

Instrumented Initial Test Facilities (IITFs)

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Instrumented Initial Test Facility (IITF)

- Definition: *A permanent location where initial testing, reporting of results, and recordkeeping are performed under the supervision of a Responsible Technician*

Proposed Guidelines Revisions

April 13, 2004 FR

1. Reason for IITFs: "...established in locations to potentially more quickly and economically meet special local testing needs."
2. Federal workplace program experience: Nuclear Regulatory Commission (NRC) Fitness for Duty Programs (10 CFR Part 26) allows licensee testing facilities to perform validity screening, initial validity, and initial drug tests

Proposed Guidelines Revisions

April 13, 2004 FR (cont'd)

3. Proposed that IITFs should:
 - Be at a permanent location
 - Meet program forensic standards
 - Participate in open and blind proficiency testing
 - Have a rigorous quality assurance program
 - Be subject to site inspections
 - Use instrumented immunoassay tests for drugs which meet FDA requirements for commercial distribution
 - Conduct required specimen validity tests
 - Use HHS cutoffs
 - Submit all “non-negative” specimens to a full service NLCP HHS-certified laboratory for testing

2010 Guidelines Requirements for IITFs

1. A complete Standard Operating Procedures (SOP) manual
 - Section 12.1: Required elements and archiving procedures for SOPs

2010 Guidelines Requirements for IITFs cont'd

2.A Responsible Technician (RT)

- Section 12.2: RT responsibilities
- Section 12.3: RT qualifications
- Section 12.4: Procedures in absence of an RT
 - 2 weeks or less: certifying technician may oversee operations
 - More than 2 weeks: must have an approved alternate RT (alt-RT)

2010 Guidelines Requirements for IITFs cont'd

3. Certifying Technician (CT) to review and report results
 - Section 12.5: CT qualifications
 - Term “certifying technician” replaces the current term “negative certifying scientist”
 - Same for CT in an NLCP HHS-certified laboratory (Section 11.5b)
4. Technical and Administrative Staff
 - Section 12.6: Personnel requirements

2010 Guidelines Requirements for IITFs cont'd

5. Security (Section 12.7)

- Control access to the facility
- Limit access to authorized personnel or others escorted by authorized personnel

2010 Guidelines Requirements for IITFs cont'd

6. Internal Chain of Custody (Section 12.8)

- To maintain control and accountability from specimen receipt until final disposition
- To document handling and transfer of specimens and aliquots
- Chain of custody documentation may be paper or electronic
- Each individual who handles a specimen or aliquot must sign and complete appropriate entries on the chain of custody form when they receive the specimen or aliquot

2010 Guidelines Requirements for IITFs cont'd

7. Initial Drug Testing

- Section 12.9: test requirements
- Section 12.10: method validation
- Section 12.11: batch quality control requirements

2010 Guidelines Requirements for IITFs cont'd

8. Specimen Validity Testing

- Section 12.12: analytical and batch quality control requirements
- Section 12.13: method validation
- Section 12.14: testing requirements (for forensic and scientific acceptability)

2010 Guidelines Requirements for IITFs cont'd

9. Reporting (section 12.15)

- A CT may report a specimen as:
 - Negative,
 - Negative-dilute (with creatinine between 5 and 20 mg/dL), or
 - Rejected (sections 15.1 and 15.2)
- All test results may be reported using the completed OMB-approved Federal Custody and Control Form (CCF) and/or an electronic report

Note: The CT must report rejected specimens using the CCF

2010 Guidelines Requirements for IITFs cont'd

10. Final Specimen Disposition

- Section 12.16: The IITF must transfer any possibly positive, adulterated, substituted, or invalid specimen to an NLCP HHS-certified laboratory for testing
- Section 12.17: The IITF discards reported specimens (i.e., negative, negative-dilute, or rejected)

Collection Process Order

- Donor
- Collector
 - Send to IITF or Laboratory
- IITF
 - Report to MRO or
 - Negative
 - Rejected
 - Negative-dilute
 - Creatinine >5, <20
 - Send to Laboratory
 - Possible positive, adulterated, substituted, invalid
- Laboratory
 - Report to MRO

IITF Specimen Transfers

- IITF actions:
 - Reseal the primary specimen bottle (Bottle A)
 - Annotate the OMB-approved Federal Custody and Control Form (CCF) to document handling
 - Send both the primary and split specimens (Bottles A and B) with the CCF in sealed package
- Lab actions:
 - Accession the specimen
 - Annotate the CCF to document receipt
 - Test the primary specimen as if it had not been tested
 - Report results to the MRO

2010 Guidelines Requirements for IITFs cont'd

11. Records

- Section 12.18: Maintain records to support test results
- Section 12.19: Send semiannual statistical summary report to each Federal Agency for which testing is performed
- Section 12.20: Make records available to a Federal employee/donor upon request

2010 Guidelines Requirements for IITFs cont'd

12. Relationships between an IITF and other entities

- Section 12.21: Limitations on relationships with MROs
- Section 12.22: No limitations on relationships with NLCP HHS-certified laboratories

2010 Guidelines Requirements for IITFs cont'd

13. Federal Agency Blind Samples (Section 10)

- Agencies must submit blinds to the IITF and laboratory to which their workplace specimens are sent
- At least 3 % blinds along with donor specimens, based on projected total number collected yearly
- 75% negative, 15% positive for 1 or more drugs, 10% either adulterated or substituted
- Section 10.2: Blind sample requirements
- Section 10.3: Blind sample submission
- Section 10.4: Actions for inconsistent results

Certification of IITFs

- Section 9: HHS Certification of Laboratories and IITFs
 - Certification under the NLCP
- Section 16: Laboratory or IITF Suspension/Revocation Procedures

NLCP Application Process

- NLCP HHS Guidelines: Scientific and Forensic Standards (in Application Package)
- Process
 - Self assessment
 - Application submission
 - Application Review
 - Correction of deficiencies
 - Performance testing
 - On-site inspection

NLCP Application Package Requests

- NLCP Contact Information for IITF Application Packages
 - Email: NLCP@RTI.org
- Questions concerning the IITF Application Package:
 - Call Suzanne Clark at (919) 541-7457
- IITF Application Packages are expected to be available in January 2010
- IITF completed applications will not be accepted prior to the anticipated implementation date, May 1, 2010

IITF Certification Maintenance

- NLCP oversight
- Quarterly PT sets
 - Samples shipped frozen
 - Results scored and reported
 - NLCP remediation process for some errors
- Periodic onsite inspections
 - Twice a year
 - Inspection component: review procedures and practice
 - Audit component: review of specimen and validation records
 - NLCP remediation process for identified deficiencies²²

IITF Challenges

- Client base
- Facility, equipment, instrumentation
- Trained staff including RT and alt-RT
- Accurate and secure mechanisms for reporting results to MROs
- Established relationship with an NLCP HHS-certified laboratory