

Guidance 066 Disposal of Rejected and Waste Materials

- Define the qualifications of the witness;
 - Determine the frequency of witnessing product and material destruction; and -Destruction certificates.
2. Complete Records should be kept of the following information for all disposed, rejected, and other waste materials:
- Material name (or Group Name, such as “Laboratory Waste” where specifically specified by EHS list);
 - Identification code, if assigned (e.g., batch number or lot number);
 - Quantity of the official weight disposed and date disposed;
 - Method of disposal;
 - Names of persons who authorized, implemented, and/or witnessed disposal; and
 - Other information required and included in the Materials and Product Destruction Plan.
3. Rejected and Waste Materials, Prior to Destructions or Shipping for Destruction should be rendered unusable following applicable local regulations to prevent misuse of such materials. Examples of these renderings practices are as follows:
- Printed materials are defaced or shredded to a size small enough to be obvious to the casual observer that the material is not intended for use and cannot be easily diverted for use;
 - Packaged products or bulk products (i.e., drums or boxes of bulk tablets) are shredded or ground to a size small enough to be obvious to the casual observer that the material is not intended for use and is in a condition where diversion and use would be a difficult and unappealing prospect;
 - Bulk products (i.e., drums or boxes of bulk tablets, APIs) are wetted to achieve partial dissolution or mixture with quantities of other wastes so as to make the entire mass impractical and unappealing for diversion;
 - Medical devices are ground or crushed to render them unusable;
 - Drinkable alcohol is rendered unusable by adding denaturants, extensive dilution, or mixing with other waste solvent;
 - Labeling, including labeled, empty product containers and similar items, and labeled product waste is destroyed or defaced with permanent ink crosses to prevent unauthorized, off-Site salvaging or use; or
 - On-Site incineration.
4. Waste Disposal Contractors should be approved and audited by Site Waste Disposal Team following the requirement specified in EHS, with notification to the Site Quality Team as to which contractors are approved for use.
5. Acceptable Methods of Waste Disposal shall be used according to the EHS requirements.