Task Group on Design and Construction Requirements
Teleconference Meeting Summary
July 31, 2023

Participating Members:
Steve Williams (NSF)
Bill Sage (NSF)
Alex Atmadi (ESCO)
Dave Phillips (Thermo Fisher Scientific)
Richard Gilpin (Dr. Richard W Gilpin LLC)
Jim Hunter (Emeritus)

Absent Members:

Participating observers:
Al Rose (NSF)

Supplemental Materials Referenced
1) Agenda - Design and Construction Requirements - TG - 2022-09-26.pdf
2) BSC-2022-03 - Design and Construction Requirements.pdf
3) BSC JC Meeting Summary - 2022-06-16 - Design and Construction Requirements Excerpt.pdf

Discussion
S.Williams is the TG Chair, welcomed everyone and called the meeting to order. A.Rose read the anti-trust statement and took attendance. Five of the 5 voting members were present (100%) representing a quorum. S.Williams presented the agenda indicating the single item was presented during the 2022 JC teleconference in June. At that time this TG was motioned into existence and this is the first meeting to discuss this topic.

Steve recapped the intent of the IP, and the results of the first meeting last September. Rewrite where necessary, remove unessary, add

Left off

This is where we left off during the September 26, 2022 teleconference

5.11 Welds

Welds shall meet the smoothness requirements of the applicable surface.

Group began going through

5.11 Welds

Welds shall meet the smoothness requirements of the applicable surface.

Alex that seems very generic. Steve indicated these welds are part of the overall section.
Alex so if it's not smooth is it non in compliance? Steve yes

Sage – does this include welds in section 4.

4.5.4 Welding

Welded seams and deposited weld material shall meet the applicable requirements of Sections 4.1, 4.2, 4.3, and 4.4.

Steve – last time we focused mostly on section 5.
Sage – in the other subsections we updated the titles to be more descriptive, maybe we should do that.

Steve – good point. Would it be better from a time standpoint for someone outside this meeting to go through and update the titles?

Action Item
Bill and steve to make cross-refernce here and title changes
Al to send working doc to sage and Williams after this meeting to sort this out

5.12 Solder

Solder shall only be used to seal structurally sound seams or as a fillet material (see Section 5.7.1.3).

Steve – I'm not certain how much solder is used.
Aaron – this is usually with copper but with wiring. Alex – not used for structural elements.
Steve – agreed; I don't like the lanague here either because how can we just look at the seam to determine sound structure.
Sage – not sure this is the same as the other subsection

5.7.1.3 Fillet material

Parent material or hard solder may be used as fillet material in structurally sound seams.

Steve – it seems we only need this in one section.
Aaron – is either of these sections even necessary?

Dave – are all these part of a larger question we should be asked.

Group agreed this language is very old, copied over from a long since obsolete source and question whether the language is necessary.

Dave – what we're trying to say is what should be structurally sound, and then say how to do that.
Dave – we are ok with the use of silicone for sealing, but not structure.

Steve –

Dave – "the containment structure needs to be structurally sound and not require the use of materials to carry a load"

Some discussion about fastening metal parts, with a limit on using silicone with the group agreeing there was some language somewhere about this. Found it under 5.23:

5.23

— the structural strength of joints or assemblies where sealant bonding has been applied shall be independent of the sealants.

Sage – if we go down the path of 'sealant' we'll need to create a definition.

Dave – it seems that our concern here is time based knowing that sealants over a long life would be questionable.

So maybe this is about using a sealant as a sealant only and not an adhesive.

Steve – to me it's more about how this is used, rather than what is used.
Very well used silicone might actually be better than very poorly used epoxy.

Dave – what do we want to add here that's not already here?

Aaron – based on failed results for BSC sent in for pressure decay, we know that the majority of that is the shipping that takes place. I'm against changing 5.23, but removing the old technology in 5.12 makes sense. Steve – outside electrical I've never seen solder. Dave – if we've arguing over this minutia, what's wrong with leaving

5.7.13

Group agreed

Next section
Steve presented the next section

5.13 Removable panels

All maintenance panels to access the blower / motor assemblies and filters shall be front access.
Panels shall remain in place when sealing fasteners are removed. All cabinets shall be provided with a blower access panel. Cabinets fabricated without an access panel large enough to allow removal of the blower motor assembly as one piece shall be prohibited. The design and construction of removable panels shall minimize projections and openings. Removable panels for access into contaminated areas shall be designed so that upon reassembly, a seal is provided as required in Section 6.2.

Dave – seems silly that we need to cover for people whom don't realize that once fastners are removed that the fittings are no longer fastened. Steve – but the ledge is nice back up.

Steve – also upon reassembly these are valuable.

Aaron – it seems that there are very different types of panels here. Maintenance versus access perhaps. When dealing with plumbing for intances there really shouldn't be any real maintence.

Dave – this section seems to consider 2 panels: motor blowers and 'other'

Steve – the last sentence doesn't seem separate necessarily or to other types of panels.

Side note – this is related to the issue paper that sage just presented and we have yet to discuss.
In the end removing the panel when using silicone is very difficult and destructive and language added here would be beneficial. Dave – if the metal is so thin that it bends when removed, that's the problem not the silicone.

Some detailed discussion concerning the use of silicone on panels.

Dave – if we go back to the gasket section, maybe this should be there.

4.5.5 Gaskets and sealants

Gaskets and sealants shall be closed cell, durable, resistant to cleaning and disinfecting agents, and resistant to general use. They shall be made of materials that do not release halogens and are nonhardening, nontoxic, stable, odor free, not detrimentally absorbent, and unaffected by exposure to gases, liquids, cleaning compounds, and decontamination agents listed in Section 4.5.2.

Exposed surfaces of gaskets for all access panels, doors, structural seams, and sashes / windows shall be skinned and smooth. Gaskets supplied with HEPA/ULPA filters shall be exempt from this requirement.

In the end maybe we need a definition for gasket and sealant

5.23 Gaskets and sealants

Exposed surfaces of gaskets shall be easily cleanable and shall not contain internal angles (angles less than 2.4 rad [135°]). All corner joints and hollow sections of gaskets shall be sealed:

— fixed gaskets shall be securely fastened and sealed in place;

— HEPA/ULPA filter seals shall be leakproof when tested in accordance with Section N-1.3. Gaskets on HEPA/ULPA filters shall have interlocking corners or sealed joints;

— gaskets used in cabinet seams or on the facing of service panels shall have sealed joints. Structural strength of seams and service panel joints shall be independent of the seal produced by the gasket; and

— the structural strength of joints or assemblies where sealant bonding has been applied shall be independent of the sealants.

Dave – how about adding something to the 3rd bullet.

The group spent about 40 minutes discussing the application, removal and reapplication of gaskets and sealants.

Some contention about the use of sealant in the field versus the initial manufacture of a BSC. Group agreed that this language will need to be clearly separated.

Dave – in the end it seems like we can all agree that the problem here is not the use of a bit of sealant on a little part of the gasket versus slathering the entire gasket with sealant.

S.Williams explained his intent of the issue paper specifically that the design and construction requirements in sections 4 and 5 of the standard haven't had much of a look by the JC in many years. Some of the requirements came from NSF food equipment standards when Standard 49 was initially set up. In some cases, they make perfect sense. In others, perhaps not. There are probably new requirements that would be appropriate to add. For example, we have labeling requirements for user modifiable pass-throughs in the definitions section of the standard. Definitions cannot contain requirements so technically they are not requirements and those need to be moved to section 5.

S.Williams opened the floor for discussion by asking the group if working on this subject adds any value; The group agreed there was, and he suggested they first focus mainly on section 5 where there have been certification violations in the past. The group agreed and began the process.

S.Williams began by suggesting there is no point in changing the first sub section; he read off this section and the group agreed:

5 Design and construction

5.1 General

Cabinets shall be designed and constructed to function properly and operate in a safe manner, minimize contamination, provide personnel and product protection, and be capable of being cleaned and decontaminated. Exposed burrs and sharp edges (including, but not limited to, sheet metal screws) shall be eliminated from surfaces of the cabinet that are subject to normal operation, field certification, and maintenance (including those maintained with simple tools).

S.Williams read off the next 2 paragraphs:

5.2 Cleanability

Interior work, exposed interior, and the other interior surfaces subject to splash or spillage shall be readily accessible and easily cleanable as assembled or when removed. Interior work, exposed interior, and other interior surfaces, including plenums, shall be capable of being vapor or gas decontaminated.

5.3 Decontamination

Cabinets shall be designed to be decontaminated with an inactivating agent (such as formaldehyde gas) without being moved. Closure to contain decontaminating agents should be limited to gas-tight sealing of air intake and exhaust openings with metal plates, or plastic film and tape, or equivalent.

Pressure tight valves, if provided, suitable for decontamination shall be located on the clean side of the HEPA/ULPA filter.

S.Williams indicated that “readily accessible” and “easily cleanable” are defined terms and explained that everything in that zone would apply, providing the example of thumb screws in the front panel.

D.Phillips suggested that as this statement reads, one interpretation might include electronics being able to handle decon vapor. S.Williams agreed adding that designing and manufacturing BSCs to withstand decon would not be ideal. J.Hunter suggested the group take the first sentence of 5.2 and copy it to 5.3.

Sage confirmed ‘easily cleanable’ is not actually defined and should be.

The group then had substantial discussion about work surface cleanability and decontamination. This led to discourse about what the second section of 5.3 means:

Pressure tight valves, if provided, suitable for decontamination shall be located on the clean side of the HEPA/ULPA filter.

The group decided given the ambiguity, that subsection should simply be removed.

In the end these 2 sections were updated to:

5.2 Surface Decontamination ~~Cleanability~~

Interior work, exposed interior, and the other interior surfaces subject to splash or spillage shall be readily accessible and easily cleanable as assembled or when removed. ~~Interior work, exposed interior, and other interior surfaces, including plenums, shall be capable of being vapor or gas decontaminated.~~

5.3 Gas / Vapor Decontamination

Interior work, exposed interior, and other interior surfaces, including plenums, shall be capable of being vapor or gas decontaminated. ~~Cabinets shall be designed to be decontaminated~~ with an inactivating agent (such as formaldehyde gas) without being moved. Closure to contain decontaminating agents should be limited to gas-tight sealing of air intake and exhaust openings with metal plates, or plastic film and tape, or equivalent.

~~Pressure tight valves, if provided, suitable for decontamination shall be located on the clean side of the HEPA/ULPA filter.~~

The group next discussed section 5.4

5.4 Canopy exhaust connection

If Type A1, A2, and C1 cabinets are connected to an exhaust system, it shall only be done so via a canopy connection; direct connections are not acceptable. They are exhausted with the assistance of a remote fan to the atmosphere. In normal operation, the volume of room air drawn into the canopy connection's openings or gaps shall be sufficient to ensure the capture of all of the BSC's HEPA filtered exhaust, as verified by a visible medium. The flow of room air into the canopy connection through openings, or gaps, or both, provides assurance of consistent BSC performance during fluctuations in exhaust system flow rate, or room pressure, or both.

Detailed discussion about what this section means in practice and the group agreed that some of this section may ultimately go to either annex I-1 and/or definitions.

The group then discussed the second part of 5.4 which includes the bulleted subsections:

For Types A1, A2, and C1 with a canopy connection, during an exhaust system failure:

— the canopy shall provide properly sized openings or gaps to allow for recirculation of HEPA filtered exhaust into the room;

— the BSC shall maintain an inflow velocity above the lowest value verified by the NSF/ANSI 49 biological challenge testing; and

Alternatively, the Type C1 canopy can direct the HEPA filtered exhaust into the exhaust duct during an exhaust system failure provided:

— the BSC shall maintain an inflow velocity above the lowest value verified by the NSF/ANSI 49 biological challenge testing, if the unit is programmed to operate longer than 15 seconds after an exhaust system failure.

It was suggested that this language already appears in normative annex 1 and it might be good to discuss removal here. D.Phillips indicated it should stay here even though it may be redundant, because it may be helpful to people less familiar with the standard as a whole. Sage suggested this might be a good use of an informative NOTE and after discussion it was decided the only change needed in Section 5.4 was the addition of the following NOTE:

Note: for further details see section N-1.14

S.Williams read off the next 2 sections and the group quickly agreed no revisions were needed:

5.5 Direct exhaust connection

The external exhaust shall draw air sufficient to capture all exhaust from the BSC and maintain a negative pressurization in the exhaust duct. The direct connection type of BSC exhaust connection is required for Class II, Type B1 or B2 BSCs.

5.6 Duct and plenum design

All biologically contaminated ducts and plenums in Types A1, A2, B1, and B2 cabinets shall be maintained under negative pressure or enclosed within a negative pressure zone.

S.Williams then presented the next section 5.7:

5.7 Internal corners and angles

5.7.1 Interior work surfaces

5.7.1.1 Two-plane intersection

An internal angle of 2 rad (110°) or less formed by the intersection of two planes, which is subject to manual cleaning, shall have a minimum continuous and smooth radius of 0.13 inch (3.2 mm) (see Figure 2).

5.7.1.2 Three-plane intersection

An internal corner formed by the intersection of three planes at 2 rad (110°) or less, subject to manual cleaning, shall have a minimum continuous and smooth radius of 0.25 inch (6.4 mm) for a vertical or horizontal intersection. The alternate intersections shall have a minimum continuous and smooth radius of 0.13 inch (3.2 mm) (see Figure 2).

5.7.1.3 Fillet material

Parent material or hard solder may be used as fillet material in structurally sound seams.

He indicated these were directly from Food Equipment standards, and the group agreed they were not aware of any BSC issues like these not meeting the standard.

S.Williams then presented section 5.8 and the group quickly agreed no revisions were needed:

5.8 External corners and angles

All external corners and angles subject to splash, or spillage, or both, shall be sealed as smooth as the surfaces being joined, and formed to eliminate sharp edges that may interfere with use, cleaning, or maintenance (see Figure 3).

The group then spent several minutes discussing the meaning, value and possible ambiguity of the next section regarding Joints and Seams. There was general agreement that since the original writing of Standard 49, the meaning of terms like interior, exterior, and work surface have been updated and the value of this section would be made better by cleaning up and removing much of the language. In the end the following was decided:

5.9 Joints and seams

5.9.1 ~~Interior work and exposed~~ Total work area and drain pan ~~interior~~ surfaces

All joints and seams subject to routine manual cleaning shall be sealed as smooth as the surfaces being joined. Perimeter drain spillage trough joints and seams shall be welded and sealed. All other seams shall be sealed. ~~Equipment parts shall be stamped, extruded, formed, or cast in one piece. Joints shall be fabricated to eliminate dirt-catching horizontal ledges.~~

5.9.2 Other interior and exterior surfaces

All joints and seams subject to routine splash, or spillage, or both, shall be sealed and smooth. All joints and seams subject to exposure to vapor, or toxic volatile substances, or both, and exposed to the outside environment shall be sealed. ~~All other seams shall be closed.~~

5.10 Fastening methods

5.10.1 Exposed fastenings

Exposed ~~screw~~ threads~~, projecting screws, and studs~~ shall not be used on interior work surfaces.
~~They shall only be used on exposed interior and other interior surfaces when other fastening methods are impractical. All metal fasteners and studs subject to maintenance shall not be subject to excessive overspray.~~

~~**5.10.2 Exterior fastenings**~~

~~Fasteners for exterior removable panels that are gasketed and subject to pressure shall be studs with solid acorn nuts, or equivalent, so that the gasket is sealed. Fasteners for other removable panels may be low~~

~~profile-type fasteners (truss, round counter sunk, flat counter sunk head [see Figure 4]), or studs with solid acorn nuts. All metal fasteners and studs subject to maintenance shall not be subject to excessive overspray.~~

5.10.3 Interior fastenings

In areas subject to cleaning, interior fastenings and joinings shall be fabricated to minimize projections, ledges, and recesses. ~~All metal fasteners and studs subject to maintenance shall not be subject to excessive overspray.~~

At this point, with time running out and only about half of the language sorted through, S.Williams volunteered to complete section 5 using the spirit of today's discussion and share this with the Task Group via a straw ballot. Time permitting he would work on section 4 as well and based on the results would work with A.Rose to set up the next TG teleconference. The group agreed with the approach.

S.Williams asked if there were any other comments; there were none and the meeting adjourned.

Action Items:

- **S.Williams to complete language updates for remaining subsections of section 5, and time permitting section 4.**
- **A.Rose to share with this TG via straw ballot.**
- **Set up the next teleconference as needed.**