Biomedical Waste - Legal Issues

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AGENDA

- Overview of Ontario regulatory regime.
- On-site treatment of biomedical waste.
- Biomedical waste generator obligations.
- Collection of pharmaceuticals and sharps.

OVERVIEW OF ONTARIO REGIME

- Waste is regulated in Ontario under Part V of the EPA and Regulation 347
- The regulatory regime distinguishes between solid non-hazardous waste and subject waste (i.e. hazardous waste or liquid industrial waste)
- “Biomedical Waste” is still not clearly regulated in the EPA or Reg. 347, despite multiple attempts by MOE
- 1994 – MOE published *Guideline C-4: The Management of Biomedical Waste in Ontario*

- 1998 - MOE made proposals to comprehensively regulate biomedical waste in Reg. 347
- 2001 - MOE proposed amendments to Reg. 347 that would,
  - add a new definition for “biomedical waste” that would distinguish between the portion of the medical waste stream that requires special management as hazardous waste and the portion that can be managed as non-hazardous waste
  - introduce packaging, storage and handling requirements
  - set standards for non-incineration technologies for biomedical wastes.

- 2002 - MOE proceeded with a companion proposal to phase-out hospital incinerators, but deferred the biomedical waste proposals to a later date
- 2010 - MOE revised Guideline C-4 to provide, *clear direction about best management practices to generators, carriers and receivers of biomedical waste*
- 2014 – The regulatory regime is still tied to the definition of “pathological waste” in Reg. 347, a term that dates back over 40 years

- "Pathological Waste" is classified in Reg. 347 as a hazardous waste (and therefore a subject waste) - it is still defined to mean,
  - any part of the human body, including tissues and bodily fluids, but excluding fluids, extracted teeth, hair, nail clippings and the like, that are not infectious
  - Any part of the carcass of an animal infected with a communicable disease or suspected by a licensed veterinary practitioner to be infected with a communicable disease
  - Non-anatomical waste infected with communicable disease
- According to MOE in a 2001 EBR posting, this definition is, *too general, resulting in generators having difficulty distinguishing which wastes from health care facilities are biomedical, requiring special handling and disposal*

- Waste that fits the definition of pathological waste are subject to the generator registration and waste manifesting requirements of Reg. 347, except for wastes from nursing and special care homes and physician and dentist offices
  - subject waste generators must register annually through HWIN
  - subject waste must be transported under manifest via an MOE-approved carrier

ON-SITE TREATMENT

- Waste treatment and processing activities generally require approval under the EPA
- Processing of waste at a waste generation facility is exempt from approval if it does not involve combustion
- As a result, on-site mixing, blending, bulking and non-incineration treatment of biomedical waste does not require MOE approval
- Reg. 347 imposes time limits on on-site storage (notice to MOE after 90 days, no storage > 2 years without approval)

WASTE GENERATOR OBLIGATIONS

- Annual registration as a generator of subject waste through HWIN
- No storage longer than 90 days without notice to the MOE
- No storage longer than 2 years without an environmental compliance approval
- Approval of on-site treatment only if it involves incineration
- Waste must be shipped out under manifest

- Additional guidance for on-site management is provided in Guideline C-4
  - containment
  - packaging
  - labelling
  - storage
  - non-incineration treatment

PHARMACEUTICALS AND SHARPS

- Producers are regulated under O. Reg. 298/12
- Producer means manufacturer, brand owner, importer or first seller
- Producer must provide for collection at collection locations, and disposal of product and collection, and recycling or disposal, of containers
- Collection locations – as of Jan. 1, 2014, 90% of retail locations and pharmacies

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