



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 1
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RISK-BASED CLEANUP AND DISPOSAL APPROVAL § 761.61(c) CHECKLIST

I. Risk-Based Cleanup and Disposal Request to EPA with the following:

- Cover letter stating purpose of the submission and signed by the Site owner or operator, or by the party responsible for conducting the cleanup, such as a former Site owner.

- A plan which includes the following information:
 - Site background and history. This should include a discussion of past activities (e.g. use of PCBs and/or PCB equipment, storage, manufacturing, etc), site ownership, and current or proposed site uses. This section should also include information on any cleanups/remediations that have occurred at the Site.

 - The nature of the contamination, including the kinds of materials contaminated (§ 761.61(a)(3)(i)(A)).

 - A summary of the standard operating procedures (SOPs) employed during characterization of the Site, including a table and/or cleanup site map showing PCB concentrations measured in pre-cleanup characterization samples. The SOPs must include information on the sample collection procedures and extraction/analytical procedures. Copies of the laboratory analytical reports should be provided to document the extraction/analytical dates and methods and laboratory QC (§ 761.61(a)(3)(i)(B)).

If extensive, the laboratory analytical reports may be provided on a CD-ROM.

- A Site map showing the PCB sampling locations cross-referenced to the sample identification numbers provided as part of the characterization information. The extent of the identified PCB contaminated area(s) must be clearly identified (§ 761.61(a)(3)(i)(C)).

- A cleanup plan for the Site, including the proposed disposal technology and approach, and a cleanup schedule. ***The plan must include contingency plans in the event that higher PCB concentrations and/or a wider distribution of PCBs are identified during the cleanup*** (§ 761.61(a)(3)(i)(D)).
- Evaluation of PCB Cleanup Alternatives – An evaluation of PCB cleanup alternatives must be submitted for the following:
 - Sites that may not be cleaned up under the self-implementing procedures (see § 761.61(a)(1)(i)), or
 - Sites where the proposed cleanup involves leaving PCBs at concentrations greater than the cleanup criteria established under § 761.61(a).

The evaluation should include an alternative to achieve the prescriptive cleanup standard(s) under § 761.61(a). The evaluation should clearly state the reasons why the provisions available under § 761.61(a) cannot be implemented.

- If a cleanup will involve the use of an engineered cap, the cap design specifications and a cross-section showing the design should be provided. Please insure that it is clear where the engineered cap will be used. *Please note: the use of an engineered cap will require a deed notation documenting this fact and the limitations on the use of the Site. Financial assurance¹ and a long-term monitoring and maintenance plan for the cap will be required. In addition, long-term groundwater monitoring may be required to document no migration of PCBs from the Site (§ 761.61(a)(7)).*
- If a cleanup will involve encapsulation of PCBs on a building or structure, please provide the MSDS of the proposed encapsulant and a discussion of the effectiveness of this product for encapsulation of PCBs based on the Site and the receptors at the Site. *Please note: the use of an encapsulant under § 761.61(c) will require a deed notation documenting this fact and the limitations on the use of the Site. Financial assurance¹ and a long-term monitoring and maintenance plan for the encapsulant(s) will be required.*

1 For certain public entities (cities, towns, and municipalities) documentation of financial assurance generally will not be required.

- A written certification, signed by: 1) the owner of the property where the cleanup site is located, and 2) the party conducting the cleanup, that all sampling plans, sample collection procedures, sample preparation procedures, extraction procedures, and instrumental/chemical analysis procedures used to assess or characterize the PCB contamination at the cleanup site, are on file at the location designated in the certificate, and are available for EPA inspection (§ 761.61(a)(3)(i)(E)).
- Subpart Q alternative method: If an alternative method of extraction and/or analysis is/will be used, the certification shall include a statement to this fact and that a comparison study which meets or exceeds the requirements of Subpart Q has been completed prior to the verification sampling. In the event that the alternative extraction and/or analytical method was previously validated under Subpart Q using materials from other projects, the laboratory must provide a certification that the sample types used during that comparison study are similar to (e.g., % organic content, grain size, etc) the sample types that will be cleaned up under the Notification. A copy of the Subpart Q comparison study should be included in the Notification (§ 761.61(a)(3)(i)(E)).
- QA/QC plan for documenting that the cleanup levels have been achieved (e.g. confirmatory sampling/analysis QA/QC, initial testing of encapsulated surfaces, etc). The QA/QC plan should at a minimum include information on the types and numbers of samples; extraction and analytical methods; MS/MSDs (both frequency and acceptance criteria), etc. The QA/QC plan should also discuss data validation.
- Human Health Risk Assessment and Ecological Risk Assessment. A Human Health Risk Assessment (HHRA) may be required to support a Risk-Based Disposal Request under § 761.61(c) where PCB concentrations above the prescriptive PCB standards at § 761.61(a) are left in-place². The HHRA should evaluate site exposures and provide a justification as to the controls proposed to address these exposures. An Ecological Risk Assessment will be required in the event that wetlands, water bodies, sediments, or other similar matrices are impacted with PCBs regulated under 40 CFR Part 761.

2 A determination on the requirement for submittal of an HHRA will be determined based on the site and the remedial approach.

- In the event that the party conducting the cleanup is not the Site owner, EPA will require documentation that the party conducting the cleanup legally has the authority to access the Site and to conduct the proposed PCB cleanup activities. This documentation for example may be in the form of a Site Access Agreement stating this fact or perhaps in a lease agreement or a property transfer agreement.

II. EPA Review of § 761.61(c) submittal

- EPA will review and provide comments on any deficiencies and/or questions it has regarding any information submitted under the § 761.61(c) process. Once EPA has determined that all deficiencies and/or questions have been addressed, EPA may require public notice and comment. EPA may determine that public notice/comment is not required based on the proposed PCB cleanup standards and plan (see Section III).

Please note: The 30-day EPA review timeframe specified under § 761.61(a) does not apply under § 761.61(c).

III. Public Participation

- For § 761.61(c) requests, EPA may conduct a 30-day public notice/comment period. *As indicated above, based on the proposed PCB cleanup standards, the remediation plan itself, and/or the public participation that may have been ongoing as part of a state and/or federal program requirement (such as the 401 Water Certification or Conservation Commission process), EPA may determine that adequate public participation has occurred. If EPA deems public participation is necessary, EPA will work with the Site owner to develop an acceptable public participation process for the Site.*

For schools, EPA may require an outreach plan for school users, including parents. This outreach plan will be required when PCBs at greater than (>) 1 part per million will remain at a school site, when a cleanup is being conducted while school is in session, or if EPA determines that such a plan may be appropriate.

IV. EPA Approval

- Following the 30-day public notice/comment period, if warranted, EPA: will respond to pertinent written comments received on the risk-based plan; or will respond to pertinent written comments received on the risk-based plan and will issue the approval with/without modifications; or will not issue the approval, but will require additional information supporting the request to be submitted.

As an additional point of clarification, please note that EPA has issued § 761.61(c) approvals to both single party and multiple parties. This determination is made based on the Site ownership as well as the proposed risk-based plan and is determined on a case-by-case basis.

IMPORTANT:

Please note that this checklist provides only a summary of the information that Region 1 recommends be included in a risk-based request for sampling, cleanup, or disposal of PCB remediation waste other than prescribed under § 761.61(a) or § 761.61(b), or for storage of PCB remediation waste other than prescribed under § 761.65. It is for reference only and does not supercede the regulations.

The requestor may include any additional information that supports the proposed PCB cleanup and disposal activities, such as information regarding state regulations, community involvement (especially for schools), and environmental justice communities. In addition, any documentation that has been developed for a state regulatory agency, such as a remedial investigation report, may be submitted to support the pertinent required documentation in lieu of generating a new document.

PLEASE BE AWARE THAT AS SPECIFIED AT 40 CFR § 761.61(c), A RISK-BASED CLEANUP ACTIVITY MAY NOT BE CONDUCTED WITHOUT APPROVAL FROM THE EPA REGIONAL ADMINISTRATOR OR HIS/HER DESIGNEE.