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|  |  | Healthy Solutions, LLC |
|  | **STANDARD OPERATING PROCEDURES** | 7812 E. Acoma |
|  |  |  Scottsdale, AZ 85260 |

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| Created by: Kara Upchurch | Title: QA Document Coordinator  |  Created Date: 6/27/2016 |
| Pages 3  | Approved by: | Title: QA Manager | Approved Date:  |
|  | Approved by: | Title:  | Effective Date:  |

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| TITLE | **THE DESIGN, CONSTRUCTION, MAINTANENCE & USE OF RESTROOMS** |
|  | **PL410** |
| VERSION: | **00** |

21 CFR 1 11

Sec. 111.15 What sanitation requirements apply to your physical plant and grounds?

(h) *Bathrooms.* You must provide your employees with adequate, readily accessible bathrooms. The bathrooms must be kept clean and must not be a potential source of contamination to components, dietary supplements, or contact surfaces.

##### Scope/PURPOSE:

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| * 1. The purpose of this procedure is to establish guidelines for the cGMP compliant design, construction, maintenance and use of restrooms.
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##### **2** RESPONSIBILITIES:

2.2. Ensuring compliance with this procedure is the responsibility of QA, QC, Managers and any employee participating in the design, construction, maintenance or use of a restroom

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##### **3** Policy:

3.1. This procedure applies to any employee participating in the design, construction, maintenance or use of a restroom.

##### **4** PROCEDURE:

 4.1. Clean & functional restrooms must be easily accessible by all employees.

4.2. Restrooms shall be constructed of waterproof materials which are able to be efficiently and effectively cleaned and sanitized.

4.3. Restrooms must contain cGMP compliant hand cleaning / sanitizing areas.

4.4. Toilets and sinks must effectively transfer waste into the city sewage system.

4.5. Restrooms must have self-closing doors that do not open into manufacturing areas.

4.6. Restrooms are to be cleaned (mopped with mopping solution, wiping of all surfaces after application of a disinfecting spray etc.) a minimum of twice a week or at such time there is a malfunction resulting in water, waste etc. coming into contact with an area of the restroom which is not specifically designed to contain it. For example, if the toilet were to overflow.

4.6.1. Equipment and utensils used to clean and sanitize the restrooms will not be used in manufacturing areas.

4.6.2. Restrooms must contain equipment & supplies necessary to ensure their efficient and effective operation (toilet paper, sinks, hands free faucets, hand cleaning soap, hand sanitizer, paper towels, covered trash bins, disinfecting spray etc.).

4.7. **IMPORTANT NOTE**: Employees and/or sanitation are responsible for replacing necessary supplies (soap, sanitizer, paper towels etc.) as they are needed!! Immediately notify Quality Control if one of the needed supplies is not available. Failure to participate in the restocking of supplies will not be tolerated.

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##### **5** APPENDIX:

 5.1 N/A

##### **6** Definitions:

##### **7** Non-Compliance & Failure to Report Non-Compliance:

7.1. Individual Non-Compliance and/or failure to report the Non-Compliance of another employee is a violation of Federal Regulations and Company Policy. Non-Compliance may result in disciplinary action and / or termination of your employment. Furthermore, any Non-Compliance shall be considered a violation of basic moral, ethical and business standards in that it jeopardizes the health and safety of you, your fellow employees, the consumer and the success of the Company.

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##### **8** History:

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| Revision | Change Description | Author | Effective |
| **00: Initial Issue**  |  | Matt Martin | 9/25/2006 |
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