Medical Waste Disposal Alternatives At Rocky Mountain Laboratories

September 2007

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EXECUTIVE SUMMARY

The objective of this study is to provide a comparative analysis of currently available biomedical waste treatment and disposal technologies that are applicable to existing and planned operations at the National Institutes of Health (NIH) Rocky Mountain Laboratories (RML) campus in Hamilton, Montana. This study analyzed and compared the method presently used, which is based on incineration, with other methods currently available. The advantages and disadvantages of each option were evaluated with respect to their applicability to RML, public and personnel safety, site constraints and environmental welfare. Because of the unique nature of the waste streams and environmental issues, the study specifically focused on the RML facility. The results of the study will be used by the NIH to determine the disposal technologies best suited for the RML medical pathological waste stream.

The RML campus was surveyed in order to evaluate the RML processes and logistics. The survey included interviews with appropriate campus personnel so as to gather the data and background information necessary for full understanding of the RML activities to ensure accuracy of the study. Areas surveyed included: personnel, product and waste flows within the facility; process and personnel schedules; waste volumes and types; segregation and staging of waste; miscellaneous relevant information regarding RML-related infectious waste; available infrastructure; evaluation of the current incineration process; and general room and building conditions.

Existing and emerging infectious waste technologies were reviewed. Detailed research produced three viable options for waste disposal at RML: incineration, alkaline hydrolysis and autoclaving. Following a scientific approach to the analysis, several current scientific publications were reviewed which discussed the specific effectiveness of each type of equipment for different levels of infectious waste. An engineering-based analysis also conducted for the three technologies identified key mechanical and logistical issues. Existing users of technologies having limited published data (i.e. alkaline hydrolysis) were interviewed for individual perspectives on the application of the technology. Information was compiled, reviewed, compared and applied to the data gathered from the RML survey. Additionally, a software-based risk analysis was performed, using a predetermined ranking scale in terms of severity or impact and likelihood, to generate a non-biased assessment of suitable technologies.

The findings from the survey, research, interviews and risk analysis, determined that the best suited technology for RML is incineration of all medical type wastes generated. This recommendation was established after consideration of the following evaluation criteria: effectiveness/ability to implement the technology given the hazardous and difficult nature of the wastes, environmental effects, available safeguards, risk and safety issues, and public relations/perceptions.

This recommendation of technology is based on current available information and maturity of technology. New and developing technologies should be continually assessed for implementation to demonstrate a clear commitment by RML to utilizing only the most safe and environmentally sound method of medical waste disposal.

INTRODUCTION

Facilities, such as RML, which produce medical waste, face a variety of challenges in handling and disposing of the waste. A fair percentage of waste produced contains biohazard classified material, or material which has been exposed to or contains a biological substance that may pose a threat to human or animal health. Biohazard materials are handled separately from other domestic wastes since they may contain pathogens which, if not properly inactivated, have the potential to infect other living organisms. In a laboratory environment, biohazard pathogens are categorized by levels of increasing risk for occupational infection, which are called biosafety levels (BSL). Depending on the operating biosafety level of the laboratory, different precautions are required by EPA Guidelines to handle the waste.[1] Protocols are developed based on the specific nature of the pathogen of interest in order to minimize risk to personnel and ensure sufficiently rigorous inactivation before the material leaves the controlled laboratory and is released to the environment.[2]

While inactivation of most pathogens (bacteria and viruses) is well characterized and easily achieved by a normal autoclave treatment, some pathological agents require more aggressive methods for inactivation. Probably the most difficult biological agents to inactivate are prions, which are the subject of a substantial amount of research at RML. A prion is a proteinaceous infectious particle which lacks nucleic acid. They are believed to infect and propagate by abnormal refolding within the host into an isoform which serves as a template for conversion of normal host proteins to fold into a densely sheeted, fibrous form. This altered structure renders prions highly resistant to denaturation by chemical and physical agents, making disposal and containment of these particles extremely difficult.[3] Prions are not susceptible to standard autoclave treatment. Even at prolonged exposure times and elevated temperatures, few standard chemical disinfectants have been proven remotely effective.[4]

Another consideration in the case of prion inactivation is the significantly long incubation period required for infection assays. Wastes that have undergone treatment for inactivation must be subjected to an *in-vivo* bioassay to test for residual infectivity. Normally, small volumes of treated waste are diluted, injected into test subjects, and monitored for 10–12 months for signs of infection.[5, 6] However, successful transmission has been documented only after much longer incubation periods in other studies, raising valid concerns as to the ability to prove efficacy of prion inactivation.[7, 8]

Prions are known to cause a number of diseases in a variety of species, including bovine spongiform encephalopathy (BSE, also known as mad cow disease) and Creutzfeldt-Jakob disease (CJD) in humans. These types of prion diseases are known as transmissible spongiform encephalopathies (TSEs). Prion diseases affect the structure of the brain or other neural tissue and all are untreatable and fatal. Additionally, it has been shown that several prion diseases, originally thought to only target specific species, are capable of being transmitted to and infecting alternate species (e.g. cow to human). Because of this high level of risk, prions are classified as either BSL 2 or 3 pathogens. It should be noted again, however, that standard inactivation procedures developed for BSL 2 or 3 pathogens are insufficient for prion deactivation.[9] Prions represent a special sub-population of pathogens that require separate considerations for inactivation.

In order to standardize laboratory practices and minimize associated risks, the government has established several regulatory agencies to oversee, provide recommendations, and impose

regulations on activities which may affect the environment or laboratory personnel. The Environmental Protection Agency (EPA) has several standards in place which address these activities. In general, several sections of the Code of Federal Regulations (CFR) apply directly to laboratory activities — especially laboratories that handle and treat their own waste. 29 CFR 1910 addresses specific hazards presented by chemical and pathological waste; 40 CFR 403-471 provides effluent guidelines for discharge to local sewers and liquid waste treatment.[2]

Several additional regulations are imposed on laboratories that incinerate their waste. In 1997, the Clean Air Act (CAA) established new source performance standards (NSPS) and emission guidelines for hospital/medical/infectious waste incinerators (HMIWI) as part of 40 CFR 60. Stricter regulations forced incinerator operators to either shut down operations or install costly emission controls. Part of the act requires the EPA to review and, if appropriate, revise the NSPS and emission guidelines every five years. The EPA has recently proposed revisions to the emission guidelines that would further tighten restrictions on emission limits for HMIWI.[10] Facilities planning to incinerate their waste must be approved for a Title V permit under the CAA and meet local and state regulations and applicable permitting.

In cases where laboratory waste is not disposed of by incineration, potential environmental impacts must be considered if the waste is to be landfilled. If the medical waste does not contain hazardous waste, it may be disposed of in a municipal solid waste landfill as long as the landfill operator accepts such medical waste. The waste must be tested by an analytical laboratory to ensure it meets landfill operator requirements and federal land disposal restrictions.[11] If characterization tests indicate the waste is a hazardous waste under 40 CFR 1910, the waste can only be legally disposed of in a specially designed hazardous waste landfill meeting the Resource Conservation and Recovery Act (RCRA) Subtitle C requirements. These types of landfills are engineered to prevent the release of hazardous chemicals into the environment and operators must comply with additional inspection, monitoring, and release response requirements.

It is the responsibility of any laboratory to adhere to and maintain these regulations. However, it should be noted that every medical waste generator has different considerations pertaining to biohazard waste disposal and therefore only appropriate to evaluate facility disposal options on a case-by-case basis. Each method of disposal has some risk and some environmental impact. The goal is to define the best method for the facility that minimizes this risk and environmental impact while still meeting all the necessary criterion for inactivation.[12]

BACKGROUND

RML, which operates under the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, has been devoted to researching infectious diseases over the last 80 years. They have contributed to national initiatives with high-impact pathogens such as: HIV, BSE (mad cow disease), chronic wasting disease (CWD), Lyme's disease agents, *Chlamydia* and *Salmonella*. It is the mission of RML to play a leading role in the nations efforts to develop diagnostics, vaccines and therapeutics to combat emerging and re-emerging infectious diseases.[13]

The RML facility is located near the city of Hamilton in West-Central Montana. The facility consists of a relatively large campus that incorporates 40 buildings, making RML one of the largest features of Hamilton. As with many small towns, the local waste management facilities in Hamilton are primitive when compared to those of larger cities. The only nearby landfill is 60 miles away in Missoula, is not permitted to allow untreated medical waste, and is arguably not

environmentally secure enough to receive decontaminated medical waste from RML. Wastewater treatment available to the area is also undersized and under-equipped. The wastewater solids processing is at capacity, equipment to handle advanced treatment of high Biochemical Oxygen Demand/Chemical Oxygen Demand (BOD/COD) wastes is lacking, and the facility has no treatment for nitrogen or phosphorous that eventually discharges into the local rivers and streams. The RML campus itself is situated near the Bitterroot River.

As part of an expanding research program, the NIH is constructing an Integrated Research Facility (IRF) and completing infrastructure upgrades to existing facilities at the RML campus in Hamilton to allow RML to extend its research to include BSL 4 organisms. The proposal for the IRF includes BSL 2, 3 and 4 laboratories, corresponding animal research facilities, administrative support offices, conference rooms and break areas, all of which total approximately 105,000 square feet.[13]

The new building will allow RML to extend its research to include pathogenic material at the highest level of containment, BSL 4. BSL 4 facilities that exist in the United States are located in Atlanta, Georgia; Frederick and Bethesda, Maryland; and San Antonio and Galveston, Texas. A new facility is being constructed in Boston, Massachusetts. With the considerable addition of new lab space and animal facilities, it is anticipated that the campus waste generation will increase by almost 30%. This will inevitably impact current waste disposal management and waste facility usage and was accounted for in this assessment of applicable waste technologies to be implemented at RML.

RML presently conducts its research on pathogenic organisms at BSL 2 or 3. RML projects include research with pathogens that have the potential to cause serious infection in humans. The facility contains five research laboratories that include bacteria, virus, and prion research, each of which spans multiple biosafety levels. Integral to the types of research conducted at RML are the animal care facilities that provide model organisms for research and test subjects for experiments. These types of support facilities present their own distinctive waste management conditions.

Due to the unique nature of the facilities and research at RML, a wide variety of waste is generated. As expected from this type of research, a significant percentage of waste is infectious medical waste. The remaining domestic waste is separated into recyclable and non-recyclable wastes to minimize landfill waste. The types and quantities generated in Fiscal Year 2006 are summarized in Table 1.

Table 1 - 2006 Waste Summary[14]

Categories	Sub-Category	Comments	Pounds	Tons	%
Municipal Solid Waste	Dumpsters	BFI	69,240	34.6	18.55%
Medical/Pathological/ Lab Waste		Incineration	172,009	86.0	46.08%
Hazardous Chemical Waste		Shipped Offsite	634	0.3	0.17%
		LBP Cleanup	570	0.3	0.15%
Radioactive Waste	Solid Waste	Stored for Decay	80	0.0	0.02%
Mixed Waste		None	0	0.0	0.00%
Recycled Materials					
	Aluminum	Ravalli Services	130	0.1	0.03%
	Batteries (non-lead acid)		152	0.1	0.04%
	Cardboard	Est. 4 yd^3/wk @ 350 lbs/yd^3	70,000	35.0	18.75%
	Fluorescent Bulbs	145 U-bulbs, 3225 linear feet			
	Glass		250	0.1	0.07%
	Lead	UPS batteries per certificate	4,519	2.3	1.21%
	Metal Waste	Pacific Recycling	22,220	11.1	5.95%
	Pallets	275 @ 40 lbs each	11,000	5.5	2.95%
	Paper	All kinds	18,403	9.2	4.93%
	Used Oil and Antifreeze	Emerald Recycling 580 gal, 7 lbs/gal	4,060	2.0	1.09%
		Recycled Waste Subtotal	130,734	65.4	35.02%
		TOTAL WASTE GENERATED	373,267	186.6	100.00%

RML annually updates a facility Waste Management Plan that describes the technical and administrative controls used to segregate wastes and prevent listed or characteristically hazardous chemical and radioactive wastes from being placed in the incinerator. Historically, RML incinerated most wastes generated at the facility, including domestic waste but excluding certain hazardous chemical and radioactive wastes. Following a litigation settlement in 2004, RML began to segregate domestic waste and implemented an extensive recycling program, as is evident in the table above. Currently, RML incinerates only 46% of its waste, all of which is infectious medical waste; 35% of waste generated is recycled; and only a small fraction (less than 19% of total RML waste) is sent to landfill. As RML prepares for the operation of its new IRF with a BSL 4 laboratory, additional waste management guidelines must be developed. Table 2 summarizes current facility waste characterization and the anticipated waste contribution from the new IRF.

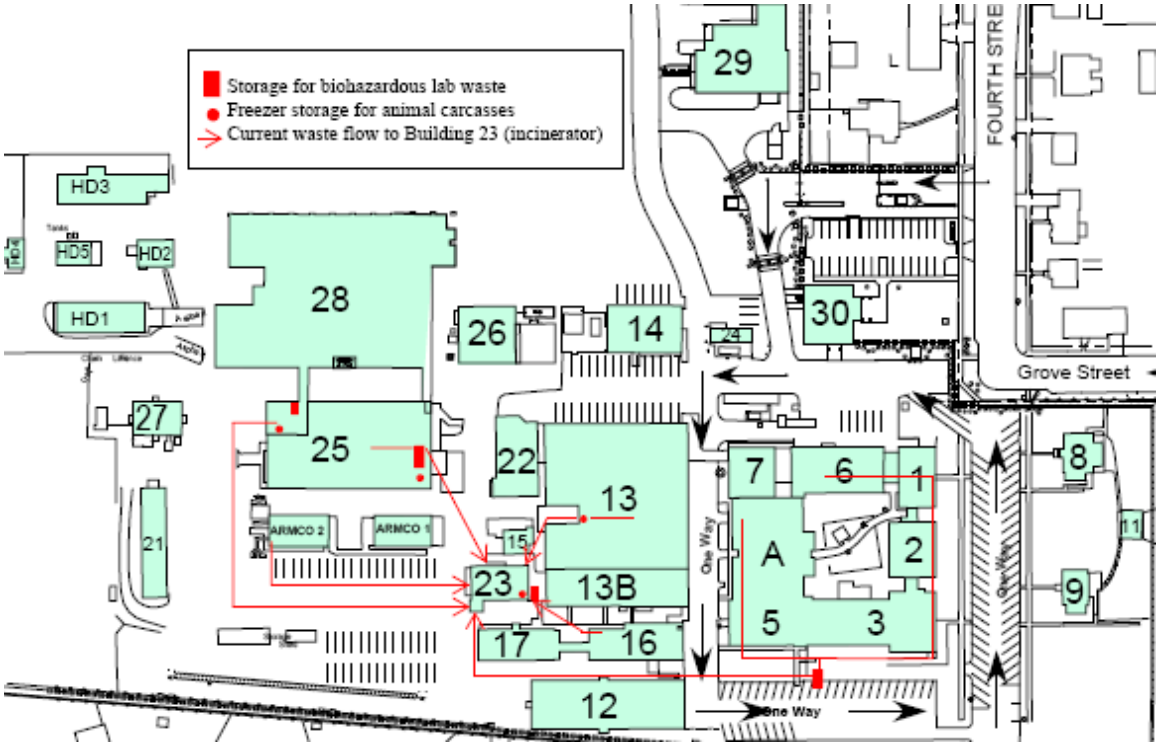
Table 2 – Medical Waste Characterization[15]

Non-Prion Laboratory Waste *excluding carcasses/tissues*	621 lbs/day *
Non-Prion Carcass/Tissue Waste	3 lbs/day
Prion-Contaminated Waste *excluding carcasses/tissues*	176 lbs/day
Prion-Contaminated Carcass/Tissue Waste	1 lbs/day
Carcasses/Tissue Waste - IRF	110 lbs/day
Other Animal-Related Waste - IRF	142 lbs/day
Lab Wastes - IRF *excluding animal-related waste*	130 lbs/day

* Of this amount, 382 lbs/day is animal bedding.

To summarize the current and planned waste flows to the incinerator, a representation of the sources and streams of infectious medical waste at RML is shown in Figure 1.

Figure 1 – Campus Map with Waste Streams



In order to prevent inadvertent cross contamination of medical waste and domestic waste, and even within certain types of medical waste, RML utilizes a system of color-coded receiving bags for different waste streams. This helps ensure that RML policy, Title V definitions and safe handling procedures are met. There are three general types of waste: recyclable materials, general waste, and medical pathological and biohazardous waste. In addition to these three types of lab wastes, hazardous chemical wastes are also generated in the labs, which are segregated and collected for offsite treatment and disposal. Recyclable materials have designated containers throughout the campus for specific types of recyclable waste such as computer paper and newspaper, magazines and catalogs, cans and clean aluminum foil, batteries and cardboard.

General wastes, such as lunchroom wastes, foodstuffs, plastic drink containers, and packing materials, are collected in clear plastic bags and transported to dumpsters by trained janitorial staff in order to avoid improper disposal measures for segregated waste.[16]

Laboratory wastes are separated into three categories, each with different colored disposal bags and transportation responsibilities. Orange or red bags labeled with the universal biohazard symbol are used to collect any waste known or perceived to possess a biohazard characteristic. Biohazard waste is always double bagged and when the bag is full, autoclaved by the generator and placed in a clear plastic bag. Autoclaved biohazard bags are placed in collection carts and transported by a waste technician to an outdoor enclosed waste storage shed. The incinerator operator loads the autoclaved bags onto a truck and transports them to the nearby incinerator. Laboratory waste that is not considered a biohazard (e.g. absorbent paper, empty phosphate buffered saline (PBS) bottles, etc.) is placed in brown or black waste bags and transported by janitorial staff to the incinerator. Animal bedding, another non-biohazard laboratory waste, is placed in carts at the incinerator by animal caretakers. Lastly, all radioactive wastes are segregated by isotope, placed in yellow disposal bags labeled with a radioactive symbol and transported by the generator to radioactive waste storage. Each isotope is left in the storage area to decay a set number of half-lives before being sent to a second incinerator that is dedicated to radioactive waste. Waste segregation is an important component of ensuring safe disposal of infectious and other hazardous material. Additionally, RML has adopted very specific standard operating procedures (SOPs) which define how to handle waste. The SOPs were developed to address issues specific to each laboratory's BSL and the types of agents being investigated in that area. For example, highly detailed SOPs were developed specifically for labs that handle TSE wastes.[17, 18]

For BSL 2 TSE laboratories, low-level TSE waste is placed in double biohazard bags with some water added to the inner bag, each loosely sealed with a twist tie or rubber band. A steam sterilization indicator tag is attached to the outer bag, and the bags are autoclaved at 270°F (132°C) for one hour with 15 minutes of drying. If adequate sterilization is indicated, the autoclaved bag is placed in a clear plastic bag and securely tied with a knot. A label bearing the name of the person who sealed the bag and his or her phone extension is placed on the bag. The bag is then deposited in a lab cart and covered with lab napkins and transported outdoors to the incinerator cart in the waste storage shed to await incineration. Pipettes and non-PVC plastic containers are treated in a similar manner, except the container is placed directly in the autoclave where the contents melt to form a plastic block. Solid low-level TSE waste, such as plastic ware from cell culture work, is placed in double bags. Plastic ware containing liquids are tightly capped before depositing in the double bags. TSE pipette tips are placed in a disposable tube with 5 ml of 5% Environ LpH (Steris Corp.). The tube is tightly capped before being deposited in the double bags. Bags are then autoclaved in the manner described above.[19]

High titer TSE wastes, such as infected neural tissues, corneas, and concentrated isolates, are known to typically be up to 1,000 times more infectious than low titer waste, are governed by BSL 3 procedures for decontamination. Those procedures are followed even in the BSL 2 TSE lab. All high titer TSE wastes are chemically decontaminated and incinerated. In general, decontamination is by 5% LpH for a minimum of 30 minutes, followed by direct incineration. [19]

Low-level radioactive TSE liquid wastes in the TSE BSL 2 laboratory (for example, waste containing ^{35}S, which has a physical half-life of 87.4 days) is placed in disposable tubes, treated with LpH and tightly capped. Treated liquid waste is double-contained, transferred to the liquid decay-in-storage area and allowed to decay before disposal. Radio-labeled TSE contaminated

pipettes are rinsed with 5% LpH and placed in a plastic radioactive waste bag, with pipette bags positioned vertically in the middle of the bag to avoid punctures. The bag is labeled and transferred to a holding facility to be stored for decay before disposal. This facility keeps detailed disposal records, which include the isotopes and amounts of radioactivity. [19]

The animal care facility used in TSE studies generates waste classified as animal Biosafety Level 3 waste. BSL 3 TSE animal carcasses are double-bagged; the outer bag is disinfected with 5% LpH, stored inside a freezer in the storage room and then transported directly from BSL 3 containment to the incinerator. High titer tissues from animals exposed to BSL 3 TSE agents are placed in disposable vials, which in turn are placed in secondary containers with lids. Large quantities of tissues are double-bagged in heavy-duty plastic bags and placed in durable containers for transport to incineration. Dirty bedding of BSL 3 TSE-infected animals is placed in heavy duty plastic bags, sealed, double-bagged using an outer biohazard bag and the outer surface disinfected with 5% LpH. The bags are deposited in the storage room and later transported directly to the incinerator. For rodents or larger animals in BSL 3 facilities, but not involving TSE agents, the animal carcasses, bedding and other waste are double-bagged, placed in clear plastic bags, stored frozen and then transported directly to the incinerator. All wastes, such as the animal tissues, carcasses, contaminated bedding, partially eaten feed, sharps and other refuse animal tissues, are transported for incineration in leak-proof, covered containers. [19]

Low titer BSL 3 TSE wastes are chemically decontaminated, autoclaved and/or incinerated, depending on the type of waste. If autoclaving is used, BSL 3 TSE waste is chemically treated before autoclaving. In general, chemical decontamination is achieved by treatment with 5% LpH for a minimum of 30 minutes, treatment with 1% LpH for at least 16 hours, or treatment with 1% LpH followed by autoclaving at 132 °C (270 °F) for 90 minutes. Solvents exposed to TSE agents are decontaminated by mixing with LpH to a final concentration of 5%, held for 16 hours, collected in durable containers partially filled with absorbents and transported for incineration. Solvents that are not miscible with LpH are collected in containers partially filled with absorbents and incinerated. However, the most secure and unambiguous method for TSE inactivation is by the redundancy provided by incineration. Therefore, whenever feasible, RML uses incineration for low titer BSL 3 TSE waste. Materials to be incinerated are at least triple-bagged and taken to the incinerator facility in unbreakable containers on a lab cart. Occasionally, researchers make advance arrangements for a direct burn of radioactive/TSE waste in a designated incinerator. Incineration occurs at >760 °C (1400 °F) in the primary chamber and >980°C (1800°F) in the secondary chamber for a minimum of four hours. [10, 20]

Radioisotope-contaminated biohazard waste from the BSL 3 TSE lab is segregated from other biohazard wastes and separated by radioisotope. The solid wastes are triple bagged (with the outermost bag displaying a radioactive label) and stored in a designated location. The yellow bags are transported in unbreakable containers and incinerated. These standards are used not only to protect laboratory personnel, but also to protect the local residents and wildlife of Hamilton. [19]

The proposal of expansion at RML drew increasing attention from local environmental activist groups that led to litigation and a court-ordered settlement in 2004: RML was obligated to contract a study to evaluate alternative waste treatment technologies suitable for use at RML. An independent consulting firm, Council Rock Consulting (CRC), was commissioned to complete the study and prepare a report. Although CRC provided a thorough analysis of available technologies and their suitability for use at RML, no clear recommendations were made other than those of specific models of technologies that would meet the throughput and decontamination requirements unique to RML.

APPLICABLE TECHNOLOGIES

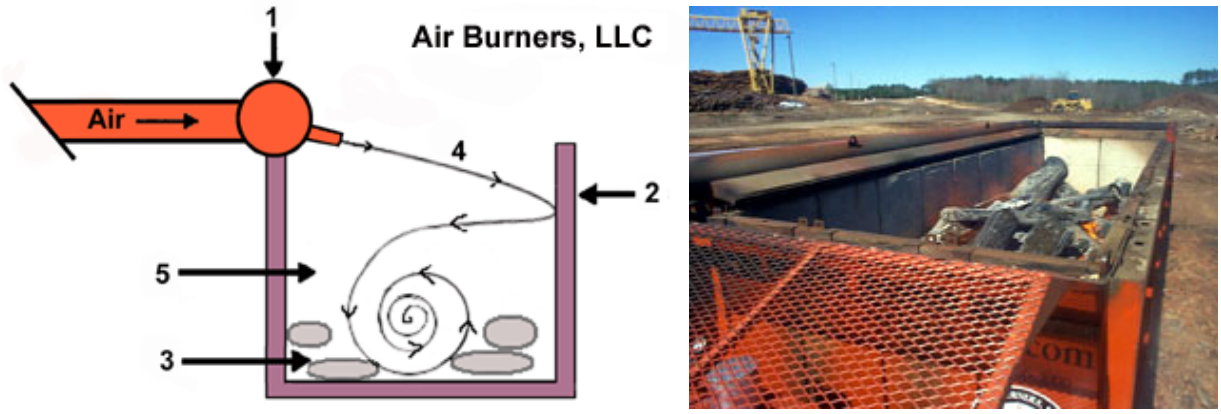
From the CRC study results, it was determined that there were two alternate technologies to incineration that might be appropriate for waste treatment at RML: alkaline hydrolysis and autoclaving with internal shredding.

Alkaline hydrolysis is a fairly new and novel process that utilizes the concept that metal salts can catalyze the insertion of a water molecule into certain molecular groups under caustic conditions. Organic molecules (proteins, carbohydrates, glycogens, etc.) that contain high levels of ester and amide linkages are prone to nucleophilic attack by the water molecule, resulting in sodium salts of peptides, fatty acids and saccharides. Other molecules undergo racemization or conformational changes that alter the functionality of the molecule. Studies have shown that increasing the pressure and temperature of the hydrolysis accelerates the process of digestion.[21, 22] Due to the fact that prions are no more than abnormal isoforms of chromosomal protein, alkaline hydrolysis is, in principle, a relatively effective method for prion inactivation. In light of the recent BSE crisis, a few companies have developed and produced industrial-scale alkaline hydrolysis systems to enable large-scale processing of infected animal carcasses. The process system incorporates an American Society for Mechanical Engineering (ASME) certified pressure-rated stainless steel tank that is directly fed with saturated steam for heat and a pumped recycling liquid loop to provide agitation. As far as other non-tissue prion wastes, alkaline hydrolysis is capable of inactivating the agent but cannot digest inorganics, most plastics or highly organized carbohydrates such as cellulose. From the analysis provided by CRC, it was determined that only one current producer of the technology would be viable for consideration at RML: WR^2, a company based in Indiana. [15] Two other companies, Progressive Recovery Inc. (Dupo, Illinois) and Waste Reduction Europe, Ltd. (Clydebank, Scotland), also produce alkaline hydrolysis systems and could be considered in the future.

The other alternative identified by the CRC study was a modification of standard steam sterilization or autoclaving. These are large decon autoclave units that employ an internal mechanism to shred and agitate waste during the sterilization process. The high temperatures and pressures of steam sterilization denature proteins and nucleic acids. However, due to the unique characteristics of prions, such a method of thermal sterilization is incapable of denaturing the TSE agent. For RML, this technology could only serve as a supplement to a method capable of prion inactivation and will be considered as such. Based on RML waste characterization and throughput, CRC identified three candidate manufacturers and models: Ecodas T-100, Hydroclave H-15 and Rotoclave 1070-H1. [15]

The method presently employed by RML is incineration. This term encompasses a wide variety of combustion methods and the sophistication of some units can be lost under misconceptions. Pyres, which are considered a type of incineration, have been used for centuries as a primitive approach for disposing of unwanted materials, although the uncontrolled emissions from pit burning render this method unacceptable in any modern facility. Air curtain incinerators shown in Figure 2 provide a reasonable alternative for remote locations that require a portable unit. These incinerators also provide much lower and controlled emissions to the environment.

Figure 2 – Air Curtain Incinerator*



1 Air curtain machine manifold and nozzles directing high velocity air flow into refractory lined fire box or earthen trench.

2 Refractory lined wall as on the S-Series machines or earthen wall as used with the T-Series trench burners.

3 Material to be burned.

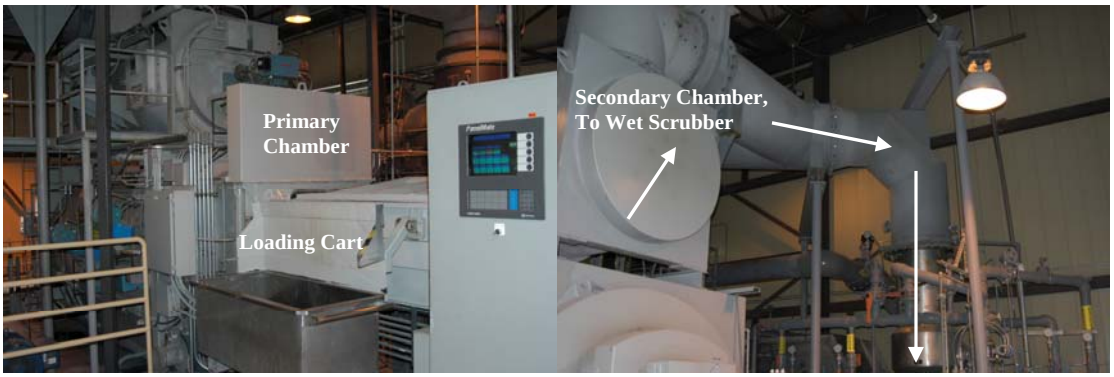
4 Initial airflow forms a high velocity "curtain" over fire.

5 Continued air flow over-oxygenates fire, keeping temperatures high. Higher temperatures provide a cleaner and more complete burn.

*Graphics property of Air Burners, LLC

Air curtain incinerators were used extensively in Europe during the BSE crisis to provide farmers and rural communities with an effective means of prion inactivation with significantly lower disturbance to the environment. For facilities that require a permanent installation and produce a consistent throughput, air curtain incinerators are not necessarily appropriate. These types of operations typically employ fixed facility incinerators. Fixed facility incinerators can have a diverse variety of sophistication — ranging from a simple furnace to advanced medical waste disposal units. Section 129 "Solid Waste Combustion" of the CAA requires the EPA to develop and adopt NSPS and emission guidelines for solid waste incinerators based on the type of incinerator used. The strictest regulations are those placed on incinerators classified as HMIWI.[10, 23]

Figure 3 – Highly Advanced HMIWI at RML



In comparison to most operational HMIWI in the United States, the incinerator employed at RML is highly advanced (see Figure 3). RML currently uses a Consumat 325 dual chamber incinerator with flue gas scrubber and a bullet design in the stack to acoustically cancel noise. Another important feature is the mixing ram that runs every 10 loads to redistribute the ash within the primary chamber to prevent cold spots and to maintain a sufficient temperature profile for prion inactivation. The primary chamber of the incinerator operates at 1400°F in deficient oxygen conditions to reduce NO_x, SO_2 and to virtually eliminate dioxin emissions. This results in ashing of the contents in the chamber, leaving only fully combusted ashes and some residual carbon smoke. The solid residue is transferred to a dumpster via an ash conveyor. The secondary chamber operates at 1800°F in oxygen-rich conditions to combust any remaining materials in the smoke. The smoke is then drawn through a flue to the scrubber system (see Figure 4). The Anderson 2000 Wet Scrubber reduces the temperature of the flue gas by more than 1600°F and passes it through three series of eight water sprayers and venturi that allow particulates to drop into the scrubber tank. Flue gas is filtered before exiting to the exhaust stack.[24] With these modifications, and a continuing commitment to equipment upgrades as they become available, RML would be maintaining a state-of-the-art incinerator with minimal environmental impact.

Figure 4 – RML Incinerator Scrubber System

LOGISTICS OF APPLICABLE TECHNOLOGIES

Landfills

Whichever method is selected for RML in the future, special consideration must be given to one key factor: disposal of the waste treatment process by products. The most obvious means is to dispose of byproducts in the local landfill. However, any landfill company that is environmentally responsible will impose strict regulations on the materials their facility can accept. The closest landfill to RML is in Missoula, Montana. This landfill is a Class 2 municipal landfill that cannot receive hazardous waste. The landfill could legally accept treated medical waste if the waste characterization test results continuously met stringent requirements of the Environmental Review Board operated by the landfill operator, Allied Waste Company, as well as the Federal land disposal restrictions. Included in the waste characterization are tests for numerous hazardous chemicals and hazardous characteristics. This implies that there must be no or very minimal chemical residue present in the effluent from any waste disposal procedure employed by RML. In incineration, all materials are combusted to simple ashes. Unfortunately, alkaline hydrolysis and steam sterilization are incapable of reducing or eliminating chemical hazards from the waste. In western Montana, numerous hospitals are sending their disinfected medical waste to a municipal landfill near Great Falls, which is approximately 300 miles from RML. This privately-owned landfill does not require medical waste to be biologically validated after sterilization/disinfection, nor does it require characterization for hazardous chemical constituents before disposal. Considering this, there are likely environmental liability issues that would preclude RML from transporting medical waste to the Great Falls landfill for disposal. The nearest Subtitle C landfill facilities capable of accepting hazardous waste are in Hillsboro, Oregon or Eagle County, Colorado. The need to transport treated medical waste from RML to one of these facilities must be a consideration in the selection of the best infectious waste disposal technology option at RML.

Incineration

Incineration has been the NIH choice for infectious waste disposal at RML for many years based mostly on one principle: effectiveness of biological agent inactivation. Until recently, incineration had been the only proven method for complete prion inactivation for large throughput operations.[25] Achieving temperatures up to 1800°F (980°C) for four hours, incineration completely combusts all materials.[26] The byproducts are gases, small particulate matter and residual ash. Several technical improvements have been made to the system at RML to improve the efficiency of combustion and minimize emissions to the environment. Equipment advances that allow this incinerator to operate at such high efficiency are available since medical waste incineration has been practiced for over 100 years. Today, several competing manufacturers and service companies drive improvement in the technology and availability of equipment and service. Many of these companies are stable, long-lived concerns that can be relied upon for many years of continuing service.

Another significant attribute of the incinerator at RML is strict control of emissions and effluent to minimize environmental effects. The most frequently criticized aspect of incineration is the specter of toxic emissions to the air. However, RML emission levels are substantially below current and projected EPA emission limits (refer to Table 3); studies conducted by the U.S. EPA demonstrate that the emissions from just one family using a burn barrel produces more emissions than a modern incinerator disposing of 200 tons of waste per day.[27]

Table 3 - RML Emissions vs. Current and Projected EPA Limits[10]

Pollutant	Units	RML (2006)	Limits	Proposed Limits
HCL	ppm	0.02	100	51
CO	ppm	0.30	40	25
Pb	gr/ 10^3dscf	0.0104	0.52	0.64
Cd	gr/ 10^3dscf	0.0025	0.07	0.06
Hg	gr/ 10^3dscf	0.0035	0.33	0.24
Particulate Matter	gr/dscf	0.02	0.03	0.03
CDD/CDF, TEQ (Dioxins)	gr/ 10^9dscf	0.05	55	15
NO_X	ppmv	107.40	250	212
SO_2	ppmv	0.10	55	28

An additional area of concern and public scrutiny is the possibility of residual infectivity of prion agents in the flue gas. However, several studies over the last seven years have alleviated this concern.[5, 6, 26] It has been shown that nearly all prion infectivity has been eliminated (approximately 4.5 Logs) by burning at 600°C and no residual infectivity could be detected after treatment at 1000°C.[6] This high level of combustion produces only inert ash residue. Although the ash residue may initially have a high pH, wood chips are mixed with the ash to neutralize the pH to a suitable level for disposal at local landfills. RML also conducts quarterly ash analysis to ensure there is no toxic metal residue remaining in the ash. An additional benefit of incineration is the minimal utility requirements for operation. The incinerator operates utilizing natural gas fuel; a diesel generator is available for emergency backup electricity as needed; and a UPS in place to provide electrical power to controls in instance of a power failure. Incineration also results in a remarkable decrease in waste mass and volume, reducing waste transported to landfill. It has been estimated that a 96-98% reduction of volume is achieved with this method and results in 42 cubic yards of ash annually that can be, in its entirety, handled by one waste transport vehicle per year.

It is also imperative to address public and personnel safety issues in an analysis of viable technologies to be employed at RML. While it should be consistent with every industry, as a governmental-sponsored agency, RML must ensure the safety of their personnel and that of the local community. The scope of this commitment also extends to the local environment. The operation and performance of the current incinerator system has been capable of maintaining this responsibility. On a quarterly basis, composite samples of incinerator ash are collected and submitted for laboratory analysis of TCLP metals and pH for characteristic hazardous waste determination. Sample results have consistently indicated the ash is not a hazardous waste. As owner of the Missoula BFI landfill, Allied Waste Service's corporate environmental review board has reviewed information on the incineration process and ash characterization/sampling methods and has provided a written acceptance of the materials since it is not a hazardous waste. The Allied Waste ash disposal permit has an expiration date of 04/13/2009. The rigorous ash and emission analyses document that no toxic or dangerous materials are released to the environment and that only acceptably low incinerator emissions are released to the environment. Thus far, no deviations from permit requirements have been recorded at RML, demonstrating their commitment to environmental protection.

A gap analysis of personnel issues presented concerns that should be investigated further. It does not appear that incinerator operator ergonomics have been well addressed. With the increase in throughput expected in the facility with the commissioning of the IRF, the incinerator will be required to run for longer periods throughout the day and for more days of the week. Another issue to be addressed is the transport of materials from the laboratory generation location to the incinerator. Currently, bags are loaded into trucks and transported to the incinerator. Waste is then stored in a shed near the incinerator until ready for incineration. Although the incinerator is a robust method for infectious waste disposal, considerations should be made for instances where the incinerator is not operational due to mechanical failure, maintenance or upgrades. During the installation of a new scrubber, 22 dumpsters (30 yd^3 each) were accumulated, causing a major backlog in operations. Positively, in the case of mechanical failure, all mid-process materials in the chamber continue incineration as much as possible for four hours before shutdown. No material is removed from the chamber until an entire burn cycle is completed.

To ensure that the strict environmental and safety guidelines are met, the incinerator is equipped with a number of safeguards to monitor and control its operating conditions. RML uses an advanced software monitoring system known as Continuous Emission Monitoring System (CEMS). This program analyzes online data collected from the incinerator and will alarm if conditions approach parameter set-points. This enables operators to correct malfunctions or upsets and to put the system in burn-down for repairs. The floor scale used to weigh incoming materials is connected to this system and ensures that the permit limit of 500 lb/hr charge rate is not exceeded. Flue gas and chamber temperature are monitored and recorded for adequate combustion temperature and chamber pressure drop is monitored for indication of complete combustion. Scrubber flow rate and liquor pH are also monitored to ensure that maximum pollutant extraction is maintained.

Although the incinerator may require significantly more operator interface than other commercially available technologies, courses certified by the ASME have been developed to train and certify operators of incinerators to reduce risk of human error and educate operators on the subtleties of operation and maintenance of these systems. RML currently has one licensed operator and is awaiting completion of training and subsequent certification of a second operator.

Despite many of the positive features of incineration for medical waste, a small number of people in certain environmental organizations in Missoula argue that incineration is a grossly inappropriate method for waste disposal. Some have accepted claims made by alkaline hydrolysis manufacturers that alkaline hydrolysis technology is a preferred substitute to incineration without thoroughly investigating the issue at hand. One organization is proposing to ban incineration completely at RML. In order to resolve this issue, more time and resources should be dedicated to public education and awareness of the special considerations necessary for prion waste disposal and for handling medical waste at this specific facility. RML's commitment to employ only the best suited technology for the community and concern for future improvement as new solutions emerge should be emphasized. Positive aspects and justification of the use of incineration should be shared with the community on a regular basis. If allowed to continue incinerating medical waste, no additional noise pollution would be created. There would be only insignificant impact on local truck traffic with the increased waste generation from the IRF. RML has already demonstrated that they are below the EPA guidelines for air emissions, for both current and projected pollutant levels.

Alkaline Hydrolysis

Alkaline hydrolysis has been touted as the new method of choice for prion waste inactivation since its debut a few years ago, based on the prospects of reduced environmental impact from incineration and similar effectiveness for prion inactivation. Although several papers have been published discussing and demonstrating the ability of alkaline hydrolysis tissue digesters to inactivate prions, studies to evaluate long-term infectivity (over 12 months) have not yet been conducted.[21, 25] It is theorized that a minimum two-year incubation period is required to fully address infectivity in the *in vivo* bioassays that are the only available measure of effectiveness.[8, 28] Another consideration is that most of the studies have been conducted at laboratory scale, which is known to achieve significantly higher inactivation counts with lower temperature, pressure and pH concentration conditions than with large-scale equipment.[29] It should also be noted that this technology is suitable for the digestion of organic tissues but not for inorganics including bone minerals, plastics, or some highly-structured lingo-cellulose-based polymers (bedding).[22] The surfaces of these types of materials will be disinfected by the process; however the technology is incapable of accessing agents contained in these types of materials (e.g., high titer prion waste in Eppendorf tubes and sealed biohazard bags). Eliminating the use of these containers is not a viable option because of the inherent risk of occupational exposure and environmental containment.

Alkaline hydrolysis tissue digestion does improve on incineration by producing minimal air emissions (apart from reportedly significant local odor issues) but is not without environmental consequence. The effluent of the digestion process contains high levels for suspended solids, pH, nitrogen, phosphorous, BOD and COD,[29] all of which would place additional demand on the local publicly-owned wastewater treatment (POTW) system, especially with the additional throughput anticipated with the IFR expansion at RML. There is cause for concern about additional suspended solids because the POTW is currently operating at maximum solids handling capacity. Also, the POTW discharges treated effluent to a local waterway for which the total daily maximum loads (TMDLs) of nitrogen, phosphorous and other constituents are being established at values near current throughput. The POTW does not have an anaerobic digester for treatment of high nitrogen and phosphorous waste. Therefore, increased discharges could possibly require either a modification at the POTW, typically financed through discharger impact fees or on-site wastewater pretreatment at RML.

Effluent treatment systems could be installed on site and/or large surge tanks could be incorporated to slowly dose the effluent into the sewer system so as to not exceed discharge permits. Effluent could also be dehydrated and shipped off site. However, due to the organic limitations of the technology, the volume required to be shipped off site would increase greatly. By current estimates, only approximately 9.6% of the waste would be susceptible to digestion, leaving the remaining 90.4% intact without any mass or volume reduction. This would result in a total volume reduction of only 9.2% for the entire RML waste stream. Such small reductions in effluent volume would greatly impact landfill transport and the associated truck traffic. It should also be considered that alkaline hydrolysis cannot treat most chemical wastes and tissue digester effluent may not even be appropriate for Class 2 landfill disposal. From interviews with current users of alkaline hydrolysis tissue digesters, it was learned that most are constrained to dehydrate their waste and ship it off site because of regulations imposed by the local wastewater treatment plants. The interviews also indicated that the byproducts from tissue digesters produce a moderately offensive odor that persists for the first 30 minutes of cool-down.

A large risk for this technology is the immaturity of the technology itself and the limited amount of service support currently available. Based on the results from the Council Rock study[15], only one manufacturer was considered worthy of consideration at RML. As a fairly new company, the future stability and the support and service WR^2 would provide are unknown and would bear investigation and evaluation. In addition, other companies may come into the picture as commercially viable alternatives in the future.

For safety concerns (other than the uncertainty previously described for the effectiveness of prion inactivation), containment in case of mechanical failure is a serious issue. Even with the longstanding production of pressurized vessels, it is not uncommon in the lifetime of the vessel or its associated piping to experience some sort of leak. If this were to occur in mid-process with prion contaminated waste, operators could be at serious risk of exposure or injury. From our engineering risk analysis, alkaline hydrolysis systems were judged as moderate to high risk with this process. This is detailed further in the risk analysis section. An additional safety concern is that exposure of aluminum to hot caustic solutions produces very explosive hydrogen gas. Very stringent SOPs and employee cooperation would have to be developed to ensure that inadvertent disposal of aluminum would be strictly avoided. The final safety concern would be the necessity of transporting highly caustic materials to feed the digester through the local community.

Safeguards have been developed for this system that actually closely mimic those used in current biological and chemical manufacturing. The equipment is primarily run from an operator-monitored control station. Advanced control systems, PLC-based (programmable logic controllers), take online process data and adjust systems accordingly to maintain preferential operating conditions. These systems also allow monitoring and recording of actual process data to validate the required temperature and pressure for prion inactivation. These advanced systems permit operators to rely on the sophisticated programming of the software to run the system and require much less manual input. Unfortunately, no training courses or certifications have yet been developed to ensure that operators are trained to handle the system manually or upon failure of the control system. This results in heavy reliance on expertise provided by the manufacturer. With given uncertainties on the future of the alkaline hydrolysis manufacturer, the risk of loss of service support should be considered.

Although alkaline hydrolysis has been the method advocated by local activists, due diligence should be taken to properly inform the public of the pitfalls and challenges presented by employing alkaline hydrolysis at RML for their medical waste disposal. While this technology would inevitably decrease air emissions and noise pollution, several more subtle environmental implications are tied to alkaline hydrolysis. What would be most apparent to the public would be the significant increase in truck traffic to and from the facility. Alkaline hydrolysis, due to its organic limitations, could only reduce RML waste volume by 9.2%; the remaining waste would most likely be required to be dehydrated and transported to an out-of-state Subtitle C compliant landfill. Alternatively, RML could install dilution vessels to slowly dose waste to the sewer. However, the local wastewater treatment plant does not have the required resources to handle the increase in wastewater pollutants and could possibly result in pollutants being discharged to local bodies of water. Additionally, the increase in building footprint required to safely house a tissue digester of sufficient size to handle the waste throughput at RML would likely warrant an additional expansion of the campus. Most importantly, but less apparent to the public, is the fact that Montana Department of Environmental Quality (DEQ) has not yet officially accepted alkaline hydrolysis as an appropriate method for medical waste disposal in Montana per the Montana Infectious Waste Management Act Montana Code Annotated, Title 75-10-10.

Autoclaving/Steam Sterilization with Internal Shredding

As previously identified, steam sterilization for the RML facility can, at best, only serve as a supplement to the method of waste disposal used to inactivate prion wastes. Steam sterilization could handle the non-prion wastes instead of incineration to reduce current incinerator utilization or could be used to assist the alkaline hydrolysis process by treating inorganic, plastic and cellulosic wastes.

Generally, steam sterilization has proven to be an excellent method of decontamination of medical wastes that contain pathogens susceptible to its operating conditions. This encompasses almost all standard biohazard agents, with the exception of prions. The technology is well established and researched and there are several strong manufacturers providing equipment and service. What is unique to this special type of unit is an internal shredding mechanism that can disrupt closed containers and provide for a slight reduction on waste volume — to approximately 70% of the original volume. There are few, if any, hazardous or environment impacting byproducts of this process, but it should be noted that steam sterilization does not decompose hazardous chemical residues that pose a threat in the local landfill. The units are fairly easy to operate with minimal necessary occupational training required. The only downfall to this technology for use at RML is the significantly lower volume reduction and lack of proximity to Subtitle C complaint landfills. Unfortunately, due to the geographic location of RML and lack of access to nearby Subtitle C compliant landfills, these become quite significant issues.

Second to logistics in selecting a technology is risk. Risk and uncertainty are key features that must be understood in order to make rational decisions. Risk assessment is the quantifying, either qualitatively or quantitatively, of the probability and potential impact of risk. Risk analysis is the whole process including risk identification, risk assessment, and the resulting response to the evaluation. Similarly, process hazard analysis (PHA) is used to identify hazardous scenarios (specific, unplanned events that have undesirable consequences). Its purpose is to provide information to make decisions to improve safety and reduce the risk of hazards and ensure reproducible product quality. Formal PHA provides the opportunity for the team to use outside, independent expertise to identify potential accident sequences. A combination of both of these strategies was employed to survey the potential technology applications at the RML campus and to provide a final check on a basically sound process design to make sure that no unforeseen effects have been overlooked. What results from this type of analysis is the application of a formal systematic critical examination of the process and engineering intentions to assess the hazard potential that arises from deviation in design specifications. The methodology of the process considers failure modes and effects analysis and starts with a listing of all components of a system on a matrix identifying potential failure mode, consequences, probability, hazard class, detection methods, and compensating provisions. Graphical representation of this analysis can be shown through a fault matrix rating consequences and frequencies of risks as shown in Table 4.

Table 4 – Fault Matrix

		Consequence			
		1 Minor	2 Serious	3 Very Serious	4 Catastrophic
Frequency	1 Highly Improbable	1	2	3	4
	2 Improbable	2	4	6	8
	3 Infrequent	3	6	9	12
	4 Frequent	4	8	12	16

Fault Matrix Consequences:

1. Minor – Minor nuisance to employees, no injuries to public, contained release, minimal facility disruptions.
2. Serious – Minor nuisance to employees, no injuries to public, environmental impact, minor damage to facility with downtime.
3. Very Serious – Major nuisance and injuries possible to public; moderate injuries to employees, moderate adverse environmental impact, operations disrupted, damage extensive but repairable.
4. Catastrophic – Death or severe health effects possible, large adverse affect on environment, operation severely disrupted, some units a total loss.

Fault Matrix Frequencies:

1. Highly Improbable – Not expected to occur during the facility lifetime.
2. Improbable – No more than once during the facility lifetime.
3. Infrequent – Occurs several times during the facility lifetime.
4. Frequent – Occurs more than once in a year.

Risk Ranking:

13-16: Urgent – Immediate engineering and/or management control. Process must shut down until repair is implemented.

8-12: High Priority – Should be addressed with engineering and/or management control with preference over medium and low priority recommendations.

5-7: Moderate Priority – Can be addressed with engineering and/or management control with preference over low priority recommendations.

3-4: Low Priority – Can be addressed with engineering and/or management control without disruption to production but within a prescribed timeline.

1-2: Acceptable – No action required.

Once the risk rankings are defined, the team identifies the safeguards in place to mitigate the consequences. The team then recommends an action item along with a responsible individual. The team prioritizes the course of action based on the risk ranking. A report is prepared and periodically updated with resolutions and status updates. Safeguards should be included

whenever possible or when threat or consequence is great. Safeguards can include systems that are designed to prevent, detect or mitigate a hazard. This analysis has been performed for prion contaminated waste disposal at RML. The results are summarized in Table 5.

Table 5 – Risk Assessment

	INCINERATION				What If	ALKALINE HYDROLYSIS				
		Consequence	Frequency	Risk		Consequence	Frequency	Risk		
Safeguard	Incinerator is designed for needed residence time at temperature to reliably destroy the prions.	4	1	**4**	Technology does not destroy the prions.	4	3	**12**	Tissue digester is designed for needed residence time, temperature and chemical conditions to reliably destroy the prions.	**Safeguard**
Recommendation	No recommendations identified.								No recommendations identified.	**Recommendation**
Safeguard	The proposed design provides sufficient reliability and over-design to assure all material is exposed to the necessary conditions.	2	2	**4**	Mixing within the equipment leads to insufficient residence time or exposure to destroy all of the prions.	3	3	**9**	The proposed design provides sufficient reliability and over-design to assure all material is exposed to the necessary conditions.	**Safeguard**
Recommendation	None identified.								None identified.	**Recommendation**
Safeguard	Controls have been upgraded to monitor and control temperature and burning conditions.	2	2	**4**	Controls are insufficient to assure reliable operations.	3	3	**9**	Controls are designed and installed to monitor recipe conditions such as temperature and chemical dosing.	**Safeguard**
Recommendation	None identified.								None identified.	**Recommendation**
Safeguard	Operating procedures controlled to load no more than 500 lbs per hour of waste. Controls are in place to assure the load imposed on the incinerator does not exceed the unit's capability.	2	2	**4**	Equipment is improperly loaded.	3	3	**9**	Operating procedures control load and chemical addition based on waste material treated. Controls are in place to assure the load imposed on the tissue digester does not exceed the unit's capability.	**Safeguard**
Recommendation	None identified.								None identified.	**Recommendation**

Table 5 – Risk Assessment continued

	INCINERATION					ALKALINE HYDROLYSIS			
		Consequence	Frequency	Risk	What If	Consequence	Frequency	Risk	
Safeguard	State and Federal law require that a certified HMIWI Operator be on duty at the facility if the incinerator is operating. HMIWI Operators must complete a 6 month apprenticeship and become ASME certified via training courses.	2	2	**4**	Equipment is improperly operated.	3	3	**9**	No safeguards identified. **Safeguard**
Recommendation	None identified.								Provide adequate training to operating personnel. **Recommendation**
Safeguard	Incinerator technology and procedures are appropriate for accommodating other wastes inadvertently mixed in with the hazardous wastes.	1	3	**3**	Improper wastes are treated with the technology.	3	4	**12**	No safeguards identified. **Safeguard**
Recommendation	None identified.								Provide procedures for appropriate further segregation of waste materials. **Recommendation**
Safeguard	Incinerator technology and procedures are appropriate for accommodating all types of infectious wastes.	1	1	**1**	Technology is not capable of treating certain types of infectious waste.	3	4	**12**	No safeguards identified. **Safeguard**
Recommendation	None identified.								Provide alternative technology (such as incineration) for materials that are not compatible with the digester technology. **Recommendation**

Table 5 – Risk Assessment continued

	INCINERATION					ALKALINE HYDROLYSIS			
		Consequence	Frequency	Risk	What If	Consequence	Frequency	Risk	
Safeguard	Incinerator technology and procedures are appropriate for accommodating all types of infectious wastes.	1	1	**1**	Small amounts of non-compatible waste (such as bedding) are mixed in with the intended wastes to be treated.	2	4	**8**	No safeguards identified. **Safeguard**
Recommendation	None identified.								Provide design to adequately deal with small volumes of incompatible waste contamination in the target waste materials. **Recommendation**
Safeguard	A state-of-the art scrubber with appropriate controls and alarms is in place to meet current and foreseen EPA standards.	2	2	**4**	The technology produces noxious, toxic or hazardous air emissions.	1	4	**4**	No safeguards identified. **Safeguard**
Recommendation	None identified.								Evaluate vapor/air emissions and consider off-gas odor abatement. **Recommendation**
Safeguard	Incinerator emissions should not affect waste water quality.	1	1	**1**	The technology produces toxic or hazardous emissions to waste water.	3	4	**12**	No safeguards identified. **Safeguard**
Recommendation	None identified.								Maintain waste segregation from waste water, dehydrate and landfill. **Recommendation**
Safeguard	The scrubber is not an inherent factor in the containment and destruction of biological hazards. Scrubber water pH and flow are monitored and alarmed. Adequate procedures are in place to recognize and respond to upset conditions in the scrubber to mitigate releases.	2	3	**6**	Improper operation or failure of emission treatment equipment leads to release of hazardous material to the environment.	2	3	**6**	No emission treatment equipment in place. **Safeguard**
Recommendation	None identified.								Evaluate potential on-site pretreatment of liquid effluent. **Recommendation**

Table 5 – Risk Assessment continued

	INCINERATION					ALKALINE HYDROLYSIS				
		Consequence	Frequency	Risk	What If	Consequence	Frequency	Risk		
Safeguard	Cooled incinerator ash is treated with wood chips to reduce pH.	1	4	**4**	Handling of toxic or hazardous chemicals is required for this technology.	2	4	**8**	No safeguards identified.	**Safeguard**
Recommendation	None identified.								Provide adequate hazardous chemical handling training and appropriate Personal Protective Equipment (PPE).	**Recommendation**
Safeguard	Procedure in place to safely store contaminated materials during incinerator shut-down periods.	2	3	**6**	Technology is out of service and/or down for maintenance and repair.	2	3	**6**	Procedure in place to safely store contaminated materials during digester shut-down periods.	**Safeguard**
Recommendation	Consider redundant incineration capability.								Consider redundant digester capability.	**Recommendation**
Safeguard	The incinerator chamber itself is maintained at temperature for an extended time prior to shut-down (four-hour clean burn procedure).	2	2	**4**	Maintenance personnel exposed to contaminated or hazardous materials within the equipment during change over or repair procedures.	2	2	**4**	The tissue digester itself is maintained at temperature for an extended time prior to shut-down.	**Safeguard**
Recommendation	None identified.								None identified.	**Recommendation**
Safeguard	Contaminated ash is held in the incinerator until adequate decontamination burn-down can be completed.	2	3	**6**	Emergency shut-down occurs preventing the normal completion of the decontamination cycle.	1	3	**3**	Process is inherently closed; protecting from release of untreated materials.	**Safeguard**
Recommendation	Adequate procedures need to be in place to deal with this event.								Adequate procedures need to be in place to deal with this event.	**Recommendation**
Safeguard	The technology, equipment and manufacturer have a long history of reliable operation. At some point in the future, the equipment will begin to have age-related breakdowns.	2	2	**4**	The long-term reliability of the technology/ equipment/ manufacturer is compromised.	3	2	**6**	Evaluate alternative suppliers with adequate technical capability, should vendor with exclusive technical position go out of business.	**Safeguard**
Recommendation	Evaluate new redundant incinerator.								No recommendations identified.	**Recommendation**

Table 5 – Risk Assessment continued

	INCINERATION					ALKALINE HYDROLYSIS			
		Consequence	Frequency	Risk	What If	Consequence	Frequency	Risk	
Safeguard	No safeguards identified.	2	2	4	Necessary supplies (chemical/natural gas) are interrupted due to outside event or influence.	2	2	4	No safeguards identified.
Recommendation	Consider on-site alternate fuel supply backup to allow normal safe shut-down procedures (4-hour + cycle).								Consider on site alternate chemical supply backup to allow normal safe shut-down procedures.
Safeguard	Emergency generator provided for electrical power, UPS for controls and alarms.	2	3	6	Loss of electrical power supply leads to loss of operation and control on the technology.	1	3	3	Emergency generator provided for electrical power. Fail safe design provided.
Recommendation	None identified.								Provide UPS backup for controls and alarms.
Safeguard	Appropriate and rigorous preventative maintenance procedures in place.	4	2	8	Mechanical failure of the equipment leads to emergency shut-down and/or leak.	4	2	8	Appropriate and rigorous preventative maintenance procedures to be put in place.
Recommendation	None identified.								Consider diked containment to protect against failure of the digester vessel and leak of inadequately treated waste materials. Also consider providing an emergency catch tank if overpressure on digester leads to rupturing of the pressure relief device.

Total Risk for Incineration: 78
Total Risk for Alkaline Hydrolysis: 144

RESULTS

This study compared present technology for infectious waste disposal at RML, which is largely based on incineration, with alternative technologies. Effectiveness, environmental impact, reliability and logistics of the alternative technologies were evaluated in order to establish an opinion of the best available technology.

Incineration is still the most effective, unambiguous method for prion inactivation.[4, 8] For other non-prion infectious waste, alkaline hydrolysis or steam sterilization cannot provide enough reduction in mass or volume to overcome the environmental effect of transporting decontaminated waste from RML to a suitable landfill. Emissions from the truck traffic required would greatly exceed the current emissions from the incinerator operation. Additionally, alkaline hydrolysis has a higher risk of failure than incineration, in terms of accidental release of prions to the environment, for effectiveness of prion inactivation and for minimizing personnel exposure. Also, alkaline hydrolysis is not applicable for the wide variety of prion waste generated at RML. Alkaline hydrolysis would prove to be a good remedy for applications where only carcass disposal is an issue. Steam sterilization (autoclaving) with internal shredding is only valid as a supplemental technology and, again, the significant impact to local truck traffic and the distance that waste must be hauled provides a case against employing the technology at RML. Finally, it should be noted that increasing the complexity of the separation of waste streams by employing multiple methods for medical waste disposal could lead to inadvertent crossing of waste streams, which could result in very serious repercussions not only for RML but for the local community and environment. Results of the study logistics are summarized in Table 6.

Table 6 – Technology Logistics Matrix

	Steam Sterilization	Alkaline Hydrolysis	Incineration
Prion Inactivation	**Not Acceptable**	Acceptable	Acceptable
Other Biohazard Inactivation	Acceptable	Acceptable	Acceptable
Process By Products	Acceptable	**Not Acceptable**	Acceptable
Equipment Availability	Acceptable	**Not Acceptable**	Acceptable
Service Availability	Acceptable	**Not Acceptable**	Acceptable
Reliability of Technology	Acceptable	**Not Acceptable**	Acceptable
Soil Effects	Acceptable	Acceptable	Acceptable
Air Effects	Acceptable	Acceptable	Acceptable
Water Effects	**Not Acceptable**	**Not Acceptable**	Acceptable
Waste Generation	**Not Acceptable**	**Not Acceptable**	Acceptable
Utility Usage	Acceptable	**Not Acceptable**	Acceptable
Volume/Mass Reduction	**Not Acceptable**	**Not Acceptable**	Acceptable
Data Recording	Acceptable	Acceptable	Acceptable
Operator Interaction	Acceptable	**Not Acceptable**	Acceptable
Potential Public Health Risk	Acceptable	**Not Acceptable**	Acceptable
Operational Risk	Acceptable	**Not Acceptable**	Acceptable
Mechanical Failure Scenario	Acceptable	**Not Acceptable**	Acceptable
Transportation Effects	**Not Acceptable**	**Not Acceptable**	Acceptable
Safety of Technology	Acceptable	**Not Acceptable**	Acceptable
Community Perception	Acceptable	Acceptable	Acceptable
Noise Pollution Effect	Acceptable	Acceptable	Acceptable
Traffic Impact	**Not Acceptable**	**Not Acceptable**	Acceptable
Permitting Requirements	**Not Acceptable**	**Not Acceptable**	Acceptable
Environmental Regulations	**Not Acceptable**	**Not Acceptable**	Acceptable

CONCLUSIONS

At present, the best available technology for disposal of infectious wastes at RML is incineration. It is recommended that RML continue to operate and maintain a state-of-the-art incineration system. In fact, consideration should be given to mitigating risk to RML operations by replacing, in a timely fashion, components of the incinerator system as they age as well as considering the cost impacts and logistics of installing a redundant HMIWI.

Neither alkaline hydrolysis tissue digestion nor steam sterilization with internal shredding can be considered a complete waste disposal solution for RML. Together these technologies could conceivably replace incineration at RML. However, the logistics, risk, and environmental impact dictate that this course should not be taken.

The NIH and RML should continue to monitor and evaluate new technologies as they emerge and mature and strive to ensure that any technology employed at the campus will be at the forefront of safety and environmental standards.

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