IREDELL HEALTH SYSTEM

Compounded Sterile Preparations Standard Operating Policy	
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P&T Committee	Date: 08/2022

Purpose:
To provide supplemental information and an overview summary of the policies guiding sterile compounding.

Policy:
Sterile compounding is performed in accordance with North Carolina Board of Pharmacy standards and with United States Pharmacopoeia Chapter 797 (USP <797>) requirements.

A pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations (CSPs) except in urgent situations where a delay could harm the patient, when the product stability is short, or another procedure has been approved (e.g. vial-to-bag system).

An ISO Class 5 environment is used in the pharmacy for preparing IV admixtures or any other sterile product that will not be used within 24 hours.

Low-risk, medium-risk, and immediate-use CSPs, as defined by USP <797>, are prepared at Iredell Memorial Hospital. High-risk preparations are not prepared. High-risk preparations may be outsourced to a pharmacy that has the required facilities and personnel

USP <797> applies to all persons who prepare CSPs and all places in the hospital where CSPs are prepared. Hospital policies and procedures include procedures for aseptic technique when preparing sterile preparations as well as operating procedures for IV rooms, required personnel training, beyond use dating, and environmental testing.

DEFINITIONS

- **Ante Area -** an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas.
- **Beyond-Use Date (BUD)** - the date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.
- **Biological Safety Cabinet (BSC)** – a ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

- **Buffer Area -** an area where the primary engineering control (PEC) is located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.
- **Compounding Area** – includes the ISO Class 5 PEC, buffer area, and ante area.
- **Compounding Aseptic Isolator (CAI) -** a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment passes through a HEPA filter.
- **Compounding Aseptic Containment Isolator (CACI)** – a CAI designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Exhaust air is removed by ventilation to the outside of the building.
- **Compounded Sterile Preparations (CSPs) -** According to USP <797>, CSPs include any of the following:
    - Compounded biologics, diagnostics, drugs, nutrients, and radio pharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.
    - Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package inserts) or prepared differently than published in such labeling.
    - **Critical Area** – an ISO Class 5 environment.
    - **Critical Site** – a location that includes any component or fluid pathway surfaces (e.g. vial septa, injection ports) or openings (e.g. opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g. ambient room or HEPA filtered), moisture (e.g. oral and mucosal secretions, or touch contamination.
    - **Direct Compounding Area (DCA)** – a critical area within the ISO class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
    - **First Air** – the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.
    - **Line of Demarcation -** the line separating the buffer area from the ante area.
    - **Negative Pressure Room** – a room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is *into* the room.
    - **Primary Engineering Control (PEC) -** a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).
    - **Positive Pressure Room** – a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out* of the room.

- **Unidirectional Flow** – an airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

RESPONSIBILITY OF COMPOUNDING PERSONNEL

Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. Personnel maintain appropriate cleanliness conditions and provide labeling and supplementary instructions for the proper administration of CSPs.

COMPOUNDED STERILE PREPARATION (CSP) MICROBIAL CONTAMINATION RISK LEVELS

Three specific categories of CSPs are described in USP <797>: low-risk level, medium-risk level, and high-risk level. In addition, an immediate use category is described that is exempt from the requirements of USP <797>.

Low-risk CSPs are compounded under all the following conditions:

1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.
2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g. bag, vial) of sterile product or administration container/device to prepare the CSP.
3. Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

Medium-risk CSPs are compounded under low-risk conditions and one or more of the following conditions exists:

1. Multiple individual or small doses of sterile preparations are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.
2. The compounding process includes complex aseptic manipulations other than the single volume transfer.
3. The compounding process requires unusually long duration such as that required to complete dissolution or homogeneous mixing.

High-risk CSPs – CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated.

1. Nonsterile ingredients, including manufactured products not intended for sterile routes of administration, are incorporated or a nonsterile device is employed before terminal sterilization.
2. Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour

- sterile contents of commercially manufactured products
- CSPs that lack effective antimicrobial preservatives, and
- sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.

3. Compounding personnel are improperly garbed and gloved
4. Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.
5. If it is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

Immediate Use CSPs– intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk Level CSPs subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs when all of the following conditions are met:

1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radio pharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container/device.
2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
4. Administration begins not later than one hour following the start of the preparation of the CSP.
5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, and name or initials of the person who prepared the CSP, and the exact 1-hour beyond-use date and time.
6. If administration has not begun within one hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS

Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 air quality and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 or cleaner air may be used up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period.

Multiple-dose containers (e.g. vials) are formulated for removal of portions on multiple occasions and may be used for 28 days after initially entering or opening unless otherwise specified by the manufacturer.

RADIOPHARMACEUTICALS AS CSPs
Radiopharmaceuticals are purchased from an outside nuclear pharmacy as finished drug products with no further compounding required. These drugs are purchased for specific patients in the dose required. 99m Technetium MAA is purchased for use in emergency diagnostic procedures. The use of the drug, which has to be reconstituted, and requires transfer of drug from one sterile vial to another, meets the requirements for immediate-use CSPs and is exempt from the requirements for low-risk level CSPs.

ALLERGEN EXTRACTS AS CSPs
Allergen extracts are not prepared at IMH.

VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY
CSPs are prepared in accordance with written procedures and the product package insert. Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount. When the correct identity, purity, strength, and sterility of ingredients and components of CSPs cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampuls, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling), such ingredients and components shall be discarded immediately.

Sterilization Methods
Low-risk, medium-risk, and immediate-use CSPs are prepared at Iredell Memorial Hospital. In preparing these CSPs, sterile ingredients and components are used and sterility is maintained.

Given high-risk level CSPs are not prepared at IMH, sterilization methods such as filtration, dry heat, and steam are not used.

ENVIRONMENTAL QUALITY AND CONTROL
Maintaining sterility and freedom from contamination of a CSP is dependent on the quality of the components incorporated, the process utilized, personnel performance, and the environmental conditions under which the process is performed.

Exposure of Critical Sites
Maintaining the sterility and cleanliness of critical sites is a primary safeguard for CSPs. Protection of critical sites by precluding physical contact and airborne contamination is given the highest priority.

ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas
Iso Class 5 air, for the exposure of critical sites, is achieved by the use of a LAFW located in a cleanroom suite.

Only authorized personnel and materials required for compounding and cleaning are permitted in the cleanroom suite.

Environmental Sampling (ES) Testing – an ES program provides information to demonstrate that the primary engineering control (PEC) is maintaining an environment within the compounding area that consistently ensures acceptably low viable and nonviable particle levels. Refer to *Environmental Sampling in the Compounding Area* policy and procedure. Environmental sampling occurs as part of a quality management program and occurs under any of the following conditions:

1. As part of the commissioning and certification of new facilities and equipment.
2. Following any servicing of facilities and equipment.
3. As part of the re-certification of facilities and equipment (i.e. every 6 months).
4. In response to identified problems with end products or staff technique.
5. In response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection).

Cleaning and Disinfecting the Compounding Area

Compounding personnel are responsible for ensuring that the frequency of cleaning and disinfecting compounding areas is in accordance with USP <797> requirements as follows:

Site	**Minimum Frequency**
ISO Class 5 PEC	At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected
Counters & easily cleanable work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

Cleaning and disinfecting practices, product names, a more comprehensive cleaning schedule, and policies for the compounding of CSPs are included in the written procedure, *Cleaning and Disinfecting the Compounding Area*.

Personnel Cleansing and Garbing

Appropriate hygiene, attire, careful cleansing of hands and arms, and the correct donning of PPE by compounding personnel constitutes the first major step in preventing microbial contamination in CSPs. Refer to *Personnel Cleansing and Garbing for the Compounding Area* procedure.

Personnel Training and Competency Evaluation - All personnel who prepare CSPs shall successfully complete a department provided training program initially and as an annual competency. Compounding personnel shall be trained by expert personnel and through multimedia instructional sources and professional publications in the theoretical principles and

practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures. Training shall be completed and documented before any compounding personnel prepare CSPs without supervision. Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing. (Refer to *Training and Competency Program for Sterile Compounding Personnel*).

Proper Procedures during Downtime and/or Maintenance

In the event that the compounding area experiences downtime due to an expected or unexpected outage or needed maintenance, the items listed below must be followed:

Definitions:
CACI – Compounding Aseptic Containment Isolator (i.e. chemotherapy hood)
LAFW – Laminar Airflow Workbench (i.e. general IV hood)
PEC – Primary Engineering Control (i.e. hood)
SEC – Secondary Engineering Control (i.e. ante and buffer rooms)

Table 1: If the PECs are still maintaining ISO 5 and the SEC is non-functioning, the following should occur:

If downtime is > 1 hour and continue to use the compounding area following proper garbing and behavior:	• Perform triple clean on all monthly clean surfaces • Utilize BUD of 12 hours or less, when applicable
If downtime is < 1 hour and continue to use space following proper garbing and behavior:	• Perform monthly cleaning • Utilize BUD of 12 hours or less, when applicable
If downtime is > 1 hour and do not use the space during the downtime:	• Perform monthly cleaning
If downtime is < 1 hour and do not use the space during the downtime:	• Perform daily cleaning

Refer to *Cleaning and Disinfecting the Compounding Area*

Table 2: If the PECs lose power and the SEC is non-functioning, the following should occur:

If downtime is ≤ 1 hour:	• Allow hood to run for 5 minutes • Perform triple clean on hood
If downtime is between 1 – 59 minutes	• Allow hood to run for 5 minutes • Perform a daily cleaning of the hood
If downtime is < 1 minutes	• Allow hood to run for 5 minutes • Clean the hood with sterile alcohol

Refer to *Cleaning and Disinfecting the Compounding Area*

- Any compounds made while LAFW is without power or before the assigned cleaning is complete, will utilize a BUD of 1 hour.
- Compounding should not take place in the CACI if it does not have power.
- When the SEC regains function, refer to **Table 1**.
- Compounding shall not take place while maintenance is occurring.

If there is an environmental incursion into classified space, the following should occur:

- The space should be triple cleaned as soon as possible. If it is an ongoing situation, attempt to mitigate contamination (e.g. place absorbent mats and low linting towels down to catch water)
- If the incursion occurs at a time when no member of management or designated person is present, document the incident as appropriate.
- The need for and extent of environmental testing following an excursion will be determined case-by-case basis.

Non-Viable Particle Count Testing shall be performed whenever the PEC is relocated, the physical structure of the buffer or ante area has been altered, or major service to the facility is performed.

Environmental Sampling (surface sampling and viable air samples) shall be performed following any servicing of facilities and equipment. Determination of the need for full recertification will be made by administration with or without collaboration with the certification company on a case-by-case basis.

Beyond Use Dates shall be applied as directed in this policy. BUDs may be shortened at the discretion of management on a case by case basis.

STANDARD OPERATING PROCEDURES (SOPs)

USP <797> recommends that compounding facilities have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared. The recommended procedures are included in written IMH policies and procedures:

Preparing Compounded Sterile Preparations
Disinfection of Supplies and Equipment Used in the Compounding Area
Personnel Cleansing and Garbing for the Compounding Area
Cleaning and Disinfecting the Compounding Area
Surface Cleaning & Disinfection Sampling & Assessment of the Compounding Area
Environmental Sampling in the Compounding Area

ELEMENTS OF QUALITY CONTROL

A description of specific training and performance evaluation for individuals involved in the preparation of sterile products is written (refer to *Training and Competency Program for Sterile Compounding Personnel*).

Sterile Ingredients and Devices

Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality using the following information: vendor labels, labeling, certificates of analysis (if appropriate), and knowledge of compounding facility storage conditions. Commercially available sterile drug products, sterile ready-to-use containers, and devices are inspected prior to use to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use.

Nonsterile Ingredients and Devices
Nonsterile components, including containers and ingredients, are not used in preparation of CSPs at IMH.

Equipment
Currently, equipment is not used to compound CSPs at IMH. If/when equipment is purchased, it will be consistently capable of operating properly and within acceptable tolerance limits. Written procedures outlining required equipment calibration, annual maintenance, monitoring for proper function, and procedures for use of the equipment will be established and followed. Personnel will be trained to operate any piece of equipment, apparatus, or device they may use when preparing CSPs.

VERIFICATION OF AUTOMATED COMPOUNDING DEVICES (ACDs) FOR PARENTERAL NUTRITION COMPOUNDING

ACDs for the preparation of parenteral nutrition admixtures are not used at IMH.

FINISHED PREPARATION RELEASE CHECKS AND TESTS

Inspection of Solution Dosage Forms and Review of Compounding Procedures
All CSPs that are intended to be solutions are visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed. Prescription orders, written compounding procedure (where appropriate), preparation records, and expended materials used to make CSPs are inspected for accuracy of correct identities and amounts or ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed. (Refer to *Labeling and Inspecting Compounded Sterile Preparations* procedure).

Compounding Accuracy Checks
Written procedures for double-checking compounding accuracy are followed for every CSP during preparation and immediately prior to release. When possible, CSPs are prepared by one individual (usually a Pharmacy Technician) and checked by a second individual (Pharmacist). (Refer to *Labeling and Inspecting Compounded Sterile Preparations* procedure).

Sterility and Bacterial Endotoxin (Pyrogen) Testing
Sterility and/or pyrogen testing of CSPs is not required at IMH because high-risk level CSPs are not prepared.

Identity and Strength Verification of Ingredients
Written procedures exist for verifying the correct identity and quality of CSPs before they are dispensed and administered.

STORAGE AND BEYOND-USE DATING

Beyond-Use Dating -

- All compounded sterile products are assigned a beyond-use (expiration) date based on the drug's known stability or risk category as defined in <USP 797>, whichever time is

shorter. (Refer to *Expiration (Beyond-Use) Dating of Pharmacy Prepared Intravenous Medications*).

- The following beyond use dates are assigned according to risk level of preparation. The beyond use date will not be exceeded in the absence of sterility testing even if the literature supports the drug's stability for a longer period:

Risk Category	**Room Temp**	**Refrigerator**	**Freezer (-25°C and -10°C)**
Immediate Use	1 hour	1 hour	N/A
Low-Risk	48 hours	14 days	45 days
Medium-Risk	30 hours	9 days	45 days
High-Risk	N/A	N/A	N/A

- All CSPs will be stored strictly in accordance with the conditions stated on the label.

Proprietary Bag and Vial Systems
The sterility storage and stability beyond-use times for attached and activated container pairs of drug products (e.g. Mini Bag Plus) shall be as indicated by the manufacturer.

Monitoring Controlled Storage Areas
Compounding personnel shall monitor the drug storage areas within the compounding facility. Controlled temperature areas include:

Storage Areas	**Range**	**Mean kinetic temperature**
Controlled Room Temperature	20° to 25° C (68° to 77° F)	25° C
Controlled Cold Temperature	2° to 8° C	8° C
Cold Temperature	2° to 8° C	8° C
Freezing Temperature	-25° to -10° C	
Microbial culture media	Media specific range	

Areas shall be monitored at least once daily and the results documented on the Daily Record of Refrigerator, Freezer, and Pharmacy Temperatures log in the Pharmacy Information System. If suitable temperature recording devices are used, compounding personnel shall verify at least once daily that the recording device itself is functioning properly.

MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPS
Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their beyond use dates are reached or they are administered to patients. Outdated and unused CSPs shall be returned to the pharmacy for disposal. Procedures exist to ensure that storage conditions in the patient care setting are suitable for the CSP-specific storage requirements. Procedures include daily monitoring and documentation of drug storage refrigerator temperatures by nursing personnel and monthly inspection of all drug storage locations by compounding personnel.

Packaging, Handling, and Transport
Compounding personnel routinely perform the tasks associated with packaging, handling and transport of CSPs to nursing units. Tamper evident closures or seals on narcotic CSP ports are used to ensure product integrity.

Use and Storage
Pharmacy personnel deliver CSPs to patient-care areas and to the proper storage location. The labeling of the CSP container contains the requirements for proper storage and expiration dating. Outdated and unused CSPs are returned to the pharmacy for disposal. Policies and procedures exist to ensure that storage conditions in the patient care setting are suitable for the CSP-specific storage requirements. Procedures require daily monitoring and documentation of drug storage refrigerators to ensure appropriate temperatures and the monthly inspection of all drug storage locations. Inspections shall confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of MDVs, and the avoidance of using single-dose products as MDVs.

Readying for Administration
Nursing procedures are in effect for ensuring sterility assurance when readying a CSP for its subsequent administration. Policies and procedures require proper hand washing, aseptic technique, site-care, and change of administration sets.

Re-dispensed CSPs
Pharmacists are responsible for determining when unopened, returned CSPs may be re-dispensed.

Education and Training
An education, training and competency assessment program includes the assessment and documentation of procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration, such as extravasation. This program is coordinated with the hospital's adverse-events and medication error reporting programs.

Packing and Transporting CSPs
CSPs are not distributed to locations off the hospital premises. CSPs are transported in containers approved by pharmacy services to Infusion Care Services by trained transporters. CSPs are placed into the containers by pharmacy personnel.

Care is taken to ensure that syringe plungers will not be depressed or syringe tips dislodged during handling and transport.

If a spill of a chemotoxic or hazardous CSP should occur, transporters are trained to call a nurse or pharmacist. Exposure reducing strategies such as luer lock syringes and connections, syringe caps, and the capping of container ports are used.

PATIENT MONITORING AND ADVERSE EVENTS REPORTING

Patients are clinically monitored and post medication assessments, observations, resulting effects, and responses are recorded in the Patient Care Record.

The Pharmacy Department, in conjunction with the Pharmacy and Therapeutics Committee, maintains a reporting program for significant adverse drug reactions (ADRs) at Iredell Memorial Hospital. Reports of adverse events and medication errors with CSPs will be reviewed by the P&T Committee and reported to the FDA and USP, as appropriate.

QUALITY ASSURANCE (QA) PROGRAM

The CSP QA program is intended to provide a mechanism for monitoring, evaluating, correcting, and improving activities and processes involved in CSP preparation. The plan is a part of and incorporated into the Pharmacy Quality Assurance Plan. Emphasis is placed on maintaining and improving the quality of systems and the provision of patient care. If problems are identified, a plan of action will include appropriate follow-up to make certain that effective corrective actions were performed.

Focus is on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone. The selection of indicators and the effectiveness of the overall QA program is reassessed annually.

INITIAL EFFECTIVE DATE: 10/2008
DATES REVISIONS EFFECTIVE: 02/2020, 08/2022
DATES REVIEWED (no changes): 09/2021