cradle to cradle products innovation institute

Addendum to the Cradle to Cradle Certified Product Standard, Version 4.0 and Version 4.1 User Guidance

Effective Date: 14 November 2024 (with additional clarifications posted on 29 January 2025)

Type of Change: Additions and Changes to the Manufacturing Facility Site Visit requirements in User Guidance Section 13, Appendix 1 – Final Manufacturing Facility Site Visit

Applicable Standard Section(s): All

Applicable Achievement Level(s): Bronze, Silver, Gold, Platinum

Applicable Guidance – 13 // Appendix 1– Manufacturing Facility Site Visit
(NOTE: this is the text as published in the full User Guidance that is currently posted. It is provided here for context. See the next section of this document for the revisions.)

Further Explanation
For all levels of certification, a final manufacturing facility site visit(s) must be conducted to verify that the standard requirements have been met.

Frequency and Type of Site Visit
An on-site (i.e., in person) visit is required:

- Prior to initial certification (for new Cradle to Cradle Certified products) or, for products transitioning from Version 3.1, at the first renewal after the first certification to Version 4.0 or Version 4.1 of the standard.

An on-site or remote site visit is required:

- Prior to all subsequent recertifications, as part of the recertification process.
- If the manufacturing process changes significantly. This includes, but is not limited to, cases where a process step, as defined in Final Manufacturing Stage Process Definitions, is added or removed, a process that was previously dry is altered so that effluent is produced, and/or if there is a major product redesign.

For products certifying to Version 4.1 of the C2C Certified Material Health Certificate Standard, an on-site visit is recommended prior to initial certification, but is not required. Instead, an on-site visit is required at each subsequent recertification, and if the manufacturing process changes significantly, as noted above.

Note: Remote site visits are permitted only in cases where it is possible to verify all required points as listed in the site visit checklist.

Location(s) [...]

Additions and Changes (i.e., Revised User Guidance) —
13 // Appendix 1 – Manufacturing Facility Site Visit

Further Explanation

For all levels of certification, a final manufacturing facility site visit(s) must be conducted to verify that the standard requirements have been met. Required site visits must occur prior to certification and prior to recertification. Site visit(s) must also occur prior to interim assessment reviews if there have been significant process changes. Site visits may be on-site (i.e., in person) or remote as outlined in #1-4 below. Note that examples of events requiring an interim assessment review include product line extensions, change of achievement level, a change in material or product composition, and/or a change in the manufacturing process. Interim Assessment Reviews are further described in the Fee Schedules which are available on C2CPII's website.

1. Requirements Applicable to all Standards
    a. Remote site visits are permitted only in cases where it is possible to verify all required points listed in the Site Visit Checklist.
    b. An on-site visit may be required (including for cases where an on-site visit is not required per #2-4 below) if the application review raises concerns that cannot otherwise be satisfactorily resolved. For example, an on-site visit may be required if significant inconsistencies (i.e., conflicting information) are identified in the submitted evidence for the required documentation for achieving certification.
    c. Exceptions may be made to the on-site (i.e., in person) site visit requirements on a case-by-case basis if there is a significant health and safety risk involved in conducting an on-site visit (e.g., conflict or unrest in the region, pandemics), or if travel restrictions, stay-at-home orders, or lockdowns prevent an on-site visit from being conducted. However, it is then mandatory to undergo an on-site visit verification in the subsequent year.

2. Requirements for the Cradle to Cradle Certified Product Standard (Full Scope standard)
    a. For products not previously certified to Version 3.1 of the Full Scope Standard:
        i. First certification to Version 4.0 or Version 4.1: An on-site visit is required.
        ii. Subsequent recertifications: An on-site or remote visit is required.
    b. For products previously certified to Version 3.1 of the Full Scope Standard:
        i. First certification to Version 4.0 or Version 4.1: A site visit (either on-site or remote) is recommended but is not required. Exception: If the manufacturing process has changed significantly, an on-site or remote visit is required. For the Full Scope standard, this includes, but is not limited to, cases where a process step, as defined in the Final Manufacturing Stage Process Definitions document,

is added or removed, a process that was previously dry is altered so that effluent is produced, and/or if there is a major product redesign.

ii. First recertification (post transition from Version 3.1): A site visit is required. An on-site visit is required if a remote visit was conducted for the first certification to Version 4.0 or Version 4.1. If an on-site visit was conducted at the first certification, a remote visit may be conducted instead.

iii. Subsequent recertifications: An on-site or remote visit is required.

c. For interim assessment reviews:

i. Significant process changes (as defined in point #2.b.i above) have occurred since the most recent certification: An on-site or remote visit is required

ii. Significant process changes (as defined in point #2.b.i above) have not occurred since the most recent certification: A site visit is not required.

3. Requirements for the C2C Certified Material Health Standard

a. For products not previously certified to Version 3.1 of the C2C Certified Material Health Standard or Version 3.1 of the Full Scope standard:

i. First certification to Version 4.0 or Version 4.1: An on-site or remote site visit is required.

ii. First recertification: An on-site visit is required if a remote visit was conducted at the first certification. If an on-site visit was conducted at the first certification, a remote visit may be conducted instead.

iii. Subsequent recertifications: An on-site or remote visit is required.

b. For products previously certified to Version 3.1 of the C2C Certified Material Health Standard or Version 3.1 of the Full Scope standard:

i. First certification to Version 4.0 or Version 4.1: A site visit (either on-site or remote) is recommended but is not required. Exception: If the manufacturing process has changed significantly, an on-site or remote visit is required. This includes, but is not limited to, cases where a process step, as defined in Final Manufacturing Stage Process Definitions, is added or removed, a process that was previously dry is altered so that product-relevant effluent is produced, and/or if there is a major product redesign.

ii. First recertification (post transition from Version 3.1): A site visit is required. An on-site visit is required if a remote visit was conducted at the first certification to Version 4.0 or Version 4.1. If an on-site visit was conducted at the first certification, a remote visit may be conducted instead.

iii. Subsequent recertifications: An on-site or remote visit is required.

c. For interim assessment reviews:

i. Significant process changes (as defined in #3.b.i. above) have occurred since the most recent certification: An on-site or remote visit is required

ii. Significant process changes (as defined in #3.b.i. above) have not occurred since the most recent certification: A site visit is not required.

4. Requirements for the C2C Certified Circularity Standard

Note: Version 4.1 is the first version of C2C Certified Circularity Standard. The following requirements apply in all cases.

a. First certification: An on-site or remote site visit is required.

b. First recertification: An on-site visit is required if a remote visit was conducted at the first certification. If an on-site visit was conducted at the first certification, a remote visit may be conducted instead.
c. Subsequent recertifications: An on-site or remote visit is required.
d. Interim assessment reviews:
    i. Significant process changes have occurred since the most recent certification: An on-site or remote visit is required. Note: For the C2C Certified Circularity Standard, significant process changes include, but are not limited to, cases where there is a major product redesign.
    ii. Significant process changes have not occurred since the most recent certification: A site visit is not required.

Table – Summary of Site Visit Requirements for Certification to Version 4.0 and Version 4.1

Please refer to the text above for additional details.

C2C Certified Standard:	Full Scope	Material Health	Circularity
Requirements for products not previously certified to Version 3.1			
First certification (no previous certificate)	On-site	On-site or remote	On-site or remote
First recertification	On-site or remote	On-site if an on-site was not conducted at the first certification. Otherwise, remote accepted.	On-site if an on-site was not conducted at the first certification. Otherwise, remote accepted.
Subsequent recertifications	On-site or remote	On-site or remote	On-site or remote
Requirements for products previously certified to Version 3.1			
First certification to Version 4.0 or Version 4.1	- Significant process changes: On-site or remote - No significant process changes: Not required	- Significant process changes: On-site or remote - No significant process changes: Not required	Not applicable. Version 4.1 is the first version of the C2C Certified Circularity Standard. The requirements for products not previously certified to Version 3.1 apply.
First recertification (post transition to Version 4.0 or Version 4.1 from Version 3.1)	On-site if an on-site was not conducted at the first certification to Version 4.0 or 4.1. Otherwise, remote accepted.	On-site if an on-site was not conducted at the first certification to Version 4.0 or 4.1. Otherwise, remote accepted.	
Subsequent recertifications	On-site or remote	On-site or remote	
Interim assessment reviews	Significant process changes: On-site or remote No significant process changes: Not required		

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Location(s)

Cradle to Cradle Certified Product Standard (Full Scope Standard) and C2C Certified Material Health Certificate Standard

At a minimum, a site visit must be conducted at the main final manufacturing facility. A site visit must also be conducted at any additional facility involved in the select manufacturing processes for which chemical exposure concerns are considered exceptionally high (per Final Manufacturing Stage Process Definitions). The product, a representative product (for product groups), or a similar product (i.e., with similar inputs and manufacturing processes), must be on the production line(s) during the site visit(s).

If there is more than one final manufacturing facility, the "main" facility is defined as the facility that is the most representative of the majority of certified products sold and that accounts for the majority of production volume. If there are significant differences in processes between facilities, sites must be visited that are representative of all processes included in the final manufacturing stage. If there are multiple facilities where chemical exposure concerns are considered exceptionally high and the exact same processes are used at each of them, representative facility(ies) may be selected for the site visit.

When there is more than one manufacturing site and data are available regarding the sites' history of failing regulatory emissions permit limits or of having occupational safety and health violations, this must be taken into consideration when selecting sites to visit. In a scenario where such data are available for all sites producing the product(s), and one site has a history of multiple failures, that site should be selected for conducting the visit. However, in cases where such data are not available for all sites producing the product(s), the verifier(s) must use their best judgment regarding which facilities are of greatest risk of material misreporting or being out of compliance with certification requirements in combination with the other rules (above and below for de facto high-risk locations) in deciding which sites must be visited.

References for determination of compliance (a non-exhaustive list):

- China - IPE database http://wwwen.ipe.org.cn/about/about.aspx
- US - OSHA database: https://www.osha.gov/pls/imis/establishment.html#disclaim

In cases where the same processes and similar production volumes occur at multiple facilities and there is one or more sites in de facto high-risk locations (defined in Social Fairness Section 8.2):

- Site(s) that are in de facto high-risk locations must be selected over low-risk locations for conducting the site visit.
- If there is more than one site in a de facto high-risk location, the number of high-risk sites that must be visited is equal to the square root of n + 1, where n= the total number of sites in high-risk locations.

This results in the following requirements:

# of de facto high-risk sites	# of sites to visit
1	1
2	2
3-6	3
7-12	4
13-20	5

- When it is time to repeat the site visits (based on the required frequency), a different set of sites must be visited until a site visit has been conducted at all facilities in high-risk locations.
- Exception: Sites with ISO 14001, 45001, or similar certifications may be excluded from the total number of sites in high-risk locations when determining the number of site visits necessary (i.e., if all high-risk sites are ISO 14001 certified, one site visit may be sufficient depending on what constitutes the main facility and compliance history, if available). Similar means that the certifications include environmental and/or occupational health and safety management systems to address risks. ISO 9001 and Good Manufacturing Practice (GMP) certificates are not considered 'similar'.
- Lacking information on sites that have a history of non-compliance, the specific sites selected for the visits must be chosen randomly from the full list of de facto high-risk sites. One simple method of choosing randomly from a numbered list of sites is to use a random number generator to order the sequence of numbers and to then select the numbers (and sites) at the top of the random sequence to visit (up until the required number of sites has been selected based on a sqrt n+1 sample size). https:// www.random.org/sequences/

More than one site visit may be necessary for the same facility if applicants choose to certify multiple products over time that are made using different processes. However, if a new product group is certified that is made using a process that was already observed and verified, a new visit will not be necessary as long as the frequency requirements have been met.

Please refer to Social Fairness Section 8.3 Monitor and Verify Performance regarding when and where a third-party social audit is required in addition to the site visit(s) described above.

C2C Certified Circularity Standard

At a minimum, a site visit must be conducted at the main final manufacturing facility. The product, a representative product (for product groups), or a similar product (i.e., with similar inputs and manufacturing processes), must be on the production line(s) during the site visit(s).

If there is more than one final manufacturing facility, the “main” facility is defined as the facility that is the most representative of the majority of certified products sold and that accounts for the majority of production volume. If there are significant differences in processes between facilities, sites must be visited that are representative of all processes included in the final manufacturing stage.

In cases where the same processes and similar production volumes occur at multiple facilities and there is one or more sites in de facto high-risk locations (defined in Social Fairness Section 8.2):

- Site(s) that are in de facto high-risk locations must be selected over low-risk locations for conducting the site visit.
- If there is more than one site in a de facto high-risk location, the number of high-risk sites that must be visited is equal to the square root of n + 1, where n= the total number of sites in high-risk locations.

This results in the following requirements:

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1	1
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- The specific sites selected for the visits must be chosen randomly from the full list of de facto high-risk sites. One simple method of choosing randomly from a numbered list of sites is to use a random number generator to order the sequence of numbers and to then select the numbers (and sites) at the top of the random sequence to visit (up until the required number of sites has been selected based on a sqrt n+1 sample size). https://www.random.org/sequences/

More than one site visit may be necessary for the same facility if applicants choose to certify multiple products over time that are made using different processes. However, if a new product group is certified that is made using a process that was already observed and verified, a new visit will not be necessary as long as the frequency requirements have been met.

Required Documentation

- Completed C2CPII Manufacturing Site Visit Checklist (available to C2CPII assessors)