Draft Interim Guidance Document for Beneficial Use Determination Regulations 310 CMR 19.060

March 18,2004

Massachusetts Department of Environmental Protection

Bureau of Waste Prevention

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Executive Summary

This Beneficial Use Determination Guidance Document provides information to assist the applicant in preparing an application for beneficial use in accordance with the Beneficial Use Regulations, 310 CMR 19.060. The Guidance also includes a table of numerical values for secondary material constituents calculated using predefined exposure assumptions.

The information contained in this document is intended solely as guidance. This Policy does not create any substantive or procedural rights, and is not enforceable by any party in any administrative proceeding with the Commonwealth. This Policy provides recommendations and guidance on approaches the Department considers acceptable for meeting the performance standards set forth in the Solid Waste Management Facility Regulations, 310 CMR 19.000 and discussed in this document.

DEP will use the information submitted by the applicant to determine if a proposed use of a secondary material can be accomplished without creating a significant risk, causing an adverse impact, or resulting in nuisance conditions. It is incumbent upon the applicant to demonstrate and otherwise provide DEP with sufficient information to determine if issuing a Beneficial Use Determination (BUD) is warranted.

There are four categories of uses for secondary materials. Each category is held to the same general standard of protection of public health, safety and the environment. However, within each category are options for demonstrating that this standard has been met. The scope of work required for each option should be consistent with the nature and extent of contamination and the type of use proposed. Therefore, uses of materials with lesser contamination and greater material control have a simpler demonstration to make. The categories include:

- Beneficial Use of Secondary Materials in Commercial Products
- Beneficial Use of Secondary Materials in Regulated Systems
- Beneficial Use of Secondary Materials in Restricted Applications
- Beneficial Use of Secondary Materials in Unrestricted Applications.

The Department has developed a quantitative risk assessment approach for use in restricted and unrestricted applications for use when evaluating risk. This approach is similar to the approach used by the Bureau of Waste Site Cleanup as documented in the Massachusetts Contingency Plan (MCP, M.G.L. Chapter 21E), but contoured to the goals of the Bureau of Waste Prevention. The assessment incorporates three methods for establishing criteria for comparison with secondary material constituent concentrations. Method 1 incorporates a list of hazardous material values that have been calculated based upon a predetermined set of exposure scenarios. Secondary materials that contain constituents of concern that do not exceed these values have demonstrated no significant risk to the public health, safety and the Environment. Method 2 may be used to derive risk criteria when unavailable in the Method 1 assessment. Method 3 involves an assessment of total risk based on site-specific information.

Where an Applicant is interested in obtaining a BUD in more than one state, there is an opportunity to pursue multi-state review of BUD applications. To do so the applicant must notify DEP at the beginning of the application process. For more information about multi-state review, see

"APPLICANT GUIDANCE DOCUMENT FOR MULTI-STATE BENEFICIAL USE DETERMINATIONS FOR NON-HAZARDOUS MATERIALS," which is available upon request.

This document does not provide solid waste facility siting guidance pursuant to 310 CMR 16.00 nor does it affect traditional recycling activities for which exemptions from site assignment exist pursuant to 310 CMR 16.05.

For further information

On the Web

Risk Assessment: Office of Research & Standards,
*http://www.state.ma.us/dep/ors/orspubs.ht*m

Solid Waste Regulations & Best Management Practices:

Bureau of Waste Prevention, Solid Waste
http://www.state.ma.us/dep/ors/orspubs.htm
or contact (sean.griffin@state.ma.us) (617) 292-5967 or
James Doucett, Bureau of Waste Prevention.
(James.Doucett@state.ma.us) (617) 292-5868

1 Application Process

The BUD application process is divided into two phases: 1) pre-application, and 2) application (see figure1). During the pre-application phase, the applicant provides the Department with a clear picture of the proposed beneficial use, and then, working with the Department, outlines the steps necessary to demonstrate that the proposed use meets the requirements of the beneficial use regulations.

1.1 Determination of Applicability

In some instances, an applicant may want an interpretation from the Department to determine if an activity is exempt from solid waste regulations pursuant to 310 CMR 16.05. The proponent may request a Determination of Applicability. A Determination of Applicability is a prescreening tool used by the Department to evaluate general information about a secondary material and use. The required information for the Determination of Applicability is found at 310 CMR 19.060(2), Determination of Applicability, and includes:

- A facility or operation description
- A list of products currently and historically manufactured by the facility
- A description of the secondary material
- Specifications for use of the secondary material
- A list of licenses, permits or other prior approvals issued for the use of the secondary material

The distinction between a solid waste and a product or commodity in commerce is not a bright line. The request for a Determination of Applicability should make the case for the activity as a commercial operation based upon the information submitted.. The request does not have to be comprehensive, as is necessary for a beneficial use application, nor is sampling a prerequisite. General information that is readily available should usually suffice.

1.2 Pre-Application

The pre-application process provides an opportunity for the applicant to receive specific guidance on submitting a comprehensive application. The applicant initiates the pre-application process by submitting pre-application information to the Department and requesting guidance. Upon receipt of the request the Department may: schedule a pre-application meeting; advise the applicant to submit a formal application (BWP SW 13 or 30); or determine that a BUD is not warranted. The information may be in a format of the applicants choosing, such as a draft of the application, but it should contain the information found at 310 CMR 19.060 (6), General Application Requirements, which includes:

- A physical and chemical characterization of the secondary material
- A general description of the secondary material (i.e. visual appearance, matrix, etc.)
- Identification of proposed amounts to be used
- A description of how the secondary material will be used
- Identification of the material it is replacing, if applicable, and specifications for use
- A description of the facility or operation that will use the material
- Identification of risk management techniques and best management practices (BMPs) to be employed in the use of the secondary material

- Identification of the proposed location of use, if applicable, or types of locations where the secondary material will be used (e.g. highway rights-of-way, industrial zoned properties, etc.)

This information will allow the Department to conduct a cursory review and to anticipate issues that may need to be discussed with the Applicant. Although the applicant may have conducted testing prior to the pre-application process, the Department recommends that comprehensive, statistically valid sampling, if necessary, be performed after consultation with the Department. The Department will provide specific application requirements, including the appropriate category of review, upon request.

1.3 Filing the Application

The application phase begins the official permit timeline and is initiated by the submittal of the completed application, transmittal form, and application fee if applicable, pursuant to 310 CMR 4.00. In most cases the review component of the process is 60-90 days. Sixty days is the standard timeline for reviews of technically complete applications. However, an incomplete or deficient application will trigger an additional 30-day technical review period. If the scope of the proposal warrants an individual rule, pursuant to 310 CMR 4.05, the applicant and Department will work together to develop a more appropriate schedule and fee with milestones and deadlines.

1.3.1 Where to File

Applicants should submit applications for sites in a specific town(s) or DEP region(s) to the appropriate regional office, c/o Solid Waste Section Chief, Bureau of Waste Prevention. The Department regional office mailing address information is found on the Web at www.mass.gov/dep/. BUDs issued by a region are valid only in the issuing regions.

If applicants want to use the material in more than one region, applicants should submit applications for statewide beneficial use to:

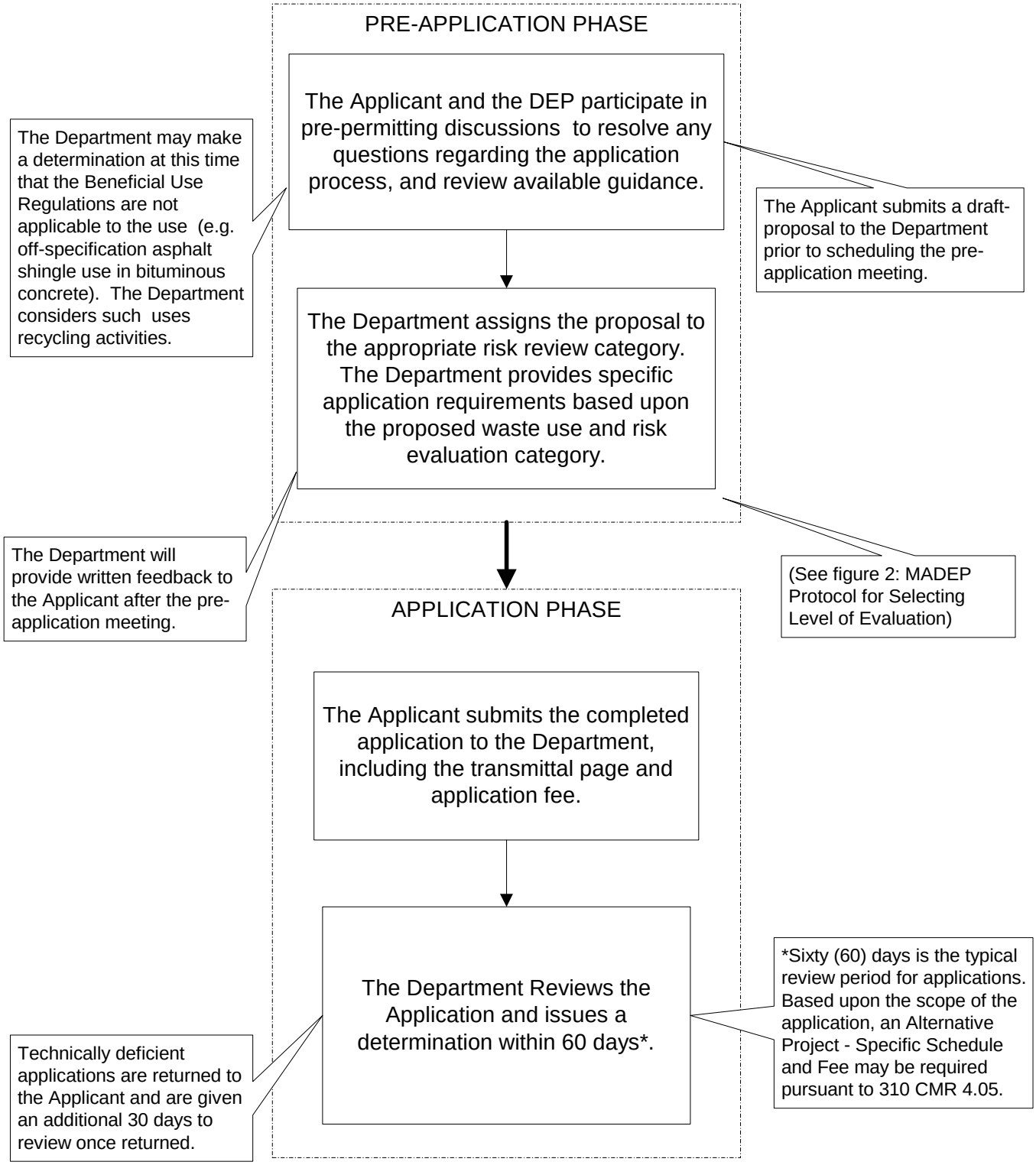
The Department of Environmental Protection
c/o Waste Branch Chief
Bureau of Waste Prevention, 9th floor
One Winter Street
Boston, MA 02108

A statewide BUD authorizes the applicant to use the secondary material throughout the Commonwealth.

1.3.2 Generic BUDs

Occasionally, the Department will issue Generic Beneficial Use Determinations as policies. These policies are specific to certain waste-use combinations and are authorized for any party provided that the user conforms to all the conditions contained in the policy. The Department's policy on contaminated soil use as daily cover at landfills (Comm. 97-001) is an example of the type of policy that is considered a generic BUD.

Figure 1: Application Process Overview



1.3.3 Processing of Secondary Materials

When a solid waste is processed, a facility site assignment is required pursuant to Chapter 111: Section 150A, Solid Waste Disposal Facilities; Maintenance and Operation; Applications For Site Assignment. Limited processing of secondary materials intended for beneficial use may be allowed without a site assignment if this processing is typical of processing of similar industrial products or feedstock materials.

However, the Department will inform the applicant if a site assignment, Determination of Need (DON) or other appropriate mechanism is necessary pursuant to 310 CMR 16.00, Site Assignment Regulations.

1.4 Demonstration Projects

The Department may grant temporary approval for a pilot project or demonstration project pursuant to 310 CMR 19.062, Demonstration Projects or Facilities. Demonstration project approvals are granted, solely at the Department's discretion, when the information gathered during the demonstration project will determine if the secondary material is an effective substitute for the material it is replacing or assist the Department in making a long-term determination regarding the potential for significant risk or adverse impact to public health, safety and the environment. The application requirements will be determined on a case-by-case basis.

2 Secondary Material Testing

2.1 Sampling, Analytical and Data Quality

Any person applying to beneficially use secondary materials needs to ensure that analytical and other data used in support of any application are scientifically valid and defensible, and of a level of precision and accuracy commensurate with its stated or intended use. Applications that do not conform to these criteria will be rejected. The following provides guidance to assist applicants in complying with these requirements.

2.2 Mixtures

Sampling performed to evaluate potential risk or identify adverse impacts shall be conducted on the material as used based upon industry specifications or specifications as developed to meet a specific need. The basis for determining the content of products produced using secondary materials should be determined prior to chemical characterization. It may be necessary to perform sampling on the secondary material as well and this should be detailed in the Quality Assurance Plan as discussed in section 2.5. Final mix ratios should not be based upon a dilution factor in order to conform to an established Department standard, value or criteria.

2.3 Secondary Material Characterization.

The application should address all potential constituents of concern (COC) that may reasonably be expected to be contained in the secondary material. These include secondary material precursor constituents, products of formation resulting from the mixing of materials, cross contamination resulting from the contact with other materials in the waste stream or during their primary use, or the presence of proprietary ingredients that may

contain COCs. If a secondary material is not adequately characterized the beneficial use may be denied.

Depending on the secondary material and its proposed beneficial use, sampling and chemical analyses may be required to determine or confirm the nature of the constituents present and determine their concentration. In these cases, a well thought out sampling plan should be developed and implemented (see Section 2.4) to ensure that the data generated is representative of the secondary material.

2.4 Sampling And Analytical Test Methods.

Sampling methods should consider in situ conditions and other factors, such as mix ratios, that contribute to releases of COCs.

It is the applicant's responsibility to insure that the analytical and sampling methods used and the data generated are appropriate and meet performance requirements (e.g. equipment sensitivity; reproducibility; etc.). Because of the diversity of secondary material constituents, it is impossible to identify specific sampling and analytical protocols to cover all situations. A variety of test methods exist that may be appropriate for chemical analyses of secondary materials (for example, see EPA SW846 at http://www.epa.gov/epaoswer/hazwaste/test/main.htm). The applicant must ensure that the methods selected are appropriate and meet necessary data quality objectives. It should be noted that if secondary material-specific COCs are identified that are not included on a method-specific target analyte list, then these additional analytes must also be incorporated into the sampling and analytical plan with appropriate calibration and QA/QC verification.

In every case, the reporting limit, based on the concentration of the lowest calibration value for each COC, must be less than or equal to the applicable BUD standard or other criteria, as appropriate (i.e., Method 1 Standards, risk management criteria; background concentration; etc.) In some cases, this may require analytical modifications, such as increased sampling weight or volume, to increase sensitivity. All such modifications should be reported.

2.5 Quality Assurance Plans.

In order to ensure that appropriate performance criteria are established and met, the applicant should, for every application, prepare a BUD Quality Assurance Plan (QAP).. The QAP is a comprehensive document that details the QA/QC protocols and goals for a specific data collection activity.

In preparing QAPs, the following sources of information should be consulted. These sites provide detailed information on the content and preparation methods for developing an acceptable QAP.

- http://www.state.ma.us/dep/bwsc/files/data/QAQCDocs.htm
- http://www.epa.gov/epaoswer/hazwaste/test/main.htm
- SW846 (chapter 1 and chapter 9)
- http://www.state.ma.us/dep/bwsc/files/data/samevrep.pdf
- MA DEP's Quality Assurance and Quality Control Guidelines for Sampling, Data Evaluation and Reporting Activities.
- http://www.epa.gov/r10earth/offices/oea/r0qadrg.htm
- US EPA's Data Review Guidelines

Common QA/QC requirements that should be included in any BUD sample collection and analysis effort are listed below. QAPs that do not include these components may be viewed as unacceptable unless a valid, detailed scientific explanation is provided.

QAPs should specify:

1. trip blanks with each batch of samples submitted to the lab for analysis of VOCs and VPH;
2. an equipment blank for analysis of all parameters. If more than 20 samples are to be taken, one blank per 20 samples should be submitted;
3. triplicate samples for a matrix spike (ms) and matrix spike duplicate (msd) analysis, with one triplicate set for every 20 samples;
4. blind duplicate samples and blind proficiency standards;
5. certification by responsible parties (laboratory director; consultant in charge; applicant) that sampling records and analytical data were reviewed and that all elements of the QAP were complied with or, if not, that all deviations were identified and adequately explained.

In addition, applicants must ensure that all staff involved with any component of the sampling and analysis plan, including those collecting samples as well as the selected laboratory:

1) Review the Project's QAP and identify any exceptions or qualifications.
2) Verify, document and maintain sample integrity (containers, preservatives, holding times, etc.)
3) Perform the requested analyses in strict conformance with the specified method and any applicable DEP method requirements.
4) Maintain complete records of all sample submittals and analytical process data.

2.6 Representative Sampling

The Department experience with BUD applications shows that statistical representation is not often considered when sampling secondary materials. This section is meant to provide a brief summary of some key statistical concepts and terms; provide references for consultation; and to emphasize the importance that statistically based testing plays in demonstrating protection to the public health, safety and the environment. Proper analysis will allow the applicant to gain the necessary information with the minimum of expense and effort. However, the physical and chemical diversity of materials, as well as the dissimilarity of storage facilities (lagoons, open piles, tanks, drums, etc.) and sampling equipment associated with them, preclude a detailed consideration in this guidance document of any specific sampling plan. Consequently, the burden of responsibility for developing a technically sound sampling plan rests with the applicant.

In most cases, the objective of a beneficial use application sampling plan is to adequately characterize the secondary material. Frequently, it is impossible, or at least impractical, to take measurements of all the entire waste material (the population). Statistical analysis is a tool for drawing conclusions about a population by evaluating a sample size that is smaller

than the entire population in order to make judgments about the entire population. Statistically valid sampling plans will have samples that are representative of the population. The purpose of the sampling plan is to derive a mean concentration (the mean concentration is the average of sample readings) that may not be the true mean (the average of the entire population) but some measure of central tendency and dispersion about the true mean. The measure of the dispersion around the mean is called the standard deviation (or standard error) and is calculated based upon the assumption that the distribution of the concentration of any contamination within a solid waste resembles a bell curve. It is important to note at this time that although a variety of distribution curves exist for varying populations, the curve for contamination within a solid waste is considered to be a normal distribution. There are methods for testing the correctness of this assumption; however, this usually requires a great number of samples beyond what is typical for solid waste analysis.

Since one cannot be 100% sure that the mean concentration is equal to the true concentration, the closer the mean concentration is to the regulatory threshold the more important it is for added precision. For purposes of evaluating solid wastes, the probability level (confidence interval) of 80 % has been selected. That is to say that for each chemical COC, a confidence interval (CI) is described around the true mean for which 80 out of 100 samples are expected to fall. The 80% CI is then compared with the appropriate regulatory threshold. Because the normal bell shaped curve is presumed for the distribution of samples around the true mean there is actually only a 10% chance (not 20%) that the threshold is equaled or exceeded. Consequently, the CI employed to evaluate solid wastes is, for all practical purposes, a 90% interval. For example, if a regulatory threshold is 5 mg/Kg and the calculated mean concentration within a waste is 4 mg/Kg then the upper range of the CI (the range for which 80 out of 100 samples are expected to fall based upon the bell curve) must also be below the regulatory threshold of 5 mg/Kg.

It is prudent to collect a greater number of samples than indicated by the preliminary estimates of the mean and standard deviation in the event that poor estimates were chosen. The information described in this section was derived from the EPA Guidance Document, *Test Methods for Evaluating Solid Waste,* SW-846.

2.7 Reporting.

Analytical results must be reported in conformance with DEP's requirements for the submittal as a whole and for the specified analyses.

Reports should include:

- Sample information (matrix, preservative, temperature on receipt, etc.)
- Request for analysis
- Method citation(s)
- Custody records
- Case narrative detailing anomalies, comments and qualifications to data.
- Analytical results (to include individual reporting limits for individual analytes, dilutions, extraction/pretreatment, etc.)

- QA/QC results (surrogate recovery, method blanks, standard deviation, etc., as applicable)
- Laboratory analytical certification (method followed, acceptance criteria met, and documentation of method modifications or anomalies)

3 CATEGORIES OF BENEFICIAL USE

Assessment options for evaluating COCs are specific to categories of use. The Department developed these categories to tailor the application requirements to similar types of uses. The categories differ in their potential for releases of, and exposures to, COC.

The categories include the following:

Category 1: Beneficial Use of Secondary Materials in Commercial Products

Products manufactured from secondary materials or secondary materials that are directly used as products are considered commercial products under the following conditions:

- When the product is used in a manner that is consistent with industry accepted product specifications or performance standards;
- When the product is controlled and managed throughout its lifecycle in a manner that effectively limits potential for illegal or inadvertent disposal or releases of hazardous material to the environment and exposure to people;
- When any adverse impacts or significant risks to public health, safety and the environment, including, but not limited to, nuisance conditions and public welfare impacts, can be evaluated by demonstrating conformance with the conditions stipulated in section 4.3;
- Products applied to the land cannot be considered commercial products.

Category 2: Beneficial Use of Secondary Materials in Regulated Systems

This category is applicable to beneficial uses that the Department already regulates through an existing permit, order or approval (e.g. landfill cover use is addressed through DEP Policy Comm. 97-001).

Category 3: Beneficial Use of Secondary Materials in Restricted Applications

Secondary materials that are beneficially used in applications that utilize risk management techniques in order to prevent adverse impact or significant risks to public health, safety and the environment, including, but not limited to, nuisance conditions and public welfare impacts, shall be reviewed in accordance with this section.

Category 4: Beneficial Use of Secondary Materials in Unrestricted Applications.

Secondary materials that are beneficially used in applications that do not limit exposure to potential human or environmental receptors from secondary material constituents are reviewed in accordance with this section when constituents have the potential to adversely impact or create a risk to public health, safety, or the environment, including, but not limited to, nuisance conditions or public welfare impacts when improperly

stored, treated, transported, disposed of, used, or otherwise managed. Unrestricted beneficial use proposals are subject to the most comprehensive risk evaluations.

4 OPTIONS FOR EVALUATING CONSTITUENTS OF CONCERN (COCs) IN SECONDARY MATERIALS

4.1 Performance Standards

All beneficial use applications must demonstrate that the proposed beneficial use will not create significant risk or cause adverse impacts to the public health, safety, and the environment or result in nuisance conditions. The Applicant may demonstrate this by conforming to specific performance criteria included in the regulation and discussed in sections 4.2 and 4.3. These vary by category and may include consistency with background COC concentrations; consistency with COC concentrations in a traditional manufactured product (subject to specific limitations as discussed below); and consistency with DEP risk management criteria.

4.2 Critical Contaminants of Environmental Concern (CCCs)

CCCs are a subset of the universe of Contaminants of Concern (see Appendix – 2 for a full listing). This list includes compounds that pose an elevated threat to public health and the environment for the reasons identified below, and therefore are of particular concern. The list includes compounds that exhibit several of the following properties: 1) persistence in the environment; 2) ability to bioaccumulate; 3) potent toxicity; and/or 4) widespread presence in the environment at levels of concern. Under the BUD program, concentrations of CCCs in secondary materials must be demonstrated to be consistent with background levels and meet other applicable requirements for beneficial use in categories 3 and 4.

4.3 CATEGORY 1- Beneficial Use of Secondary Materials in Commercial Products

Category 1 beneficial uses may be approved provided that:

A. Concentrations of COC are demonstrated to be consistent with or below those in the traditional material it is replacing. This determination can be made through a statistical comparison of the concentrations of COC in samples of the secondary material with concentrations of COCs in samples of the traditional material. Applicants may be able to make this demonstration based on existing data or general information regarding the composition of the original and secondary materials.

Note that Category 1 approvals are not applicable to “products” intended for, or that will likely result in, unrecoverable dissemination in the environment (e.g. soil additives/amendments).

OR

B. Concentrations of all COC are demonstrated to be below MA background soil levels;

4.4 CATEGORY 2- Beneficial Use of Secondary Material in Regulated Systems

If the use of a secondary material is subject to an existing facility permit, order, policy, regulation or other approval, the use is considered adequately regulated for purposes of the Solid Waste Facility Regulations, 310 CMR 19.000. However, if there are any aspects of the beneficial use not covered that have the potential to create significant risk or cause adverse impacts to the public health, safety, and the environment or result in nuisance conditions then these concerns will be regulated under a BUD. When all solid waste concerns are overseen by an existing faciliy permit, order, policy, regulation or other approval, a BUD is not required. In all cases, the storage, transfer, processing, treatment, use and disposal of the secondary material shall be achieved using best management practices that prevent adverse impacts and significant risks to public health, safety and the environment, including, but not limited to, nuisance conditions and public welfare impacts.

4.5 CATEGORY 3: Beneficial Use of Secondary Materials in Restricted Applications

Category 3 beneficial use applications may be approved provided:

A. Concentrations of all COC are below Upper Contamination Limits (See Section - 5*.2.1.5, Upper Contamination Limits (UCLs)*).

AND

B. The proposed beneficial use, considering all COC, can be demonstrated to be in compliance with all applicable risk criteria using BUD Risk Assessment (RA) Methods 1 and/or 2, or Method 3 (note Methods 1 and 2 may be used together; Methods 1 and 2 cannot be combined with Method 3). If using a Method 1 BUD RA then concentrations must fall below the appropriate BUD Method 1 category (e.g. S-1/GW-2 or S-2/GW1 etc). If using a Method 3 BUD RA then assessments must use exposure pathways appropriate to the beneficial use.

OR

C. Concentrations of all COC are demonstrated, through sampling, to be below DEP approved MA background soil levels;

OR

D. The applicant can adequately demonstrate that environmental release and exposure pathways are substantively eliminated over the product's lifecycle under conditions of the beneficial use and DEP concurs. This option is not applicable to Unrestricted Beneficial Use (Category 4) proposals.

For Critical Contaminants of Concern (CCC)

If Critical Contaminants of Concern (CCC) are present then the applicant must demonstrate compliance with acceptable risk limits as in (B) above

AND

Demonstrate consistency with background (as in C above). (D) is not an option for CCC.

4.6 CATEGORY 4- Beneficial Use of Secondary Material in Unrestricted Applications

Category 4 beneficial use applications may be granted if:

A. Concentrations of all COC are below UCLs.

AND

B. The proposed beneficial use, considering all COC, can be demonstrated to be in compliance with all applicable risk criteria using BUD RA Methods 1 and/or 2, or Method 3 (note Methods 1 and 2 may be used together; Methods 1 and 2 cannot be combined with Method 3). Because use in this category is unrestricted, COC concentrations must fall below the most stringent BUD Method 1 standard or Method 2 values must be derived using the guidance discussed below or Method 3 assessments must be completed using conservative (residential-type) exposure pathways.

OR

C. Concentrations of all COC are demonstrated to be below DEP approved MA background soil levels.

For Critical Contaminants of Concern (CCC).

If Critical Contaminants of Concern (CCC) are present then the applicant must demonstrate compliance with acceptable risk limits as in (B) above;

AND

Demonstrate consistency with background (as in C above).

5 BUD RISK ASSESSMENT METHODS

The BUD risk assessment approach is based on, but not identical to, that used under the MCP (M.G.L. Chapter 21E Subpart I: Risk Characterization) to address hazardous waste sites in MA. Although the methodologies are similar, significant differences exist. In order to understand these differences and avoid potential delays in processing and reviewing BUD applications, it is important that the following guidance be reviewed carefully. Project proponents are advised to retain consultants with expertise in MA and USEPA risk assessment methods to complete BUD risk assessment work.

For a BUD to be approved the applicant must make an adequate demonstration that public health, safety and welfare and the environment will not be endangered because of the beneficial use. Criteria that may be used to make this determination for each of the beneficial use categories are discussed in Section 4, Options For Evaluating Constituents Of Concern In Secondary Materials. In

all cases, the burden of proof rests with the applicant who must make this demonstration using appropriate data and methods. The level of complexity of the assessment required depends on the nature of the secondary material and the proposed beneficial use. Unrestricted beneficial use applications require very thorough and comprehensive assessments.

The following section provides guidance on risk assessment methods that applicants may use to evaluate beneficial use risks. In order to enhance consistency and to minimize potential creation of liability under the MCP associated with secondary material use and to streamline the process, BUD risk assessment methodologies have been based on those used in the MA MCP program. These methods are summarized below. Sections of the MCP risk assessment guidance and related documents, where more detailed information may be obtained, are identified. Differences between the MCP approach and that used to evaluate BUD risks are highlighted.

5.1 BACKGROUND: MCP RISK ASSESSMENT APPROACH

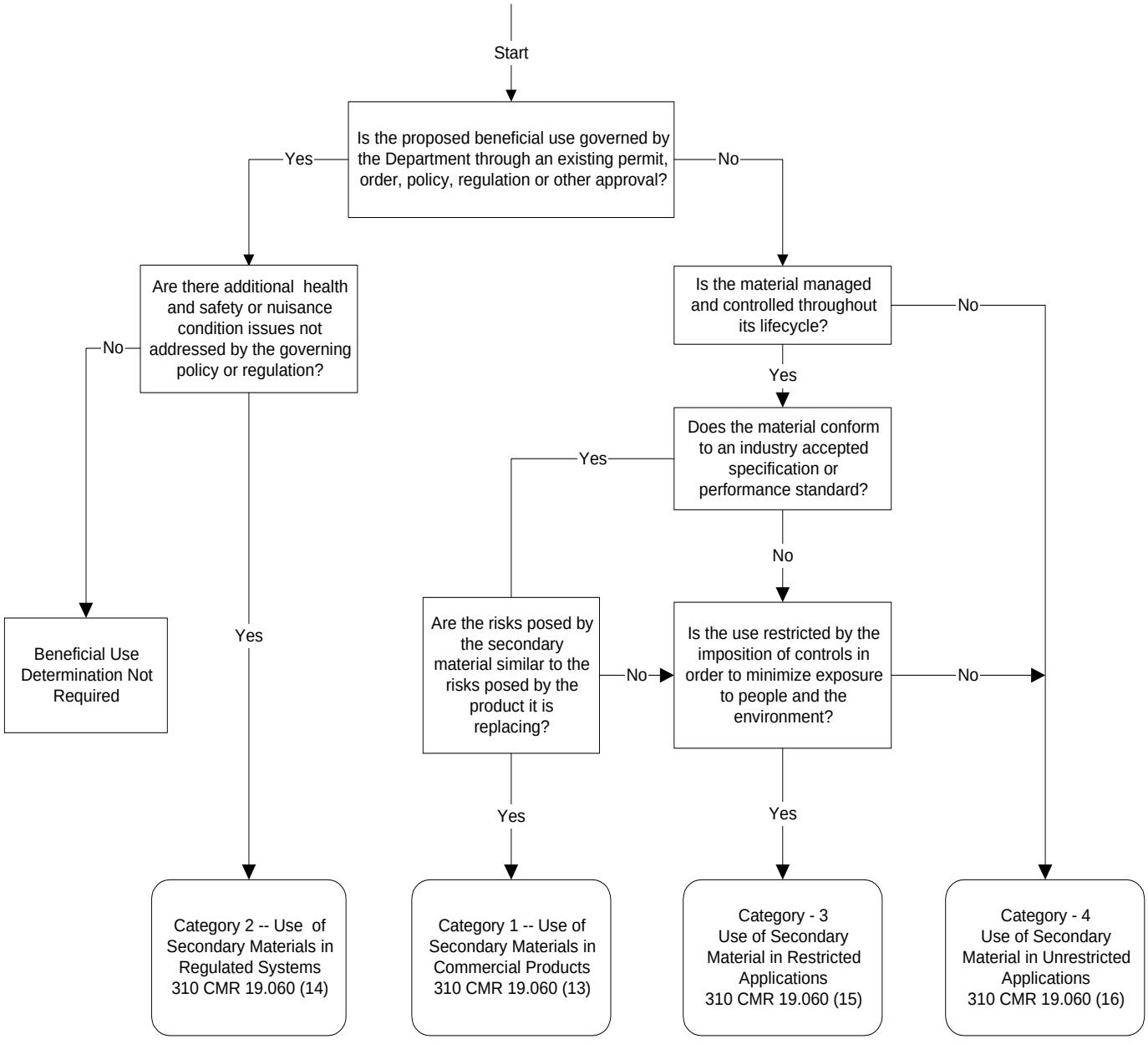
In Massachusetts, hazardous waste sites are assessed and cleaned-up under the regulations known as the Massachusetts Contingency Plan ("MCP"). The MCP specifies conditions under which contamination must be reported to the Department and conditions under which site contamination would pose "No Significant Risk" of harm to health, safety, public welfare and the environment. In the case of BUDs, if constituents in secondary materials are not adequately characterized and risks appropriately assessed, use of secondary materials has the potential of creating liability under the MCP.

The MCP provides three approaches for characterizing risks and the need for remediation at sites. These are: 1) use of standards established by DEP (Method 1); 2) use of standards developed by the applicant using appropriate methods as delineated by DEP (Method 2); and, 3) comprehensive site-specific risk evaluation (Method 3).

Method 1 standards include three categories for groundwater and three categories for soil. Method 2 provides for the derivation of a standard if one is not available under Method 1, using methods and risk management criteria specified by DEP. Method 3 involves an assessment of total risk based on site-specific information.

Under the MCP, sites must be cleaned up until constituent concentration risks meet the applicable risk management criteria or until concentrations are consistent with background. If feasible, background concentrations must be achieved.

Figure 2: Flowchart for Defining the Appropriate Waste Use Category



5.2 BUD RISK ASSESSMENT APPROACH

The BUD risk assessment approach parallels that used under the MCP. Key differences are summarized below, followed by guidelines for the appropriate use of the Method 1-3 options to assess BUD risks.

5.2.1 Key Differences: BUD vs. MCP Methods.

5.2.1.1 Risk Management Criteria.

The risk management criteria used in the BUD program differ from those established under the MCP. More stringent health protective criteria have been used in the BUD process to prevent the introduction of new constituents into the environment to prevent the creation of new environmental contamination. The MCP, on the other hand, is for the cleanup of existing contamination. The risk management criteria established under the MCP and the BUD program are compared in Table 1.

Table 1: Risk Management Criteria

Risk Type	**Risk Management Criteria (acceptable risk level)**	
	BUD Program	**MCP**
Individual Chemical Risk		
Cancer	0.5 X E-06	1 X E-06
Non-cancer	HI = 0.1	HI = 0.2
Total Risk		
Cancer	0.5 X E-05	1 X E-05
Non-cancer	HI = 0.5	HI = 1

5.2.1.2 Basis for Determining Background

BUD background values rely on the 50th percentile of appropriate sample distributions. In contrast, under the MCP, upper-range values were generally used. For example, under the MCP, the 90th percentile of an applicable distribution of contaminant concentrations in "clean" soils was used to establish generic background values for metals *(http://www.state.ma.us/dep/ors/files/backtu.pdf).* These values are used in the

MCP to evaluate consistency of site contamination with background. Under the BUD process, consistency with background requires a demonstration that secondary material constituent concentrations are at or below the 50th percentile of an appropriate background soil concentration data set. To derive generic background values such data must be derived from samples of clean soils (e.g. rural, uncontaminated soils). Site specific background balues may also be derived and used in the case of Categories 1-3. These must be appropriate to the proposed use and/or site of use and must again be based on the 50th percentile. (note that hte MCP background values for PAHs were based on fill materials that are expected to have somewhat elevated levels compared to undisturbed soils. Thus, these were not used in the derivation of the BUD Method 1 values.)

5.2.1.3 Reportable Concentrations ("RCs")

Under the MCP, contamination in groundwater or soil must be reported to DEP if any concentration exceeds the applicable Reportable Concentration in either groundwater or soil. For use of secondary materials containing chemical COCs, reportable concentrations ***are not applicable.*** All secondary materials containing COCs, whether or not their concentrations are above or below RCs, must be evaluated through the BUD process using appropriate methodologies.

5.2.1.4 Basis of Values

In contrast to the derivation of the MCP Method 1 standards, drinking water standards and guidelines are not always adopted, when available, as the basis for the BUD Method 1 Values. The drinking water standards and guidelines are not all risk based. These values may take into account additional considerations, such as feasibility and cost issues, in their derivation. Because the BUD program addresses the potential introduction of new contamination into the environment, DEP concluded that it was inappropriate to establish BUD Method 1 Values using values that may be based on the feasibility and costs of treatment and cleanup of existing contamination. Instead, BUD Method 1 Values are based on risk, background concentrations, detection limits and nuisance conditions (odor potential).

For some chemicals the drinking water standard or guideline may be lower than the value derived using these alternatives (e.g. due to the inclusion of an additional uncertainty factor for possible carcinogens for which slope factors are not available). In these cases the drinking water value has been used in the derivation of the BUD standard.

5.2.1.5 Upper Contamination Limits (UCLs)

Under the MCP, DEP established Upper Concentration Limits for chemicals to limit the extent to which a site-specific risk assessment can be used to

justify high residual concentrations of contaminants. In the MCP, if site concentrations exceed the UCLs established for groundwater or soil, the site cannot be considered "permanently cleaned up", except in the case of soil contaminants encapsulated beneath an engineered barrier.

For BUD evaluations, if constituent concentrations exceed the MCP UCLs, the material cannot be considered acceptable for beneficial use under Categories 3-4. It is important to note that compliance with UCLs does not mean that the material is acceptable for beneficial use. Compliance with all the other appropriate beneficial use decision criteria must also be demonstrated.

5.2.1.6 Critical Contaminants of Environmental Concern (CCCs)

As previously discussed special provisions are included in the BUD regulations for CCCs, which are not included in the MCP. Under the BUD program, concentrations of CCCs in secondary materials must be demonstrated to be consistent with background levels *and* meet other applicable requirements for beneficial use in categories 3 and 4.

6 RISK ASSESSMENT OPTIONS FOR BUDS

6.1 BUD Method 1

Method 1 may be used to assess beneficial use risks for any beneficial use category when Method 1 standards are available for all COCs in the secondary material. Each constituent must meets its applicable Method 1 standard. In addition the aggregate or summed risk of all constituents present must meet the BUD risk management criteria (Table 1).

The Beneficial Use Method 1 Values are presented in Appendix 5. These values differ from the MCP Method 1 values. As noted previously, the BUD Method 1 values are based on different risk management criteria which establish a higher bar for demonstrating that a secondary material beneficial use does not endanger public health and the environment.

6.1.1 Applicability and Interpretation

6.1.1.1 Beneficial Use of Secondary Materials in Unrestricted Applications

For all unrestricted beneficial use applications the concentrations of all COCs must be below the most conservative (lowest) Method 1 value from Table 1. If COCs are present for which Method 1 values do not exist, the applicant must either develop a Method 2 value using approved DEP methods (see Section

6.2) or must complete a Method 3 assessment. If toxicity data do not exist that allow for completion of a Method 2 or 3 assessment, the material may not be used in Category 4 (Unrestricted Beneficial Use) applications unless consistency with background is demonstrated.

6.1.1.2 Beneficial Use of Secondary Materials in Restricted Applications

For Restricted Beneficial Use Applications (BUD Category 3), COC concentrations must be compared to the Method 1 value most appropriate to the release and exposure pathways of concern for the beneficial use in question, as discussed below.

If the use substantively eliminates release and exposure pathways, DEP may determine that a quantitative risk assessment is not needed. Such a determination is contingent upon the applicant providing detailed information and data demonstrating that release and exposure pathways are, in fact, adequately controlled under current and future conditions of the beneficial use.

6.1.2 BUD Method I Values

1) Groundwater –1 (GW-1) values apply to any beneficial uses that may result in releases within Current and Potential Drinking Water Source Areas. These values are calculated assuming the potable use of the water.

2) Groundwater – 2 (GW-2) values apply to beneficial uses within 30 feet of an occupied building where the depth to groundwater is 15 feet or less. These values are calculated assuming the infiltration of vapors from a dissolved groundwater source of contamination.

3) Groundwater –3 (GW-3) values apply to beneficial uses that may directly impact any groundwater, and are calculated assuming that the groundwater will discharge to a nearby water body. The GW-3 values are based on the aquatic toxicity of chemicals.

4) Soil - The BUD Soil Values are based on a range of exposure scenarios. The most stringent values (S-1) assume long-term exposure to children and adults, while the least stringent values (S-3) are based on short-term, infrequent, adult-only exposures. The appropriate Soil Categories for comparison depend upon the accessibility of the beneficially used material (e.g., depth); nature of the material vis-à-vis potential exposure pathways; the nature of the potential receptors exposed (e.g., child or adult); the frequency of exposure; and, the intensity of the exposure that could result from the beneficial use.

6.2 BUD Method 2.

For COCs lacking established Method 1 values, the applicant may assess potential risks using Method 2. Detailed guidance on appropriate methods is available at http://www.state.ma.us/dep/ors/orspubs.htm. Applicants must keep in mind the differences between the BUD and MCP approaches as discussed in Section 4.2.1. This approach must be used if the applicant wishes to use Method 1 values to evaluate other secondary material constituents. Alternatively, the total waste risk may be assessed using Method 3 (Section 5.3). Method 2 may also be used to derive modified values that account for exposure and release variables specific to a proposed restricted beneficial use. In Method 2 the applicant derives a value for the chemical in question using appropriate data, methods and risk management criteria as specified by DEP. Method 2 values are thus functionally equivalent to Method 1 values but are derived by the applicant.

6.3 BUD Method 3.

The third method for characterizing risk relies on a use-specific risk assessment approach analogous to the site-specific approach under the MCP. Detailed guidance on appropriate methods is available at http://www.state.ma.us/dep/ors/orspubs.htm. Applicants must keep in mind the differences between the BUD and MCP approaches as discussed in Section 5.2.1. A Method 3 assessment describes and quantifies the current and future exposures that would occur attributable to the proposed beneficial use and compare the estimated risks to the Total Waste Cancer and Noncancer Risk Limits specified in the BUD regulations. If the risk assessment includes limitations on site use, such as a prohibition of residential development, such limitations must be included in a deed notification. Such notification shall be recorded in the registry of deeds or in the registry section of the land court for the district wherein the property lies. Such notification shall describe the limitations on the use of the property and reference to the Department file number or other Department means for identifying the file

A use-specific risk assessment could be used to demonstrate that constituent concentrations higher than the published Method 1 Values pose “No Significant Risk” due to limited exposure potential with a given beneficial use. A Method 3 assessment is also required if exposure pathways, which were not considered in the derivation of Method 1 and Method 2 values, exist.

As stipulated in the Regulations, dilution may not be used to meet risk criteria. Thus, when using Method 3 to assess compliance with the acceptable risk criteria, exposure point concentrations must be based on the COC concentrations in the secondary material product as used. Additives may only be used if they are required to impart a critical function or attribute to the final material to be beneficially used.

APPENDICES

Appendix 1. Definitions

310 CMR 16.00 refers to the siting regulations that address solid waste management facilities. These include siting requirements for landfills, municipal waste combustors, and transfer and processing facilities.

Adverse Impact means an injurious impact that is significant in relation to the public health, safety, or environmental interest being protected. Adverse Impact refers to qualitative impacts resulting from beneficial uses that may affect people and the environment. The Massachusetts Department of Environmental Protection is responsible for protecting human health and the environment by ensuring clean air and water, through the safe management and disposal of solid and hazardous wastes. DEP's role under Article 97 of the Massachusetts Constitution is the guarantor of the people's right to "clean air and water", as well as "the natural scenic, historic and aesthetic qualities of the environment.

Beneficial Use means the use of a material as an effective substitute for a commercial product or commodity.

Beneficial Use Determination (BUD) means the permitting by a State environmental agency of the use of a non-hazardous RCRA solid waste in a product, or used as a product itself, when certain environmental and public health standards are met. In general, for such a waste to be beneficially used it must have chemical and physical properties similar to the raw material that it is replacing or, when incorporated into another product, its use must contribute to the effectiveness of the final product.

Commercial means of, relating to, or being goods, often unrefined, produced and distributed in large quantities for use by industry.

Constituents of Concern ("constituent") means any component of a secondary material that may present a risk of injury to health or the environment.

Critical Contaminants of Environmental Concern (CCCs) are a subset of the universe of Contaminants of Concern (see Appendix – 2 for a full listing). This list includes compounds that pose a elevated threat to public health and the environment because they exhibit: 1) persistence in the environment; 2) ability to bioaccumulate; 3) potent toxicity; and/or 4) widespread presence in the environment at levels of concern.

Destructive Practices means any process that results in breakage of products manufactured using secondary materials increasing surface area and potentially releasing COCs to the environment.

Exposure Pathway means the mechanism by which human or environmental receptors inhale, consume, absorb, or otherwise take in oil and/or hazardous material at an Exposure Point.

Performance Data means any parameter or piece of information collected or produced from measurements, analyses or models of environmental processes, conditions and effects of COCs on human health and the environment including results from laboratory analyses, demonstration or pilot project and the work performed to obtain, use, or report information pertaining to process, method, procedure, equipment, system or facility.

Quality Assurance (QA) means an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected.

Quality Control (QC) means the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

RCRA means the Resource Conservation and Recovery Act.

Recyclable or Recyclable Material means a material that has the potential to be recycled and which is pre-sorted and not contaminated by significant amounts of toxic substances.

Recycle means to recover materials or by-products that are:

a) Reused; or
b) Used as an ingredient or a feedstock in an industrial or manufacturing process to make a marketable product; or
c) Used in a particular function or application as an effective substitute for a commercial product or commodity.

"Recycle" does not mean to recover energy from the combustion of a material.

Regulated Systems means any storage, transfer, processing, treatment, use, or disposal activity governed, approved, or otherwise ordered by the Department.

Restricted Applications means uses of secondary materials that utilize risk management techniques in order to prevent adverse impacts to the public health, safety and the environment.

Secondary Material means a discarded material that has the potential to be recycled and is not classified as a "recyclable material" – i.e. not pre-sorted, contains COCs, or is used at facilities and operations to which 310 CMR 16.00 applies.

Solid Waste or Waste means useless, unwanted or discarded solid, liquid or contained gaseous material resulting from industrial, commercial, mining, agricultural, municipal or household activities that is abandoned by being disposed or incinerated or is stored, treated or transferred pending such disposal, incineration or other treatment, but does not include:

(a) Hazardous wastes as defined and regulated pursuant to 310 CMR 30.000;

(b) Sludge or septage which is land applied in compliance with 310 CMR 32.00;

(c) Waste-water treatment facility residuals and sludge ash from either publicly or privately owned waste-water treatment facilities that treat only sewage, which is treated and/or disposed at a site regulated pursuant to M.G.L. c. 83, §§ 6 & 7 and/or M.G.L. c. 21, §§ 26 through 53 and the regulations promulgated thereunder, unless the waste-water treatment residuals and/or sludge ash are co-disposed with solid waste;

(d) Septage and sewage as defined and regulated pursuant to 314 CMR 5.00, as may be amended, and regulated pursuant to either M.G.L. c. 21, §§ 26 through 53 or 310 CMR 15.00, as may be amended, provided that 310 CMR 16.00 does apply to solid waste management facilities which co-dispose septage and sewage with solid waste;

(e) Ash produced from the combustion of coal when reused as prescribed pursuant to M.G.L. c. 111, § 150A;

(f) Solid or dissolved materials in irrigation return flows;

(g) Source, special nuclear or by-product material as defined by the Atomic Energy Act of 1954, as amended;

(h) Those materials and by-products generated from and reused within an original manufacturing process; and

(i) Compostable or recyclable materials when composted or recycled in an operation not required to be assigned pursuant to 310 CMR 16.05(2) through (5).

Unrestricted Applications means uses of secondary materials that result in unlimited routes of exposure to human and environmental receptors from secondary material constituents.

Appendix 2: CRITICAL CONTAMINANTS OF CONCERN LIST

MADEP has identified the following compounds as critical contaminants of concern for assessment under the revised BUD regulations. These compounds include the Level 1 and Level 2 priority Persistent Bioaccumulative Toxic Chemicals PBTs identified under the Binational Toxics Strategy (http://www.epa.gov/glnpo/bns/chemicals.html) as well as select compounds from the RCRA Waste Minimization PBT Chemical List (http://www.epa.gov/fedrgstr/EPA-WASTE/1998/November/Day-09/f29952.htm). MADEP has also included the brominated diphenyl ether compounds as a group on this list because of their persistence, bioaccumulative nature and toxicity, as well as data that demonstrates that environmental levels and exposures to these chemicals are close to those associated with overt toxicity and are increasing. Lead has been included because of its toxicity to children.

Modifications to this list may be made as new information becomes available.

Binational Toxics Strategy Level 1 Substances:

aldrin/dieldrin
benzo(a)pyrene
chlordane
DDT, DDD, DDE
hexachlorobenzene
alkyl-lead
mercury and its compounds
mirex
octachlorostyrene
PCBs
dioxins and furans
toxaphene

Binational Toxics Strategy Level 2 Substances:

cadmium and cadmium compounds
1,4-dichlorobenzene
3,3'-dichlorobenzidine
dinitropyrene
endrin
heptachlor (and heptachlor epoxide)
hexachlorobutadiene and hexachloro-1,3-butadiene
hexachlorocyclohexane
4,4'-methylenebis(2-chloroaniline)
pentachlorobenzene
pentachlorophenol
tetrachlorobenzene (1,2,3,4- and 1,2,4,5-)
tributyl tin

PAHs as a group, including anthracene, benzo(a)anthracene,
benzo(ghi)perylene,perylene, and phenanthrene[2]

Other Compounds of Concern To DEP

Brominated diphenyl ethers
Lead

Select Compounds from the Draft RCRA Waste Minimization PBT Chemical List

Chlorinated Solvents:
- Chloroform
- 1,1-Dichloroethane
- 1,1,1-Trichloroethane

Chlorobenzenes:
- 1,2-Dichlorobenzene
- 1,3-Dichlorobenzene
- 1,2,4-Trichlorobenzene

Other Halogenated Organics:
- 4-Bromophenyl phenyl ethers

Pesticides
- alpha-Endosulfan
- beta-Endosulfan
- Methoxychlor
- Pentachloronitrobenzene
- 2,4,5-Trichlorophenol

Organonitrogens:

Nitrobenzene

Nonhalogenated Phenolics:

Phenol

2,4,6-tris-(1,1-Dimethylethyl)phenol

Phthalate esters:

Bis-(2-ethylhexyl) phthalate

Butylbenzyl phthalate

Dibutyl phthalate

Polycyclic aromatic hydrocarbons:

Acenaphthene

Acenapthylene

Anthracene

Fluoranthene

Fluorene

2-Methylnaphthalene

Naphthalene

Pyrene

Metals

Antimony

Arsenic

Beryllium

Chromium

Copper

Nickel

Selenium

Zinc

Cyanide

Appendix 3. Permit Schedule

Application Phase Process Steps	Purpose	Applicant Actions	Department Actions	Timetable		Fee
Pre-Application / Determination of Applicability Phase						
Preliminary Application / Determination of Applicability Meeting	To obtain sufficient information to classify the use. Provide guidance to the applicant.	Submit pre-application information	Meet with the applicant. Explain the beneficial use process. Identify approval standards. Provide final application requirements.	Applicant submits preliminary information at least 10 business days prior to meeting.		NA
Beneficial Use Category Determination	To establish review criteria based upon material use and potential hazards.	NA	Decide which review category is applicable to the beneficial use.	Prior to the pre-application meeting, if possible.		NA
Scope of Evaluation Determination	Determine final application requirements.	NA	Specify specific application requirements. Identify standards for approval. Establish timeline and fee, if applicable.	Within 10 business days after the pre-application meeting.		NA
At the end of the pre-application phase the Department will have assigned the application to a tier review category, provided the applicant with characterization requirements and standards for review, and established the timeline and fee for individual rule permit applications.						
Application Phase						
Administrative Review	Ensure application contains necessary information.	Applicant submits full application.	Department reviews the application to assess administrative completeness.	Tier I	30 days	Tier I: $ Tier II: $ Tier III: individual rule Tier IV: individual rule
				Tier II	30 days	
				Tier III	30 days	
				Tier IV	30 days	
First Technical Review	Review application to ensure use is safe.	The applicant has 180 days from receiving a technical deficiency to respond to the technical deficiency.	Department reviews the application for technical completeness and issues BUD or deficiency.	Tier I	30 days	
				Tier II	30 days	
				Tier III	individual rule	
				Tier IV		
Second Technical Review	Review application to ensure use is safe (if necessary).	Submits deficient information. If deficient again the BUD is denied.	In the case that technical information is inadequate the applicant shall submit requested information.	Tier I	30 days	
				Tier II	30 days	
				Tier III	individual rule	
				Tier IV		

Appendix 4: References

Massachusetts Department of Environmental Protection (DEP). July, 1988. Ash Sampling and Analysis Guidance. SWM-9-7/88 (as further clarified in 7/97 DEP communications to facility operators).

Massachusetts Department of Environmental Protection. (DEP). July, 1995. Guidance for Disposal Site Risk Characterization – in Support of the Massachusetts Contingency Plan. Bureau of Waste Site Cleanup and Office of Research and Standards.

United States Environmental Protection Agency (US EPA). December, 1989. Risk Assessment Guidance for Superfund (Volume 1) – Human Health Evaluation Manual (Part A) – Interim Final. Office of Emergency and Remedial Response.

United States Environmental Protection Agency (US EPA). 1997a. Compilation of Air Pollutant Emission Factors, AP-42. 5th ed. Supplement C. Office of Air Quality Planning and Standards. Research Triangle Park, NC.

United States Environmental Protection Agency (US EPA). 1997b. Exposure Factors Handbook. National Center for Environmental Assessment

United States Environmental Protection Agency (US EPA). 1997c. Health Effects Assessment Summary Tables (HEAST). Solid Waste and Emergency Response. FY 1997 Update.

United States Environmental Protection Agency (US EPA). 1997d. Emission Factor Documentation for AP-42 Section 2.4 – Municipal Solid Waste Landfills –Revised.

United States Environmental Protection Agency (US EPA). February, 1998. User's Manual – Landfill Gas Emissions Model. Air Pollution Prevention and Control Division; Control Technology Center; and Office of Research and Development.

United States Environmental Protection Agency (US EPA). 2001. Integrated Risk Information System (IRIS) database. http://www.epa.gov/ngispgm3/iris/subst/index.html.

Appendix 5 Tables of Values