, unavailability of ethylene oxide would have an impact on public health. Its effectiveness against a broad spectrum of microorganism has been well-established. As I noted earlier an ethylene oxide sterilization cycle is scalable allowing for large amounts of devices to be sterilized at once. This ensures the supply chain medical devices is preserved and removing ethylene oxide as an option may create delays getting these devices to market. I also noted earlier that ethylene oxide has excellent material compatibility. As a result this is the only current option for a large number of complex medical devices. For example ethylene oxide is one of the only modalities used for electronic medical devices.

So this brings us to FDA's efforts to address these concerns. We have been working with sterilization experts, medical device manufacturers and other government agencies to both advance current methodologies using ethylene oxide for medical device sterilization and to prevent the potential for medical device shortages due to a lack of alternative to ethylene oxide. This also includes discussion of other methods that may be used instead of ethylene oxide. These issues are important because while we are interested in alternative modalities for devices that may not necessarily need to use ethylene oxide we recognize that there will likely always be a place for ethylene oxide in medical device sterilization but further mitigating its risks is

of great interest to the agency. These concerns tie into our innovation challenge which I'll expand on just a bit. But the FDA is also planning on holding an Advisory Committee Panel on November 6 and 7 of this year to obtain stakeholder feedback regarding challenges and opportunities for ethylene oxide reduction and the use of alternative strategies to inform the FDA's decision making. There will be more on that in the coming weeks.

Now more about the innovation challenges themselves. The FDA is reaching out to anyone involved in sterilization to foster innovative new sterilization technologies and methods both based around ethylene oxide and not to mitigate the risks associated with ethylene oxide as well as ensure there is no interruption of medical device availability. The first challenge is to identify new sterilization methods or technologies to EO sterilization. This means any method or technology that demonstrates compatibility with the largest cross-section of materials used to make medical devices or packaging materials or sterile barriers is scalable, allows for high capacity, and demonstrates quantifiable reduction in viable microorganisms to an acceptable sterility assurance level.

The second challenge is asking for any methods that can reduce the level of ethylene oxide emissions. As noted earlier we recognize the prevalence and usefulness of EO sterilization for medical devices and realize that even if an alternative modality is found there will likely always be a need for ethylene oxide sterilization in some capacity.

However given the risks I mentioned there is room for innovation to modify existing practices to reduce ethylene oxide emissions as close to zero as possible. We are looking for methods that still achieve an acceptable validated sterility insurance level and reduces the amount of emissions typically seen in the process. This may include strategies to reduce EO concentration, control

bioburden, using a bioburden approach, reduction in the amount of ethylene oxide used, capture of emissions and transformation into harmless bioproducts, emission containment and abatement, et cetera.

So I talked about some of this on the last slide but eligibility for these challenges includes any safe and effective alternative methods or technologies to ethylene oxide sterilization for medical devices as well as any innovative strategies and procedures in any stage of ethylene oxide sterilization process that is demonstrated through reduced ethylene oxide emissions to near zero. We are casting a wide net so if you have anything that fits these criteria we encourage you to submit an application.

I will now go into a bit more detail about what is expected in these challenges. For challenge one, that is identifying new methods and technologies other than ethylene oxide, we are looking for methods that can sterilize a wide range of polymeric materials without a change in the chemical and physical properties of the polymers by degrading them for example through oxidation, chain scission, or other unfavorable reactions or by generating unacceptable levels of toxic byproducts such as leachables. There may be some materials that have been traditionally sterilized using ethylene oxide that may have alternatives. We are looking for methods where these materials could be diverted to a different modality.

We are looking for methods that can or have the potential to sterilize bulk volumes or large loads of products at an industrial scale. While we would not rule out methods that sterilize smaller loads, industrial level methods would have the best chance of mitigating the concerns I discussed earlier. We are also looking for methods that have the potential to be adapted to existing infrastructure and can be rapidly deployed to medical device manufacturers

and sterilization providers in the US. Again no method will be ruled out but if it has the potential to be adapted to current infrastructure that would be a plus.

For challenge two, that is reducing emissions of existing ethylene oxide processes to as close to zero as possible, we are looking for methods that do not negatively impact throughput of current ethylene oxide sterilization processes. Like challenge one, we are also interested in methods that are able to use existing infrastructure and can be rapidly deployed. This includes strategies to control and reduce bioburden prior to sterilization. We would like to see strategies that use lower levels of ethylene oxide in general while still maintaining an acceptable sterility assurance level.

We would like to see methods that capture ethylene oxide emissions and transform them into harmless byproducts. This includes methods of detection, measurement, tracking and containment of emissions or byproducts to minimize or prevent dissemination into the sterilization facility and environment. Methods that can minimize exposure to workers in nearby communities will also be looked at.

As for who can apply, we are looking for applications from any companies involved in sterilization: medical device companies, startups, academic researchers, healthcare facilities, professional societies, foundations or anyone else I haven't listed that is involved in sterilization to look at any safe and effective alternative methods or technologies to ethylene oxide sterilization and any innovative strategies in any stage of ethylene oxide sterilization that are demonstrated to reduce EO emissions to close to zero as possible. I will note however that review of these challenge submissions does not constitute regulatory acceptance or endorsement of a process associated with a premarket submission. Following the challenge these methods or technologies would still have to be reviewed through the relevant premarket pathway.

So now I'll get a little more into what we expect in your actual application. For either submission we would like to see the development plan for the method or technology, how far is it from being able to be implemented at an industrial level? Is it still in a conceptual stage? What is the supporting science or evidence? We would like you to list the development team including names of essential team members and prior experience of each team member in sterilization methods or technologies. We would like the scientific basis and/or preliminary data to support the proposed method or technology and as much detail as you have available while still meeting our submission criteria. You should also describe the anticipated benefit and the impact of the method or technology on public health.

Compatibility of the method or technology with medical device materials should also be discussed. For example if it's a new method, are there materials that are compatible with this method that EO is not and then vice a versa. Also we would like to see the capability of the method or technology to ensure scalability and high throughput for safe and effective sterilization of large volumes of devices. If the method or technology is still at more of a conceptual stage but you can envision that it might eventually be scalable to an industrial level we would like to learn about that.

So while I did note that review of these submissions does not constitute regulatory acceptance there is the - there are incentives to participating in this innovation challenge. There is the obvious potential benefit of positively impacting public health. You will be receiving more interaction with the FDA and as a result potentially accelerate the development and review of your technology or you may also receive FDA recognition for a successful application. All right so here is the timeline for the innovation challenges. The challenge began July 15 of this year and it - the submission period started July

15 and will end October 15. You can submit your application to the email address on this page which is also on our Web site. And the judging period will be from October 16 to November 16. And we will be announcing applicants selected for the challenge in December 2019.

When reviewing the challenge submissions a panel of subject matter experts within the agency will be considering the anticipated benefit of the strategy or technology. And just to emphasize the criteria I noted earlier some of what we will be considering include is it easier or more difficult to implement than existing practices, does it introduce additional concerns even if it eliminates some of the concerns associated with ethylene oxide. We will be looking at the impact on public health compared to other alternatives. Since EO is compatible with most commonly used medical device materials we will be comparing compatibility with the proposed method or technology in every submission as well.

A new method or technology that is highly effective on only a small number of materials may not address the challenges we are facing. As I mentioned several times before we will be considering scalability, how feasible is it to implement the proposed change and we will be considering whether further interaction with the FDA would help foster a potentially beneficial method or technology.

All right here is the application format. We are asking that these submissions be no longer than 20 pages and include a cover page with a company name, address and primary contact with name, phone number and email, name of the alternative sterilization method or technology, FDA regulatory history if appropriate and name of the challenge that you are addressing. Please also include an executive summary limited to one page with a summary of the method or technology, the significance of the problem it will solve and a

summary of the proposed development plan. So you may submit more than one application and there is no official application form and the format is outlined of the Web page. The link for this page and other resources are listed at the end of this presentation.

If your application is selected, expect confirmation from FDA and instructions on next steps. There may also be the potential for Web presentations to evaluate finalists. Please note that we will confirm receipt of every application so if you submit one and you don't hear from us please reach out. Also note that even if we do not select your application as a finalist or if you have technology or a new method that is in early stages we encourage you to continue to reach out to the agency through our typical channels including pre-submissions or breakthrough device designation outside of this challenge.

Please note that all communications with the FDA will be considered confidential and will not be released by us. Any announcement to be made about a particular application will be vetted through the applicant prior to announcing. As I noted here are the resources and now we will have time for questions.

Irene Aihie: While we get started or get ready to prepare for questions I do want to make a note that if we do have any members of media listening in our press officers will follow up with you separately. And if you have any questions please send those media related questions to the following email address that is fdaoma@fda.hhs.gov.

Chris Dugard: And now we have time for questions.

Coordinator: And thank you. At this time to begin the question and answer session you may press Star followed by number 1 to ask a question. Star 2 that will withdraw

the question. Again please unmute your line and record your name clearly as prompted to be introduced. Again with questions please press Star followed by number 1. Please standby.

Irene Aihie: So we have a few questions that we feel may come up. I believe Steven?

Steven Elliott: Okay so...

Coordinator: And the first question comes from (Darren Demetric). Your line is open.

(Darren Demetric): Yes, hi. With regard to reduction of EtO emissions I work for a company called (Renew Medical). We're a processor of single-use medical devices. Most of the reprocessing industry utilizes EO sterilizers as part of their process to reprocess these single-use devices. They do this even though only critical medical devices are defined by CDC requires sterilization where semi-critical devices or non-critical device is deemed necessary to do a high level disinfection. Does FDA or more importantly could FDA consider putting emphasis on high level disinfection for reprocessing semi-critical and noncritical medical devices in lieu of sterilization? This could significantly reduce the impact of EO gas in the reprocessing industry?

Steven Elliott: That is a very interesting question. Right now I'd say that there is potential to do that and reevaluate the appropriate classification for certain devices be they critical or semi-critical. However it does raise potential concerns. There's already confusion and debate over the appropriate classification under the Spaulding Classification system. So that might be a potential strategy that we could explore in detail if you intended to put in a submission along those lines.

(Darren Demetric): Great, thank you.

Coordinator: Thank you. Our next question is from Edward Life Sciences. Your line is open. The company with Edward Life Science your line is open. You may want to check your mute button.

Irene Aihie: We'll take our next question.

Coordinator: All right our next question is from (Ayanna Alexander). Your line is open.

(Ayanna Alexander): Hi. Can you all hear me?

Irene Aihie: Yes, we can hear you.

(Ayanna Alexander): Okay, just making sure. I am a part of the media but I do have a clarifying question. I know you guys are looking for substitutes to ethylene oxide but if you - you're saying if you find one there is probably still going to be a good chance that EtO is still going to be used to clean devices?

Irene Aihie: If you wouldn't mind sending that question to the mailbox that I mentioned earlier so that we can have...

(Ayanna Alexander): Got you.

Irene Aihie: ...a member of our press team get that answer for you.

(Ayanna Alexander): Thank you.

Irene Aihie: You're very welcome.

Coordinator: Thank you. Next question is from (Brent Ashton). Your line is open.

(Nicole McCleaf): Hi. Actually it's (Nicole McCleaf) from 3M. Can you hear me?

Irene Aihie: Yes, we can hear you.

(Nicole McCleaf): So I actually have two questions one for challenge one, are you looking for alternatives to EO that aren't already known, you know, like nitrogen dioxide, hydrogen peroxide. There is some data out there on that. Are you looking to - looking for alternatives beyond that?

Steven Elliott: Yes, that's another excellent question. With that it could be either way. So I'd say that it could be an alternative that we do not have a sterilization history with or it could be utilizing an existing sterilization technology such as vaporized hydrogen peroxide, nitrogen dioxide, chlorine dioxide anything like that in a broader application than we've seen. One of the issues we have is that when we see some of these sterilization modalities we're seeing them in a device specific processing context.

So we don't know the greater capability of the process and that's something that could be explored with the challenge. Again in this case we're looking for a fix for compatibility and processing of devices that were historically sterilized with ethylene oxide so that's a much broader usage than some of the submissions we'd see for doing, or using those processes and a much more narrow or limited sense.

(Nicole McCleaf): Okay. Thank you. And then my second question is kind of related to that but it's for challenge two. Are you looking for methods other than the methods that are currently in the ISO 11135? For example the BI bioburden or cycle calculation approach will likely help with EO concentration but I guess if you can clarify if you're looking for alternatives to those methods?

Steven Elliott: Okay. We are looking for alternatives that will result in a reduction of ethylene oxide emission. However you get there with, as indicated previously, hitting those, you know, defined process sterility assurance levels to assure a sterile specification for advice, so absolutely. The approaches that are less conservative as defined by the ISO 11135 standard would be an appropriate point but if there's alternate methodology that is worth considering we would absolutely love to see that come in, in the form of a challenge submission.

(Nicole McCleaf): Okay great, thank you.

Coordinator: Thank you. Our next question is from (Sumner Barenburgh). Your line is open.

(Sumner Barenburgh): Hi. This is (Sumner Barenburgh). I have two questions. How do you plan to coordinate with the EPA and the EPA registrations that will be required? That's part one. And then part two with this innovation will the FDA be underwriting any of the work in developing this alternative?

Steven Elliott: Okay can you please clarify underwriting? So you mean subsidizing some of your costs?

(Sumner Barenburgh): Yes.

Steven Elliott: Okay, that unfortunately, would be outside of the scope of the challenge incentives. In terms of our work with the EPA, this challenge is an independent FDA venture. There are certain steps that are required for addressing chemical sterilants with the EPA registering as pesticides and such. And for those I would refer you to EPA's Web site to address those regulatory requirements. Those are a little bit outside of the scope of the challenge.

(Sumner Barenburgh): No, the question I'm asking because I was involved with chlorine dioxide as controlling bio contamination and for sterilization. And so we get FDA approval on a couple of applications but we also needed concurrently as an antimicrobial or a sterilant we had to get EPA registrations historically.

Steven Elliott: Yes, and with any challenge incentives or proposed ideas that would not negate any other regulatory requirements from a different agency.

(Sumner Barenburgh): Okay, thank you.

Irene Aihie: We'll take our next question.

Coordinator: One moment please. Our next question is from (Thomas Rickel). Your line is open.

(Thomas Rickel): Well yes I'm speaking on behalf of Medtronic this afternoon. Can FDA share their thoughts on the differences in engaging innovation challenge versus maybe a more traditional presubmission? That's the first part of the question. And the second part of the question would be how many submissions does FDA intend to support say they get numerous bid applicants how many would FDA intend to support?

(Afton): Let me just start with the second part of the question with regard to how many applications do we intend to support. So as both Steve and Chris mentioned we are looking for very innovative ideas. And if we get several challenge applications that have that we can definitely accept multiple applicants into the challenge itself. So really we're going to focus on the quality of the ideas and we will support those high quality ideas.

(Thomas Rickel): Thank you.

((Crosstalk))

Coordinator: (Phil Coghill), your line is open.

(Phil Coghill): Yes thank you, (Phil Coghill) from Medtronic. Is the FDA collaborating with other medical device regulatory bodies such as Notified Bodies, Health Canada, PMDA or, you know, with these challenges?

(Afton): Good afternoon. So FDA is not currently collaborating with our OUS regulators on this particular challenge but we are aware of other activities. And so that is the challenge is as one of several components that we're doing as we address this issue. We have other stakeholder engagement and outreach in a forthcoming Advisory Committee Meeting on that. And so that might be a more appropriate area to think about some of those other jurisdictions.

(Phil Coghill): Thank you.

Coordinator: At this time I'm seeing no further questions. As a reminder that is Star followed by 1 with any questions.

Steven Elliott: Actually I did want to reach back just briefly because I - we realize we didn't respond fully to one of the questions regarding incentives and how the interaction for the innovation challenge would differ from a typical interaction with FDA along the lines of presubmission process. And I'm sure that this would be of interest and I think it is important to note that the type and nature of interactions that we would be having with companies would be dependent on the content of the submission. Obviously, we want to gauge the efficacy of

us providing significant interaction. Some processes we could offer more in the way of help, some processes less.

And obviously being a challenge winner would not replace or remove any need for objective review in a medical device submission. Processes would obviously need to be able to support a sterile specification for a medical device. And there might be some outstanding concerns that would need to be addressed prior to implementation of a sterilization process for a specific medical device. Having considered all of those caveats we definitely will be looking for I'd say more frequent interaction potentially iterative review of a process. In this case we would recognize that at this point we have incentive and interest in developing solutions to our outstanding processes which is a little bit different than a presubmission process where we're looking at just answering questions and concerns based on something that's of interest to a sponsor or a company coming in.

Definitely we want to help identify and provide suggestions to any, to address any scientific and regulatory concerns that would facilitate the use of this process. And we would also be trying to facilitate our own internal training and education to address any potential review challenges we'd get with a new process coming in. So those are elements we just wanted to point out to distinguish and address an earlier caller's question.

Irene Aihie: Operator, are there any other questions?

Coordinator: I'm sure no questions at this time. As a reminder please Star 1 if you do have a question. And I'm showing no questions at this time. We do have a couple of questions that just came in. (Thomas Rickel) your line is reopened. You may ask your question.

(Thomas Rickel): Great, Steve thanks for clarifying the answer to the question. I think that was Steve. One additional question that has to do with disclosure of innovation challenge I think Chris covered it briefly and I wonder if you could perhaps just go over it one more time. I think I heard Chris mention that any announcements FDA intends to post with regard to progression in the challenges particular submissions would be reviewed with the company before being posted. Maybe just talk through the way in which FDA intends to communicate on progress along the way both through vetting and then also through interacting with an applicant?

Steven Elliott: Okay. I think it might be helpful at this point if we can get just a little bit of clarification at this stage you're speaking. Are you speaking during the review or judging process or are you speaking to post-selection of a winner or meritorious submission?

(Thomas Rickel): I think clarification of both stages probably once FDA has landed on the selected applicants then the way in which they intend to communicate on about the population of submissions. And then secondarily, you know, I'm presuming that perhaps FDA would like to discuss the progression of the challenge and if there's any sort of discussion points along the way as they're working with applicants?

Steven Elliott: Okay, with that, in terms of process, the level of interaction required might be determined at this point. Some of these elements are not firmly decided and that will - that was - that's based on the number and I'd say consistency and quality of applications we're getting. And if there's any elements in those that would require us to reach out and have some potential additional interactions would definitely take place with that. But it's - if it's a case of if we're receiving an enormous multitude of these things obviously our selection process needs to be a little bit more cutthroat in terms of how we're going

through and reviewing these things so resources might come into play for that as well.

(Aftin): And then this is (Aftin). To add on with to what Steve is saying with regard to communications. So FDA would certainly have interest in announcing those applicants that were selected into the challenge because they would have been selected because they have novel ideas that we think could have a positive impact on public health. But as Chris indicated in his statements a little earlier in the presentation we would work with those that are selected into the challenge with regard to what will be communicated as well as when so that goes also to your timing question as well.

(Thomas Rickel): Great, thank you.

Coordinator: Thank you. Our next question is from (Bill Cavell). Your line is open.

(Phil Coghill): Thank you, (Phil Coghill) Medtronic again. My question is that the two challenges are quite different. And the second challenge for reducing ethylene oxide there may be a lot of companies coming in with very similar ideas. Has there been a thought to try to combine those and have companies work together since they're really industry wide benefits versus the alternatives to EO may be unique and really dependent on the particular company. Have you thought about combining applications or methods that come in on the reduction of ethylene oxide?

Steven Elliott: Okay. That is a very interesting thought. We would welcome any designated collaborative submissions from industry to address this problem. Again, our angle on this is advancing and supporting public health. So in terms of that we'd absolutely welcome those things. Unfortunately, one of the concerns with that as we just mentioned would be that we can't share independent,

similar submissions between companies due to the existing confidentiality that we would have to maintain. But we would welcome that coming in from an external perspective, if any companies or interested parties would like to collaborate on that, we would definitely welcome that type of pursuit.

(Phil Coghill): So thank you for the clarification.

((Crosstalk))

Coordinator: Excuse me, (Brad Dumpke) joined.

(Brad Dumpke): Oh thanks. Could you elaborate on industrial level throughput or scalability please?

Steven Elliott: Okay. Yes essentially with the concerns associated with use of ethylene oxide we're definitely all aware that ethylene oxide is a major contributor to industrial sterilization of medical devices. So with that, it's something that has a high throughput, large volume processing infrastructure in place.

And while we don't expect something to come out tomorrow at the exact same capacity and replace it [EtO sterilization], that would be one of our desired outcomes would be trying to identify or, you know, see processes coming in that could be potentially in the future scalable to work at a similar capacity to, you know, an ethylene oxide or gamma radiation sterilization. So we understand that it's not there for a lot of modalities yet but that's one of the purposes of the challenge would be encouraging back going forward.

(Brad Dumpke): Thank you.

Coordinator: Thank you. And our next question is from (Al Tilia). Your line is open.

(Al Tilia): Hello. So my question is about challenge number two, does this challenge also cover conversion of the emitted EtO to others safer gases or just reducing it?

Steven Elliott: That is an excellent point. For clarification any process that is going to reduce ethylene oxide emissions be it a change to the actual sterilization process itself or some sort of external abatement, cleanup or chemical conversion all of those things would be considered relevant.

(Al Tilia): Okay, thank you.

Coordinator: And thank you. I'm seeing no further questions at this time. I'd like to turn the meeting back over to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. And we appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at www.fda.gov/training/cdrhlearn by Wednesday, August 21. If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation. As always we appreciate your feedback.

Following the conclusion of today's Webinar please complete a short 13 question survey about your FDA CDRH Webinar experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live Webinar. Again thank you for participating. This concludes today's Webinar.

Coordinator: And thank you. This does conclude today's call. You may disconnect your lines and thank you for your participation.

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