

# HPDC Quality Control Protocol

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**Update Notice:** This version updates Version 1.0 of this document, “HPDC Quality Control Protocol and Procedure for Published HPDs,” Effective Date 12/11/17.

## BACKGROUND AND SCOPE

The intention of this policy is to ensure the quality of published Health Product Declarations (HPDs), and compliance with all provisions of the HPD Open Standard.

An HPD report is a declaration made by a product manufacturer (with a Product HPD), or supplier (with a Supplier HPD). HPDC recognizes the expertise of manufacturers and suppliers in authoring their own HPD reports. At the same time, it is the mission of the Health Product Declaration Collaborative (HPDC) to provide, with the HPD Open Standard, a clear, consistent, rigorous, and verifiable set of rules for completing an HPD report.

An HPD must be published to the [HPD Public Repository](#) to be considered “public,” “publicly disclosed,” “published,” or similar. Once an HPD is published, a manufacturer may take additional steps to publicly share it, e.g. posting on its website, sharing it with customers, and publishing it in public libraries and databases.

HPDC enforces quality requirements during the publishing process, and for all published HPDs. This policy describes quality control measures that HPDC takes to ensure that published HPDs are compliant with the HPD Open Standard.

For purposes of this document, the term, “manufacturer” will be understood to include both end product manufacturers and suppliers of components and ingredients for those products.

Compliance with this quality control process is a fundamental prerequisite for all published HPDs, including third-party verified HPDs. HPDC’s optional [third-party verification program](#) goes beyond this Quality Control Protocol in providing an additional level of assurance that a completed HPD fully complies with the HPD Open Standard, including that its content inventory reporting is supported by source documentation.

All HPDs published after December 11, 2017, i.e., HPD version 2.1 and later, are subject to this protocol.

For more information on the HPD Open Standard and publishing requirements, view the most current version of the HPD Open Standard here: <https://www.hpd-collaborative.org/hpd-open-standard-all-versions/>.

## PRINCIPLES OF HPD QUALITY CONTROL

The following principles provide context for how this protocol was established and how it should be applied. These principles are not exhaustive; full context requires reviewing all provisions of the [current HPD Open Standard](#), [Best Practices](#) policies, and [Guiding Principles](#) of HPDC.

- The HPD report is a manufacturer declaration. The manufacturer is the top authority on reporting of their product(s). Published HPD reports are the property of the manufacturer, who is solely responsible for their content.
- HPDC and its Board of Directors representing its hundreds of member organizations, is the final authority on application of HPD Open Standard rules.
- HPD users are a community of practice—in material transparency and health. As a community, they have the right to expect accurate, reliable, consistent reporting of data. They also have the obligation to provide their expertise to support the continuous improvement and utilization of HPD reports and data. Individual manufacturers, suppliers and third-party verifiers are also members of this community of practice, and their company-level work should reflect this larger responsibility.

## COMPONENTS OF THE HPD QUALITY CONTROL PROCESS

The HPD quality control process consists of the following components:

1. Compliance Checking: Pre-Publishing
2. Compliance Checking: Post-Publishing
3. Appeals of Compliance Checking
4. Community Requests for Compliance Checking
5. Specific Requirements for Third-Party Verified HPDs

### SECTION 1. COMPLIANCE CHECKING: PRE-PUBLISHING

Prior to being published in the [HPD Public Repository](#), all HPDs are reviewed for compliance with the current version of the HPD Open Standard, including all Best Practices guides current at the time of publishing.

Most HPDs are published to the Repository using the online HPD Builder. In this case, the pre-publishing compliance check is performed as an automated check by the HPD Builder software tool. Manufacturers publishing HPDs often are doing so under a deadline. By automating this completeness check in the HPD Builder, HPDC endeavors to give the manufacturer control over their publishing schedule, and also reduces the costs of publishing.

An HPD may be reviewed against any aspect of the HPD Open Standard at this time, including required Format and Best Practices. However, the primary reference used by the HPD Builder's automated check is Section 4 of the HPD Open Standard: Checklist for a Compliant HPD. The

current effective version of the HPD Open Standard—including current Best Practices—is the official reference for this process.

An HPD that does not pass this pre-publishing compliance check will not be published. In the HPD Builder, a manufacturer will be prompted to correct errors. The compliance check can then be re-run, and the HPD can be published when it is passed.

As a customer support function, HPDC staff may also review HPDs prior to publishing when requested by the manufacturer. ([Contact HPDC via the customer support portal.](#)) At this time, HPDC staff may advise manufacturers on why an HPD is being flagged by the automated check and how to address the issue. HPDC staff may also answer manufacturer questions, and review data entered on the pre-published HPD, on how best to apply the HPD Open Standard to the manufacturer’s reporting situation. HPDC will endeavor to provide information to assist the manufacturer. However, it is the sole responsibility of the creator of the HPD to supply the expertise and effort necessary to make corrective actions.

In rare cases when an HPD is manually published, i.e. not using the HPD Builder automated publishing function, it must be submitted using the manual publishing function of the HPD Public Repository. In this instance, the pre-publishing compliance checking is performed manually by HPDC staff. As noted earlier, all HPDs, including those produced manually, must be published to the HPD Public Repository before they can be published on a manufacturer’s website, or elsewhere.

## SECTION 2. COMPLIANCE CHECKING: POST-PUBLISHING

Due to the many reporting options that are offered in the HPD Open Standard, it is not currently feasible to rely on an automated, on-demand method for compliance checking in all situations. Therefore, HPDC may also use non-automated (manual), *post-publishing* checking to ensure full compliance with the HPD Open Standard.

### Scope of Review

The following are a handful of examples of how an HPD may contain reporting errors even if it passes Compliance Checking: Pre-Publishing. This is not an exhaustive list.

- A manufacturer may omit a substance or material from the inventory.
- A manufacturer may select a CAS RN for a material and enter it on the HPD as a substance, when it should be reported using [Special Conditions](#) policies.
- A manufacturer may enter a range for a substance exceeding 20%, and not include a relevant explanation in the Substance Notes.
- A manufacturer may mistakenly indicate that accessories are not required for a product.

Post-publishing compliance checking may address a variety of errors:

- Unambiguous misapplications of the HPD Open Standard (such as the examples above).

- Minor reporting errors, e.g., the manufacturer mistakenly indicated that a substance is a nanomaterial, or a consultant is listed as the contact name on the HPD, rather than the manufacturer.

Some errors may be self-evident, especially to someone familiar with the use of the HPD Open Standard. Some potential errors may be ambiguous and require inquiry. HPDC reserves the right, under this policy, to make such inquiries.

### Timing

Post-publishing compliance checking may be performed at any time after an HPD is published.

### Triggering of Review

Except in the case of a community request (see Section 4 below), there is no specific trigger for a post-publishing compliance check. For example, it may be conducted as a routine spot-check, or it may result from research by HPDC staff on how a specific requirement of the HPD Open Standard is being applied. (HPDC is continually monitoring use of the HPD Open Standard to clarify and improve reporting requirements, and to improve instructions and functionality in the HPD Builder.)

### Steps of Compliance Checking: Post-Publishing

1. Review: HPDC staff review a published HPD.
2. Possible compliance error: HPDC staff may note the appearance or strong possibility of a compliance error.
3. Notification: If an error or possible error is noticed, HPDC staff will notify the manufacturer contact listed on the HPD via email, as well as the third-party preparer, if applicable. HPDC will request further information, clarification, or additional documentation, etc., as needed to clarify whether an error has been made on the HPD report.
4. Change of Status: HPDC may change the published status of the HPD as needed over the course of this process as follows:
  - In case of an unambiguous, significant error (as determined solely by HPDC), HPDC may immediately change the status of the HPD from “Published” to “Withdrawn.” A “Withdrawn” HPD is no longer viewable in the HPD Public Repository.
  - HPDC may elect, in case of a less unambiguous and/or less significant error, to change the status of the HPD to “Pending.”
  - Note: Independently of HPDC, the manufacturer may also elect to “Withdraw” the HPD from “Published” status at any time in this process.
5. Corrective action period: The manufacturer will have 30 calendar days from initial notification to correct any issues of non-compliance and submit the corrected HPD for review. If requested by the manufacturer, the corrective action period may be extended in 30-day increments.
6. Result of corrective action and notification:

- If HPDC finds that issues of non-compliance have been corrected:
    - If the HPD has been put into “Pending” status HPDC will change the status of the HPD to “Published.”
    - If the HPD has been put into “Withdrawn” status by either HPDC or the manufacturer, HPDC will notify the manufacturer that they have clearance to “Publish” the HPD. The manufacturer is responsible for completing this process via the HPD Builder.
  - If HPDC finds that issues have not been corrected:
    - If not already in “Withdrawn” status the HPD will be put into that status.
  - In either case, the manufacturer contact, and third-party preparer, if applicable, will be notified via email of the resulting action and reasons why the corrective action was or was not sufficient.
  - When an HPD is “Withdrawn” from publication in the HPD Public Repository for any reason, HPDC’s library/database partners are notified to also remove those HPDs from their databases. HPD users who download specific HPDs or otherwise express interest may also be informed of Withdrawn HPDs, to the extent feasible.
7. New publishing of HPD: If a manufacturer’s HPD is subject to being “Withdrawn” based on this Compliance Checking process, the manufacturer may publish a new HPD reporting on the same product. This new HPD must account for the necessary corrective actions that were identified previously and maintain overall compliance with the HPD Open Standard. The manufacturer must notify HPDC staff of the new HPD, and HPDC staff will review the HPD under the “Compliance Checking: Post-Publishing” process.
  8. Tracking and continuous improvement: HPDC will track the results of any corrective action and use that information to inform its continuous improvement process with the HPD Open Standard, Best Practices, and HPD Builder. Metrics on utilization of this process are tracked and reported to HPDC’s Technical Committee.

### SECTION 3. APPEALS OF COMPLIANCE CHECKING

The manufacturer that created an HPD, or other complainants (see Section 4) may appeal the result of the “Compliance Checking: Post-Publishing” process. This appeal may take place at any time prior to the Expiry Date of the HPD. The appeal will be heard within 90 days by HPDC’s Technical Committee, which will appoint an ad hoc subcommittee of five members for this purpose. Expertise in relevant areas will be considered in makeup of the subcommittee. Conflicts of interest will be avoided to the extent possible or declared openly in compliance with HPDC’s conflict of interest policy for its technical committees. The subcommittee may review documentation and hear information from the manufacturer, HPDC staff, third-party verifier (if applicable), complainant (if applicable), and any other experts that the subcommittee deems relevant.

After hearing and deliberation, the subcommittee will recommend corrective action, and if appropriate, a change in published status for the HPD. The subcommittee will communicate its

decision to all applicable parties. The manufacturer and complainant will have 15 days to accept or appeal the decision.

If accepted, the decision is final, and the Technical Committee will be notified of the outcome. If not accepted by either party, the Technical Committee itself will hear the case within 45 days. The Technical Committee will have access to all information gathered to date and may request additional information. After hearing from all sides and deliberating, the Technical Committee will vote and its decision will be final.

#### SECTION 4. COMMUNITY REQUESTS FOR COMPLIANCE CHECKING

Any member of the HPD community of practice, i.e., architects, manufacturers, suppliers, organizations, or other members of the public, may request the initiation of Compliance Checking: Post-Publishing.

The person or organization (“the complainant”) may [contact HPDC](#) to make the request. The complainant’s message should reference the specific HPD and rationale for review in their request, and reference this policy. A request must include specific data and information warranting the inquiry.

Please note that community members do not have to make a formal request for compliance checking to contact HPDC with any questions or clarifications about a published HPD.

A valid, i.e., sufficiently documented, public request will result in the initiation of Step 1 of Compliance Checking: Post-Publishing.

- If HPDC does not agree that there is an error or the strong possibility of an error, HPDC will not proceed with the remaining steps of the process. The complainant will be notified of the result. The complainant may appeal this result according to the process in Section 3.
- If HPDC staff agree that there is an error or the strong possibility of an error, HPDC will proceed with the remaining steps of the process, with the following notes:
  1. HPDC will determine if information from the complainant, e.g., industry-specific knowledge, is necessary to the inquiry.
    - i. If such information is necessary, it will be used by HPDC throughout the process as needed. The complainant may be consulted during the process for further information. Note #2 below is also relevant to this situation.
    - ii. If HPDC can conduct its inquiry without additional input from the complainant, it will do so. Note #2 below is *not* relevant to this situation.
    - iii. The complainant will be notified of the result of corrective action.
  2. If a complainant has an ongoing role in the Compliance Checking process (see #1 above), the manufacturer will by default be notified of the complainant’s identity and role.

- i. However, the complainant may request anonymity in this process. Such a request will be honored unless challenged by the manufacturer. If the manufacturer makes such a challenge and the complainant prefers to maintain anonymity, the matter will be referred to the subcommittee of the Technical Committee as in Section 3 above, with both parties providing a rationale for their position.
- ii. If the subcommittee's decision is in favor of removing anonymity, the complainant will have the option of withdrawing their request before it proceeds further. If this occurs, HPDC may still continue with the compliance checking process, and will gather any supportive information or expertise as needed.
- iii. If the complainant remains involved in the inquiry they will be notified of the result of corrective action.

## **SECTION 5. SPECIFIC REQUIREMENTS FOR THIRD-PARTY VERIFIED HPDs**

If the HPD is Third-Party Verified under HPDC's verification program, the following considerations also apply to Section 2: Compliance Checking: Post-Publishing:

- Notification: The verifying organization will also be notified.
- Corrective action: In the case corrective action is required by HPDC, the third-party verifier must review any new or updated data on the HPD in accordance with HPDC's third-party verification procedures. This may result in additional corrective action documentation steps being required by the verifier. It may also result in the decision by the verifier that the HPD cannot be positively verified and should not be published.
- Audit: If in the course of this process HPDC identifies an error on the HPD requiring corrective action, an audit of the verifying organization and the processes it used to complete the verification will be performed in accordance with the procedures of HPDC's third-party verification program.