

Committee Final Reports are considered DRAFT until acknowledged by Council or accepted by the Executive Board

COMMITTEE NAME: Clean In Place (CIP) Committee

DATE OF FINAL REPORT: January 4, 2018

COMMITTEE ASSIGNMENT: Council I Council II Council III Executive Board

REPORT SUBMITTED BY: Sandra Craig, Dale Grinstead

COMMITTEE CHARGE(S):

Issue # 2016-I-010

1. Review applicable American National Standards Institute (ANSI) sanitation standards for clean in place processes with inaccessible food contact surfaces and ascertain their compatibility with Food Code definitions and recommendations;
2. Review current literature on scientific research of clean in place systems to ascertain relative food safety risk associated with improperly cleaned and/ or sanitized systems;
3. A Survey to determine the current prevalence and processes used to evaluate CIP Equipment during inspections;
4. Report back to the 2018 CFP Biennial Meeting with recommendations.

COMMITTEE WORK PLAN AND TIMELINE:

Work plan and milestones are below

1. Committee roster submitted to CFP executive for approval (7/16)
2. Commenced monthly committee calls (8/16)
3. Review of ANSI standards, scientific literature, and conduct survey of processes used to evaluate CIP equipment during inspections completed (5/17)
4. Initial draft report completed (9/17)
5. Final report any appropriate issues for submission to CFP (1/18)

COMMITTEE ACTIVITIES:

1. Dates of committee meetings or conference calls:

- **August 22, 2016 (Full committee)**
- **September 29, 201⁶(Full committee)**
- **November 1, 2016 (Survey Sub-committee)**
- **December 9, 2016(Literature review Sub-committee)**
- **December 9, 2016(Survey Sub-committee)**
- **February 6, 2017(Literature review Sub-committee)**
- **March 9, 2017 (Full Committee)**
- **March 23, 2017 (Literature review Sub-committee)**
- **April 18, 2017 (Survey Sub-committee)**
- **June 27, 2017 (Full Committee)**
- **July 31, 2017 (Full Committee)**

2. Overview of committee activities:

- a. By October 2016 it was clear that the best way to address the charge was to divide into 2 subcommittees, the literature review subcommittee that focused on the charges 1 and 2. The survey subcommittee was focused on charge 3.
- b. Sub-Committee Formation

- b.i. Literature review Subcommittee: The literature review Subcommittee was formed in November 2016 and had several calls to discuss charges 1 and 2 and to discuss the literature and the key findings of the subcommittee. The key findings of the committee were:
- b.i.1. Charge 1: Review applicable ANSI sanitation standards for clean in place processes with inaccessible food contact surfaces and ascertain their compatibility with Food Code definitions and recommendations: The Food Code and ANSI standards are relatedly well aligned with few differences. The differences that the committee noted and recommended solutions are below:
 - b.i.1.a. The term CIP (Food Code 1.201.10(B)) is not used in ANSI standards. The ANSI standards use In Place Cleaning (NSF 170-2015 3.110)
 - b.i.1.a.i. **RECOMMENDATION: the term CIP as defined in the Food Code is more specific and is, in the opinion of the committee, more common usage than “In Place Cleaning”. It is recommended that NSF initiate the consensus process to change “in place cleaning” to “CIP” to match the Food Code (See issue CIP 2-ANSI/Food Code definition and research).**
 - b.i.1.b. The Food Code definition of CIP (1.201.10) specifically excludes “*the cleaning of EQUIPMENT such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.*” The ANSI definition (NSF 170-15 3.110) implies this exclusion but does not explicitly state it.
 - b.i.1.b.i. **RECOMMENDATION: It is recommended that NSF initiate the consensus process to include the same specific exclusion used by the Food Code in the ANSI definition. It is already implied in the ANSI definition so including the exclusion will make the ANSI definition of CIP clear (See issue CIP 2-ANSI/Food Code definition and research).**
 - b.i.1.c. ANSI standard NSF 170-15 Glossary of Food Equipment Terminology states the definition of “Easily Cleanable” in section 3.67 as: Manufactured so that food and other soiling material may be removed by manual cleaning methods. Note that by the ANSI definition, a surface cleaned via CIP CANNOT be “easily cleanable” However the Food Code definition of “easily cleanable” given in section 1.201.10 says, in part: “Easily cleanable” means a characteristic of a surface that: (a) Allows effective removal of soil by normal cleaning methods. The Food Code definition does not preclude surfaces that are cleaned via CIP because it does not specify what is meant by “normal cleaning methods.”
 - b.i.1.c.i. **RECOMMENDATION: The ANSI definition of easily cleanable is narrower than the Food Code’s and therefore more precise. In principle this suggests that the Food Code definition should be altered to better align with the one in the ANSI standards. However, the committee felt that refining the definition of easily cleanable is outside of the charge to this committee.**
 - b.i.2. Charge 2: Review current literature on scientific research of clean in place systems to ascertain relative food safety risk associated with improperly cleaned and/ or sanitized systems:
 - b.i.2.a. The charge is not clear what “relative” risks are to be compared. It may be the risk of clean vs. unclean surfaces that are intended to be CIP. Or it may be the risk of surfaces that are cleaned via CIP vs. those that are manually cleaned. It is also not clear exactly what “risk” is to be compared. Is it the risk of cross contamination, pathogen contamination, biofilm contamination, foodborne illness, or something else? It should be noted that the committee realizes that obtaining foodborne illness risk data is difficult and that while such “clinical endpoint” data is desirable, relative risk levels may need to be determined using “surrogate endpoint” risk such as the risk of contamination or pathogen transfer. This review addresses these possibilities. While there are some data available on CIP systems, the committee could not find much that addressed the specific details of this charge. As a result there are a number of specific research gaps that the committee has identified. Another flaw of much of the literature reviewed is that methods vary from lab to lab and that made it extraordinarily difficult to compare results or evaluate one study against another.
 - b.i.2.b. There was no literature or data found by the committee that addressed the relative risk of an uncleaned surface that is intended to be cleaned via CIP vs. the risk of a surface to be cleaned manually. Literature was found that addressed optimum processes for CIP systems and there is some understanding of the risk of unclean

surfaces in general, but there is no specific data that calls out the relative risk of an uncleaned CIP surface vs. a surface to be cleaned manually. Specific research gaps in this area that the committee believes should be addressed include:

- b.i.2.b.i. **Is the risk of cross contamination from an unclean CIP surface the same or different from a manually cleaned surface?**
- b.i.2.b.ii. **Is the risk of pathogen contamination of an unclean CIP surface the same or different from a manually cleaned surface?**
- b.i.2.b.iii. **Is the risk of acquiring foodborne illness from an unclean CIP surface the same or different from a manually cleaned surface?**
- b.i.2.c. Another question on which there is very little data is relative likelihood that a surface to be cleaned via a CIP process will be inadequately cleaned vs. a manually cleaned surface. The Food Code says in section 4-201.12 (B): CIP EQUIPMENT that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior FOOD-CONTACT SURFACES throughout the fixed system are being effectively cleaned. The Food Code also says in 4-601.11 (A) EQUIPMENT FOOD-CONTACT SURFACES and UTENSILS shall be clean to sight and touch. However the nature of equipment that is cleaned via CIP makes it impossible to access all food contact surfaces to evaluate cleanliness via sight and touch. It is tempting to believe that this difficulty in verifying that a surface cleaned by CIP has been cleaned makes it more likely to be inadequately cleaned however the committee could find no data on that. This is another research area that includes the following specific research gaps:
 - b.i.2.c.i. **Is compliance with cleaning processes and schedules different for CIP surfaces and manually cleaned surfaces?**
 - b.i.2.c.ii. **Is the soil load on a surface cleaned and sanitized via CIP different from a manually cleaned surface?**
 - b.i.2.c.iii. **Is the microbial load on a surface cleaned and sanitized via CIP different from a manually cleaned surface?**
 - b.i.2.c.iv. **If the soil and microbial load or likelihood of being cleaned is different for a CIP surface, does that difference lead to a different risk of foodborne illness or cross contamination?**
- b.i.2.d. The committee did find several papers that discussed biofilm contamination of surfaces cleaned via CIP. Organisms in biofilms are known to be more resistant to sanitizers than planktonic cells or cells that are attached to a surface but not part of a biofilm. Again, however, what the committee could not find is specific data that addresses the relative risk of biofilm contamination of surfaces cleaned via CIP compared to surfaces cleaned manually. Another specific gap is the relative risk of foodborne illness or food contamination resulting from the presence of a biofilm on a surface cleaned by CIP vs. a biofilm found on a manually cleaned surface. These questions lead then to the following specific research gaps:
 - b.i.2.d.i. **Is the likelihood of a biofilm colonizing a food contact surface that is cleaned via CIP different from the likelihood of a biofilm colonizing a surface that is cleaned manually?**
 - b.i.2.d.ii. **Is the risk of foodborne illness or food contamination from a biofilm on a surface that is cleaned via CIP different from the risks resulting from a biofilm on a manually cleaned surface?**
- b.i.2.e. The difficulty in accessing all surfaces in a piece of equipment that is cleaned via CIP in order to assess the cleanliness of the equipment makes validation and verification of CIP system performance important. In ANSI standards NSF 12 and 18 Sections 6.1.2 and 6.1.3 there are recommended procedures for validation of CIP cleaning performance. The method recommended in these standards is a microbiological method that involves contamination of the equipment with a test organism (*Pseudomonas fluorescens* for NSF 12 and *E. coli* for NSF 18), followed by a CIP process, and then filling the equipment with sterile buffer, collection of the buffer and enumeration of the coliforms recovered from the collected buffer. This test does not validate the ability of the CIP process to remove biofilms, organisms other than *E.coli*, or the ability to remove soil. In short, is the procedure recommended in the ANSI standards the correct one to validate cleaning performance of CIP processes? In addition to questions about CIP process validation, there is no data or literature about the best way to verify CIP operation. The validation process proposed in the ANSI standards is not intended to be used by operators or regulators

to routinely test equipment in food establishments. The intent of the test is that it serve as a benchmark to validate the manufacturer's recommended CIP procedures are capable of being effective on new equipment. However this is of no use to an operator who wishes to verify the operation of their CIP system. The committee could find no recommended methods to conduct such verification and that is another research gap. The specific questions that these gaps lead to are:

- b.i.2.e.i. **Is the ANSI recommended procedure to validate cleaning performance of CIP systems adequate?**
 - b.i.2.e.i.1. **Does it predict cleaning performance in use?**
 - b.i.2.e.i.2. **Do the microbiological methods recommended in the ANSI standards predict cleaning performance and microbial removal of soil and organisms present on equipment in use at a food operation and if not, what test method would be able to predict cleaning and microbial removal performance?**
 - b.i.2.e.i.3. **Should the method include biofilms rather than planktonic or attached organisms?**
 - b.i.2.e.i.4. **If the ANSI procedure is not correct, what is the proper validation procedure?**
 - b.i.2.e.ii. **Should operators and regulators verify the cleanliness of surfaces cleaned via CIP?**
 - b.i.2.e.ii.1. **If yes, how?**
 - b.i.2.e.ii.2. **If no, why not?**
- a.i. The third charge was to conduct a Survey to determine the current prevalence and processes used to evaluate CIP Equipment during inspections. The survey subcommittee prepared a survey and circulated it to the membership of CFP, AFDO, FMI, and NRA. The survey included 19 questions. There were 62 respondents to the survey. The questions and the responses for each are presented in the accompanying document: CFP CIP committee survey results. Notable findings from the survey include:
- a.i.1. Even though the definition of CIP is very clear and narrow in the Food Code, it is obvious from this survey that many operators and inspectors do not understand the difference between CIP and In Place Manual Cleaning. The response to question 9 indicated that 25% of respondents were not aware of this distinction as described in the code. This is further evidenced by the response to question 15 where many of the items of equipment that respondents indicated were cleaned via CIP are far more likely to be cleaned in place. Slicers and ice machines are rarely if ever cleaned via CIP.
 - a.i.2. It is curious that in question 1, 45% of respondents indicated that the cleaning frequency for CIP equipment was based on manufacturers recommendations yet many manufacturers only suggest that cleaning occur "as needed." It is possible that respondents were providing answers to some questions that they believed to be correct or appropriate rather than the responses that were actually correct. The response to question 10 in which 90% of respondents indicated that they complied with Food Code requirements for cleaning frequency of food contact surfaces stands in contrast to the responses to question 1 and may indicate that many respondents are not aware that areas of CIP equipment are food contact surfaces.
 - a.i.3. The apparent lack of understanding of the frequency of cleaning evidenced in the responses to question 1 may be why 10% of respondents to question 2 indicated that they cleaned CIP equipment weekly or bi-weekly. And it is likely that a large portion did not know as 23 of the 62 respondents skipped this question. That is an interesting result given that according to question 1, 59 of the respondents know how often the equipment SHOULD be cleaned but apparently a large portion of them do not know how often they are actually cleaned.
 - a.i.4. It is clear from the survey that the standards of cleanliness may not be adequate for CIP equipment. 50% of respondents indicated that were not confident that non-visible portions of CIP equipment had been adequately cleaned. This may be linked to the responses to questions 12-14 which show that 40% of respondents do not evaluate cleaning efficacy of CIP equipment.

3. Charges COMPLETED and the rationale for each specific recommendation:

- a. Review applicable ANSI sanitation standards for clean in place processes with inaccessible food contact surfaces and ascertain their compatibility with Food Code definitions and recommendations. Recommendation: a letter to NSF requesting that NSF initiate the consensus process to change “in place cleaning” to the more commonly used “clean in place” which would also align with the Food Code. And to request that NSF include the same specific exclusionary language used by the Food Code in its definition of Clean In Place into the ANSI definition. (See Issue titled: CIP 2-ANSI/Food Code definition)
- b. Review current literature on scientific research of clean in place systems to ascertain relative food safety risk associated with improperly cleaned and/ or sanitized systems. The literature review determined that peer reviewed data addressing the relative risk was not available therefore the relative food safety risk could not be ascertained..
- c. A Survey to determine the current prevalence and processes used to evaluate CIP Equipment during inspections: The survey was completed and results are summarized above. It is clear from the survey that there is generally poor understanding of CIP, sanitation practices as they are applied to CIP and how to evaluate the effectiveness of sanitation for CIP surfaces. It is the opinion of the committee that the poor understanding of CIP, CIP practices, and how to evaluate their effectiveness that was seen in the survey results cannot be adequately addressed until the data gaps identified by the Literature review subcommittee have been resolved. Therefore it is recommended that the CIP committee be dissolved.(See issues titled: Report-Clean In Place (CIP) Committee.)
- d. Report back to the 2018 CFP Biennial Meeting with recommendations. This report and accompanying issues complete this charge. The committee recommends that the CIP Committee report be acknowledged and the Committee be disbanded and not reformed at this time. (See Issue titled: Report – Clean in Place (CIP) Committee)

4. Charges *INCOMPLETE and to be continued to next biennium: none*

COMMITTEE REQUESTED ACTION FOR EXECUTIVE BOARD:

X No requested Executive Board action at this time; all committee requests and recommendations are included as an Issue submittal.

LISTING OF CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. ***Issue #1: Report - Clean In Place (CIP) Committee***
 - a. **List of content documents submitted with this Issue:**
 - (a.1) ***Committee Final Report (see attached PDF)***
 - (a.2) ***Committee Member Roster (see attached PDF)***
 - (a.3) ***Other content documents: Results of CIP Committee survey.***
 - b. **List of supporting attachments:**
 - (b.1) ***Bibliography of literature reviewed***
2. ***Committee Issue #2:CIP 2- ANSI/Food Code definition.***
 - a. **List of content documents submitted with this Issue: none**
 - b. **List of supporting attachments: X No supporting attachments submitted**