Tab 2
Biosafety Cabinetry Standards Update

Mindy Costello, NSF International
December 13, 2007

NSF/ANSI 49-2002e

The changes present in NSF/ANSI 49–2002e include editorial corrections in section 5.18 and extensive revisions.
NSF/ANSI 49-2002e

– Section 2 The Normative References section was added
– Section 3 The Definitions section was updated, including the renaming of Type B3 cabinets to Type A2.
– Section 5, Design and Construction New language was added
  • Section 5.20 A decrease in the total allowable face area of HEPA filter patches
  • Section 5.23 New alarms section which replaces the previous Fans section
  • Section 5.29 New work area components placement
  • Section 5.31 New data plate requirements

NSF/ANSI 49-2002e

– Section 6 Performance testing and the corresponding Annex A and Annex F (Field Tests) underwent significant revisions:
  • Annex F.5 and F.6 The Halogen test was altered to become a tracer gas leak test, and a pressure decay test was added – both tests determine whether the cabinet is free of leaks.
  • Annex F The Temperature rise test was removed.
  • Annex F.9 Lighting intensities including background levels, average intensity, and individual readings were all altered to reflect more realistic conditions.
NSF/ANSI 49-2002e

– Annex F.2 The requirements for uniform downflow velocity and non-uniform downflow velocity were made more specific.
– Annex F.3 Inflow velocity requirements were clarified for the various cabinet types.
– Annex F.4 The Airflow smoke patterns test was revised for clarity.
– Annex F.8 The Electrical leakage, ground circuit resistance, and polarity test were removed for new cabinets as they must comply with UL-3101-1.

NSF/ANSI 49-2002e

– Annexes B, C, and D were rewritten for clarification purposes.
– Annex E was rewritten to include more specific recommendations for installation of all types of cabinets including requirements for roof exhaust systems.
– Annex F was incorporated into the standard as a normative annex.
– Annex G was clarified and allows for alternate procedures for the removal of formaldehydes.
NSF/ANSI 49-2004

• NSF/ANSI 49-2004 contains the following revisions:
  – The NSF/ANSI 49 – 2002, Addendum 1.0 was incorporated into this Standard.
    • Section 2. Normative References were updated
    • Section 3.13 The definition of high efficiency filters was updated to include specifications for both high efficiency particulate air (HEPA) filters and ultra-low-penetrating air (ULPA) filters and revisions to rounding errors that affect the pass/fail criteria throughout the document.
    • Annex A & F Changes were made to the accuracy specification tolerance for DIM instruments
Issue 10 – Hard Ducting

- 5.23.3 – added a requirement that Type B cabinets and direct connected Type A shall be exhausted by a remote fan.
- First presented in 2005 as an Issue Paper; It was balloted in June 2006.
- Negatives were received and remain unresolved.
- In January 2007 the Technical Committee recommended the issue be further investigated prior to re-balloting.
- The Hard Ducting task group was formed to address this issue.
Issue 11 – HEPA and ULPA filters

- Expansion of section 3.13 to allow the use of the new types of filters now defined within IEST-RP-CC001, and modification of section 5.20 to include all current and new filters defined in section 3.11.
- Incorporated change into NSF/ANSI 49-2007

Issue and Information Papers
Issue Papers

- Changes or additions
- Forms obtained by request
- Tracking number
  - Ex. BS-2007-3
- JC Chair:
  - Open forum
  - Balloted
- JC Meeting Agenda

Information Papers

- Updates
- Obtained by request
- Tracking number
  - Ex. BS-2007-3
- Usually discussed at Joint Committee meetings
- JC Meeting Agenda
Thank you!

Questions/Comments?

Mindy Costello
mcostello@nsf.org
Chlorine Dioxide Task Group
August 8, 2005

Attendance
Maureen Best- Health Canada
Jaclyn Bowen- NSF International
Cheryl Bunagen- NSF International
Mel First- Harvard School of Public Health
Jim Flannery- Certified Air Solutions
Richard Gilpin- R. Gilpin Limited
Jim Hunter- Labconco Corp.
Henry Luftman- Micro Clean
David Lupo- B & V Testing
Bill Peters- Nuaire, Inc.
David Phillips- ENV Services
Bob Powitz- R.W. Powitz and Assoc.
Mike Regits- Micro Clean
Mauren Roash- NSF International
Gregg Schuling- NSF International
Jim Wagner- Controlled Environment Consulting
Steve Williams- NSF International

Jaclyn Bowen read the anti-trust statement and took roll call. Jaclyn Bowen stated that the purpose of this task group is to provide guidance to the proponent of an issue paper who is looking to provide validation-testing showing that chlorine dioxide can be used as a decontaminant for Biosafety Cabinetry.

Steve Williams of NSF International was chosen as chair of this task group. Jaclyn Bowen stated that the chair of this task group is only responsible for reviewing meeting summaries, facilitating discussion, and voting if there happens to be a tie. As a task group, this group will be responsible for making the recommendation to the Biosafety Cabinetry Joint Committee on future potential language inclusion with regard to chlorine dioxide.

Henry Luftman gave a brief overview of his issue paper. Chlorine dioxide is used as a decontaminant in various applications. He has tested 4 cabinets, with 35-40 runs, with biological indicators above the exhaust filter, on and below the work surface, and inside the positive pressure plenum. This testing has consistently shown a log 6 kill at all four locations. Mel First questioned what type of spore strip was used. Henry Luftman responded that *Geobacillus stercothermophilus* was used and this was chosen since it is less resistant to formaldehyde and more resistant to hydrogen peroxide. Henry Luftman stated that he is conducting validation testing but wants to ensure that he is addressing all parameters and environments to satisfy any concerns that the Biosafety Cabinetry Joint Committee may have. Henry stated his hope is that this, along with other validation testing will ultimately validate the use of chlorine dioxide as a decontaminant under certain conditions. Formaldehyde leaves a residue, takes a lot of time, is highly toxic, and is a known carcinogen. Chlorine dioxide is also highly toxic but does not take as much time to react and leaves no residue.

Mel First suggested that Henry Luftman submit his protocol to the task group for review as well as the results. Mel First expressed some concerns that chlorine dioxide is generated at the point of use and only has a shelf life of a few days. Mel suggested that how the chlorine dioxide was created would need to be verifiable. Additionally, the quantity of cabinets to be used, the runs, the biological indicators, their respective locations, also need to be considered. Bob Powitz stated the spore could be used to judge the kill. Bob Powitz also suggested that the formaldehyde protocol be reviewed. Richard Gilpin added that he has seen some recent articles in regards to using chlorine dioxide as a decontaminant. These articles presented some issues in regards to necessary humidity levels. He will send this to Jaclyn Bowen to circulate to the group prior to the next teleconference call. Bill Peters also stated that he might have a method to present and circulate to the group.

Bob Powitz stated that ultimately this task group would need to define what a successful decontamination with chlorine dioxide means. Mel First added that the protocol submitted by Henry Luftman could act as a minimum. Jaclyn Bowen reminded the group that ANSI standards are living documents, and if the proposed language inclusion is deemed insufficient (too conservative) the requirements can be adjusted. Bob Powitz suggested looking back at historical data to see why the Biosafety Cabinetry Joint Committee was comfortable with a log 6 kill.

Steve Williams asked Jim Hunter and Bill Peters if they would be willing to volunteer in the validation studies and they agreed.

Henry Luftman and Bill Peters will send Jaclyn Bowen their protocols for the Chlorine Dioxide TG to review. Richard Gilpin will send Jaclyn Bowen the Patel studies. Jaclyn Bowen will prepare a meeting summary and circulate dates/time approximately 4 weeks from now to reconvene via teleconference.
Chlorine Dioxide Task Group  
September 8, 2005

**Attendance**

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
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<tbody>
<tr>
<td>Madhu Anand</td>
<td>Halide Group</td>
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<tr>
<td>Jaclyn Bowen</td>
<td>NSF International</td>
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<td>Cheryl Bunagen</td>
<td>NSF International</td>
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<td>Rob Donofrio</td>
<td>NSF International</td>
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<td>Richard Gilpin</td>
<td>R. Gilpin, Limited</td>
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<td>Peter Harris</td>
<td>B &amp; V Testing</td>
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<td>Peter Hobbs</td>
<td>Halide Group</td>
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<td>Jim Hunter</td>
<td>Labconco Corp.</td>
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<td>Henry Luftman</td>
<td>Micro Clean</td>
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<td>David Lupo</td>
<td>B &amp; V Testing</td>
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<td>Bill Peters</td>
<td>Nuaire, Inc.</td>
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<td>David Phillips</td>
<td>ENV Services</td>
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<td>Bob Powitz</td>
<td>R.W. Powitz and Assoc.</td>
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<td>Mauren Roash</td>
<td>NSF International</td>
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<td>Gregg Schuiling</td>
<td>NSF International</td>
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<tr>
<td>Jim Wagner</td>
<td>Controlled Environment Consulting</td>
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Jaclyn Bowen called the meeting to order, took roll call, and read the anti-trust statement. Jaclyn Bowen explained that Steve Williams, the task group chair, was on vacation and Gregg Schuilling would be facilitating the discussion in his place.

Gregg Schuilling questioned Bill Peters and Jim Hunter if they had ever worked on chlorine dioxide as an alternative to formaldehyde. Both explained that they had not.

Henry Luftman stated that there are two different processes to generate chlorine dioxide however both having the same result.

1. The Chlorine Dioxide concentration is maintained and monitored.
2. Use a fixed mass of chlorine dioxide

Henry Luftman preferred to use a broad protocol that allows for both methods.

Gregg Schuilling questioned if he could draft a scope and a protocol since a protocol is necessary if this task group decides that validation testing needs to take place. Ultimately, it needs to be proven that Chlorine Dioxide performs equal or better than formaldehyde. Bob Powitz corrected Gregg Schuilling and stated that Chlorine Dioxide doesn’t need to perform equal or better than formaldehyde more so equal or better than a $10^6$ kill. Henry Luftman questioned what the benchmarks are on formaldehyde. Bill Peters questioned what type of strips need to be used, the placement, etc. Henry Luftman questioned if we need to know absolute concentration on a routine basis since it is expensive. A member of the task group responded that concentration is only needed to be measured if the variance causes change. Henry Luftman explained that with a fixed mass, i.e. not a fixed concentration; you do see some absorption through the filter. Madhu Anand stated that some unpublished studies show some consumption of chlorine dioxide is attributed to the filter. If not using BIs, the concentration and humidity needs to be monitored during the decontamination cycle. Sealing Biosafety Cabinets is complicated and there are usually leaks.

Everyone agreed that a worst-case scenario needed to be established.

A member of the task group proposed that this task group address all alternative decontamination materials. Jaclyn Bowen stated that the charge of this task group was to pursue adopting a procedure for using chlorine dioxide as a substitute for formaldehyde. While this proposal can be pursued with the Biosafety Cabinetry Joint Committee, this task group and it’s respective expertise is focusing on Chlorine Dioxide. Please contact Jaclyn Bowen bowen@nsf.org to ask for an issue paper to initiate any change to standard 49.

Some members questioned if a kill of $10^{12}$ would be better. The task group agreed that a $10^6$ is sufficient. Bob Powitz added that the group needed to agree on a minimum challenge. He stated that $10^6$ is good. It creates $10^6$ inside of the cabinet and where inside of the cabinet would you actually find $10^6$ organisms. Rich Gilpin agreed that $10^6$ is sufficient.
Gregg Schuilling stated that a comparative analysis may be necessary and someone needs to formulate the parameters. Jaclyn Bowen asked Henry Luftman if he could get in contact with the Halide Group to draft some language on the protocols each of them uses since one maintains concentration of chlorine and the other uses a fixed mass. Jaclyn Bowen stated that they needed to come up with minimum parameters that they could both meet, including temperature, humidity etc. Bob Powitz, the Biosafety Cabinetry Joint Committee chair, added that it is fundamental that while both companies use different processes it is imperative that the language proposed is harmonious. Additionally, even though Halide Group and Micro-Clean are drafting this language, this language need to be circulated to other members, including other manufacturers and certifiers, to ensure they are comfortable with the proposal.

Rob Donofrio, the director of Microbiology for NSF International, stated that he believed that $10^6$ is reasonable but questioned if any studies have been conducted on the bioload of filters? This task group may want to survey this to check the bacteriological concentration, as he would hate to be surprised with $10^8$ or $10^9$ quantities. Henry Luftman responded that the actual vegetative load is low because it is an extremely unfriendly environment. Wagner noted that Mel First did a study that inoculated HEPAs and after 22 hours there was 0 living cells.

Henry Luftman will work with the Halide Group and send their protocols for the Chlorine Dioxide TG to review. Jaclyn Bowen will prepare a meeting summary and circulate dates/time approximately 4 weeks from now to reconvene via teleconference.
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Chlorine Dioxide Task Group
November 21, 2005

Attendance
Madhu Anand – Halide Group
Jaclyn Bowen- NSF International
Cheryl Bunagen- NSF International
Mel First- Harvard School of Public Health
Richard Gilpin- R. Gilpin, Limited
Peter Harris – B & V Testing-
Peter Hobbs – Halide Group-
Jim Hunter- Labconco Corp.
Henry Luftman- Micro Clean
Bill Peters- Nuaire, Inc.
David Phillips- ENV Services
Mauren Roash- NSF International
Gregg Schuiling- NSF International
Jim Wagner- Controlled Environment Consulting
Steve Williams-CHAIR- NSF International

Jaclyn Bowen called the meeting to order, took roll call, and read the anti-trust statement.

Henry Luftman walked through the joint protocol, proposed validation procedures for Chlorine Dioxide, which he and the Halide Group assembled.

Henry Luftman stated that following the last teleconference, he and the Halide group worked on unifying a protocol permitting different processes to generate chlorine dioxide however both having the same result. The main difference between this protocol and the former is that while the method is the same, the delivery of chlorine dioxide is different. In one form, the Chlorine Dioxide concentration is maintained and monitored. The other approach is to use a fixed mass of chlorine dioxide. Henry Luftman stated that both groups have consistent monitoring of the concentration, but there was no refilling of the chlorine dioxide in the MicroClean approach.

Mel First questioned if there was any minimum concentration that would be considered a failure. Henry Luftman responded that once the concentration is reached, receives a 90-minute contact, and has no gross leakage, it should be considered acceptable.

The task group next discussed specifics regarding:

- Biological Indicators
- Temperature
- Humidity
- Pass/ Fail Criteria
- Sample size for validation procedures
- Location of Indicators
- Chemical Indicators

The task group discussed pass/fail criteria. Most agreed that a 6-log reduction would be an ideal target. However, Henry Luftman explained that this could not be demonstrated using the biological indicator strips he was using. The reason for this is that positive controls were analyzed with a density slightly less than 10^6. The task group accepted this but did not settle on a final pass/fail number.

The task group also discussed if cabinets of different size, type, and make should be considered for the validation studies. Mel First suggested testing a total of 2 A1’s, 2 A2’s, 2 B1’s, and 2 B2’s for a total of 8 cabinets. The group agreed that 2 different manufacturers would be sufficient. Bill Peters and Jim Hunter agreed that the testing could take place at their manufacturing facilities and they would provide the cabinets.

Placement of biological indicator strips was discussed. Bill Peters related his experience with placing strips between the pleats of the filter indicated that these could be areas of concern within a cabinet. The group agreed that the validation testing should include some test strips placed between the pleats of the filters. The group settled on the following biological indicator test strip placement:

1 under the work surface
1 above the exhaust filter
1 inside the positive pressure plenum
3 between the pleats of the downflow filter
The 3 in the pleats of the downflow filter would be at the center and near two opposite corners.

There was discussion about testing with loaded filters due to the demand that the biological load might place on the chlorine dioxide. There was a suggestion that the task group put out a request to field certifiers to provide decontaminated loaded filters to be installed for the validation testing. There were also suggestions for loading clean filters artificially prior to conducting the validation tests.

- Jaclyn Bowen will circulate dates/time for a follow-up teleconference in mid-December
- All task group members are encouraged to e-mail Henry Luftman at henryluftman@microeln.com with any specific suggestions for the validation protocol
- Henry Luftman will be in contact with the Halide group to incorporate suggestions and additional specificity into the proposed validation testing.
Chlorine Dioxide Task Group  
December 15, 2005

Attendance

Jaclyn Bowen- NSF International  
Mel First- Harvard School of Public Health  
Richard Gilpin- R. Gilpin, Limited  
Peter Harris – B & V Testing  
Peter Hobbs – Halide Group  
Henry Luftman- Micro Clean  
Bill Peters- Nuaire, Inc  
Jim Wagner- Controlled Environment Consulting  
Steve Williams-CHAIR- NSF International

Jaclyn Bowen called the meeting to order, took roll call, and read the anti-trust statement.

Steve Williams started the meeting by reviewing the action items. Henry Luftman stated that he had spoken with the Halide Group and Bill Peters at Nuaire to incorporate the suggestions made during the last meeting. Henry Luftman reviewed the modified protocol. The proposed protocol is attached.

The first topic of discussion was Henry’s proposal for running three replicate tests on each cabinet. Mel First indicated that he did not think it was necessary to have 3 replicates. If you get a 5.5 log kill with 2 replicates, why do a third? Henry Luftman replied that it would be a total of 24 runs; 8 cabinets and three replicates. Because the testing would be completed in rapid succession, results of the first two tests would not be available until all three replicates had been completed. Mel First asked what would happen if the third was out of spec? Henry Luftman replied that he didn’t know but assumed it would result in a testing failure. Mel First suggested 2 replicates in an effort to reduce workload. Henry Luftman stated that he could do testing on A1s at his own facility and this would reduce the burden of having to do additional cabinets at manufacturer locations. Henry offered his facility for testing the same A1 cabinets to the Halide Group as well. Henry Luftman next asked how a HEPA filter would be determined loaded. The task group was comfortable assuming that if a filter had to be replaced, it was loaded. The group was also comfortable that the filters in the A1 cabinets at Micro Clean were sufficiently loaded since those cabinets have been in operation for many years. Steve Williams asked if decontamination residue on a decontaminated filter could have an impact on this testing. Henry Luftman replied that he had not seen any impact from this in previous tests and that the residue evaporates quickly off the decontaminated filter so it would not be present in a significant quantity by the time a filter was packaged and sent in for testing. The rest of the group agreed with this.

Next, Henry Luftman reviewed the changes he made to the biological indicators section. In the last meeting summary, some suggestions may not have been incorporated. The task group agreed with the proposed revisions but wanted test strips at opposite corners of the downflow filter as well as the exhaust filter.

Henry Luftman explained that he had incorporated the task groups suggestion to move away from his table and instead base the quantity of chlorine dioxide used on the volume of the cabinet. He plans to test at 0.1 g/cu ft. Peter Hobbs noted that the Halide Group also plan to lower their target concentration for the validation studies. Mel First suggested that the units should not be combined metric/English units (g/cu ft). Other group members explained that this was the industry standard so Henry agreed to include both g/cu ft. and g/L or g/cu meter.

Henry Luftman explained that this method now had a safety factor built in. This was done by reducing the chlorine dioxide concentration and exposure time from the recommended levels in this validation protocol. For the validation, the group agreed a safety measure should be incorporated and suggested the safety factor should be published with the results of validation testing.

The task group discussed pass/fail criteria. They settled on a minimum of a 5.5-log kill on every strip and a minimum average kill for all strips in each replicate of 5.8-log.

The next meeting will be mid-late January. Henry Luftman will perform preliminary testing and send us preliminary results to make sure the documented protocol and pass/fail criteria are appropriate.

- Jaclyn Bowen will circulate dates/time for a follow-up teleconference in mid-January
- All task group members are encouraged to e-mail Henry Luftman at henryluftman@microcln.com with any last minute specific suggestions for the validation protocol
- Henry Luftman will be in contact with the Halide group to incorporate suggestions and additional specificity into the proposed validation testing.
- Henry Luftman will research potential testing facilities
- Henry Luftman will perform preliminary testing and send us preliminary results to make sure the documented protocol and pass/fail criteria are appropriate.
1. Cabinet preparation
   a. This study shall include at least two different makes each of Class II Type A1, A2, B1 and B2
      biological safety cabinets. Each cabinet shall be decontaminated by the following procedures a
      minimum of three times.
   b. HEPA filters within the tested cabinets will have been previously “loaded” to [what extent?]
   c. Place a minimum of six unwrapped biological indicators (Geobacillus stearothermophilus spore strips, 10^6
      spores) within the biological safety cabinet (BSC). Locations include where possible:
      i. Between pleats within the upstream side of the exhaust HEPA filter near the center and at
         two opposite corners of the filter
      ii. Within the positive pressure plenum.
      iii. Beneath the cabinet workspace.
      iv. Between the pleats near the center of the supply HEPA filter.
   d. Place the chlorine dioxide generator within the BSC, or attach the external chlorine dioxide gas (CD)
      generator delivery system to the BSC in a manner that CD shall be delivered at the effective concentration
      to all potentially contaminated zones within the BSC. For an external generator, the inlet and outlet
      tubes/hoses to the BSC, will preferably be connected to or beneath the workspace and the generator
      system/BSC will be equipped with a means of recirculation to ensure adequate distribution of CD including
      above the exhaust filter
   e. Provide a means, either within or external to the BSC, by which the air within the BSC may be humidified
      and the humidity monitored and maintained above a level of 60% RH throughout the decontamination
      process.
   f. Seal the BSC at the opening to the workspace and at or above the exhaust port. Verify the adequacy of the
      seal.
2. Decontamination procedure
   a. If the humidity within the BSC is less than 60% RH, raise the humidity within the BSC to at least 60% RH. A
      target range of 60-75% RH is desired.
   b. Initiate introduction of CD gas. If at any time during the decontamination process CD is detected in the
      environment exterior to the BSC by instrument or odor at a concentration approaching 0.3ppm, stop
      generation of CD and do not resume until the leak source(s) has been corrected and it is safe to do so.
   c. When CD is to be introduced as a fixed mass for the purpose of the validation study, it will be used
      at no more than 0.1 gram per cubic foot of cabinet volume for an 80-minute exposure.
   d. If CD is to be introduced such that its gas concentration will be directly controlled and maintained
      during the decontamination, raise the CD concentration within the BSC to the target level as per the
      following table:

<table>
<thead>
<tr>
<th>Minimum Exposure Time</th>
<th>60 minutes</th>
<th>80 minutes</th>
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<tbody>
<tr>
<td>Minimum CD Concentration</td>
<td>2000 ppm</td>
<td>1170 ppm</td>
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</tbody>
</table>

   e. The exposure time will be deemed to have commenced when both:
      i. The RH throughout the BSC attains at least 60% and
      ii. If CD is to be introduced as a fixed mass, as soon as the CD has been introduced into the
          system, or
      iii. If CD is to be introduced such that its gas concentration will be directly controlled and
           maintained during the decontamination, when the concentration of CD throughout the BSC
           attains an initial target level of 1170 ppm for an exposure time of 80 minutes or an initial target level
           of 2000 ppm for an exposure time of 60 minutes.
   f. In order to ensure a uniform concentration of CD throughout the BSC it may be advantageous to
      periodically operate the BSC’s internal blower (bump the BSC).
   g. Monitor the RH and the concentration of CD gas at regular intervals during the decontamination process;
      automatic continuous monitoring may be employed.
   h. When the uninterrupted exposure time attains 60 minutes where the target level concentration of CD was at
      or above 2000ppm, or when the uninterrupted exposure time attains 90 minutes where the target level
      concentration of CD was at or above 1600ppm, cease decontamination and initiate scrubbing/venting.
3. Scrubbing /venting
   a. Initiate scrubbing of CD gas. Scrubbing may be done within the BSC, or air may be withdrawn from the BSC
      and scrubbed in an exterior unit. If scrubbed outside of the BSC, the scrubbed air may be returned to the
      BSC to maintain pressure balance.
   b. In order to ensure a full removal of CD from throughout the BSC it may be advantageous to periodically
      operate the BSC’s internal blower, a blower supplied with the scrubber, or both.
   c. When the concentration of CD throughout the BSC is below NIOSH STEL 0.3ppm, and preferably below 0.1
      ppm, the BSC may be unsealed and vented.
4. Analysis
   a. Collect biological indicators
   b. Have log enumeration or go/ no-go analysis (3-7 days) performed for surviving spores on strips, with the
      use of positive controls.
Chlorine Dioxide Task Group  
January 23, 2006

**Attendance**

Jaclyn Bowen- NSF International  
Henry Luftman- Micro Clean  
Robin Bechanko- NSF International  
Maren Rousch- NSF International  
Cheryl Bunagen- NSF International  
Dave Lupo- B & V Testing  
Paul Lorcheim- ClorDiSys Systems, Inc.  
Dave Phillips- ENV Services  
Bill Peters- Nuaire, Inc  
Richard Gilpin- R. Gilpin, Limited  
Jim Wagner- Controlled Environment Consulting  
Peter Harris – B & V Testing  
Steve Williams-CHAIR- NSF International

Jaclyn Bowen called the meeting to order, took roll call, and read the anti-trust statement.

Steve Williams stated that the purpose of this call was to review the preliminary results. Henry Luftman updated the group on how the preliminary testing was progressing.

During the last teleconference, Mel First asked Henry to incorporate the concentration in mg/m³. This concentration is 3.6g/m³. This has been updated in the original draft protocol. Since the last call, Henry Luftman had not received return correspondence from the Halide Group. He has been working on the validation procedure with A1’s. He followed the protocol as stated. The good news is that in the first run, the worst strip (Geobacillus stearothermophilus) had a 5.63 log reduction with an average reduction of better than a 6-log on the 8 BI strips. This exceeds the original pass/fail criteria that were proposed. The results for the next two runs were even cleaner. The bad news is that in an effort to follow due diligence, Henry also was testing this validation method at a lower concentration to show reduced kill. With a concentration of .04g/ft³ and an exposure time of 10 minutes, the worst case showed complete kill. The question is how valid are any of the results given that an unanticipated total kill is observed with such a low concentration and short exposure time?

Henry Luftman questioned several other researchers about what could have caused this complete kill result. Henry got responses suggesting that how the strips are prepared, stored, and analyzed can have a significant impact on the results. The focus of his research seems to be the possibility that refrigeration of the strips prior to use could have caused the spores to go vegetative, which would weaken them for the chlorine dioxide. Jaclyn Bowen questioned if BIs have shelf life or a percent error. Henry Luftman responded that they did, however they were within these parameters. Henry also explained that he has begun to use Bacillus atophaeus biological indicators, as these may ultimately prove to yield less variability than the G. stearothermophilus indicators.

Henry Luftman stated that he would try and get a better understanding of what happened with the biological Indicators and will follow up with Jaclyn once he gets results he is 100% comfortable with. At that time, Jaclyn Bowen can circulate dates/time for a follow-up teleconference with the group.

The task group thanked Henry Luftman for his persistence and diligence.
Information Paper

NOTE: Information Papers can include: Task Group updates, news of events or activities related to the field of interest of the Joint Committee. Time permitting, these papers will be reviewed at the Joint Committee meeting. They must be received at least 21 days prior to the meeting to ensure inclusion in the agenda and distribution.

Submit to:

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Ann Arbor, Michigan 48105

Fax: 734-827-6831
e-mail: standards@nsf.org

Contact information:

Name: Henry Luftman, PhD

Company: Micro-Clean, Inc.

Mailing Address: 177 N.Commerce Way
City: Bethlehem State: PA Zip Code: 18017

Telephone Number: 800-523-9852 x223 E-mail: henryluftman@microcln.com

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Signature Henry S. Luftman Date December 3, 2007

*Type written name will suffice as signature
Subject:
(If the topic concerns a Task Group's activity or status, please identify the Task Group and the relevant NSF Standard. If the report involves an issue to be balloted or for which a decision of the Committee is need, an Issue Paper should be completed.)
Chlorine Dioxide Task Group, NSF/ANSI 49, Annex G

Brief statement of information provided:

A protocol has been developed for the validation studies that will permit the use of **chlorine dioxide gas (CD gas)** as an acceptable process for the decontamination of Biological Safety Cabinets as an alternative to the use of formaldehyde gas. As long as the NSF proscribed method would be used, there would not be the requirement for further validation work, as is currently the case with formaldehyde. In essence, two methods of delivering CD gas will be validated. Each study will involve testing the process three times in each of 4 cabinets (A1, A2, B1 and B2). 12 biological indicators will be in place for each trial, many of them located within the cabinet HEPA filters. Studies have been performed pre-validating the process as well as in determining the appropriate usage of biological indicators for this study. The final validation trials are planned to commence in January 2008.

Signature: _Henry S. Luftman_  Date _December 3, 2007_
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Joint Committee Issue Document

NOTE: An issue document may be submitted at any time – it comprises two parts: the cover sheet (this page) and a description of the issue to be submitted to the Joint Committee (following page). A separate issue form is required for each issue submitted. Issue papers include proposals for modification of a standard, information reports and (of current research, etc.). An issue paper shall be categorized as being for ACTION or for INFORMATION. Submitters should limit the Issue Paper to 1 or 2 pages – attachments detailing full recommendations or background information may be attached with supplementary information. The Chairperson of the appropriate Joint Committee will respond within 30 days of receipt of the issue document advising what steps will be taken. Any issue document intended for discussion at a Joint Committee meeting must be received at least 21 days prior to the meeting to ensure inclusion in the agenda.

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Signature of Submitter * ________________________________ Date ________________
David S. Phillips
7/7/2005

*Type written name will suffice as signature

Issue document.doc
Please insert a check (X) in the appropriate place to indicate if you wish the item to be considered as an action item or as an information item.

Action _______X________ Information _____________________

NSF Standard(s) Impacted: NSF/ANSI 49

Issue Statement:
Provide a concise statement of the issue, which reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

Section 5 – Design and Construction requires exhaust flow alarms on direct connected Class II, Type B1 and B2 BSCs.

5.23.3 Type B exhaust alarm

Type B cabinets shall be exhausted by a remote fan. Once the cabinet is set or certified in its acceptable airflow range, audible and visual alarms shall be required to indicate a 20% loss of exhaust volume within 15 seconds. The internal cabinet fan(s) shall be interlocked to shut off at the same time the alarms are activated.

The same section recommends but does not require exhaust flow alarms on canopy connected Class II, Type A1 and A2 BSCs.

5.23.4 Type A1 or A2 exhaust alarm (informative)

Type A1 or A2 cabinets, when canopy connected and exhausted by a remote fan, should have an audible and visual alarm to indicate a loss of exhaust airflow.

Section 7 of Annex F addressing the Site Installation Tests done as a part of field certification requires the field certifier to verify the performance of any exhaust alarm.

F.7.3.1.1 Airflow alarms (excluding building automation systems)

a) Whenever an alarm is present to monitor the performance of airflow, it must be performance verified. The alarms shall be performance verified at every certification.

b) Follow the procedures outlined in the owner’s manual. Once the cabinet is set or certified in its acceptable airflow range, audible and visual alarms shall be required to indicate a 20% loss of exhaust volume within 15 seconds.

Any Class II, Type B1 or B2 BSC lacking a functioning exhaust alarm has been considered as failing the Site Installation Test and failing certification. This interpretation and application is consistent with the intent of the Joint Committee to assure the reliable performance of a ducted BSC.

Some BSC users have argued that the absence of an exhaust alarm on a direct connected Class II, Type A1 or A2 BSC is not specifically forbidden in NSF/ANSI 49 and does not cause the BSC to fail certification.
Background:
Provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc, and any other reason why the issue should be considered by the Committee.

A directed connected Class II, Type A1 or A2 BSC is as dependent on proper exhaust flow for the personal protection as a direct connected Class II, Type B1 or B2 BSC. The direct connected Type A BSCs need the same exhaust protection as direct connected Type B BSCs.

By allowing this loophole in the standard, direct connected Type A BSC users are being denied a level of protection that is widely recognized and feasible and useful.

Recommendation:
If action by the Joint Committee is being requested, clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of strike-out and additions by highlighting or underlining; e.g., reference of the issue to a Task Force for detailed consideration; etc. If recommended text changes are more than a half page, please attach a separate document.

I recommend Section 5.23.3 be modified as shown below to include the not recommended but allowed instance of direct connected Type A BSCs.

5.23.3 Type B and direct connected Type A exhaust alarms

Type B and direct connected Type A cabinets shall be exhausted by a remote fan. Once the cabinet is set or certified in its acceptable airflow range, audible and visual alarms shall be required to indicate a 20% loss of exhaust volume within 15 seconds. The internal cabinet fan(s) shall be interlocked to shut off at the same time the alarms are activated.

Supplementary Materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

Submitter _____David S. Phillips___________ Date __7/7/2005_____
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Class II (laminar flow) biosafety cabinetry

5.23 Alarms

5.23.1 Sliding sash alarm

Sliding sash enclosures shall include an audible and visual alarm, activated when the sash is raised above the manufacturer’s specified opening height.

5.23.2 Internal cabinet supply/exhaust fan interlock alarm

When a cabinet contains both an internal downflow and exhaust fan, they shall be interlocked so that the downflow fan shuts off whenever the exhaust fan fails. An audible and visual alarm shall signal the failure. If the downflow fan fails, the exhaust fan shall continue to operate, and an audible and visual alarm shall signal the failure.

5.23.3 Type B and direct connected Type A exhaust alarm

Type B cabinets and direct connected Type A shall be exhausted by a remote fan. Once the cabinet is set or certified in its acceptable airflow range, audible and visual alarms shall be required to indicate a 20% loss of exhaust volume within 15 seconds. The internal cabinet fan(s) shall be interlocked to shut off at the same time the alarms are activated.

5.23.4 Type A1 or A2 exhaust alarm (informative)

Type A1 or A2 cabinets, when canopy connected and exhausted by a remote fan, should have an audible and visual alarm to indicate a loss of exhaust airflow.

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MEMORANDUM

TO: Joint Committee on Biosafety Cabinetry

FROM: Robert W. Powitz Chairperson of Biosafety Cabinetry Joint Committee

DATE: June 5, 2006

SUBJECT: Proposed revision to NSF/ANSI 49 (49i10r1)

Enclosed is the ballot for Draft 1 of NSF/ANSI 49 issue 10. Please review the proposal and return your ballot by the ballot due date of June 26, 2006 via the e-balloting system or by e-mail to Ms. Pippa Durbin at durbin@nsf.org.

Purpose
To incorporate language into Section 5, Design and Construction, to require exhaust alarms for direct connected Type A Biosafety Cabinetry.

Background
A directed connected Class II, Type A1 or A2 Biosafety Cabinet is as dependent on proper exhaust flow for the personal protection as a direct connected Class II, Type B1 or B2. Therefore, the direct connected Type A Biosafety Cabinets need the same exhaust protection as direct connected Type B Biosafety Cabinets.

Some Biosafety Cabinetry users have argued that the absence of an exhaust alarm on a direct connected Class II, Type A1 or A2 is not specifically forbidden in NSF/ANSI 49 and therefore cabinets without alarms meet the requirements of Standard 49.

The proposed language clarifies that direct connected Type A Biosafety Cabinetry must have an exhaust alarm.

Public Health Impact
As currently written, direct connected Type A Biosafety Cabinet users are being denied a level of protection that is widely recognized, feasible and useful. The proposed language will ensure this protection.

If you have any questions about the technical content of the ballot, you may contact me in care of:
Chairperson of Biosafety Cabinetry Joint Committee
Sarah Kozanecki
Standards Specialist, Standards
NSF International
Tel: (734) 827-6867
Fax: (734) 827-3886
E-mail at kozanecki@nsf.org
This proposal has two fatal flaws: (1) An A1 cabinet must never be hard ducted, hence the use of a canopy when it is desired to vent directly to the atmosphere. (2) When the decision was made to eliminate the B3 cabinet designation it was also agreed that when such a B3 cabinet was hard ducted and equipped with an exhaust fan it became a B1 cabinet and was subject to all requirements of that class. In my opinion the cited changes are unnecessary, misguided, and contain incorrect and dangerous instructions.

Name: Richard Gilpin
Comments: It was the intention of renaming the A cabinets that it was clear that they were NEVER to be hard connected. Therefore, I vote no for the proposal since it delineates the primary intention for A1 and A2 cabinets to either be canopy connected or recirculated.

Name: Jim Hunter
Comments: I assume ‘direct connected’ refers to a ‘hard’ connection as opposed to a ‘canopy’ connection. If so, I am concerned that referencing a direct connection associated with an ‘A’ cabinet gives credibility to a method that we clearly went out of our way to make a thing of the past. ‘A’ style cabinets should not be hard connected. As the standard is currently written, an ‘A’ cabinet used with non-particulate hazards must have the same alarm as a ‘B1’ or ‘B2’ cabinet (5.23.4 & E.1.2.1). In the informative section on venting (Annex E) it was decided that an alarm was not considered necessary for canopy connected hoods with non volatile hazards because the canopy protects the user from an exhaust failure and the HEPA filters out particulate hazards. At least 3 places in the document state that an A cabinet should not be direct connected to an exhaust system, page 5, E1, and E2.

Name: Steve Williams
Comments: "The basic crux of my argument is that type A cabinets should never be hard ducted. If they need the exhaust vented outside, they should be connected to a canopy connection that allows the cabinet to function normally, especially in the event of an exhaust failure. This is something that the JC apparently settled in 2002. I agree that if someone is going to go against the Standard and hard duct a type A cabinet, having an exhaust alarm would be better than not having one. However, I wonder if we want to have the Standard say "don't do this ...but if you do, install an alarm".

Name: Melvin First
Comments: This proposal has two fatal flaws: (1) An A1 cabinet must never be hard ducted, hence the use of a canopy when it is desired to vent directly to the atmosphere. (2) When the decision was made to eliminate the B3 cabinet designation it was also agreed that when such a B3 cabinet was hard ducted and equipped with an exhaust fan it became a B1 cabinet and was subject to all requirements of that class. In my opinion the cited changes are unnecessary, misguided, and contain incorrect and dangerous instructions.

Name: Richard Gilpin
Comments: It was the intention of renaming the A cabinets that it was clear that they were NEVER to be hard connected. Therefore, I vote no for the proposal since it delineates the primary intention for A1 and A2 cabinets to either be canopy connected or recirculated.

Name: Jim Hunter
Comments: I was under the impression that ANSI/NSF 2002 redefined Type A cabinets such that they were only to be connected to an exhaust system by a canopy. The logic as I recall it was that the blower(s) of an A1 or A2 force the BSC's exhaust air out of the cabinet. Connecting it to a sealed connection with a remote blower will create a 'push-pull' exhaust system, that experience has shown will not work satisfactorily. Are we now to allow sealed A2 exhaust connections to exist, when the Joint Committee agreed 4 years ago not to allow this type of connection?

Name: Jim Wagner
Comments: "The basic crux of my argument is that type A cabinets should never be hard ducted. If they need the exhaust vented outside, they should be connected to a canopy connection that allows the cabinet to function normally, especially in the event of an exhaust failure. This is something that the JC apparently settled in 2002. I agree that if someone is going to go against the Standard and hard duct a type A cabinet, having an exhaust alarm would be better than not having one. However, I wonder if we want to have the Standard say "don't do this ...but if you do, install an alarm".

Changed vote and comments 07-28-06. SW/pd
Sarah Kozanecki took roll call and read the antitrust statement. David Phillips called the meeting to order.

Prior to the call, the recommendations from the previous conference call were circulated to get feedback from the task group (there was not a quorum on the previous call). Comments were received from Melvin First, and circulated. David Phillips asked Dr. First to expand on his comments regarding recommendations versus requirements. Dr. First stated that it is his belief that the prohibition of certain practices is not something that can be implied in the standard, and it would be better to make recommendations for good practices. He stressed that it the government or regulatory agency’s job to enforce that. He stated that he agrees conceptually with prohibiting direct connected type-A cabinets, but again, that the standard should not enforce that. However, it was clarified that hard ducted type-A cabinets are not recognized by NSF/ANSI 49, and thus cannot be certified.

Rick Gastner stated that he was excited by the language proposed and sees it as an answer to what certifiers have been looking for – namely, removal of the ambiguity.

Two issues were presented, each requiring additional language, stating that:
1) Direct-connected Type-A cabinets are not approved.
2) Roof blowers must have an alarm at the cabinet.

David Phillips reiterated that the inconsistencies need to be addressed in the language, but the original intent should remain.

The group walked through the proposed language, making the following changes:

- Add “control of nuisance fumes” to definition of canopy connection (as one of the listed purposes).
- The sixth paragraph under E.1.2.1 should read: “When a Type A1 or A2 cabinet is found to be directly attached to the exhaust system and vented to the outside without the use of a canopy connection, the exhaust connection must be modified to a canopy connection in order to maintain compliance with Annex F of this standard.”
- F.7.3.3 should read: “Using a visible smoke source, verify negative pressure at the gap. No smoke shall escape into the room once it enters the exhaust system. Direct connected Type A1 or A2 BSCs shall not be considered in compliance with this standard.”
- Reword any part that uses the term “prohibited” and replace with language stating that the requirements shall be met “in order to maintain compliance.”

The group discussed the issue of gap minimum, and conceded that there need not be size criteria as long as the performance criteria are met.

Dave Phillips agreed to revise the language and recirculate it to the group for approval before it is sent to ballot. Other issues that the group will discuss in the future include alarms, performance testing, and canopy connections.