Guidance for Prescription Drug Disposal by Incineration

Nevada Division of Environmental Protection
Bureau of Air Pollution Control (BAPC)
Permitting Branch
901 South Stewart Street, Suite 4001
Carson City, Nevada 89701-5249
Phone (775) 687-9349

August 24, 2017

Disclaimer: The BAPC reserves the right to modify this guidance at any time. This document supersedes any previous documents that relate to prescription drug incineration issued by the BAPC.
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Section 1. Introduction

1.1 Purpose

The purpose of this document is to provide guidance to law enforcement on the disposal by incineration of prescription drugs collected at Law Enforcement and Drug Enforcement Administration (DEA) Authorized Collector Take-Back Events.

The goal of this guidance is to establish a sustainable solution for the disposal of collected prescription drugs.

1.2 Prescription Drugs in Nevada

Nevada has several year round prescription drug take-back or round up programs that are run through prevention coalitions and law enforcement. Typically, these are events where the public can drop off their prescription drugs; and the collected prescription drugs are then disposed of appropriately (Figure 1).

![Figure 1. Prescription Drug Take-Back Program Process: Public Brings Prescription Drugs to Take-Back Events and Law Enforcement/DEA Disposes of the Collected Prescription Drugs Appropriately.](image-url)
Section 2. Regulatory Applicability

The incineration of prescription drugs would be subject to Nevada Administrative Code (NAC) 445B Air Controls; but would not be subject to federal new source performance standards because the prescription drugs are collected and incinerated by law enforcement and are subject to an exemption. Additionally, prescription drugs collected at law enforcement take-back events are considered household waste and comply with the Controlled Substance Act Requirements by being collected and incinerated by law enforcement.

2.1. Nevada Administrative Code

Nevada Administrative Code (NAC) 445B.086 provides the following definition of an Incinerator:

“Incinerator” means an engineered apparatus capable of withstanding heat and designed to efficiently reduce solid, semisolid, liquid or gaseous waste at specified rates and from which the residues contain little or no combustible material.

Burning in any incinerator other than the multiple-chamber type is prohibited pursuant to NAC 445B.2207.

2.1.1. Opacity

NAC 445B.2207 provides that incinerator burning which produces, for periods totaling 1 minute in 1 hour, a visible emission which is of an opacity equal to or greater than 20 percent is prohibited.

Figure 2. This Figure Provides an Estimate of 20%, 40% and 80% Opacity for Reference.
2.1.2. Odors

NAC 445B.22087 requires that no person may discharge or cause to be discharged, from any stationary source, any material or regulated air pollutant which is or tends to be offensive to the senses, injurious or detrimental to health and safety, or which in any way interferes with or prevents the comfortable enjoyment of life or property.

2.2. Environmental Protection Agency (EPA) – New Source Performance Standard

EPA’s *Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs*, September 26, 2012, notes:

- Our preference is that they be sent to a permitted hazardous waste combustor, but when that is not feasible, at a minimum, they should be sent to a large or small municipal waste combustor.
- EPA is currently recommending incineration as the preferred disposal method for household take-back programs because we believe that incineration will address both environmental and diversion concerns.

Other solid waste incineration (OSWI) unit, as proposed in this guidance, means either a very small municipal waste combustion unit or an institutional waste incineration unit. These units are subject to the requirements of Part 60 – Standards of Performance for New Stationary Sources, Subpart EEEE – Standards of Performance for Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006.

However, the incinerator as proposed in this guidance is exempt from the federal new source performance standard based on 40 CFR Part 60.2887(p):

> Units that combust contraband or prohibited goods. The incineration unit is excluded if the unit is owned or operated by a government agency such as police, customs, agricultural inspection, or a similar agency to destroy only illegal or prohibited goods such as illegal drugs, or agricultural food products that can not be transported into the country or across State lines to prevent biocontamination. The exclusion does not apply to items either confiscated or incinerated by private, industrial, or commercial entities.

While there is no promulgated federal regulatory definition of “contraband” available, Nevada Revised Statutes 453.336(1) makes it unlawful for a person to possess a controlled substance unless that substance was obtained from, or pursuant to, a prescription or order of a licensed professional. As such, once a prescription drug leaves the possession of the person holding the lawful prescription, such as a law enforcement drop box, it becomes unlawful for any other person to possess that prescription drug. Under its delegated Clean Air Act authority, the Nevada Division of Environmental Protection (NDEP) classifies prescription drugs that are either seized by, or voluntarily surrendered to, a Law Enforcement Entity to meet the definition of contraband. Therefore, the scope of this guidance refers only to prescription drugs (including controlled substances) collected at Law Enforcement and DEA Authorized Collector Take-Back Events and disposed of by incineration by a Law Enforcement Entity.
Additionally, it is also required that the incinerator be owned and operated by a Law Enforcement Entity.

2.3. Environmental Protection Agency (EPA) – Hazardous Waste Exemption

Pursuant to 40 CFR §261.4(b)(1), the following solid wastes are not hazardous wastes:

Household waste, including household waste that has been collected, transported, stored, treated, disposed, recovered (e.g., refuse-derived fuel) or reused. “Household waste” means any material (including garbage, trash and sanitary wastes in septic tanks) derived from households (including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas).

2.4. Drug Enforcement Administration (DEA) – Controlled Substance Act Requirements

The Disposal Act amended the Controlled Substances Act (CSA) to give the DEA authority to promulgate new regulations, within the framework of the CSA, that will allow ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The goal of the Disposal Act is to encourage public and private entities to develop a variety of methods of collection and disposal in a secure, convenient, and responsible manner. (DEA, Disposal Act: General Public Fact Sheet).
Section 3. Operating Parameters and Emission Limitations

3.1 Acceptable Materials for Incineration

Solid materials that have been removed from plastic containers, foil packs, or other packaging are acceptable for incineration.

3.2 Unacceptable Materials for Incineration

The following materials *MAY NOT* be disposed of by incineration:

- Materials that contain heavy metals, such as antimony, arsenic, beryllium, cadmium, chromium, cobalt, lead, manganese, mercury, nickel, or selenium.
  - *Example:* chromium or selenium supplements
  - *Example:* Mercury thermometers
- Iodine containing medications.
- Items containing sharps, such as hypodermic needles, syringes, auto injectors, infusion sets, and lancets.
  - *Example:* EpiPens
- Non-Residential waste.
  - *Example:* Waste from clinic, doctor, or dentist practices
- Radiopharmaceuticals.
- Chemotherapy or cytotoxic compounds.
- Compressed gas cylinders or aerosol containers.
  - *Example:* asthma inhalers
- Liquids in glass, metal or plastic containers.
- Creams.

3.3 Operating Parameters

The operating conditions outlined in Table 1 below *must* be followed in order to comply with this guidance and be exempt from permitting under the Nevada Administrative Code.

If any of these conditions are not met, the operator *must* immediately contact the Nevada Division of Environmental Protection – Bureau of Air Pollution Control (BAPC) for assistance in determining the potential impacts of noncompliance, which may include the requirement to obtain an Air Quality Operation Permit.
### Table 1. Operating Limits.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Unit</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fuel</td>
<td>--</td>
<td>Diesel¹</td>
</tr>
<tr>
<td>Rated Heat Input Rate</td>
<td>MMBtu/hour</td>
<td>0.42</td>
</tr>
<tr>
<td>Consumption Rate - Fuel</td>
<td>gallons/hour</td>
<td>3</td>
</tr>
<tr>
<td>Consumption Rate – Acceptable Materials for Incineration</td>
<td>pounds/hour</td>
<td>66</td>
</tr>
<tr>
<td>Operation – Daily²</td>
<td>hours/day</td>
<td>8</td>
</tr>
<tr>
<td>Operation – Annual²</td>
<td>hours/year</td>
<td>3,285</td>
</tr>
</tbody>
</table>

The incinerator shall have a primary burn chamber that combusts prescription drugs and a secondary burner (afterburner) that combusts off-gases that are generated in the primary burn chamber. The primary burn chamber shall operate at minimum temperatures of 1,400 °F. The afterburner shall operate at minimum temperatures of 1,800 °F (measured at the exhaust stack) with a minimum retention time of 1 second.

Notes:

1. Fuel types for the incinerator burners may include ultra-low sulfur #2 diesel, natural gas or propane; with equivalent rated heat input rate.
2. Operational limitations are to ensure compliance with the National Ambient Air Quality Standards for Criteria Air Pollutants and Emissions of Hazardous Air Pollutants based on health and regulatory values (see Tables 4 and 5 below).

### 3.4 Emission Limitations

Table 2 below presents the estimated factors and estimated emissions of an incinerator operating in compliance with this guidance including the above operating conditions (Table 1). As illustrated by Table 3, so long as the incinerator is operating in compliance with this guidance, the incineration of prescription drugs by law enforcement will not exceed the Nevada Ambient Air Quality Standards where the general public has access. Additionally, Table 4 addresses Hazardous Air Pollutant emissions. Finally, the emission limits are such that an Air Quality Operation Permit is not required (NAC 445B.037).

Emission factors were compiled from AP-42 references and available source test data; see notes section for specific details. Prescription drug incineration emission factors are estimated from residential wood stoves since: (1) there are no specific emission factors for prescription drug incineration and (2) wood and prescription drugs have similar composition, i.e., wood is a carbon-hydrogen-oxygen based organic material and prescription drugs are typically carbon-hydrogen-oxygen-sulfur based materials. More conservative emission factors utilized in this guidance include: NOₓ and HCl emission factors were
estimated from the AP-42 emission factors for medical waste incineration and the SO₂ emission factor was estimated from previous source test results.

Diesel fuel combustion is also included in the emission calculations. Criteria pollutants considered for calculations were Particulate Matter (PM₁₀ and PM₂.₅), nitrogen oxides (NOₓ), sulfur dioxides (SO₂), carbon monoxide (CO), and volatile organic compounds (VOC).

Table 2. Emission Factors and Estimated Emissions.

<table>
<thead>
<tr>
<th>Criteria Pollutant</th>
<th>Diesel Fuel Consumption</th>
<th>Prescription Drug Incineration</th>
<th>Total Emissions³ (tons/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Emission Factors</td>
<td>Estimated Emissions¹</td>
<td>Emission Factors</td>
</tr>
<tr>
<td></td>
<td>(lbs/10³ gal)</td>
<td>(lbs/hour)</td>
<td>(lb/ton)</td>
</tr>
<tr>
<td>PM₁₀</td>
<td>1.30ᵃ</td>
<td>0.004</td>
<td>14.60ᵈ</td>
</tr>
<tr>
<td>PM₂.₅</td>
<td>1.30ᵃ</td>
<td>0.004</td>
<td>14.60ᵈ</td>
</tr>
<tr>
<td>NOₓ</td>
<td>18.00ᵇ</td>
<td>0.054</td>
<td>--</td>
</tr>
<tr>
<td>SO₂</td>
<td>0.22ᵇ</td>
<td>0.001</td>
<td>2.17ᶠ</td>
</tr>
<tr>
<td>CO</td>
<td>5.00ᵇ</td>
<td>0.015</td>
<td>140.80ᵈ</td>
</tr>
<tr>
<td>VOC</td>
<td>2.50ᶜ</td>
<td>0.008</td>
<td>28.00ᵉ</td>
</tr>
<tr>
<td>HCl</td>
<td>--</td>
<td>--</td>
<td>33.50ᵇ</td>
</tr>
</tbody>
</table>

Notes:

1. Emissions from Fuel Consumption (lbs/hour) = Emission Factor (lbs/1,000 gallons) X Consumption Rate of Fuel (gallons/hour)
2. Emissions from Incineration of Acceptable Materials (lb/hour) = Emission Factor (lb/ton) X Consumption Rate of Acceptable Materials for Incineration (lbs/hour) X (1 ton/2,000 lbs).
3. Total Emissions (tons/year) = Σ Emissions (lbs/hour) X Operation (hours/year) X (1 ton/2,000 lbs).

a. AP-42, Section 1.3, Fuel Oil Combustion, Table 1.3-2, No. 2 oil fired.
b. AP-42, Section 1.3, Fuel Oil Combustion, Table 1.3-1, Residential furnace, where S indicates that the weight % of sulfur in the oil should be multiplied by the value given. Specifically, the fuel is 0.0015% sulfur, therefore S = 0.0015.
c. AP-42, Section 1.3, Fuel Oil Combustion, Table 1.3-3, Residential furnace, TOC.
d. AP-42, Section 1.10, Residential Wood Stoves, Table 1.10-1, Noncatalytic, Phase II.
e. Elastec, Inc., Source Test Results, 1996.
f. AP-42, Section 2.3, Medical Waste Incineration, Table 2.3-1, Controlled Air, Uncontrolled.
g. AP-42, Section 1.10, Residential Wood Stoves, Table 1.10-1, Noncatalytic, TOC.
h. AP-42, Section 2.3, Medical Waste Incineration, Table 2.3-3, Uncontrolled.
### Table 3. National Ambient Air Quality Standards (NAAQS) Modeling Results.

<table>
<thead>
<tr>
<th>Pollutant</th>
<th>Averaging Period</th>
<th>Modeled Concentration</th>
<th>Background Concentration</th>
<th>Total Impact</th>
<th>NAAQS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM$_{2.5}$</td>
<td>24-hr ($\mu$g/m$^3$)</td>
<td>16.6</td>
<td>8</td>
<td>24.6</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Annual ($\mu$g/m$^3$)</td>
<td>4.8</td>
<td>2.3</td>
<td>7.1</td>
<td>12</td>
</tr>
<tr>
<td>PM$_{10}$</td>
<td>24-hr ($\mu$g/m$^3$)</td>
<td>57.2</td>
<td>10.2</td>
<td>67.4</td>
<td>150</td>
</tr>
<tr>
<td>SO$_2$</td>
<td>1-hr (ppb)</td>
<td>11.5</td>
<td>--</td>
<td>11.5</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>3-hr ($\mu$g/m$^3$)</td>
<td>27.5</td>
<td>--</td>
<td>27.5</td>
<td>1,300</td>
</tr>
<tr>
<td></td>
<td>24-hr ($\mu$g/m$^3$)</td>
<td>8.6</td>
<td>--</td>
<td>8.6</td>
<td>365</td>
</tr>
<tr>
<td>NO$_2$</td>
<td>1-hr (ppb)</td>
<td>60.2</td>
<td>--</td>
<td>60.2</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Annual ($\mu$g/m$^3$)</td>
<td>2.8</td>
<td>--</td>
<td>2.8</td>
<td>100</td>
</tr>
<tr>
<td>CO</td>
<td>1-hr ($\mu$g/m$^3$)</td>
<td>2,041</td>
<td>--</td>
<td>2,041</td>
<td>40,500</td>
</tr>
<tr>
<td></td>
<td>8-hr ($\mu$g/m$^3$)</td>
<td>1,546</td>
<td>--</td>
<td>1,546</td>
<td>7,000</td>
</tr>
<tr>
<td>Ozone</td>
<td>8-hr (ppm)</td>
<td>0.01</td>
<td>--</td>
<td>0.01</td>
<td>0.075</td>
</tr>
</tbody>
</table>

### Table 4. Hazardous Air Pollutant Modeling Results.

<table>
<thead>
<tr>
<th>Pollutant</th>
<th>Averaging Period</th>
<th>Modeled Concentration</th>
<th>Background Concentration</th>
<th>Total Impact</th>
<th>Health and Regulatory Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCl</td>
<td>1-hr (mg/m$^3$)</td>
<td>0.5</td>
<td>--</td>
<td>0.5</td>
<td>4.50</td>
</tr>
<tr>
<td></td>
<td>Annual (mg/m$^3$)</td>
<td>0.01</td>
<td>--</td>
<td>0.01</td>
<td>0.02</td>
</tr>
</tbody>
</table>

#### 3.5 Additional Requirements

The operator must develop operating procedures for the incinerator; and all personnel who operate the incinerator are required to familiarize themselves with the operating procedures. The operating procedures must be readily available to all personnel who operate the incinerator.

The ash from the incineration of prescription drugs must be collected and disposed of in an appropriate landfill.

The incinerator must be placed a minimum of 6 feet from an appropriate barrier to general public access (e.g., fencing) and the minimum requirements of the stack from the incinerator are 8 feet in height, 1 foot in diameter, and 16 feet per second minimum flow velocity. If these conditions cannot be met, please contact the Nevada Division of Environmental Protection – Bureau of Air Pollution Control (BAPC) for assistance.
Section 4. Monitoring and Recordkeeping, Reporting, and Posting

4.1. Monitoring and Recordkeeping

The following monitoring and recordkeeping for the incinerator must be maintained in a contemporaneous log:

- Record the calendar date when a batch of prescription drugs is incinerated.
- Record the weight of prescription drugs incinerated per batch.
- Record the start and stop time on a per batch basis.
- Monitor and record the afterburner exhaust temperature on a per batch basis.
- Monitor and record any maintenance that is conducted on the incinerator.

Maintain all records for a minimum of five years.

4.2. Reporting

The BAPC must be notified in writing of the following:

- Notification to acquire and operate an incinerator under the requirement of this guidance document (see Appendix A of this document).
- The date that the incinerator is acquired, postmarked no later than 30 days after such date.
- The anticipated date of initial startup, postmarked not more than 60 days nor less than 30 days before such date.
- The actual date of initial startup, postmarked not more than 15 days after such date.

Additionally, the BAPC must be notified in writing of the following:

- Any excess emissions within 24 hours after any malfunction or upset of the process equipment.
- Any physical or operational change(s) to the incinerator. The notice must be postmarked 60 days, or as soon as practicable, before the change(s) are commenced.

4.3. Posting

The rated burning capacity, operating and maintenance procedures must be posted conspicuously at or near the incinerator.
Section 5. Bureau of Air Pollution Control (BAPC) Staff Contacts

BUREAU CHIEF:
Lisa Kremer
(775) 687-9336
lkremer@ndep.nv.gov

PERMITTING SUPERVISOR:
Jennifer Collier
(775) 687-9551
jcollier@ndep.nv.gov

*Note: For questions on operating parameters and emission limitations.*

COMPLIANCE AND ENFORCEMENT SUPERVISOR:
Travis Osterhout
901 S. Stewart Street, Suite 4001
Carson City, Nevada 89701
(775) 687-9530
travis.osterhout@ndep.nv.gov

*Note: For questions on monitoring and recordkeeping, reporting, and posting.*
Appendix A. Notification
Notification of Prescription Drug Disposal by Incineration

Facility Name: Click or tap here to enter text.

Please Submit Notification to:
Nevada Division of Environmental Protection
Bureau of Air Pollution Control
901 South Stewart Street, Suite 4001
Carson City, Nevada 89701-5249
Phone (775) 687-9349
Fax (775) 687-6396
IMPORTANT INFORMATION

The Notification packet contains:

- General Company Information Form
- Combustion Equipment Form
- Notification Certification Document

Please see the Guidance Document for additional instructions on how to complete the notification.

This notification shall be used for a Prescription Drug Disposal by Incineration Facility.

This notification must be signed by the Responsible Official, as defined in NAC 445B.156. The certification/signature page is the last page of the notification and the original “wet” signature must be provided.

All items in the notification must be addressed. If an item does not apply, “N/A” or similar notation must be entered in the appropriate blank. All other information must be provided.
GENERAL COMPANY INFORMATION FORM

1. Law Enforcement Facility Name and Address:
   
   Name: ________________________________________________________________
   Address: ______________________________________________________________
   City: ________________________________________________________________
   State: _______________________________ Zip Code: ________________________

2. Responsible Official Name, Title and Mailing Address:
   
   Name: ________________________________________________________________
   Title: ________________________________________________________________
   Address: ______________________________________________________________
   City: ________________________________________________________________
   State: _______________________________ Zip Code: ________________________
   Phone Number: (xxx) xxx-xxxx
   Fax Number: (xxx) xxx-xxxx
   E-mail Address: ________________________________________________________

3. Facility Operator:
   
   Name: ________________________________________________________________
   Title: ________________________________________________________________
   Address: ______________________________________________________________
   City: ________________________________________________________________
   State: _______________________________ Zip Code: ________________________
   Phone Number: (xxx) xxx-xxxx
   Fax Number: (xxx) xxx-xxxx
   E-mail Address: ________________________________________________________
4. **Location and Driving Directions to the Facility (For Example: From Elko, Nevada, 4 miles south of I-80 at xx Interchange):**

   Township(s): ____________ N; Range(s): ____________ E; Section(s): ____________

   UTM Coordinates for the Front Gate of the Facility (NAD 83, Zone 11):
   ____________ m North; ____________ m East;

   Nearest City: ____________________________

   County: ____________________________

   Driving Directions from nearest city to the Facility:

   ________________________________________________________________

   Nearest setback distance from the unit to the Facility’s fence line (feet):

   ____________________________

5. **I acknowledge that I have read and referenced the Guidance for Prescription Drug Disposal by Incineration to aid in the completion of this notification.**

   □ Yes       □ No
## COMBUSTION EQUIPMENT NOTIFICATION FORM

**Emission Unit Description:** Incinerator

<table>
<thead>
<tr>
<th>Description</th>
<th>Data</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equipment Description</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source Classification Code (SCC)</td>
<td>5-01-001-01</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Manufactured</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model and Serial Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Design Heat Input [NAC 445B.3135]</td>
<td>MMBtu/hour</td>
<td>0.42</td>
</tr>
<tr>
<td><strong>Location of Emission Source</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UTM Northing (NAD 83, Zone 11)</td>
<td>m</td>
<td></td>
</tr>
<tr>
<td>UTM Easting (NAD 83, Zone 11)</td>
<td>m</td>
<td></td>
</tr>
<tr>
<td><strong>Operating Parameters /Fuel Usage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fuel Type</td>
<td>Diesel</td>
<td></td>
</tr>
<tr>
<td>Operating Time per Day [hour/day]</td>
<td>8 AM to 5 PM</td>
<td></td>
</tr>
<tr>
<td>Operating Time per Year [hour/year]</td>
<td>3,285</td>
<td></td>
</tr>
<tr>
<td>Hourly Usage Rate Maximum [pounds/hour]</td>
<td>66</td>
<td></td>
</tr>
<tr>
<td>Provide Equipment Specification Sheet</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stack Parameters</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stack Height [feet]</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Stack Diameter [feet]</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Stack Release Type [Vertical/Capped/Horizontal]</td>
<td>Vertical</td>
<td></td>
</tr>
</tbody>
</table>
NOTIFICATION CERTIFICATION DOCUMENT

Please check all applicable boxes below to indicate the information provided in your notification submittal:

☐ General Company Information Form
☐ Combustion Equipment Form(s)
☐ Notification Certification Document with Original Signature

CERTIFICATION:

I certify that, based on information and belief formed after reasonable inquiry, the statements and information contained in this notification are true, accurate and complete.

______________________________
Signature of Responsible Official

______________________________
Print or Type Name and Title

______________________________
Date

NAC 445B.156 “Responsible official” defined. (NRS 445B.210) “Responsible official” means:

1. For a corporation:
   (a) A president;
   (b) A vice president in charge of a principal business function;
   (c) A secretary;
   (d) A treasurer; or
   (e) An authorized representative of such a person who is responsible for the overall operation of the facility and who is designated in writing by an officer of the corporation and approved in advance by the Director.

2. For a partnership or sole proprietorship, a general partner or the proprietor, respectively.

3. For a municipality or a state, federal or other public agency, a ranking elected official or a principal executive officer, including, for a federal agency, a chief executive officer who has responsibility for the overall operations of a principal geographic unit of the agency.

4. For an affected source, the designated representative or his or her alternate, as defined in 42 U.S.C. § 7651a(26).