A. Purpose
Regulated Medical Waste (RMW) is material that may be contaminated with blood, bodily fluids, or other infectious materials, as well as sharps. RMW must be properly handled, collected, segregated, packaged, stored, labeled, transported and disposed of in order to minimize the risk of transmitting infection or endangering human health. This policy describes the proper handling of RMW, sharps, cultures of BSL-2 or BSL-3 microorganisms that must be autoclaved or otherwise decontaminated on-site prior to disposal, and large quantities of liquid RMW that must be chemically decontaminated on-site, as well as biomedical material (such as carcasses for incineration), that does not enter the RMW stream.

B. Applicability/scope
This policy is applicable to Investigators and lab staff and describes procedures to ensure compliance with regulatory requirements. The US Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard regulates handling and storage of RMW in labs and patient care areas. The New York State Departments of Health (NYS-DOH), Environmental Conservation (NYS-DEC), US Environmental Protection Agency (EPA) and US Department of Transportation (DOT) regulate RMW decontamination, transport and disposal. RMW regulations apply to disposal of potentially infectious research-associated or clinical materials. University-administered facilities offering clinical care, such as the College of Dental Medicine and Kreichman PET Center, follow the NYS-DOH guidelines.

University-administered research laboratories go above and beyond the NYS-DOH guidelines in that waste contaminated with organisms that are handled at BSL-1 is also treated as RMW. Since the municipal (“clear bag”) waste is not handled with the same precautions as RMW, the potential of exposure to these materials by those handling municipal waste is greater. Following an exposure, it is not possible to tell by looking at laboratory or medical waste whether it originated from a lab working with potentially infectious materials. To ensure the safety of Columbia Facilities workers, who handle municipal waste, and to reduce confusion among Investigators segregating biomedical waste based on the agents that may be in it, all such waste is treated as RMW.

Furthermore, material that looks “medical” (for example, petri dishes of food for Drosophila melanogaster) is also treated as RMW. Items that look as if they may have been used to handle material at BSL-2 or above (for example, gloves) are treated as RMW, even though they may have not been used to handle anything infectious or microbial in nature (chemicals, RNA etc.). The NIH guidelines for research involving recombinant or synthetic nucleic acid molecules specify that waste containing recombinant or synthetic nucleic acid molecules must be treated as RMW, unless the research is deemed exempt from Institutional Biosafety Committee (IBC) review.

However, Investigators must be judicious about what they put into the RMW stream since it is significantly more costly to dispose of RMW than municipal waste. Packaging materials (e.g., paper towels for hand washing, media bottles etc.) are not to enter the RMW stream.
C. Responsibilities

All parties handling or transporting biomedical materials in Columbia University laboratories or patient care areas are subject to this policy. All producers of RMW must have EH&S biosafety and/or bloodborne pathogens training and don any recommended personal protective equipment (PPE). Off-site transport, decontamination, rendering and disposal of RMW are performed by the University’s contracted provider of RMW disposal services.

D. Definitions

**BSL-1 materials** – Agents and organisms not typically associated with disease in healthy adults that are handled at biosafety level-1 (examples include *E. coli* K12, *Bacillus subtilis*, *S. cerevisiae*, adeno-associated virus, and laboratory animals).

**BSL-2 materials** – Infectious agents having the potential for causing disease or adverse health effects in healthy adult humans that are handled at biosafety level-2 (examples include *Salmonella* spp., *Staphylococcus aureus*, Hepatitis B virus, lentiviral vectors). Infection is typically the result of direct contact, such as a needle stick, splash to mucous membrane or non-intact skin, or ingestion.

**BSL-3 materials** – Infectious agents having the potential for causing disease in healthy adult humans through the respiratory route, that are handled at biosafety level-3 (examples include *Mycobacterium tuberculosis*, SARS coronavirus).

**Biomedical material** – Includes human or animal blood, serum, tissue, cultured cells or cell lines and cultures of infectious or microbial agents that are handled in a laboratory or patient care area. Refers to the products themselves or common lab supplies that become contaminated with these materials.

**RMW** – (Regulated Medical Waste). The NYS-DOH definition of RMW includes five categories:

*Category 1 - Cultures and Stocks*

Cultures and stocks of agents infectious to humans, and associated biologicals, cultures from medical or pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live or attenuated vaccines, or culture dishes and devices used to transfer, inoculate or mix cultures.

In context of this subcategory, cultures and stocks refer to systems used to grow and maintain infectious agents in vitro, including, but not limited to nutrient agars, gels, broths (including those utilizing human blood or blood products), human and primate cell lines, and impure animal cell lines.

The term biologicals is intended to mean preparations made from living organisms and their products which are used in diagnosing, immunizing, or treating human beings or animals, including, but not limited to serums, vaccines, antigens, and antitoxins.
The phrase "culture dishes and devices used to transfer, inoculate or mix cultures" refers to the use of items that have come in contact with high concentrations of infectious agents as in the recovery of such agents in culture from clinical specimens and includes plastic or glass plates, flasks, vials, beakers, bottles, jars, and tubes, inoculation loops and wires, manual and mechanical stirring devices, rubber, plastic, and cotton stoppers and plugs, filtering devices made of natural and artificial substances and materials used to clean and disinfect items indicated above after routine use or accident.

Category 2 - Human Pathological Wastes
This waste shall include tissue, organs, and body parts, body fluids that are removed during surgery, autopsy, or other medical procedures, or specimens of body fluids and their containers, and discarded material saturated with such body fluids other than urine. This waste shall not include urine or fecal materials submitted for other than diagnosis of infectious diseases (see Procedures; below).

Category 3 - Human Blood and Blood Products
This waste shall include: (I) discarded waste human blood, discarded blood components (e.g. serum and plasma), containers with free flowing blood or blood components or discarded saturated material containing free flowing blood or blood components; and (II) materials saturated with blood or blood products.

Category 4 - Sharps
This waste shall include but not be limited to discarded unused sharps and sharps used in animal or human patient care, medical research, or clinical or pharmaceutical laboratories, hypodermic, intravenous, or other medical needles, hypodermic or intravenous syringes to which a needle or other sharp is still attached, Pasteur pipettes, scalpel blades, or blood vials. This waste shall include, but not be limited to, other types of broken or unbroken glass (including slides and cover slips) in contact with infectious agents. This waste shall not include those parts of syringes from which sharps are specifically designed to be easily removed and from which sharps have actually been removed, and which are intended for recycling or other disposal, so long as such syringes have not come in contact with infectious agents.

Category 5 - Animal Waste
This waste shall include discarded materials including carcasses, body parts, body fluids, blood, or bedding originating from animals known to be contaminated with infectious agents (i.e. zoonotic organisms) or from animals inoculated during research, production of biologicals, or pharmaceutical testing with infectious agents.

**RMW stream** – RMW that is collected and transported off site by the University’s contracted provider of RMW disposal services for subsequent decontamination, rendering and disposal.

**Biomedical material that does not enter the RMW stream** –
_Urine and Feces - Urine is not considered regulated medical waste unless it is submitted as a clinical specimen for laboratory tests. However, if a patient is found to have a disease_
which may be transmitted through urine, then the material containing this fluid (including diapers) must be considered regulated medical waste. Similarly, incontinence materials are not regulated medical waste provided that the patient does not have an infectious disease transmissible by urine. Fecal contaminated materials are not considered to be regulated medical waste. Feces contain microorganisms that even if potentially pathogenic, cannot be transmitted from trash containers or disposal sites.

**Blood and liquid RMW** - The NYS-DOH regulations permit blood to be discharged directly to a sewerage system which is connected to a municipal secondary wastewater treatment facility. This means that blood can be flushed down the sink with plenty of water. However, University policy requires that blood undergo chemical decontamination prior to sink disposal. Small quantities of blood in tightly capped tubes should be disposed into the RMW stream (see Procedures; below). Other liquid RMW (including bacterial cultures, tissue culture media) can also undergo sink disposal following chemical decontamination.

**Animal Bedding** - Bedding from research animals is disposed into the municipal waste stream. Bedding from animals inoculated with infectious agents during research is considered RMW and is either autoclaved prior to disposal in the municipal waste stream or deposited into red bags if disposable caging is used.

**BBP** - Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

**Contaminated** - means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

**Decontamination** - means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

**Disposal** – means the final disposition of the RMW following decontamination. This is typically accomplished via landfilling and is performed following decontamination by the University’s contracted provider of RMW disposal services. In some cases (animal carcasses) incineration is utilized as a disposal method by the contractor.

E. Procedures

1. **RMW in red bags**
   RMW must be carefully containerized to eliminate the chances of exposure during transport to its ultimate disposal site. Red RMW bags are imprinted with the universal biohazard symbol, or the word “biohazard”, and the generator name and address. Red RMW bags must always be housed in a rigid container. Red bags are for items that are not expected to poke or tear the bag when it is lifted. This includes all of following if they are unwrapped/unpackaged or appear as anything other than unused: Plastic test tubes, Eppendorf™ tubes, plastic culture dishes, tissue
culture flasks and gloves. Serological pipettes may not be placed in red bags. Open rigid containers lined with a red bag are acceptable in laboratories, since these are restricted environments, but not in public areas such hallways. Open rigid containers lined with a red bag are not permitted in patient care areas. These containers must have a lid that is closed when the container is not being used; pedal bins are preferable. Red bags that are ready for collection must be taped or tightly tied closed. RMW cannot be maintained in laboratories in a putrescent state and must therefore be collected on a regular basis.

2. **Campus-specific RMW procedures**

   **CUMC Campus**
   
   RMW services requests are administered by Facilities Operations. Contact 212-305-HELP (4357), ext. 3 for replacement/additional red bags, sharps containers and other services. Reusable sharps containers are provided and removed by University’s contracted provider of RMW disposal services on a one-for-one exchange basis.

   Tied red bags that are ready for collection are placed inside the large gray dumpsters in the hallway (Hammer Health Sciences Center and Superblock; Black Building, Vanderbilt Clinic, Physicians and Surgeons, Presbyterian Hospital, Millstein Pavilion, Eye Institute). Since these dumpsters are in common areas outside of a lab, they must be closed when they contain red bags (clean unused dumpsters are permitted to be left open). To reduce the likelihood of injury from inappropriately disposed sharps, tied red RMW bags should be carried to the dumpster within the rigid container in the lab and then lifted into the dumpster. If the dumpster is full, the red bags must not be left on top of the dumpster, or on the floor; they should be transported to another dumpster that has capacity. If this involves transport to another floor the freight elevator should be used, not the passenger elevator. If full dumpsters are a persistent issue, submit a request for additional dumpsters to Facilities Operations.

   Cardboard boxes are used to contain red bags in other buildings (Russ Berrie Medical Pavilion and Irving Cancer Research Center). Contact Facilities for (urgently needed) replacement containers between service days. When these boxes are moved to common areas outside of a lab, they are to be closed. All full sharps containers and boxes are to be placed outside of labs first thing in the morning on the day of service.

<table>
<thead>
<tr>
<th>Building/Campus</th>
<th>Service Days</th>
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<tbody>
<tr>
<td>Hammer Health Sciences Center</td>
<td>Tuesday, Friday</td>
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<tr>
<td>Black Building</td>
<td>Monday, Thursday</td>
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<tr>
<td>Physicians and Surgeons</td>
<td>Monday, Thursday</td>
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<td>Vanderbilt Clinic</td>
<td>Monday, Thursday</td>
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<tr>
<td>Presbyterian Hospital</td>
<td>Monday, Thursday</td>
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<tr>
<td>Irving Cancer Research Center</td>
<td>Monday, Thursday</td>
</tr>
<tr>
<td>Russ Berrie Medical Pavilion</td>
<td>Monday, Thursday</td>
</tr>
</tbody>
</table>
**Morningside Campus**

RMW services requests are administered by EH&S. Submit an online pick up request for replacement containers and bags or additional services or supplies (http://vesta.cumc.columbia.edu/ehs/wastepickup/). Red plastic RMW containers with red bag liners are supplied, removed and replaced by the University’s contracted provider of RMW disposal services on a one-for-one exchange basis. Open containers lined with a red bag are acceptable in laboratories but bags and containers must be closed once they are moved to the hallway for collection. Labs must place properly containerized waste into the hallway only between 9 am and 11 am on Tuesdays and Fridays. RMW must not be placed out on the night prior to service. Note, collections occur every Tuesday and Friday between 11 am – 2 pm.

<table>
<thead>
<tr>
<th>Building/Campus</th>
<th>Service Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morningside campus (all buildings)</td>
<td>Tuesday, Friday</td>
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</tbody>
</table>

3. **Sharps**

Any sharps or materials that may puncture a red bag must be deposited in a sharps disposal container, whether or not they are contaminated with infectious agents. Sharps containers must be used for disposal of the following items used in patient care or research activities: hypodermic needles, syringes, scalpel blades, razor blades, slides, cover slips, serological pipettes (glass or plastic), plastic pipette tips, and glass Vacutainer™ blood collection tubes; essentially, any contaminated item that may tear a red bag during transport. Syringes and needles must never be separated and needles must not be recapped prior to disposal. Unused sharps must also be deposited in sharps containers. Containers must not be filled to the point where pipettes or other items stick out through the top; containers with protruding items will not be collected for exchange.

Reusable sharps containers are available in a 10 or 17 gallon size for floor usage (CUMC), and 8 or 17 gallon size for floor usage, and 1 gallon size for bench-top use (Morningside). These are provided and removed by the University’s contracted provider of RMW disposal services. Sharps containers are also available for the bench-top collection via purchase through most lab supply vendors. Temporary storage of BSL-1 pipette tips (only) in open plastic bench-top containers is permitted but these containers must be emptied into a sharps container at the end of every work session.

4. **RMW that must be decontaminated on-site prior to entering the RMW-stream**

Waste that contains cultures or specimens of *Category A infectious substances* must be treated by laboratory staff on-site by autoclaving or chemical deactivation, prior to entering the Regulated Medical Waste stream. This is also a requirement for any agents handled at *BSL-3* and recombinant microorganisms requiring work at *BSL-3*. Waste that contains cultures of some *Biological Substance Category B* organisms (e.g. MRSA, *S. typhi*) must be treated on-site by autoclaving or chemical deactivation, prior to entering the Regulated Medical Waste stream. Please consult EH&S (biosafety@columbia.edu) to determine whether a particular Category B material meets this requirement. Human and animal specimens that contain, or are suspected of containing, *Biological Substance Category B* organisms do not need to be autoclaved on-site,
due to the reduced load of pathogens. However they must still be disposed into the RMW stream. Autoclaved material is then placed in red bags and can enter the RMW stream. Large amounts of tissue, carcasses, or recognizable animal parts must be handled as carcasses for incineration rather than generic red bag waste (see “Carcasses” section).

5. **Liquid RMW that must be decontaminated on-site prior to sewer disposal**

Plastic tubes that are tightly sealed and contain small quantities of blood or other biomedical material (<50 ml) can be placed directly into a red bag for disposal. Due to potential for breakage and injury, glass tubes are to be placed in a sharps container.

Large volumes of liquid RMW (>50 ml), are not to be placed in a red bag; these materials must undergo chemical decontamination. Sufficient decontaminant concentration and contact time must be allowed. In the case of bleach, the final concentration should be no less than 10% of the overall volume of the liquid to be disposed, with 20 minutes of contact time. The decontaminated liquid can then be flushed down the sink with plenty of water.

6. **RMW mixed with hazardous or radioactive materials**

If RMW is a hazardous chemical waste, or a radioactive waste, or is mixed with hazardous or radioactive waste, it must be chemically decontaminated on site (for example, by bleach) and then managed as either a hazardous chemical waste or radioactive waste, respectively. Autoclaves or incinerators are not to be used for decontaminating such waste.

7. **Tissues Fixed in a Hazardous Chemical (e.g., formaldehyde, formalin).**

If tubes/jars containing small amounts of tissue are being discarded (e.g. mouse and rat organs), the liquid fixative must be decanted/strained off and treated as a hazardous waste. The tissue can be deposited into a red RMW bag. If jars containing large quantities of fixed tissue are being discarded (e.g. pig or human organs), please contact EH&S for a consultation. Animal carcasses that have been perfused and contain no free fixative should be returned to the ICM facility and do not need to be treated differently from unfixed carcasses (see below).

8. **Carcasses**

Animal carcasses are stored frozen by Investigators until collected by ICM staff in fiberboard drums. Drums are then transported for incineration by the University’s contracted provider of RMW disposal services. Some Principal Investigators at Morningside have made specific arrangements with EH&S for direct collection of carcass-containing fiberboard drums by the University’s contracted provider of RMW disposal services.

9. **Carcasses containing radioactive materials**

Animal carcasses containing less than 0.05 micro curies/gram of $^{14}$C or $^{3}$H, or containing short-lived isotopes (half-life <90 days) that have been decayed on-site for >10 half-lives are treated as regular carcasses (Section 7, above). Animal tissues meeting the same criteria can be placed directly into a red bag. Animal carcasses or tissues that do not meet these criteria require disposal by the University’s contracted provider of hazardous waste disposal services. Contact EH&S for more information.
10. Waste Minimization:
Red bags and sharps containers are used exclusively for those materials that meet the University’s definition of RMW. Red bags or sharps containers must not be used for 'regular' trash (e.g., packing materials, papers, cardboard boxes, paper towels, and cell media or buffer bottles that are otherwise free of biological contamination).

11. Labeling
Red bags, secondary containers and sharps containers identified with the universal biohazard trefoil symbol or word “Biohazard” are to be used to contain RMW. Doors to laboratories where RMW is generated, and rooms used to store RMW, must also be labeled with the universal biohazard trefoil symbol or word “Biohazard”.

12. Spills of RMW
Refer to the University’s Biological Spills Policy; (http://ehs.columbia.edu/BiologicalSpills.pdf)

F. Emergency contacts
Medical Center
   Facilities (212)-305-HELP (4357), ext. 3
   EH&S (212)-305-6780
Morningside – EH&S (212)-854-8749

G. Medical Surveillance
Personnel exposed to RMW through parenteral, mucous membrane contact or ingestion should receive immediate medical attention. For details on health care providers see: http://www.ehs.columbia.edu/WhereToGoForMedicalAttention1.pdf
For more information on post exposure response, review the Bloodborne Pathogens Exposure Control Plan (http://ehs.columbia.edu/BloodbornePathogensExposureControlPlan.html#exp).

H. Recordkeeping
None

I. Appendices
None

J. Forms
None

K. References
Biological Safety Manual - Regulated Medical Waste
http://www.ehs.columbia.edu/Policy2.12.html

NYS-DOH RMW guidelines
http://www.health.ny.gov/facilities/waste/
NYS-DEC Guidance for Regulated Medical Waste Treatment, Storage, Containment, Transport and Disposal
http://www.dec.ny.gov/regulations/8752.html

https://www.fedcenter.gov/assistance/facilitytour/solid/medical/index.cfm?&printable=1

US-EPA Medical Waste Tracking Act of 1988
http://www.epa.gov/wastes/nonhaz/industrial/medical/tracking.htm

US-DoT 49 CFR Part 171 Infectious Substances; Final Rule