

**Excerpts from the Department's License Record**

- **Copy of DEP Order O-221-BD-M**



STATE OF MAINE  
DEPARTMENT OF ENVIRONMENTAL PROTECTION  
STATE HOUSE STATION 17      AUGUSTA, MAINE 04333

DEPARTMENT ORDER

IN THE MATTER OF

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| ASSOCIATED HEALTH RESOURCES, INC.  | ) | MAINE HAZARDOUS WASTE, |
| PITTSFIELD, SOMERSET COUNTY, MAINE | ) | SEPTAGE AND SOLID      |
| BIOMEDICAL WASTE TRANSFER AND      | ) | WASTE MANAGEMENT ACT   |
| TREATMENT FACILITY LICENSE         |   |                        |
| LICENSE #O-221-BD-B-M              | ) | LICENSE MODIFICATION   |
| (APPROVAL WITH CONDITIONS)         | ) |                        |

Pursuant to the provisions of 38 M.R.S.A. Section 1301 – 1319-Y and 06-096 CMR Chapter 900, Maine Biomedical Waste Management Rules (August 4, 2008), the Department of Environmental Protection (hereinafter “DEP” or the “Department”) has considered the modification application of ASSOCIATED HEALTH RESOURCES (hereinafter “AHR”) with its supportive data, agency review comments, and other related materials on file, and FINDS THE FOLLOWING FACTS:

1. APPLICATION SUMMARY

A. Application: On December 22, 2008 AHR applied to the Department to modify their biomedical waste treatment and transfer facility application. AHR proposes to replace their two Hydroclave treatment vessels at their Pittsfield, Maine facility with a treatment vessel manufactured by Bondtech, Inc. The Hydroclave and Bondtech technologies are both steam sterilization methods of treatment.

AHR was initially licensed on May 20, 2005 to treat the 2.6 to 3 million pounds of biomedical waste generated annually by their 39 member hospitals. The Maine Hospital Association (MHA) is the sole shareholder of AHR. The Maine Hospital Association is a statewide not-for-profit association of Maine hospitals and their affiliated health care organizations. All of their members are licensed under Title 22 of the Maine Revised Statutes. Currently all 39 Maine hospitals are members of MHA. Other generators of biomedical waste including medical practices, veterinary practices and laboratories also utilize this facility.

AHR was incorporated in 1992 as a Maine corporation with a principal place of business in Augusta, Maine. AHR is governed by a 12 member board of directors and the President of MHA serves as the President of AHR. AHR is the sole owner of the existing biomedical waste treatment facility that is the subject of this application.

B. History: This is the second application to the Department from AHR. The facility is located at 264 Industrial Park Road which is located in the Pittsfield

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Industrial Park. This site has a permit under the Site Location of Development Law. In Board Order #39-2638-25240, dated January 21, 1976 the Board approved a Site Location of Development Order to the Town of Pittsfield for the development of Phase I of the Pittsfield Industrial Park, consisting of 10 lots on 47 acres. In Department Order # L-2638-39-B-C, dated September 9, 1992, the Department approved the development of Lot 5 with an 8,000 square foot building and associated storm drainage, solid waste disposal, and landscaping. In Department Order #L-2638-26/31-B-N, dated October 16, 1996, the Department approved expansion of the industrial park and wetland alteration on the existing and expansion lots. The wetland mitigation package approved in that order included preservation of wetlands in the eastern portion of Lot 5. In comments dated December 19, 1995, The Maine Department of Transportation (MDOT) stated that there are no off site traffic operational impacts anticipated. MDOT suggested that the entrance to the industrial park be widened to allow trucks to turn without encroaching into the opposing lane of travel. Plans were revised at that time to reflect their suggestions. The Department's Bureau of Land & Water Quality has determined that this proposed facility will not impact additional wetlands on Lot 5 or encroach into the wetland compensation area. On November 9, 2004 AHR applied for in application (#L-2638-26-E-M) to the Department's Bureau of Land & Water Quality proposing to change the permitted use on Lot 5 to a biomedical waste treatment and transfer facility. AHR also relocated parking areas within existing gravel areas. No other site work was proposed.

In 1999 the Natural Resources Committee of the Maine Legislature instructed the Maine Hospital Association and the Department to work together with other interested parties including the Natural Resources Council of Maine and Health Care without Harm, to examine options for expanding in-state treatment and disposal methods for biomedical waste. The consensus of that group was that steam sterilization and microwaving are appropriate technologies for the safe treatment of biomedical waste. It was also the consensus of the group that biomedical waste should be classified as a special waste with final disposal in a DEP licensed special waste landfill. Several parties in the group expressed a strong desire that the treated waste not be incinerated in a municipal solid waste incinerator. Scientific evidence supports the contention that the incineration of polyvinyl chloride (PVC) based plastics, which comprise a significant percentage of biomedical waste, generates dioxins, especially in the ash.

The facility began treating biomedical waste in June of 2005. Most of Maine's hospitals utilized the facility as well as many other generators of biomedical waste

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including doctors and dentists offices. The facility, however, had a number of operational problems. These problems included the entanglement of tubing, large fabrics like sheets and electrical wires in the Hydroclave's paddles. There were also worker complaints about chemical fumes when the treatment unit doors were opened after treatment cycles.

A Department compliance inspection of the facility on October 12, 2007 documented violations of the Biomedical Waste Management Rules as well as the terms and conditions of their license. As a result of this inspection a Notice of Violation was issued to AHR in November 2007. This action was followed by an Administrative Consent Agreement in May 2008.

At the time of inspection both Hydroclave treatment units were leaking liquids onto the operating room floor from worn drive shaft packings. The two units were shut down permanently on December 31, 2007. An inspection by the Chief Boiler Inspector for the State condemned the two treatment vessels because of excessive corrosion of the interior carbon steel jackets on January 3, 2008. It is believed that part of the corrosion was due to inappropriate waste materials being placed into biomedical waste containers at various generators' facilities. As a result of this finding AHR has begun a training program stressing the importance of waste segregation at generating facilities.

Other violations documented during the October 2007 inspection included the failure to record written parameter records of treatment cycles due to inoperable recorders and no chart recording paper. The failure of the post treatment shredder to render the waste unrecognizable, intact sharps and other pieces of treated biomedical waste could be identified. The freezer space was not maintaining biomedical waste in a frozen state as specified in AHR's facility license. Three boxes of biomedical waste were not stored in designated storage areas. One box was open. Apparently, facility employees were using it to store materials such as lengths of instrument wires that they had removed from wastes designated for Hydroclave treatment but which frequently became entangled in the interior paddles of the treatment unit.

- C. Summary of Modification Proposal: Associated Health Resources has proposed to contract with Bondtech Corporation (hereinafter "Bondtech") of Somerset, Kentucky for the installation of the treatment unit and with Oxus Environmental, LLC (hereinafter "Oxus") of Pittsfield, Maine for the operation of the facility. Oxus will provide transportation of biomedical waste from the 39 Maine

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Hospitals to the treatment facility. Trace chemotherapy waste and pathological waste will be temporarily stored at the facility prior to transportation to an appropriate treatment facility for those waste streams. At this time Oxus plans to transport all the biomedical wastes including the trace chemotherapy and pathological waste. In the future biomedical waste transported from other DEP licensed biomedical waste transporters or the biomedical waste generators themselves may be accepted. Biomedical waste generators may transport less than fifty pounds of biomedical waste without obtaining a license from the Department. In addition to replacing the two Hydroclave treatment units with one Bondtech treatment unit; AHR has also proposed several other operational and equipment changes in this application. These include replacing the Hydroclave shredder with a new shredder for the grinding of the sharps portion of the waste stream; the replacement of the interior refrigeration space with a 53 foot trailer with a freezer unit with an electrical hookup and access from inside the treatment facility. The original freezer unit has been dismantled and is stored at the facility. An automatic cart tipping unit is now proposed to dump the treated biomedical waste into a dumpster that is located adjacent to the treatment unit inside the facility. The removal of the treated waste conveyor that had moved the waste from the treatment unit to the shredder has occurred. Finally the waste is no longer rendered unrecognizable as is now allowed by the Rules.

- D. Physical Description of Property: AHR has secured a long-term lease on a 6.5 acre parcel with an existing building of approximately 8000 square feet. The physical address is 264 Industrial Park Road in the municipality of Pittsfield, Maine. The property can be further defined by the coordinates N 44 degrees-46 minutes-794 seconds and W 69 degrees-23 minutes-863 seconds.

## 2. DETAILED PROJECT DESCRIPTION

- A. Treatment Process Description: AHR has contracted with Bondtech to install one model BTT6X16 autoclave treatment unit. The technology uses steam, pressure and time to render the waste non-infectious.

Upon arrival at the facility, the biomedical waste is manually removed from the reusable totes into wheeled carts. These carts have a volume of 60 cubic feet. Four carts comprise a load. The weight of each cart is known prior to its contents being placed into the autoclave. The BTT6X16 autoclave unit is designed to treat a maximum of 240 cubic feet per autoclave cycle with a maximum per cart of 400 pounds and a maximum weight per cycle of 1,600 pounds. Each autoclave cycle

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is approximately 50 minutes. This is a change in biomedical waste handling. Formerly, biomedical waste was loaded directly into the treatment chamber from the reusable tote.

Once the autoclave has been loaded and the door secured the operator begins the treatment cycle. Based on validation testing conducted on June 2<sup>nd</sup> and 3<sup>rd</sup>, 2009 by WNNW International, Inc., it was determined that the most consistent results and thermal profile are achieved when the unit is vacuumed to a minimum of 40 psig, heated at 284 degrees F for 3 minutes, repeated twice, with a final heating at 284 degrees for 15 minutes, followed by venting and cool down. These operating parameters can be programmed into the control panel computer. These parameters are also recorded on a continuous chart recorder. Process steam will be vented through a barometric steam condenser and discharged outside the facility. The condensate is discharged to the municipal sewer. Finally, a post vacuum pull is conducted to remove any residual steam or moisture prior to opening the autoclave thus completing the treatment cycle. The autoclave cycle parameters will be programmed in accordance with the validation testing report submitted to the DEP. This system has the capability of being shut down in an emergency. Any contents inside the vessel during any such shutdown must be subjected to another complete treatment cycle.

After the cycle has ended, the operator verifies that the steam pressure has been vented. At that point the operator is able to disengage the mechanical safety arm. The autoclave's hatch may now be opened and the carts are removed and transferred to the compactor dumpster. Formerly treated biomedical waste was discharged from the treatment vessel onto a conveyor belt and through a shredder before traveling another conveyor belt to the dumpster. Conveyor belts have been eliminated and the compactor dumpster is now located on the main room floor adjacent to the treatment unit.

Revisions to the Biomedical Waste Management Rules since AHR's last license, no longer require all treated biomedical waste to be shredded. Only the sharps portion of the waste stream is now required to be shredded. Waste sharps will now be segregated from other biomedical wastes by the generators at their facilities. Upon arrival at the facility, the sharps containers are emptied in the existing Sharps Consolidation Unit. These sharps are dumped into a cart reserved only for sharps and treated with three other carts in the treatment unit. The sharps waste stream will then be shredded in a 40 inch shredder supplied by Bondtech, Inc. (Model # BTT/Q55). Once shredded and rendered unrecognizable, the sharps

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waste is deposited into the bulk compactor with the rest of the treated biomedical waste stream. This is a new shredder designed for this waste stream. The older shredder was removed from the facility.

The necessary steam for the autoclave is generated by a steam boiler fired by natural gas or propane gas. The heat input necessary to generate the required steam is 2.2 million British Thermal Units per hour (BTUs/Hr.). The threshold for an Air Emission License from the Department's Bureau of Air Quality is 10 million BTUs/Hr. No Air Emission License is required for this proposal. This is the same boiler that powered the Hydroclaves.

- B. Biomedical Waste Receiving, Handling and Storage: Oxus is licensed (BWT # 495) by the Department to transport biomedical waste. They transport biomedical waste from generators to the Pittsfield facility. At the generator's facility, all boxes are inspected for evidence of leaking and compliance with packaging and labeling requirements. Manifests are also initiated. The driver then loads the waste onto the truck and secures the load.

Upon arrival at the treatment facility, the truck is unloaded and grouped into the following categories based on container labeling:

1. Human pathological, trace chemotherapy and non hazardous cytotoxic wastes and animal carcasses are grouped for temporary storage and placed into the freezer prior to being sent for final disposal elsewhere; and,
2. Non anatomical human wastes from surgery, autopsy and patient care, microbiological laboratory wastes and sharps are grouped for treatment at the facility. These wastes will be treated at the facility as soon as possible. While awaiting treatment, the waste is stored adjacent to the loading platform. Under normal operating conditions biomedical waste to be treated at the facility will be treated the day of arrival.

Manifests are signed by the treatment facility representative and the waste identified in B(2) above is transferred to the Bondtech autoclave for treatment. At the Bondtech autoclave, the biomedical wastes are removed from the reusable plastic totes and placed into wheeled treatment carts. Once the treatment chamber is at capacity, the treatment cycle is engaged. Biomedical waste is proposed to be treated by the Bondtech autoclave unit as soon as possible after the waste is received and logged into the plant. In

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the event of an extended plant outage of greater than 48 hours, the Department shall be notified by AHR. As part of the notification, a contingency plan shall be submitted that will prevent an excessive accumulation of untreated biomedical waste at the treatment facility. At no time will the operator accumulate more than 25 tons, about 35 cubic yards, of biomedical waste prior to activating the contingency plan and commencing the shipment of biomedical waste to the designated back up facility. This waste would be stored on the main floor adjacent to the loading area (see Attachment C to view a floor plan of the facility).

The reusable totes are taken to the container wash system for cleaning and disinfection. The system consists of a conveyor, washer, dryer and control panel. The container wash system accommodates up to ten containers on the soiled side and ten on the washed and drying side. Containers are pre-cleaned by soaking in a tub of hot water and sodium hypochlorite solution prior to being introduced to the system. A U.S. Environmental Protection Agency (EPA) registered disinfectant will be used.

Once the containers have been dried, they are stacked and reused. This is the same cart washing system that was approved in AHR's 2005 application.

Oxus utilizes reusable sharps containers for some generators. Oxus has developed two sizes of proprietary Sharps Consolidation Units. The systems work as follows:

- A. The Sharps Consolidation Unit One (SCU-I) handles ten and seventeen gallon reusable sharps containers. Trained personnel snugly fit two reusable sharps containers into the first and second position in the sharps consolidation unit. The lids are then manually removed with a hand tool. A mechanical shaft then rotates and inverts the containers. Gravity and agitation dumps the waste sharps into a consolidation bin. The bin then is emptied into a wheeled autoclave cart and pushed to the Bondtech autoclave. The empty sharps containers are then placed into the washing system.
- B. The Sharps Consolidation Unit Two (SCU-II) handles smaller sized sharps containers from nursing stations, patient rooms and other areas of hospitals where waste sharps are generated. In this system, four sharps

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containers are positioned in the SCU-II so that the lids may be removed by vacuum cups. Again the sharps containers are rotated, inverted and dumped via gravity into consolidation bins and wheeled to the Bondtech autoclave as described above. The empty sharps containers are then placed in the washing system. At the end of the shift the consolidation bins are sent through the washer.

The tipping phases described above are completely contained to eliminate personnel being exposed to the waste sharps. There is no worker contact with the waste sharps.

The cleaning and sanitizing phase employs a commercially available dishwashing unit modified to aggressively rinse the emptied containers with hot water and surfactants and remove visible contaminants. After washing, the containers are sprayed with an EPA registered sanitizing agent. This is the same sharps management system that was approved in AHR's 2005 application.

- C. Treated Biomedical Waste Handling and Disposal: Once the treated biomedical waste has been removed from the treatment unit, it is accumulated and compacted in a dumpster that is located in the treatment facility and protected from the elements. The inside storage of the dumpster is a change from AHR's 2005 application. Once full, the dumpster will be shipped to a landfill licensed to handle special waste. The treated biomedical waste will be accompanied by a "Certificate of Treatment" stating the waste has been disinfected and poses no threat to human health or the environment.
- D. Management of Biomedical Waste to Be Transferred From the Facility: AHR also operates a biomedical waste transfer facility at the site. The biomedical wastes that are transferred are pathological waste, animal carcasses, trace chemotherapy and non-hazardous cytotoxic wastes. The current industry standard is for these wastes to be incinerated. However incineration capacity is being steadily reduced nationwide and alternative treatment and disposal methods are being studied. In the future, incineration of these wastes may not be an option. Pathological waste generally comprises up to two percent of the biomedical waste stream.

Pathological waste is frozen while at the facility and all biomedical waste and other wastes to be transferred from the facility are also stored in the refrigeration unit for consolidation purposes. All biomedical waste stored at the facility is

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stored in a manner that inhibits rapid microbial growth and putrefaction. AHR operates a refrigeration unit of 2500 cubic feet. This unit is a 53 foot trailer with electrical hook up capability. Access is only available from inside the building. The outside door of the trailer is locked at all times. The trailer has a king pin lock to prevent unauthorized movement of the trailer. It is also monitored by the building security system. This replaces the 1800 cubic feet space within the building that was described in AHR's 2005 license. All biomedical waste that is to be treated on site will be treated as soon as practical, but in no case longer than one week after arrival. Oxus proposes to utilize Healthcare Environmental Services treatment facility in Oneonta, New York as a back-up to the Pittsfield facility if needed.

### 3. TYPES OF BIOMEDICAL WASTE AND OTHER WASTES ACCEPTED FOR TREATMENT OR TRANSFER

A. AHR has defined and described in their application the types of biomedical waste proposed for treatment at their facility. The description is consistent with 06-096 CMR 900.7 the Biomedical Waste Management Rules (August 4, 2008), and consists of waste that may contain human pathogens of sufficient virulence and in sufficient concentrations that exposure to them by a susceptible host could result in disease and are, therefore, biomedical wastes. Biomedical waste subject to the Biomedical Waste Management Regulations and proposed to be accepted for temporary storage or to be treated at the facility are the following:

1. Discarded human blood products including serum and plasma, and body fluids: Body fluids are defined as fluids, which are generated or removed during surgery, autopsy, obstetrics, emergency care, or embalming and include cerebrospinal fluid, synovial fluid, plural fluid, peritoneal fluid, pericardial fluid and amniotic fluid. This portion of the biomedical waste stream will be treated at the facility.
2. Waste saturated with human blood, blood products, or body fluids. This category includes items such as sponges, surgical gloves and masks, drapes, aprons, dressings, disposable sheets and towels, underpads, plastic tubing and dialysis unit waste. This portion of the biomedical waste stream will also be treated at the facility.
3. Pathological waste consisting of human tissues, organs and anatomical parts including teeth that have been discarded from surgery, autopsy,

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obstetrical procedures, and laboratory procedures. This portion of the waste stream will be temporarily stored at the facility and then transferred to a facility permitted to treat pathological wastes.

4. Discarded cultures and stocks of infectious agents and the culture dishes and devices used to transfer, inoculate and mix cultures; discarded clinical specimens and associated containers or vials; discarded biologicals and waste from the production of biological and recombinant DNA research. This portion of the biomedical waste stream will be treated at the facility.
5. Discarded carcasses, body parts, bedding and other waste generated by research facilities from animals containing organisms or agents not usual to the normal animal environment and which are pathogenic or hazardous to humans. This portion of the waste stream will be temporarily stored at the facility and then transferred to a facility permitted to accept pathological waste.
6. AHR temporarily stores at the facility chemotherapy waste and non hazardous cytotoxic (antineoplastic) drugs. This waste is transferred to a permitted facility for disposal.

#### 4. STATUTORY CRITERIA

- A. The Department finds under the statutory criteria of 38 M.R.S.A. §1319-O that biomedical waste must be identified, managed, transported, stored, treated and disposed of in a manner that protects public health, safety and welfare and the environment.
- B. The Department in accordance with 38 M.R.S.A. Section 1310-X cannot issue a biomedical waste treatment or disposal facility license to a commercial entity unless, "at least 51% of the facility is owned by a licensed hospital or hospitals as defined in Title 22, section 328, subsection 14 or a group of hospitals that are licensed under Title 22 acting through a statewide association of Maine Hospitals or a wholly owned affiliate of the association."
- C. Pursuant to 38 M.R.S.A. Section 1319-X and 38 M.R.S.A. Section 484, the Department must find that a new or substantially modified biomedical waste treatment or disposal facility will meet the following criteria:

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1. Financial capacity. The applicant has the financial capacity and technical ability to develop the project in a manner consistent with state environmental standards.
2. No adverse effects on the natural environment. The applicant has provided adequately for fitting the project harmoniously into the existing natural environment and the project will not adversely affect existing uses, scenic character, air quality, water quality or other natural resources in the municipality or neighboring municipalities.
3. Ground water. The proposed project does not pose an unreasonable risk that a discharge to a significant ground water aquifer will occur.
4. Soil types and erosion. The project will be built on soil types suitable to the nature of the undertaking and will not cause unreasonable erosion of soil or sediment.
5. Traffic movement. The applicant has provided adequately for traffic movement of all types into, out of or within the project area. The Department shall consider traffic movements both onsite and offsite, including safety and congestion along waste conveyance transportation routes.
6. Infrastructure. The applicant has provided adequately for utilities including water supplies, sewerage facilities, solid waste disposal and roadways required for the project and the project will not have an unreasonable adverse effect on the existing or proposed utilities and roadways in the municipality or area served by those services.
7. Flooding. The project will not unreasonably cause or increase the flooding of the alteration area or adjacent properties nor create an unreasonable flood hazard to a structure.

5. REGULATORY CRITERIA

The Biomedical Waste Management Rules require all new and substantial modifications to existing biomedical waste transfer and treatment facilities to be subject to the following:

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- A. In accordance with Chapter 900, Section 16 (A) for transfer facilities and Section 18 (A) for treatment facilities, the criteria for the Site Location of Development Law, 38 M.R.S.A. Section 481 et seq. applies;
- B. The Biomedical Waste Management Rules, Chapter 900, Section 16(A)(1) for transfer facilities and Section 18(B)(1) for treatment facilities require the Department to find that all biomedical waste transfer and treatment facilities will be located, designed, constructed, altered, operated, maintained and closed in a manner that will ensure protection of public health and welfare and the environment including:
1. no adverse effects on groundwater quality;
  2. no adverse effects on surface water quality;
  3. no adverse effect on air quality; and
  4. no adverse effects due to migration of waste constituents in the subsurface environment;
- C. The Biomedical Waste Management Rules, Chapter 900, Section 19 allows the Department to approve the use of a treatment and / or disposal method other than incineration. The approval must determine that the effectiveness of the proposed alternative treatment method is adequate and provides a degree of protection for the public and the environment that is equal to the protection provided by incineration;
- D. The application requirements for biomedical waste transfer facilities as stated in Chapter 900, Section 15 (B) including compliance history, title, right or interest, financial capacity, public notice and the biomedical waste management and operations plan;
- E. The standards for biomedical waste transfer facilities as stated in Chapter 900, Section 16 (A),(B) and(C) covering facility location criteria, design standards, and operating standards;
- F. The application requirements for biomedical waste treatment or disposal facilities as stated in Chapter 900, Section 17 (B) including compliance history, title, right

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or interest, financial capacity, public notice and the biomedical waste management and operations plan:

- G. The rebuttable presumptions stated in Chapter 900, Section 18 (B) (2); and
- H. The standards for biomedical waste treatment facilities contained in Chapter 900, Section 18 (C),(D),(E) and (F) covering facility location criteria, design standards, and operating standards.

#### 6. OTHER DEPARTMENT FINDINGS

- A. Title, Right or Interest: Central Maine Investments, LLC (CMI) is the owner of the real estate and building located at 264 Industrial Park Road in Pittsfield, where the project is located. CMI has executed a Long Term Lease Agreement with AHR to lease the property and buildings. The period of the lease agreement is for ten years. The lease was entered into on November 7, 2004.
- B. Public Notice: AHR filed public notice of their modification application in the Bangor Daily News and the Waterville Morning Sentinel on January 19, 2009. At the request of the Town of Pittsfield, a Public Informational Meeting was held in the town office on April 28, 2009. No citizens attended the meeting. Abutters were notified by certified letter of the application filing. No public comments were received by the Department.
- C. Financial Capacity: AHR must demonstrate in their application to the Department that they have the financial capacity to construct, operate, maintain, and close all aspects of the biomedical waste treatment and transfer facility. AHR submitted information regarding the financing for the project. AHR has a Purchase and Sale Agreement with Bondtech, Inc. in the amount of \$424,700 for the facility equipment.

AHR has also entered into a Delivery, Installation and Startup Agreement with Bondtech, Inc. for the installation of the equipment and transfer facility in the amount of \$60,500. This produces a total facility cost of \$485,200.

AHR is leasing the property and existing building from Central Maine Investments, LLC for a period of ten years. AHR paid a monthly rent of \$5,000 in 2004 which is adjusted with the Consumer Price Index on an annual basis.

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| ASSOCIATED HEALTH RESOURCES, INC.  | 14 | MAINE HAZARDOUS WASTE, |
| PITTSFIELD, SOMERSET COUNTY, MAINE | )  | SEPTAGE AND SOLID      |
| BIOMEDICAL WASTE TRANSFER AND      | )  | WASTE MANAGEMENT ACT   |
| TREATMENT FACILITY LICENSE         | .  |                        |
| LICENSE #O-221-BD-B-M              | )  | LICENSE MODIFICATION   |
| (APPROVAL WITH CONDITIONS)         | )  |                        |

AHR's revenue stream is estimated to be a minimum of \$236,000 annually. This amount is derived from a revenue allocation fee of nine cents per pound of biomedical waste received. The most recent information is that Maine hospitals are producing 218,000 pounds of biomedical waste per month. The facility has a design capacity of 330,000 pounds per month. AHR plans to also provide treatment services to non-member, biomedical waste generators such as medical practices and nursing homes. This will further increase revenues. The facility has a minimum design life of ten years. If the facility were to close, the required activities subject to the biomedical waste management rules will be the removal of all biomedical waste residues and disinfection of all equipment and surfaces. Based on industry costs and assuming 25 tons of untreated biomedical waste left onsite, abatement cost is estimated to be approximately \$50,000 in 2004. In addition, the removal and disposition of the treatment equipment will be necessary. This should involve a minimal cost. There should be no hazardous chemical issues with surface or groundwater as the facility is not licensed to handle hazardous chemical wastes and provided segregation plans are properly followed. All regulated activities occur inside on a solid floor providing minimal opportunity for site contamination from biomedical waste.

- D. Liability Insurance: AHR has submitted proof of liability insurance in the amount one million dollars per incident and two million dollars annual aggregate.
- E. Biomedical Waste Management and Operations Plan: AHR has submitted Oxus's biomedical waste management and operations plan adapted to the Pittsfield facility. The plan fulfills the requirements as described in the Rules Chapter 900 Section 15 (B) (8) (a-b) for transfer facilities and Section 17 (B) (5) (a-b) for treatment facilities. The plan states that operations will initially be from 0600-2200 (6:00AM-10:00PM), six days per week, although this schedule may vary. It is anticipated that all waste to be treated at the facility will be treated the same day. All pathological waste to be stored on site will be frozen in the refrigerated space. The operator has stated that in the event of an outage at the plant, the Department shall be notified within 48 hours and informed of the plan to prevent an excessive accumulation of biomedical waste. The operator has stated that at no time will they store more than 25 tons (about 35 cubic yards) on the facility operating floor and in no case will biomedical waste be stored outside the building, except in the freezer trailer attached to the facility.
- F. Technical Ability: AHR first contracted operations at the plant to SteriLogic, Inc. SteriLogic also operated all of the biomedical waste transportation functions. In

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| ASSOCIATED HEALTH RESOURCES, INC.  | 15 | MAINE HAZARDOUS WASTE, |
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| BIOMEDICAL WASTE TRANSFER AND      | )  | WASTE MANAGEMENT ACT   |
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2006, SteriLogic, Inc. changed the name of their company to Oxus Environmental, LLC. From 2007 to 2008, Hydroclave Systems was responsible for operating the treatment unit. Oxus continued to provide transportation functions to the facility operations. Oxus (formerly SteriLogic) has operated a biomedical waste treatment facility in Syracuse, New York since 1996. They have also designed and implemented transportation systems for biomedical waste in New York and Pennsylvania.

- G. Building Security: AHR has submitted information in their application detailing security at the facility. Access to the property is restricted by a gate at the facility entrance. This gate is locked when the plant is not operating. The facility also has an alarm system for break-ins and fire. All biomedical waste activities occur inside the building, except for storage of human pathological waste, trace chemotherapy, non hazardous cytotoxic wastes and animal carcasses which are stored in the outside freezer trailer.
- H. Site Location of Development Act: The Town of Pittsfield applied for and was granted permits from the Department for the site. The first decision was a Board Order dated January 21, 1976, approving the Town of Pittsfield's request to develop a 47 acre industrial park. Licensing decision #L-2638-39-B-C dated October 16, 1996 approved the town of Pittsfield's application to expand the industrial park and modify wetlands. AHR applied to the Department (#L-2638-26-E-M) to modify this permit to allow for a change in use to a biomedical waste treatment and transfer facility and relocating parking areas within the existing gravel area.
- I. Project effects on the natural environment: The project is primarily located in an existing building in the Pittsfield Industrial Park. The surrounding area is commercial in nature. The proposal, if operated in accordance with AHR's application should have no adverse impact on scenic character, water quality, air quality or other natural resources.
- J. Groundwater: The biomedical waste treatment and transfer facility is located in an existing building and an adjacent trailer. No biomedical waste treatment activities will occur outside the building. The only activity to occur outside the building is the temporary storage of waste in a freezer trailer. As a result of the design and operation aspects of the facility, the area groundwater resources are at little risk from the facility.

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| ASSOCIATED HEALTH RESOURCES, INC.  | 16 | MAINE HAZARDOUS WASTE, |
| PITTSFIELD, SOMERSET COUNTY, MAINE | )  | SEPTAGE AND SOLID      |
| BIOMEDICAL WASTE TRANSFER AND      | )  | WASTE MANAGEMENT ACT   |
| TREATMENT FACILITY LICENSE         |    |                        |
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- K. Flood plain: AHR submitted a flood zone map of the area in their original application. The project is not located in a flood zone.
- L. Soil types and erosion: The Town of Pittsfield constructed the lots with gravel fill several years ago. The activity at the time was permitted by the Department. There has been no erosion on the site to date and the fill remains stable.
- M. Traffic: AHR has stated in their application that the proposed activity will result in traffic flows of eight to ten passenger vehicles and five or six trucks per day. The Maine Department of Transportation (DOT) has jurisdiction over reviewing and issuing Traffic Movement Permits. The present standard triggering permit review is 100 passenger car equivalents (PCE) during peak hours. A tractor-trailer combination is calculated as two PCEs. The passenger car equivalents for this proposed project is 22.
- N. Infrastructure: AHR has stated in their application that the proposed facility will be connected to the municipal water supply as well as the municipal sewerage collection system and treatment facility. Solid waste from the facility will be disposed of at Penobscot Energy Recovery Corporation (PERC). The proposed facility will not have an adverse effect on any utilities in the municipality.
- O. Biomedical Waste Efficacy Testing: Maine considers autoclaves to be an alternative or non-incineration treatment technology for biomedical waste. As the Biomedical Waste Management Rules were developed, Maine biomedical waste generators relied on about two dozen on site biomedical waste incinerators for the treatment of their biomedical waste.

Recent validation testing on autoclaves treating biomedical waste have determined that the efficacy, or ability to disinfect biomedical waste is dependent upon many variables including, but not limited to, the composition, density, liquid content, weight, and types of containers present in the loads, as they all affect the physics of heat transfer and steam penetration.

The Department approved this original license for a type of the autoclave technology known as the Hydroclave. An integral part of the Hydroclave treatment technology was the physical destruction and maceration of the biomedical waste being treated. This created a homogenous blend of biomedical waste that received maximum exposure to the steam. The Bondtech technology is more traditional in that the waste remains stationary throughout the treatment

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| ASSOCIATED HEALTH RESOURCES, INC.  | 17 | MAINE HAZARDOUS WASTE, |
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| BIOMEDICAL WASTE TRANSFER AND      | )  | WASTE MANAGEMENT ACT   |
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process. This may produce areas within the waste load that are slower to achieve the critical temperature of 250 degrees F. These areas, referred to as "cold spots" are areas where steam has difficulty penetrating without additional time or vacuum cycles. Cold spots are likely to occur in suction canisters and large sharps containers.

AHR has submitted a protocol to the Department in their Biomedical Waste Management and Operations Plan as a part of their application, for the initial and periodic efficacy testing for the BTT6X16 autoclave treatment unit. The plan must address waste load variables such as moisture content, waste density, waste packaging and sample placement within the load.

The indicator organism for challenge testing is *Bacillus stearothermophilus* spores. A 99.99% reduction or greater in colony forming units as compared to an unexposed control sample is necessary as the measure of successful disinfection of this technology under AHR's normal operating procedures. Prior to accepting biomedical waste, the Department requires that challenge testing of the BTT6X16 autoclave treatment unit shall be successfully completed. The testing must include loads of varying densities. Thereafter, challenge testing shall be done once per month. AHR shall also maintain printed parameter records of temperature and pressure for every load for three years.

Validation testing was performed on June 3<sup>rd</sup> and 4<sup>th</sup>, 2009 by WNWN International, Inc. A total of six cycles were completed to establish the appropriate treatment cycle parameters. Biological indicators included Self Contained Biological Indicators (SCBI) (3M ATTEST) for qualitative analysis. Integrators were also used to monitor the thermal conditions at each sample's location. Additionally, Mesa Lab Data Trace wireless thermocouples were also placed at the same locations as the SCBIs and the Integrators. The wireless thermocouples and integrators were useful in recording actual temperatures within the waste load adjacent to the biological indicators. Temperature data from the thermocouples could be read on a computer screen within minutes of their retrieval from the waste. This provides the information as to whether critical temperatures were attained during the treatment cycle. Had the temperatures not reached critical temperatures, the load could have been cycled again. This high degree of temperature documentation is used during initial validation testing but is not used during regular processing. The computerized control panel on the Bondtech treatment unit has the capability to monitor the operating parameters necessary to achieve the required treatment parameters.

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| ASSOCIATED HEALTH RESOURCES, INC.  | 18 | MAINE HAZARDOUS WASTE, |
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Upon recovery, all samples were incubated onsite for further analysis. 3M ATTEST samples were incubated for 48 hours at 55 degrees Centigrade.

The qualitative SCBI results demonstrated a >5 log reduction in 31 out of 32 samples. The testing for these 31 samples met the standards for biological efficacy as stated in the Rules. The one positive sample was from inside a 17 gallon sharps container. The facility does not treat these large sharps containers. One sample in an 8 gallon container of a size handled by the facility demonstrated no growth. Several suction canisters with water and no solidifiers were also processed and demonstrated physical destruction as a result of the treatment process. Loose sharps also were treated and demonstrated acceptable efficacy.

Suction canisters with solidifiers were more difficult to treat. One run was conducted using two large suction canisters filled with water and then the solidifier Isosorb was added to congeal the contents. Thermocouples placed in the center of these canisters were only able to achieve a temperature of 40 degrees Centigrade after a normal run cycle. As a result of this finding, AHR is surveying member hospitals for information regarding whether solidifiers are used, whether they contain disinfectants and whether they use a recycling program for on site infectious fluid management. AHR has proposed a plan for facilities shipping biomedical waste to the facility to insure that suction canisters with solidifiers are not treated here unless it can be demonstrated to the Department that they will receive adequate treatment.

- P. Wastewater discharge: The facility discharges to the municipal wastewater collection and treatment system. AHR has the necessary permission from the Town of Pittsfield to connect to the system and to discharge. The discharge from the Bondtech consists of cooled steam condensate, sterilized waste moisture, and municipal water. This discharge is expected to amount to 1,400 gallons per day. The reusable tub washer discharge does not continuously feed to the sewer as the tank is only emptied once or twice per week. The tank has a capacity of 500 gallons. It has a sodium hypochlorite solution at a concentration of 50-150 ppm. The sharps container unit washer is a loop system where hot water from the rinse cycle flows into the scrubbing chamber where dishwashing detergent is present. Excess water flows out the drain at a maximum rate of 330 gallons per hour. Finally, there will be a wastewater discharge from the facility restrooms and shower area. All disinfectant chemicals used are registered with the EPA. Comments received from the Town of Pittsfield on the draft order expressed

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| ASSOCIATED HEALTH RESOURCES, INC.  | 19 | MAINE HAZARDOUS WASTE, |
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concerns about pharmaceutical and chemical wastes being included in the discharge to the municipal sewer system. As a result of this concern, the Department will require AHR to submit a plan to the Department to perform testing on the facility's effluent initially and on an as needed basis.

- Q. Air emissions: AHR's facility does not require an air emission license from the Department. The natural gas fired boiler has a heat input of 2.2 million BTUs per hour. The threshold for an air emission license is 10 million BTUs per hour. The Bondtech system is not designed or licensed to treat hazardous chemical wastes. Introduction of these wastes could pose a threat to human health and safety. AHR as facility owner and Oxus as operator require all customers to sign a contract that contains explicit language regarding prohibited and excluded waste materials that are not to be shipped to the treatment facility in the generator's biomedical waste stream. During operation, the Bondtech is under a vacuum. At the end of the treatment cycle the treatment chamber undergoes depressurization. During the venting process all steam and any odors or other vaporized materials are vented outside. The former Hydroclave facility had several incidents of irritant vapors that were reported to the Department. Subsequent investigations and inspections of generating facilities were inconclusive, however, a number of inappropriate wastes were documented as going through the Hydroclave.

AHR provides training to generators regarding waste segregation and hazardous waste identification and management. Oxus plant personnel are also trained in hazardous waste management and emergency response.

- R. Employee Training: All employees are required to complete training on all aspects of facility operations to insure the safe operation of the facility. The training program requirements are detailed in the Biomedical Waste Management and Operations Plan submitted as part of the application. Specific training subjects include personal protective equipment, lock out – tag out procedures, emergency response, chemical safety, exposure control and tools and housekeeping.
- S. Alternative Treatment Technologies: Chapter 900, Section 19 of the Biomedical Waste Management rules provides a mechanism for the Department to approve a treatment technology for biomedical waste. The Department along with the Maine Hospital Association and other interested parties studied various types of alternative treatment technologies for biomedical waste. The consensus was that steam sterilization, also known as autoclaving is a desirable treatment technology

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| ASSOCIATED HEALTH RESOURCES, INC.  | 20 | MAINE HAZARDOUS WASTE, |
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when conducted properly to take into account more recent research on hard to treat biomedical waste loads.

BASED on the above Findings of Fact, and subject to the Conditions listed below, the Department makes the following CONCLUSIONS:

1. The biomedical waste treatment and transfer facility will be located, designed, constructed, operated, maintained, altered, and closed in a manner that will ensure protection of public health and welfare and the environment. If operated according to the rules, their application and conditions of approval, the proposed facility will have:
  - A. no adverse effect on ground water quality;
  - B. no adverse effect on surface water quality;
  - C. no adverse effect on air quality provided there is no non-authorized waste or hazardous waste introduced into the treatment unit; and,
  - D. no adverse effects due to migration of waste constituents in the subsurface environment.
2. The applicant has demonstrated adequate financial capacity to operate, maintain, and close all aspects of the facility in accordance with all applicable statutes and rules.
3. The applicant has satisfied the public notice requirements of the Department's Rules Concerning the Processing of Applications, Chapter Two, (06-096 CMR 002, April 1, 2003), Section 14.
4. The applicant has demonstrated adequate title, right, or interest by submission of their lease agreement with Central Maine Investments, LLC.
5. The biomedical waste treatment facility as described in the application and subject to the attached conditions, meets all design, operating, and performance standards of 06-096 CMR 900.18, the Biomedical Waste Management Rules (August 4, 2008).
6. The biomedical waste transfer facility as described in the application and subject to the attached conditions, meets all design, operating and performance standards of 06-096 CMR 900.16, the Biomedical Waste Management Rules (August 4, 2008).

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| ASSOCIATED HEALTH RESOURCES, INC.  | 21 | MAINE HAZARDOUS WASTE. |
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7. Issuance of this license is consistent with the applicable standards, requirements and procedures of the Maine Hazardous Waste, Septage and Solid Waste Management Act including 38 MRSA Section 1310-X.
8. The Bondtech treatment technology, if operated in accordance with AHR's modification application and validation testing report and provided inappropriate wastes are not introduced into the unit, will provide an effective method of protecting the public and the environment from the hazards associated with biomedical waste.
9. AHR has met the statutory requirements expressed in 38 M.R.S.A, Section 1319-X
10. AHR has stated that they will notify the Department of outages of 48 hours or more and not accumulate excessive amounts of untreated biomedical waste.
11. AHR has stated that the maximum amount of biomedical waste stored on site will not exceed 25 tons and specific storage areas will be located where identified in AHR's application.

THEREFORE, the Department APPROVES the above noted modification application of ASSOCIATED HEALTH RESOURCES SUBJECT TO THE ATTACHED CONDITIONS and all applicable standards and regulations:

1. The Standard Conditions of Approval, for Biomedical Waste Treatment Facilities, a copy is attached as Appendix A.
2. The Standard Conditions of Approval for Biomedical Waste Transfer Facilities, a copy is attached as Appendix B.
3. The invalidity or unenforceability of any provision, or part thereof, of this License shall not affect the remainder of the provisions or any other provisions. This License shall be construed and enforced in all aspects as if such invalid or unenforceable provisions or part thereof had been omitted.
4. Each year, on the anniversary date of this license, the AHR will submit to the Department an annual report documenting the licensed activity during the previous year. The annual report shall include at a minimum:

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| ASSOCIATED HEALTH RESOURCES, INC.  | 22 | MAINE HAZARDOUS WASTE, |
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- A. The name, location and license number of the facility;
  - B. The source, types and quantities of any biomedical waste received;
  - C. The method of treatment or disposal for each category of biomedical waste;
  - D. A certificate of liability insurance;
  - E. A summary of training conducted with customers on the matter of waste segregation;
  - F. A demonstration of sufficient financial capacity to operate, maintain, and close all aspects of the facility;
  - G. The annual treatment facility fee of \$1000;
  - H. The annual transfer facility fee of \$500; and,
  - I. A summary of any incidents of inappropriate or unapproved waste shipped to the facility including the type of waste, source of the waste and actions taken to prevent reoccurrence.
5. AHR will comply at all times with all design, operating, performance, and closure standards as stated in 06-096 CMR 900(16) (18), the Biomedical Waste Management Rules (August 4, 2008).
  6. This license expires May 20, 2014 provided AHR is in compliance with the requirements of the Biomedical Waste Management Rules, Chapter 900 their biomedical waste treatment and transfer application to the Department.
  7. AHR will not accept at the facility or treat hazardous waste in the Bondtech unit or other waste for which it is not designed or licensed for treatment.
  8. AHR will develop for the Department's review and approval a contingency plan to be activated should the units experience an outage of more than 48 hours. This plan shall be submitted by August 30, 2009.

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| ASSOCIATED HEALTH RESOURCES, INC.  | 23 | MAINE HAZARDOUS WASTE, |
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| LICENSE #O-221-BD-B-M              | )  | LICENSE MODIFICATION   |
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9. AHR will notify the Department of any outages lasting more than 48 hours and at that time activate the contingency plan to address the accumulation of untreated biomedical waste.
10. AHR will render the sharps portion of the treated biomedical waste unrecognizable and shall dispose of all treated biomedical waste as a special waste in a licensed landfill.
11. AHR will report to the Department instances of malfunctioning parameter monitors such as chart recordings or other instrumentation failures that affect the treatment documentation records of the facility.
12. AHR will report to the Department, within 48 hours, incidents whereby the facility has received hazardous, universal and radioactive wastes or other unauthorized wastes. The report must identify what steps were taken to prevent reoccurrence.
13. AHR will not accept suction canisters with solidifier or sharps containers greater than 8 gallons in size for treatment until it has been documented to the Department's satisfaction that the suction canister and sharps containers will receive adequate treatment in the autoclave.
14. AHR will submit to the Department by August 30, 2009, a sampling and testing protocol of the treatment system's effluent to screen for pharmaceutical and chemical wastes. This plan shall include at a minimum testing during the initial operation of the facility, on a periodic basis and in response to a request from either the Town of Pittsfield or the Department.

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| ASSOCIATED HEALTH RESOURCES, INC.  | 24 | MAINE HAZARDOUS WASTE, |
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15. AHR will not treat more than 1600 pounds of biomedical waste per cycle.

DONE AND DATE AT AUGUSTA, MAINE, THIS 2<sup>nd</sup> DAY  
 OF July, 2009

DEPARTMENT OF ENVIRONMENTAL PROTECTION

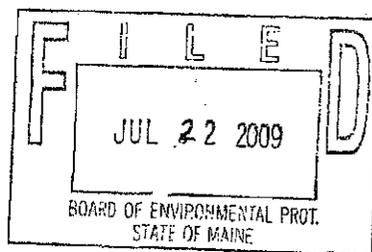
BY *David P. Littell*  
 David P. Littell, Commissioner

PLEASE NOTE ATTACHED SHEET FOR GUIDANCE ON APPEAL PROCEDURES.

Date of initial receipt of the modification application: December 22, 2008

Date of modification application acceptance: January 20, 2009

XSA69965/djp



**Appendix A**  
**Standard Conditions of Approval**  
**Biomedical Waste Treatment Facility**

All biomedical waste treatment facility licenses issued by the Department are subject to the following standard conditions:

- (1) The licensee must not operate, construct or maintain a biomedical waste treatment facility other than as described in the application approved by the Department.
- (2) **Relation of License to Application.** A license issued under this rule is valid only as long as the information supplied in the application remains accurate. Approval of an application is dependent upon and limited to the proposals and plans contained in the application and supporting documents submitted and affirmed by the applicant. Any variation from the plans, proposals and supporting documents is subject to the review and approval of the Department prior to implementation.
- (3) **Duty to Comply.** The licensee shall comply with all conditions of the license and these rules. Noncompliance with the license or rule constitutes a violation of law and is grounds for enforcement action, for license suspension or revocation, or for denial of any renewal application.
- (4) **Liability Insurance.** A licensee must have liability insurance coverage in force at all times. The coverage will be appropriate for the licensed activity and for the risk involved. Under no circumstance may the amount of liability insurance in force be less than \$1,000,000 per occurrence or \$2,000,000 in aggregate.
- (5) **Local, State and Federal Permits.** A licensee must hold all other local, state and federal permits, licenses and certifications required for the licensed activity and must comply with all applicable local, state and federal laws and rules.
- (6) **Record Keeping.** A licensee must comply with all applicable state and federal requirements regarding the use of a manifest or log and the maintenance of other required records.
- (7) **Duty to Ensure Safe Operation.** It is the duty of a licensee to ensure that the licensed activity is carried out safely and does not create a threat to public health or safety or the environment. A licensee must ensure that methods, equipment and personnel are adequate and capable to achieve this end.
- (8) **Inspection and Training Requirements.** A licensee must comply with all state and federal inspection and training requirements as may from time to time be applied by law, rule or license condition to the licensed activity.
- (9) **Response to an Emergency.** A licensee agrees to provide to the Department and to public safety agencies all information necessary for response to emergency situations involving the licensed activity and agrees to assist the Department in obtaining compliance with this rule.
- (10) **Discharge of Biomedical Waste.** In the event of a discharge of biomedical waste in any amount, the licensee shall take immediate action to protect public health, safety

and welfare and the environment, including the immediate implementation of the spill containment and cleanup procedures contained in the approved biomedical waste management and operations plan, and shall immediately report the discharge to the Maine Department of Environmental Protection.

- (11) Duty to Mitigate. The licensee shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from noncompliance with the license.
- (12) Duty to Reapply. If the licensee wishes to continue an activity regulated by the license after the expiration date of the license, the licensee must apply for and obtain a new license. Such application must be made at least one year prior to the expiration of the license.
- (13) Duty to Provide Information. The licensee shall furnish to the Department, upon request, any information that the Department may require to determine compliance with the license and this rule. The licensee shall also furnish to the Department, upon request, copies of records required to be kept by the licensee and not otherwise required to be filed with the Department.
- (14) Prior to Construction. All preconstruction terms and conditions must be met before construction begins.
- (15) Construction/Operation within Two Years. If the construction or operation of the activity is not begun within 2 years, the approval will lapse and the applicant must reapply to the Department for a new approval. The applicant may not begin construction or operation of the facility until new approval is granted. Reapplications for approval must state the reasons why the facility was not begun within 2 years from the granting of the initial approval and the reasons why the applicant will be able to begin the activity within 2 years from the granting of a new approval, if granted. Reapplications for approval may include information submitted in the initial application by reference.
- (16) Bid Specifications. A copy of this approval must be included in or attached to all contract bid specifications for the development.
- (17) Contractor Copy. Work done by a contractor pursuant to this approval must not begin before the contractor has been given a copy of the license by the licensee.

**Appendix B**  
**Standard Conditions of Approval**  
**Biomedical Waste Transfer Facility**

All biomedical waste transfer facility licenses issued by the Department are subject to the following standard conditions.

- (1) The licensee shall not operate, construct or maintain a biomedical waste transfer facility other than as described in the application approved by the Department.
- (2) Relation of License to Application. A license issued under this rule is valid only as long as the information supplied in the application remains accurate. Approval of an application is dependent upon and limited to the proposals and plans contained in the application and supporting documents submitted and affirmed by the applicant. Any variation from the plans, proposals and supporting documents is subject to the review and approval of the Department prior to implementation.
- (3) Duty to Comply. The licensee shall comply with all conditions of the license and these rules. Noncompliance with the license or rule constitutes a violation of law and is grounds for enforcement action, for license suspension or revocation, or for denial of any renewal application.
- (4) Liability Insurance. A licensee shall have liability insurance coverage in force at all times. The coverage must be appropriate for the licensed activity and for the risk involved. Under no circumstance may the amount of liability insurance in force be less than \$1,000,000.
- (5) Local, State and Federal Permits. A licensee shall hold all other local, state and federal permits, licenses and certifications required for the licensed activity and will comply with all applicable local, state and federal laws and rules.
- (6) Record Keeping. A licensee shall comply with all applicable state and federal requirements regarding the use of a manifest and the maintenance of other required records.
- (7) Duty to Ensure Safe Operation. It is the duty of a licensee to ensure that the licensed activity is carried out safely and does not create a threat to public health or safety or the environment. A licensee shall ensure that all methods, equipment and personnel are adequate and capable to achieve this end.
- (8) Inspection and Training Requirements. A licensee shall comply with all state and federal inspection and training requirements as may from time to time be applied by law, rule or license condition to the licensed activity.
- (9) Response to an Emergency. A licensee agrees to provide to the Department and to public safety agencies all information necessary for response to emergency situations involving the licensed activity and agrees to assist the Department in obtaining compliance with this rule.
- (10) Discharge of Biomedical Waste. In the event of a discharge of biomedical waste in any amount, the licensee shall take immediate action to protect public health, safety

and welfare and the environment, including immediate implementation of the spill containment and cleanup procedures contained in the approved biomedical waste management and operations plan, and shall immediately report the discharge to the Maine Department of Environmental Protection.

- (11) Duty to Mitigate. The licensee shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from noncompliance with the license.
- (12) Duty to Reapply. If the licensee wishes to continue an activity regulated by the license after the expiration date of the license, the licensee must apply for and obtain a new license. Such application shall be made at least 6 months prior to the expiration of the license.
- (13) Duty to Provide Information. The licensee shall furnish to the Department, upon request, any information that the Department may require to determine compliance with the license and this rule. The licensee shall also furnish to the Department, upon request, copies of records required to be kept by the licensee and not otherwise required to be filed with the Department.

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