UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

February 6, 2026

NRC INFORMATION NOTICE 2026-02: USING GENERIC PROCESS CHECKLISTS IN MEDICAL CARE TO PREVENT HUMAN ERROR

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice (IN) to inform licensees of a recommendation to use generic process checklists prior to and during the medical use of byproduct material. This recommendation was the result of the assessment of medical events and their causes. The NRC expects that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid errors while providing medical care.

INs may not impose new requirements, and nothing in this IN should be interpreted to require specific action; therefore, no written response is required. The NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees, as appropriate.

DESCRIPTION OF CIRCUMSTANCES

Licensees are required to report medical events that meet the criteria defined in Title 10 of the *Code of Federal Regulations* (CFR) 35.3045, “Report and notification of a medical event,” except those that result from patient intervention. Licensees are also required to develop, implement, and maintain written procedures to provide high confidence that a patient’s identity is verified before each administration and that the administration is in accordance with the written directive in accordance with 10 CFR 35.41, “Procedures for administration requiring a written directive.” The identification of medical events allows licensees to identify their causes in order to correct them and to prevent their recurrence. Additionally, the reporting of medical events allows the NRC to review these activities during inspection and to notify other licensees on any commonalities so they can avoid similar incidents. Both the NRC staff and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) regularly review medical event reports to identify generic concerns and to recognize any inadequacies or the unreliability of specific equipment or procedures. The NRC staff and the ACMUI present their findings at biannual ACMUI meetings. The presentations from recent years are posted on the NRC Medical Uses Licensee Toolkit webpage at https://www.nrc.gov/materials/miau/med-use-toolkit.html. In addition, an analysis of medical events is included in the annual Nuclear Materials Event

ML25253A455

Database (NMED) report. These annual reports are maintained on the NMED website at https://nmed.inl.gov/default.

During the 2022 spring meeting of the ACMUI, the committee discussed the benefit of developing generic process checklists for all user procedures. The discussion centered around the causes of an increase in medical events in 2021 and the acknowledgement of human error and how it impacted the process. The ACMUI Subcommittee on the Development of a Generic Process Checklist to Help Reduce Medical Events presented recommendations at the Spring 2025 ACMUI meeting (meeting transcript; Agencywide Documents Access and Management System (ADAMS) No. ML25127A173) and issued their final report (ML25177A051) on February 12, 2025. The ACMUI identified components of generic process checklists that could prompt licensees to avoid errors that cause medical events and considered the applicability of that guidance to the different modalities of medical use.

During the review of medical events, the staff noted that human error contributed to many of the events and that licensees implement corrective actions after the errors are identified and understood. While generic process checklists may not prevent all medical events, adoption of unique checklists and consistent use of them in the clinical setting could help avoid errors in the use of byproduct material. The use of checklists could have mitigated multiple medical events from previous years. Examples of medical events that could have been prevented if licensees had included certain procedures in a generic process checklist are provided below.

Treatment based on photograph without sufficient detail

On June 3, 2022, a licensee determined that an authorized user had misidentified the treatment site and reported that the patient had received an Iridium (Ir)-192 treatment to the wrong site using a high dose rate (HDR) unit.

The treatment site was incorrectly identified because pre-treatment photographs were taken right after the lesion was biopsied by the dermatologist. No photographs were taken of the treatment site before the biopsy. When the patient started radiation therapy the biopsied lesion had completely healed and the correct treatment site could not be identified from the photographs, pathology reports, consult requests, or the patient's recollection. In response, the licensee created an HDR planning policy for dermal brachytherapy, which included specific steps. The licensee updated its Commitment to Quality Care Policy to state that HDR skin cancer sites will be reviewed at a peer review meeting before treatment begins. Furthermore, better photographs of treatment site(s), including pre-biopsy photographs, will be required before beginning radiation therapy. Ambiguous information on the treatment site obtained during the pre-treatment review will require a request to verify the correct treatment site. This event might have been prevented by the use of a generic checklist that required verification of treatment site before administration (ML23158A228).

Implanted radiopharmacutical seeds in the wrong location due to insufficient information

On July 26, 2021, a licensee reported that during a prostate seed implant treatment, a patient received a dose to the wrong treatment site. The treatment plan was to insert 54 iodine (I)-125 seeds into the prostate, for a total activity of 1.013 gigabecquerel (GBq) (27.38 millicuries (mCi)), achieving a prescribed dose of 145 gray (Gy) (14,500 rad) to the prostate. On August 18, 2021, a follow-up Computed Tomography scan showed that all 54 I-125 seeds had inadvertently been implanted into the penile bulb.

The cause of the event was determined to be human error. After interviews with the medical physicist and radiation safety officer, the inspector ruled out the possibility of a malfunction of the ultrasound unit. The medical physicist's retrospective review indicated that if the catheter was not clearly visible on the ultrasound images, then this could have caused seed implantation in a location other than the prostate. In response to the event, the licensee added a step to the prostate brachytherapy protocol to ensure that personnel clearly identify the prostate gland and the surrounding anatomy. This event might have been prevented by using a generic checklist that required verification of the ultrasound probe before treatment as well as verification of catheter placement before inserting the seeds (ML22213A019).

Miscommunication between the centralized scheduling department and the nuclear medicine representative

On December 23, 2020, a licensee notified the NRC of a medical event that had occurred on December 15, 2020. A physician had referred a patient for a thyroid uptake and scan (a diagnostic procedure). This diagnostic procedure generally uses approximately 7.4 megabecquerels (MBq) (200 microcuries (μCi)) of I-123. While the physician referred the patient for a diagnostic dose, the licensee's central scheduling system generated, after miscommunication with the licensee's nuclear medicine department on the diagnostic order, an erroneous written directive, which called for the administration of a therapeutic dose to the thyroid using 555 MBq (15 mCi) of I-131. The administered amount was 584.6 MBq (15.8 mCi) of I-131, which is significantly beyond the dose intended for the patient and sufficient to ablate the patient's thyroid gland.

A miscommunication between the centralized scheduling department and the nuclear medicine representative resulted in the authorized user preparing an erroneous written directive for a therapeutic dose of I-131 instead of the intended diagnostic dose of I-123. The authorized users that prepared and carried out the written directive did not review the patient's clinical situation, including the information from the patient's physician, to determine if the treatment option was appropriate for the patient's situation. The licensee revised written procedures to require that, before creating a written directive, the authorized user physically verify the prescribing physician's order for the treatment and also review the patient's electronic medical record, instead of simply relying on the electronic order sent from centralized scheduling to the nuclear medicine department. Finally, the licensee revised the procedure for ordering doses for therapeutic administrations to require an assigned nuclear medicine worker to collect information on the order. This assigned worker would then create a hard-copy folder containing this information and provide it to the authorized user, who would use it to verify that the written directive conforms to the original physician's order. A generic process checklist that obtained informed consent from the patient, harmonized the written directive and dose, and verified the radiopharmaceutical used for treatment might have prevented this medical event (ML22213A019).

Treated the wrong part of an organ

On October 16, 2020, a licensee reported that during a yttrium (Y)-90 microsphere treatment, a patient received a dose that was more than 50 percent greater than that prescribed. The patient had been prescribed 7 Gy (700 rad) to the left lobe of the liver and 17.5 Gy (1,750 rad) to the right lobe of the liver. The patient's left lobe was treated first and mistakenly received the higher

dosage intended for the right lobe, resulting in a dose of 17.5 Gy (1,750 rad) to the left lobe of the liver (2.5 times the intended dose).

The error occurred for two reasons. First, the technician had labeled the containers with the two dosages incorrectly, switching the intended liver lobes. All other labeling information was correct. Second, the physician administering the dosage failed to verify that the dosage on the container's label matched the dosage prescribed in the written directive for the left lobe. In response, the licensee changed its procedures to require a pause after the dosage is received in the treatment room, during which all information related to the dosage to be delivered must be verified to match the written directive. The reference to the target organ on the label will also be removed, to force the comparison with the dosage prescribed in the written directive. Additionally, the licensee incorporated a timeout into the procedure to allow the authorized user and health physicist to verify that each dose is identical to that of the written directive. After the timeout, the authorized user signs the written directive before administration of the dose(s). This event might have been prevented using a generic process checklist that included verifications for treatment site and dosage and a check that the dosage being delivered matched the written directive (ML22213A019).

DISCUSSION

This IN is intended to provide licensees with awareness on medical events and how a generic checklist as part of a licensee's internal procedures could increase confidence as they may enhance the potential for reducing human errors, thereby reducing reportable medical events.

The licensee is encouraged to consider areas in which human error could result in patient harm and consider administrative solutions that could be implemented within the medical practice. Generic process checklists could be incorporated into operating procedures, supported by new software platforms, and/or enable the use of barcodes for tracking radioactive drugs.

Components of a generic process checklist recommended by the ACMUI are included below. These items are not a comprehensive list, and licensees could adapt this information and information from other sources (personal experience, professional societies, national patient safety groups, industry leaders, and international standards) to effectively manage their medical practices. The NRC encourages the adoption of generic process checklists to be specific to the licensee's own processes and available resources, including manufacturer's instructions, as applicable.

All 10 CFR Part 35 Modalities:

- Verify patient identity
- Verify pregnancy status (if applicable)
- Obtain informed consent from appropriate parties
- Verify prescription (i.e., radioisotope, dose or dosage)
- Assemble appropriate members of the medical team
- Dispose of waste properly
- Keep appropriate records (see 10 CFR 35 Subpart L)

Unsealed Byproduct Material – Written Directive Required

- Ensure proper completion of the written directive and harmony with prepared dose

- Verify correct route and mode of administration
- Post-administration check for extravasation

Manual Brachytherapy

- Verify correct number of sources
- Ensure correct placement of sources
- During explanation, verify number and integrity of sources

Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

- Verify parameters of treatment (e.g., placement of sources, dwell times, source positioning, etc.)
- Ensure use of appropriate equipment (e.g., catheters, applicators)

Microsphere Sources

- Ensure use of appropriate equipment (e.g., catheter diameter)
- Use appropriate pre-treatment imaging/angiography
- Ensure good patency

Other Medical Uses of Byproduct Material or Radiation form Byproduct Material

- Use guidance documents and manufacturer recommendations when producing checklists for specific emerging medical technologies

CONTACTS

This information notice requires no specific action or written response.

Please direct any questions about this matter to the technical contact listed below.

/RA/

Dafna Silberfeld, Director
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards

/RA/

Phillip McKenna, Acting Director
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Technical Contact: Daniel DiMarco, NMSS
E-mail: Daniel.Dimarco@nrc.gov

Note: NRC generic communications may be found on the NRC public website, http://www.nrc.gov, under NRC Library/Document Collections.

NRC INFORMATION NOTICE 2026-02: USING GENERIC PROCESS CHECKLISTS IN MEDICAL CARE TO PREVENT HUMAN ERROR, DATED FEBRUARY 06, 2026

ADAMS Accession No.: ML25253A455

OFFICE	NMSS/MSST/ MSEB	NMSS/MSST/ MSEB	NMSS/MSST/ MSEB	NMSS/MSST/ MSEB	OE
NAME	DDimarco	JFisher	KTapp	CEinberg	JPeralta
DATE	12/18/2025	12/1/2025	12/19/2025	1/12/2026	1/6/2026
OFFICE	NRR/DRO/ IOEB	NRR/DRO/ IOEB	NMSS/MSST	NRR/DRO	
NAME	GSpaulding	BBenney	DSilberfeld	PMcKenna	
DATE	2/2/2026	1/26/2026	2/2/2026	2/6/2026	

OFFICIAL RECORD COPY