

From: [Tobias B Gilk](#)
To: [CDPH Ofc of Regulations](#)
Subject: GOV § 11340.6 Petition - Minimum MRI Safety Standards at Hospitals and Imaging Centers
Date: Wednesday, September 17, 2025 9:12:21 AM
Attachments: [DRAFT REGULATORY TEXT.docx](#)

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Sir or Madam,

What follows is a petition, submitted to CDPH pursuant to GOV § 11340.6, for rulemaking to adopt MRI safety regulations into the body of CDPH and Radiologic Health Branch rules and standards. Additionally, attached to this message with this petition, please find a Word document with a proposed draft of the regulatory text which would follow from this petition.

Please acknowledge, on behalf of CDPH, receipt of this petition and attached proposed draft.

At your earliest convenience, please advise of the acceptance of this petition for consideration, or identify any defects or shortcomings which will require correction for consideration, as well as the most expedient means of having any corrected defects reconsidered by CDPH.

Respectfully,

Tobias Gilk

Petitioner: Tobias Gilk

Agency Petitioned: California Department of Public Health (Radiologic Health Branch / Licensing & Certification Program)

Date: 16 September, 2025

Subject: Petition for Rulemaking to Adopt MRI Safety Regulations

I. Authority and Basis of Petition

- This petition is submitted pursuant to **California Government Code § 11340.6**, which provides that any interested person may petition a state agency requesting adoption, amendment, or repeal of a regulation.
- CDPH has statutory authority under the **Radiation Control Law (Health & Safety Code §§ 114960–115273)** to regulate health facilities and the safe use of radiation machines. While MRI is non-ionizing, CDPH already regulates radiologic technologists, facilities, and hospital radiology services under **Title 22 CCR**, providing the jurisdictional nexus to establish enforceable MRI safety requirements.

- Current regulations (Title 22 CCR, hospital radiology service regulations) require only that hospitals maintain written policies and procedures, but **do not set minimum MRI safety standards**, creating variability and avoidable patient risks. While presently RHB regulates ionizing radiation safety at outpatient imaging facilities, current state oversight relegated to the Medical Board of California is jurisdictionally-precluded from considering MRI safety, leaving those facilities (representing approximately 50% of MRI imaging performed) wholly ungoverned by the state with respect to MRI safety standards.
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II. Statement of Need

- MRI is performed over **35 million times annually in the U.S.**; nearly every Californian will undergo or know someone who undergoes MRI each year.
 - MRI injury is under-recognized but well-documented in FDA MAUDE reports and professional literature.
 - Four injury categories account for the majority of reported MRI adverse events:
 1. Burns (RF heating, skin contact, device interactions)
 2. Projectile incidents (ferromagnetic attraction)
 3. Auditory injury (high decibel acoustic noise)
 4. Implant/device interference (malfunction or displacement)
 - At present, the public is afforded functionally zero assurances that healthcare providers within the state are required to adhere to standards of care for MRI safety.
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III. Proposed Regulatory Framework

A. Facility Oversight and Personnel Requirements

1. Every MRI provider shall designate:
 - **MRI Medical Director (MRMD):** licensed physician responsible for overall MRI safety compliance.
 - **MRI Safety Officer (MRSO):** trained technologist or nurse with operational authority over day-to-day safety.
 - **MRI Safety Expert (MRSE):** physicist or device safety specialist available to review implant/device compatibility and complex cases.
2. Written MRI safety policies and **standard operating procedures (SOPs)** shall be maintained, covering at minimum:

- Burn prevention
 - Patient implant/device screening
 - Emergency procedures (burns, projectile events, device malfunctions, fire, quench, patient evacuation)
 - Annual review and update.
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B. Risk-Specific Safety Requirements

Risk 1: MRI Burns

- **Prevention 1a:** Require all MRI patients to change out of street clothes into MRI-safe gowns or scrubs provided by the facility.
- **Prevention 1b:** Require padding of patients from bore wall and coil contact in accordance with MRI system manufacturer minimum requirements.
- **Prevention 1c:** Require the use of MR Conditional physiological monitoring equipment (ECG, pulse oximetry, etc.) and medication delivery devices (injectors, infusion pumps, etc.) whenever patient condition indicates use of such devices.

Risk 2: Magnetic MRI Projectiles

- **Prevention 2a:** Require use of ferromagnetic-only detection devices for screening all persons/objects entering MRI scanner rooms.
- **Prevention 2b:** Require new MRI construction/renovation to conform to **ACR 4-Zone model** for access control and workflow safety.
- **Prevention 2c:** Require conspicuous labeling of all objects routinely stored in Zone III with MR safety conditions/restrictions.
- **Prevention 2d:** Require reporting of all large projectile incidents, even absent injury, to CDPH within [7] days.

Risk 3: Auditory Injury

- **Prevention 3a:** Require hearing protection for all patients/visitors/companions in scanner rooms with MRI systems producing sound > 99 dB(A).
- **Prevention 3b:** Require posting of instructions for proper use/placement of hearing protection in waiting and changing areas.
- **Prevention 3c:** Require availability of at least one alternative form of hearing protection (e.g., foam plugs, earmuffs, pediatric-sized).

Risk 4: Implant / Medical Device Interference

- **Prevention 4a:** Require the use of MRI screening forms for each exam, completed or reviewed by the patient or per facility policy, retained as part of the patient medical record.
 - **Prevention 4b:** Require reporting to CDPH of all inadvertent exposures of an implant/device not identified as safe for that level of MRI exposure, regardless of injury outcome.
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C. Reference to Established Standards of Care

- **American College of Radiology (ACR) Manual on MR Safety (2024 edition):** provides consensus best practices on zoning, screening, and injury prevention.
 - **U.S. Veterans Health Administration Directive 1105.05 (MRI Safety, 2017):** establishes minimum MRI safety practices for all VA MRI facilities.
 - Petitioners request CDPH incorporate these documents by reference as defining the baseline *standard of care* for California MRI providers.
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IV. Reporting, Enforcement, and Compliance

- Mandatory reporting of MRI adverse events (burns, projectile incidents, device interference) to CDPH, parallel to hospital incident reporting under existing health facility regulations.
 - CDPH to inspect for compliance during routine licensing surveys (hospital and outpatient imaging centers).
 - Effective date: [12–18 months] after adoption to allow for compliance.
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V. Expected Benefits and Impact

- **Patient Safety:** reduction in avoidable burns, hearing injuries, projectile accidents, and device complications.
 - **Uniform Standards:** harmonization between hospital and outpatient settings.
 - **Transparency:** systematic reporting of MRI adverse events to CDPH, closing current data gaps.
 - **Cost Considerations:** compliance costs (gowns, padding, detection devices, training) are modest relative to costs of treating preventable injuries and defending malpractice claims.
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VI. Conclusion

Petitioners respectfully request CDPH to initiate rulemaking to adopt the proposed minimum MRI safety standards as set forth above.

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