TIP No. 37-057-0421

DETERMINING ELIGIBILITY FOR EPR FUNDING OF A LABORATORY VIAL DISPOSAL SYSTEM

PURPOSE. To discuss and evaluate Environmental Program Requirements (EPR) funding eligibility for the purchase and use of a vial disposal system, such as the Vyleater® or Thermo Scientific™ National Vial Crusher, to reduce and consolidate certain laboratory hazardous wastes (HW).

REFERENCES. See Appendix A for a list of reference information.

POINTS OF MAJOR INTEREST AND FACTS

Background

Medical treatment facility (MTF) laboratories generate wastes to include, but not limited to, containers of unprocessed urine samples remaining after analysis is complete (a non-HW and nonregulated medical waste (non-RMW)), as well as cytology specimen vials containing approximately 20 milliliters (mL) of a methanol-based cyto-preservative solution (i.e., ThinPrep® PreservCyt®, which is an HW).

Urine samples are typically managed by personnel manually emptying the container to the sanitary sewer (via toilet or sink). Because of the potential for personally identifiable information (PII) on the empty container, some MTFs may incorrectly place them in the RMW for disposal rather than remove any patient information and place them in solid waste. However, the container (empty or full) is not RMW. The majority of RMW is autoclaved and landfilled, not incinerated or otherwise made unrecognizable after treatment (unless required by State or local regulations). Any PII information on the containers may remain intact and legible. Placing non-RMW items in the RMW as a means to address PII is not authorized and depletes necessary RMW environmental funding. Any PII on the urine sample containers should be removed prior to disposal as solid waste.

There are two possible ways to manage the HW cytology specimen vials. One method is to place the intact vials and their liquid contents into a larger secondary container prior to disposal as an HW. This unnecessarily increases the volume of HW being managed and disposed because the mass of each individual specimen vial is included (e.g., a 55-gallon drum of vials may only contain 5 to 6 gallons of hazardous waste liquid, but the entire contents of the drum must be managed as HW). The second method is personnel may manually open the vials and collect the cyto-preservative solution in a single larger container prior to disposal as HW. (However, this manual emptying process may increase the potential for spills and/or exposure of personnel to the HW being collected.) The emptied specimen vials are not subject to HW regulations and should be disposed as solid waste. In both situations listed above, any PII on the cytology specimen vials should be removed prior to disposal.

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Use of Automated or Manual Vial Disposal Systems

Automatic or manually operated vial disposal equipment is available to crush (for glass or hard plastic) or cut and/or shred (for plastic) small laboratory vials (generally from 1mL to 100mL in size), separating the sample containers from their liquid contents. The equipment will automatically send plastic, glass, or metal vial fragments to one accumulation container for disposal as a solid waste while the liquid vial contents will be sent to a separate destination; either another accumulation container (especially for HW) or some units can be connected to a drain for direct disposal to the sanitary sewer (for non-HW).

If the vials containing the HW cyto-preservative are currently managed intact when disposed by the MTF, the vial disposal system will utilize waste consolidation to significantly reduce overall HW volume by eliminating the mass of the individual vials and collecting the liquid in one larger container, resulting in waste disposal cost savings. For both HW and non-HW, the equipment eliminates labor costs associated with laboratory personnel manually emptying the contents of the vials.

The MTF's designated environmental officer or supporting installation Environmental Office should be consulted in the planning phases of acquisition of the vial disposal system to ensure compliance with all Federal, State, and local environmental requirements.

When choosing a vial disposal system, it is important to know what type of vials you have (glass or plastic) and to verify the vial disposal system you choose will process them correctly (i.e., separate the liquid from the vial for disposal in separate containers, and whether it will destroy any PII on the vials, if applicable). Some vial disposal equipment designed for plastic will only cut, not shred, the plastic vials. Any PII may remain after cutting and should be manually removed prior to insertion into the disposal system.

For example, of the two models of the Vyleater available (Standard and Enhanced), the Standard model utilizes a roll crusher and is better suited to shatter glass containers and brittle plastic. The Enhanced Vyleater model utilizes a high-torque/low-speed shredder which is better suited for plastic (both pliable and brittle plastic containers), reducing the vials to an unrecognizable mulch. Additionally, both models come in a standard version or an explosion-proof version (i.e., explosion-proof motors and controls) for managing vials with flammable liquid wastes. Similarly, the Thermo Scientific National Vial Crusher is better suited for glass vials instead of plastic.

Management of Vials of Hazardous Waste[1]

ThinPrep PreservCyt is a methanol-based preservative solution with a flashpoint of 26 °Celsius/78 °Fahrenheit. When disposed, the used solution is a characteristic

[1] Only Federal HW requirements are addressed; State and local HW requirements are outside the scope of this document.

ignitable HW, with Environmental Protection Agency (EPA) HW number D001. For this reason, use of an explosion-proof model vial disposal system, or one that ventilates fumes away, is required to safely manage this waste.

Use of a vial disposal system to consolidate waste from small sample vials into a larger container is not considered treatment of an HW by the EPA and is allowed as long as the only function of the equipment is waste consolidation and no HW is released or altered during the process.

Some vial disposal systems may have an optional internal-flushing system accessory. This flushing system is not required and should not be used for the cyto-preservative waste or any other HW. Flushing the cyto-preservative would alter the waste stream (through dilution) and constitute treatment of an HW without a permit. Treatment of HW without a permit is subject to a fine of up to $76,764 per day for each day the violation occurred.

Two types of locations exist for operating the vial disposal system that will collect HW; an HW satellite accumulation area (SAA) or an HW central accumulation area (CAA).

Satellite Accumulation Area

If the vial disposal system is located in an established HW SAA that meets all Resource Conservation Recovery Act (RCRA) requirements in Title 40, Code of Federal Regulations (CFR) Section 262.15, no additional RCRA record keeping or air-emission standards will apply. The SAA must be at or near the waste generation process and under control of the process operator.

Some vial disposal systems could require a substantial amount of space that may prohibit installation in the laboratory. For example, the Vyleater has a 28” x 63” footprint, with adjustable height depending on the size of the collection containers underneath (up to 55-gallon drum), ranging from 73” to 83”. Smaller vial disposal systems are available, like the Thermo Scientific National Vial Crusher (approximately 12” x 24” x 35” high), which can be bench mounted or can come on a stainless steel trolley (approximately 17” x 24” x 26” high). Mounting on a trolley allows it to be moved when not in use, as well as allows a small drum for collection of liquids from the debris to be fitted in the cabinet of the trolley, together with a separate receptacle for the glass vial waste.

Additionally, the vials and their contents are not considered waste under RCRA until cytology laboratory personnel complete their slide preparations and patient diagnoses. Once a decision is made to discard the vials they should be relocated to the SAA in the lab, where the vial disposal system is located, for accumulation and eventual crushing, cutting, or shredding. However, no more than 55 gallons of waste may be maintained in an SAA. This includes the amount of waste awaiting crushing, cutting, or shredding and the amount of waste accumulating in the waste collection container attached to the vial disposal system.

Central Accumulation Area

If the vial disposal system is not located in an SAA (at or near the point of generation in the lab), the RCRA regulations for CAA storage in Title 40 CFR 262.17 will apply. This regulation additionally requires compliance with Title 40 CFR 265, Subparts AA (Air Emission Standards for Process Vents), BB (Air Emission Standards for Equipment Leaks), and CC (Air Emission Standards for Tanks, Surface Impoundments, and Containers).

- Subpart AA *will not apply* because use of a vial disposal system is not a distillation, fractionation, thin-film evaporation, solvent extraction, or air- or steam-stripping operation.

- Subpart BB (40 CFR 265.1050–1064) requirements *will apply*. The Title 40 CFR 265.1050(e) excludes equipment that contains or contacts HW for less than 300 hours (hrs) per year from regulation with this Subpart. As an example, the Vyleater takes approximately 30 seconds to 2 minutes to consolidate liquid and crush/shred a typical batch of 20-mL vials. A typical batch size is 300 vials. Therefore, the Vyleater would have to process 2,700,000 vials per year to exceed this limit.

$$\left(\frac{300\ hrs}{1\ year}\right)\ x\ \left(\frac{60\ min}{1\ hr}\right)\ x\ \left(\frac{1\ batch}{2\ min}\right)\ x\ \left(\frac{300\ vials}{1\ batch}\right) = 2{,}700{,}000\ vials/year$$

To implement this exemption, the record keeping requirement in 40 CFR 265.1064(g)(6) must be maintained. It requires identification, either by list or location of the vial disposal system (in this example, the Vyleater), recorded in a log that is kept in the facility operating record.

- Subpart CC (40 CFR 265.1080–1090) requirements *will apply*. The Title 40 CFR 265.1080(b)(2) exempts containers of less than or equal to 26 gallons (0.1 meters^3) from regulation with this Subpart. According to Title 40 CFR 265.1087(c)(1)(i) and (f), containers that meet U.S. Department of Transportation (DOT) regulations are considered to meet all Subpart CC container requirements for this waste stream. Therefore, a closed container greater than 26 gallons may be used to collect the HW from the vial disposal system if it complies with all applicable DOT regulations and is kept closed at the site.

Management of Containers of Non-Hazardous Waste

Urine in the sample containers is a non-HW and is also a non-RMW. Once the urine is emptied from the containers, the containers themselves are solid waste and should be disposed as regular trash.

Although not eligible for EPR funding (see section below on "Eligibility for EPR Funding"), a vial disposal system could be used to automate the separation of urine from the sample containers. The liquid discharge from some vial disposal systems, for example the Vyleater, can be connected to a drain so that the urine empties directly to the sanitary sewer, and the shredded sample containers can be collected in a container for disposal as solid waste.

As noted above, the Enhanced Vyleater model utilizes a high-torque/low-speed shredder which is better suited for plastic containers (such as urine cups), reducing the sample containers to unrecognizable mulch. Because the urine is non-flammable, the explosion-proof model of the Vyleater is not required.

Finally, when using a vial disposal system to process urine sample containers or other non-HWs that may leave a residue or an odor, prior to purchase investigate if the unit has included, or as available options for purchase and use, items such as an internal conveyor and hopper flushing accessory, or a chemical metering pump accessory (for adding a chemical rinse agent to the water used to flush the unit, such as bleach).

Eligibility for EPR Funding

The U.S. Army Medical Command (MEDCOM) uses the EPR data as one of its tools for programming and justifying environmental funding requirements to higher headquarters. This information is also used to program annual funding distributions. It is critical that only legitimate environmental projects be entered into the EPR database. Cost and obligation data must also be accurate.

The preferred method for meeting compliance requirements, reducing operating costs, and maintaining environmental stewardship is through waste minimization projects. The appropriate purchase of vial disposal equipment as an EPR project would fall under the Army Management System Code 56.42, Non-Recurring Hazardous and Medical Waste (Equipment).

For management of specimen vials containing HW such as the ThinPrep PreservCyt cyto-preservative, where the vials are originally collected and disposed of intact without removing the waste, the purchase of the vial disposal system *is eligible* for EPR funding as a waste minimization project. In this example, the use of the vial disposal system will reduce the overall amount of HW being disposed by eliminating the mass/volume of each individual vial and only collect and dispose of the used cyto-preservative solution as an HW. This in turn reduces the costs paid for HW disposal. Whether the purchase and use of the vial disposal system will have a return on investment in the amount of time required by MEDCOM for EPR-funding requirements (5 years or less) will depend on the MTF's current costs for management and disposal of the HW vials when compared to management and disposal costs of the same number of vials using the vial disposal system.

For management of containers of non-HW urine, the vial disposal system should crush/shred the plastic containers, separating the urine from the container; however, it

is not eligible for EPR funding because the urine is not an HW or an RMW and can be discharged to the sanitary sewer at no cost. Therefore, no reductions in disposal amounts exist for urine. Additionally, there is no reduction in solid waste disposal as the containers themselves are still disposed of as solid waste regardless if they have been emptied by hand or crushed/shredded. In this case, use of a vial disposal system does not serve an environmental function. Funding for the purchase of a vial disposal system for only non-HW container management would have to come from the MTF's operating budget.

EPR Eligibility Funding Example Calculation

The following provides estimates and examples of the type of information required to determine the return on investment for implementing the purchase and use of a vial disposal system to manage vials containing HW. Each MTF considering implementation will need to perform site-specific calculations as actual information and costs will vary by location and over time. These calculations must be included in the EPR submission.

Required information to complete the calculations includes: the costs for the current management of the HW vials, costs for management of the same number of HW vials using the vial disposal system, and the costs associated with the purchase of the vial disposal system.

The calculations assume that the current management practice for the HW vials is that they are disposed of intact (still containing the methanol-based cyto-preservative) in a 5-gallon bucket prior to disposal as an HW. These calculations mainly focus on the HW disposal costs and do not include other applicable costs such as:

- Differences in the amount of labor (current management procedures versus new procedures using the vial disposal system). This is because the amount of time for the vial disposal system to process a batch of vials can be relatively quick (depending on the unit, it can be approximately 300 vials per 2 minutes) and is not expected to vary significantly from the current management practice of placing each vial intact into a collection bucket.

- Electrical energy costs for the use of the vial disposal system (current management method has no electrical energy costs). Because the equipment is not continuously running but only operates periodically in batches, the cost to run the equipment would not greatly increase the time of the return on investment.

- Weekly preventive maintenance (PM) of the vial disposal system. Weekly PM would include labor to clean/brush any separation screens and spray/rinse the interior. This is not expected to be labor intensive and would not contribute greatly to increase the return on investment.

- Solid waste disposal costs of the empty/shredded vials. Plastic vials are relatively light and solid waste disposal fees are relatively inexpensive such that this also is not expected to greatly affect the return on investment calculation. Additionally, personnel could research the possibility of finding a recycler for the plastic, which would divert it from the solid waste stream. Glass vials would weigh slightly more, but again, the solid waste disposal costs are not expected to be significant.

While the above costs are not included in this example, MTF personnel should consider adding them when performing their own return on investment calculations, especially if they believe them to be more significant given their specific circumstances.

Assumptions

The below amounts, prices, and costs are *estimates only.* For this example, calculations will be shown for the purchase and implementation of the Vyleater Enhanced Model, Explosion-Proof (Model II-Xe), which is suitable for managing plastic vials containing a flammable HW such as the ThinPrep PreservCyt cyto-preservative.

- 500 specimen vials containing HW cyto-preservative are disposed per week.
- Specimen vials are disposed whole (no removal of the cyto-preservative) by placing each vial in a secondary 5-gallon collection bucket.
- Each 5-gallon bucket will hold approximately 125 specimen vials.
- Number of 5-gallon buckets required per week:

$$\frac{500\ specimen\ vials}{1\ week}\ x\ \frac{1,5\text{-}gallon\ bucket}{125\ specimen\ vials} =\ 4,5\text{-}gallon\ buckets\ per\ week$$

- Each specimen vial contains approximately 20-mL of HW cyto-preservative.
- Weekly volume cyto-preservative disposed (in 500 specimen vials):

$$\left(\frac{500\ vials}{week}\right)\ x\ \left(\frac{20\ ml}{vial}\right) x\ \left(\frac{0.000264172\ gallons}{1\ ml}\right) =\ 2.64\ gallons\ per\ week$$

- Purchase cost of one, 5-gallon plastic bucket with lid, $15.
- Purchase cost of one, 30-gallon steel drum, $120.
- Disposal cost for a 5-gallon bucket of D001 HW, $75.

- Disposal cost for a 30-gallon steel drum of D001 HW, $200.

Vial Disposal System Equipment Options:

- Vyleater Standard Model, Standard (Non-explosion-proof, Model II-S), $37,235[2]. (recommended for glass vials, non-HW, and non-ignitable waste)

- Vyleater Standard Model, Explosion-Proof (Model II-X), $42,026[2]. (recommended for glass vials and ignitable HW)

- Vyleater Enhanced Model, Standard (Non-explosion-proof, Model II-Se), $53,098[2]. (recommended for plastic vials, non-HW, and non-ignitable waste)

- Vyleater Enhanced Model, Explosion-Proof (Model II-Xe), $57,8402 (recommended for plastic vials and ignitable HW).

Example Vyleater Options/Accessories (additional options are available):

- Basic Conveyor and Hopper Flush, $1,482[2] (recommended for non-HW operations only).

- Chemical Metering Pump, $679[2] (recommended for non-HW operations only).

- Hand Held Spray Wand, $698[2] (for cleaning interior of separating conveyor).

- Delivery and Set-up of Equipment, $3,300[2].

- One-Day Onsite Training, $1,500[2].

- Thermo Scientific National Vial Crusher (pneumatic operation), $19,800[3] (recommended for glass vials).

- Thermo Scientific National Vial Crusher (manual operation), $8,000[3] (recommended for glass vials).

[2] S & G Enterprises, Inc. Vyleater equipment pricing current as of January 2021.
[3] Fischer Scientific Thermo Scientific National Vial Crusher equipment pricing current as of March 2021. As of March 2021 these products are also available on a Fisher Scientific GSA contract. The contract price can be viewed by searching for these items on the GSA Advantage website, https://www.gsaadvantage.gov.

Cost Estimate, Current Management of HW Vials (Recurring Costs)

HW containers (5-gallon buckets) disposed per year:

$$\frac{4\ buckets}{1\ week}\ x\ \frac{52\ weeks}{1\ year} = 208\ buckets\ per\ year$$

Annual purchase cost HW containers (5-gallon bucket):

$$\frac{208\ buckets}{1\ year}\ x\ \frac{\$15}{1\ bucket} = \$3,120\ per\ year$$

Annual HW (D001) disposal costs (5-gallon buckets):

$$\frac{208\ buckets}{1\ year}\ x\ \frac{\$75}{1\ bucket} = \$15{,}600\ per\ year$$

Current Management of HW Vials, Annual Recurring Cost:

$$\frac{\$3{,}120}{1\ year} + \frac{\$15{,}600}{1\ year} = \$18{,}720\ per\ year$$

Cost Estimate, Vyleater (Model II-Xe) Management of HW Vials (Recurring Costs)

Amount HW cyto-preservative solution disposed per year:

$$\frac{2.64\ gallons}{1\ week}\ x\ \frac{52\ weeks}{1\ year} = 137.3\ gallons\ per\ year$$

HW Containers (30-gallon drum) required to collect/dispose cyto-preservative per year:

$$\frac{137.3\ gallons}{1\ year}\ x\ \frac{1\ drum}{30\ gallons} = 4.6 \approx 5,30\text{-}gallon\ drums\ per\ year$$

Annual purchase cost HW containers (30-gallon drums):

$$\frac{5\ drums}{1\ year}\ x\ \frac{\$120}{drum} = \$600\ per\ year$$

Annual HW (D001) disposal costs (30-gallon drums):

$$\frac{5\ drums}{year}\ x\ \frac{\$200}{drum} = \$1{,}000\ per\ year$$

Vyleater (Model II-Xe) Management of HW Vials, Annual Recurring Cost:

$$\frac{\$600}{1\ year} + \frac{\$1{,}000}{1\ year} = \$1{,}600\ per\ year$$

Purchase Costs, Vyleater (Model II-Xe) for Management of HW Vials

Vyleater Enhanced Model, Explosion Proof (Model II-Xe), $57,840

Vyleater Accessory, Hand Held Spray Wand, $698

Delivery and Set-up of Equipment, $3,300

One-Day Onsite Training, $1,500

Vyleater (Model II-Xe) for Management of HW Vials, Total Purchase Costs:

$$\$57{,}840 + \$698 + \$3{,}300 + \$1{,}500 = \$63{,}338$$

Return on Investment, Vyleater (Model II-Xe) Management of HW Vials

The EPR-eligible projects must achieve a 5-year (or less) return on investment for approval by MEDCOM. Calculate the return on investment (i.e., payback-period) by dividing the implementation purchase costs by the difference between the annual recurring costs of the current management method and the annual recurring costs using the Vyleater:

$$\frac{\$63{,}338}{\left[\left(\frac{\$18{,}720}{1\ year}\right) - \left(\frac{\$1{,}600}{1\ year}\right)\right]} = 3.7\ years$$

CONCLUSIONS

In the example above, for the disposal of 500 vials per week, the purchase and use of the Vyleater Enhanced Model, Explosion Proof (Model II-Xe) would have a return on investment of approximately 3.7 years. This is within the required 5-year time frame expected for MEDCOM EPR-eligible projects.

Using the above assumptions and calculations, an estimated minimum amount of HW specimen vials disposed per week which would still meet the MEDCOM EPR return on investment of 5 years would be somewhere between 350–375 HW vials. Below that number of vials being disposed of per week, the purchase and use of the Vyleater equipment would have a return on investment exceeding 5 years.

Using the assumptions above and applying them to laboratories that do not generate as many waste specimen vials, purchasing a smaller, less expensive vial disposal system like the Thermo Scientific National Vial Crusher (pneumatic operation), which is designed to process glass vials, would have a return on investment of approximately 5 years with somewhere between 100 and 125 HW vials disposed per week.

Although the calculations are not shown here, if the HW specimen vials were originally managed by the more labor-intensive process of manually opening and emptying the vials instead of disposing with the contents intact, the difference in labor costs alone would be required to justify the return on investment. This is because there would be no difference in the amount of HW being disposed (both processes collect and dispose of the cyto-preservative only); the only difference is in the amount of time it takes to separate the vials from their contents (i.e., manually vs. automated).

The assumptions presented above only address the use of a vial disposal system for the processing of the HW vials. The processing of non-HW containers, such as the urine cups, is not addressed because they are not eligible for EPR funding.

Finally, if the vial disposal equipment is purchased with the intent to process both HW and non-HW (i.e., dual use), only the costs for managing the HW vials would be pertinent for performing the calculations for EPR funding return on investment.

Equipment for dual usage must be designed to meet the most conservative requirements such as explosion control and liquid discharge collection. The equipment purchased would primarily be that for processing the HW (i.e., need to be explosion-proof) but would include additional accessories for processing non-HW (such as conveyor and hopper-flushing system and a chemical meter pump, which would also have to be explosion proof). These additional accessories would increase the implementation costs and would affect the return on investment.

For the intended dual use of the Vyleater in this example, the manufacturer can install a “double drain arrangement” for the liquid effluent coming from the equipment. This utilizes two hoses: one dedicated to a container to collect the HW and the other dedicated to the sanitary sewer for disposal of the urine and flushing/rinse water. The hoses are connected to a manual diverter valve to allow the operator to switch between the floor drain and the HW collection container, depending on which waste is being processed.

In this instance, great care, such as specific operating procedures, labeling of equipment and valves, and training of personnel operating the equipment, will need to be taken to ensure the two wastes are managed separately and correctly (i.e., to avoid discharging HW to the sanitary sewer, or diluting the HW in the collection container with urine/rinse water).

Failure to manage the diverter and flush systems properly can result in unpermitted treatment (dilution) of HW which is subject to fines and penalties. If adequate precautions and safeguards cannot be met, the Vyleater should be dedicated to processing only one type of waste (HW or non-HW) and not both.

Other vial disposal equipment such as the Thermo Scientific National Vial Crusher may not have this “double-drain” option and should be dedicated to one type of waste only.

POINT OF CONTACT

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APPENDIX A

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