Guideline for Class 3 Institutional Dispenser
&
Class 3A Institutional Dispenser, Limited Licensees
Seeking to Utilize
“Waste” Disposal Systems

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Guideline Purpose:

The purpose of this guideline is to provide information to Class 3 Institutional Dispenser and Class 3A Institutional Dispenser, Limited licensees regarding the on-site use of a “waste” disposal system for single-unit doses or partial doses remaining after the administration or attempted administration of a portion of a liquid or solid unit dose of a controlled substance.

Summary and Limitations:

Please note that pursuant to Title 10 NYCRR Part 80, Section 80.51(a), “the destruction of controlled substances shall mean that the substances have been rendered totally unrecoverable and beyond reclamation”. Further, Title 10 NYCRR Part 80, Section 80.51(b) states that: “Single-unit doses or partial doses remaining after the administration or attempted administration of a portion of a liquid or solid unit dose of a controlled substance may be destroyed on the premises of an institutional dispenser by a pharmacist or nurse provided that:

1) a notation is made on the administration record sheet; and
2) the destruction is witnessed by a second pharmacist or nurse or other responsible person designated by the administrator.”

In the event that an Institutional Dispenser (Class 3 licensee) or Institutional Dispenser, Limited (Class 3A licensee) makes an independent determination that a particular “waste” disposal system is capable of rendering a single-unit dose or partial dose remaining after the administration or attempted administration of a portion of a liquid or solid unit dose of a controlled substances as totally unrecoverable and beyond reclamation, neither Public Health Law Article 33 nor Title 10 NYCRR Part 80 prohibit such use. The Institutional Dispenser or Institutional Dispenser, Limited licensee remains responsible for ensuring said “waste” disposal system adheres to all Public Health Law Article 33 and Title 10 NYCRR Part 80 requirements.

“Waste” disposal systems may not be used for undesired, deteriorated, obsolete, or unneeded controlled substances.

An Institutional Dispenser (i.e., Class 3 licensee) shall dispose of undesired, deteriorated, obsolete, or unneeded controlled substances pursuant to Title 10 NYCRR Part 80 Section 80.51(c)(1), 80.51(c)(2) or 80.51(c)(5). Records of disposal must be kept pursuant to Title 10 NYCRR Part 80 Section 80.51(d). Records shall be kept for a period of five years.

An Institutional Dispenser, Limited (i.e., Class 3A licensee) shall dispose of undesired, deteriorated, obsolete, or unneeded controlled substances pursuant to Title 10 NYCRR Part 80 Section 80.51(c)(2), 80.51(c)(3) or 80.51(c)(5). Records of disposal must be kept pursuant to Title 10 NYCRR Part 80 Section 80.51(d). Records shall be kept for a period of five years.