

From: Tobias B Gilk <tgilk@MRIpatientsafety.com>

Sent: Tuesday, October 14, 2025 10:29 AM

To: CDPH Ofc of Regulations <Regulations@cdph.ca.gov>

Subject: GOV § 11340.6 Petition - Modification of 22 CCR § 70251 definition of Radiological Services to include MRI and specify point-of-care safety regulatory authority

Sir or Madam, Please acknowledge receipt of this GOV § 11340.6 Petition for the modification of 22 CCR § 70251 definition of Radiological Services to include MRI and specify point-of-care safety regulatory authority. At your earliest convenience,

ZjQcmQRYFpfptBannerStart

This Message Is From an External Sender

[Report Suspicious](#)

This message came from outside your organization.

ZjQcmQRYFpfptBannerEnd

Sir or Madam,

Please acknowledge receipt of this GOV § 11340.6 Petition for the modification of 22 CCR § 70251 definition of Radiological Services to include MRI and specify point-of-care safety regulatory authority.

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

PETITION FOR RULEMAKING

Submitted Pursuant to California Government Code § 11340.6

I. Petitioner

Tobias Gilk

II. Agency Petitioned

California Department of Public Health (CDPH)
Licensing and Certification Program

III. Purpose of Petition

Petitioner respectfully requests that CDPH initiate formal rulemaking to:

1. **Amend 22 CCR § 70251** (“Radiological Service – Definition”) to expressly include **Magnetic Resonance (MR) and Magnetic Resonance Imaging (MRI)** among the radiologic services recognized under California hospital licensing regulations.
2. **Add a new section (§ 70251.1)** establishing **minimum point-of-care safety standards** applicable to all radiologic service modalities that may present safety risks to patients, healthcare workers, or the public.

These changes would align state regulations with contemporary clinical practice, patient safety expectations, and existing CDPH enforcement authority under the Health & Safety Code, Division 2.

IV. Background and Current Regulatory Context

A. Existing Law

- **22 CCR § 70251** defines *Radiological Service* as “the organizational unit and its assigned personnel responsible for diagnostic or therapeutic uses of X-ray, other forms of radiant energy, or sealed or unsealed radioactive materials.”
- **Health & Safety Code §§ 1275 et seq.** authorize CDPH to promulgate regulations governing hospital services to ensure safe and adequate care.

- **Health & Safety Code §§ 114960 et seq.** (Radiation Control Law) and related CDPH Radiologic Health Branch (RHB) regulations govern ionizing radiation (X-ray, nuclear medicine, radiation therapy).
- **Gap:** MRI employs **non-ionizing electromagnetic radiation** (time-varying gradient, radiofrequency, and static magnetic fields) and thus is not explicitly covered by Title 22’s Radiological Service definition or the RHB’s ionizing radiation authority, leaving MRI safety oversight largely voluntary.

B. Need for Amendment

- MRI is now a standard diagnostic modality in California hospitals and outpatient facilities, with more than 35 million MRI exams annually nationwide.
- MRI incidents—including **burns, projectile accidents, hearing injuries, and implant/device malfunctions**—are well-documented by the FDA and CDPH’s own adverse-event investigations.
- Current regulations do not mandate minimum MRI safety requirements or integration into hospitals’ Radiological Service structures, producing inconsistent safety oversight.

V. Proposed Regulatory Text

1. Amendment to § 70251 – Radiological Service (Amended Text)

§ 70251. Radiological Service.

(a) *Definition.*

“Radiological Service” means the organizational unit and its assigned personnel responsible for the diagnostic or therapeutic use of **ionizing or non-ionizing forms of radiant energy**, including but not limited to:

- (1) Diagnostic or therapeutic uses of X-rays, fluoroscopy, computed tomography (CT), or other ionizing radiation;
- (2) Radiation therapy;
- (3) Nuclear or molecular medicine utilizing sealed or unsealed radioactive materials; and
- (4) **Magnetic Resonance (MR) and Magnetic Resonance Imaging (MRI)** systems employing magnetic and radiofrequency fields for diagnostic or interventional purposes.

(b) The Radiological Service shall include written policies and procedures ensuring safe operation of all modalities listed in subsection (a), consistent with manufacturer

specifications, applicable state and federal law, professionally approved standards of safety, and Department regulations.

2. Addition of § 70251.1 – Point-of-Care Safety Standards for Radiologic Modalities (New Section)

§ 70251.1. Point-of-Care Safety Standards for Radiologic Modalities.

(a) Applicability.

This section applies to all radiologic service modalities that, by their operation, may present risk of harm to patients, healthcare workers, or the public, including but not limited to X-ray-based modalities, radiation therapy, nuclear or molecular medicine, and Magnetic Resonance Imaging (MRI).

(b) Safety Oversight.

Each facility providing radiologic services under § 70251 shall:

(1) Designate a qualified **Modality Safety Officer** responsible for point-of-care safety for each modality (e.g., Radiation Safety Officer for ionizing radiation, MRI Safety Officer for MRI);

(2) Maintain written **Modality-Specific Safety Policies and Procedures**, including screening, incident response, and emergency protocols;

(3) Conduct **annual safety training** for all personnel with access to controlled areas;

(4) Maintain **incident reporting and corrective-action procedures** for patient or staff injuries or near-miss events;

(5) Perform **environmental and equipment safety audits** consistent with manufacturer guidance and industry standards of care, such as:

(A) the American College of Radiology (ACR) *Manual on MR Safety (2024)* for MRI; and

(B) applicable National Council on Radiation Protection and Measurements (NCRP) reports for ionizing modalities.

(c) Point-of-Care Risk Management.

Facilities shall implement safety controls commensurate with each modality's hazard profile, addressing risks such as:

(1) Thermal and radiofrequency burns;

(2) Magnetic projectile hazards;

(3) Acoustic exposure;

(4) Ionizing radiation dose management;

(5) Exposure to sealed or unsealed radioactive materials; and

(6) Equipment malfunction or shielding failure.

(d) *Compliance and Enforcement.*

Failure to maintain the safety structures and practices required by this section constitutes a deficiency under the facility's state license and may result in administrative action under *Health & Safety Code §§ 1280.1–1280.3*.

VI. Expected Benefits

- **Clarity:** Officially defines MRI as a regulated radiologic service under hospital licensing law.
 - **Safety Consistency:** Aligns MRI with X-ray, nuclear medicine, and radiation therapy in requiring point-of-care safety oversight.
 - **Public Protection:** Reduces risk of preventable MRI and radiation-related injuries.
 - **Regulatory Cohesion:** Bridges current gap between CDPH's Radiologic Health Branch (ionizing radiation) and Licensing & Certification oversight (non-ionizing MRI).
-

VII. Editorial & Policy Notes (Not Part of Regulatory Text)

1. **Jurisdictional Coordination:** CDPH's Radiologic Health Branch may need to clarify its authority over non-ionizing radiation. The Licensing & Certification Division could administer MRI standards under hospital licensure authority.
 2. **Facility Burden:** Hospitals already maintain modality safety programs (e.g., Joint Commission, ACR accreditation); the rule would codify existing best practices rather than impose novel burdens.
 3. **Terminology Alignment:** Including “non-ionizing radiant energy” harmonizes with federal FDA and IEC device safety terminology.
 4. **Public Impact:** Codification would enable CDPH enforcement of MRI safety comparable to other radiologic services.
-

VIII. Requested Action

Petitioner respectfully requests that CDPH:

1. Initiate rulemaking under *Gov. Code §§ 11346 et seq.* to amend 22 CCR § 70251 as proposed and add new § 70251.1;
2. Publish notice of proposed rulemaking in the California Regulatory Notice Register;
and
3. Convene stakeholder consultation with hospital, imaging, and safety organizations to develop implementation guidance.