MGH MRI Imaging Platform
Research Institute of the McGill University Health Centre
Policy for Safety in Magnetic Resonance

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NOTE: In case of conflict between the English and French versions, the English version shall prevail.

Index

The policy covers the following topics:

1. Policy statement and Commitment to MR safety

This policy of the MGH MRI Platform outlines our commitment to providing a safe environment for staff, researchers, research participants, participants, visitors, and third parties visiting or working in the MGH MRI suite.

Safety is an issue of primary importance to all working in the field of medical imaging. To ensure safety in the practice of MR imaging in the MGH MRI suite, we must integrate a culture of safety in the operation of the platform. The group responsible for oversight of the MGH MRI suite—listed on the cover page of this policy—have adopted a policy for MRI safety. All trained MR personnel are engaged in keeping themselves and others in the facility, safe. The culture of MR safety urges all involved to engage in safe practices in MRI and to openly question activities that may impact safety in the MRI environment.

Our statement on MR safety emphasizes that all staff are responsible for safe operation:

> **As a team, we commit to treating all staff, researchers, research participants, and visitors with courtesy, dignity, and respect. We work together to ensure the safety of staff, researchers, research participants, and visitors while performing exemplary scientific work, research, and education. We are collectively responsible for activities conducted in the MGH MRI suite. We acknowledge and respect the authority of the Scientific Director, the Associate Director, the Platform Manager, the MR Medical Director, and the MR Safety Officer.**

2. Oversight

This policy is approved by an ad hoc committee composed of the following individuals:

- Scientific Director
- Associate Director
- MR Medical Director (if different from others listed)
- MR Safety Officer (if different from others listed)
- MR Platform Manager
- A representative from the platform users

The policy must be reviewed annually.

3. Hazards of Magnetic Resonance

The Magnetic Resonance (MR) environment presents hazards to staff, researchers, and scan participants due to (a) forces due to static magnetic fields, (b) radiofrequency (RF) effects during active imaging, (c) time-varying gradient magnetic fields during imaging, and (d) MR system misuse or malfunction.

a) **The static magnetic field (measured in *tesla*, *i.e.* 3 tesla or 3 T) is always on.** It can rapidly attract ferromagnetic objects into the bore of the MR system. The static field can also rotate ferromagnetic objects to align them with the field orientation, which is a concern chiefly for implanted metallic devices. The field is on at all times, so the associated risks are always present. In addition to forces, the performance of certain devices, whether implanted or external to the participant, can be affected by the static field beyond the point of safe operation and should be kept outside the room. The static field can also produce forces on non-ferromagnetic metallic (*e.g.* aluminium) objects that oppose their movement within the field. This resistive force, also known as Lenz Law force, is not a primary safety concern but will nonetheless be surprising to the user.

b) **Radiofrequency (RF) effects are present only during active imaging**, *i.e.* when images are being collected. These are most hazardous in the bore and are therefore relevant to the safety of the participant being scanned. RF fields can result in inductive heating of human tissue. This is quantified by the specific absorption rate (or SAR) and is monitored and limited by the system. In extreme cases, RF heating can result in burns, which are the most common form of MR safety incidents. The performance of certain devices, whether implanted or external to the participant, can be also affected by RF fields beyond the point of safe operation and should be kept outside the room.

c) **Time-varying magnetic *gradient* fields are used to define location in the image**, and, like the RF fields, these are present only during imaging. The fast switching of these gradient fields produces the loud acoustic noise characteristic of most MR exams. In addition, these quickly varying magnetic fields can result in stimulation of nerves, especially at the periphery (at either end of the bore) where the field variation is greatest. Stimulation can result in a tingling sensation or even muscle stimulation, during certain imaging procedures.

d) **MR systems malfunctions** can include but are not limited to leaks or catastrophic releases of the cryogenic liquid (helium), which can displace oxygen or cause cryogenic burns; electrical malfunctions leading to short-circuits, arcing, and/or fire. **Mis-use of devices** leading to injury can arise from from the moving table or other moving parts, or mis-use of receive coils or peripheral equipment.

4. Safety, Training, and Supervision Guidelines

The guidelines outlined in the American College of Radiology (ACR) Manual on MR Safety (2020) are followed in defining Level 1 and Level 2 MR-safety training and supervision privileges. This policy is constructed from these ARC guidelines.

Special safety guidelines and standard operating procedures will be established by the Platform Manager for the safe use of peripheral devices supplied by the Platform (such as EEG or TSMS), non-standard devices (such as gradient inserts and custom coils) introduced to the MR environment. Standard operating procedures, including safety review will also be required for devices introduced into the MR environment by platform users, under the supervision of the Platform Manager.

5. Risk Management in Magnetic Resonance Imaging

The risks summarized in Section 3 are managed through:

a) zoning of the MRI environment and restricting access to limit preventable incidents from lack of awareness,
b) signage,
c) identification and training of magnetic resonance (MR) personnel,
d) screening of personnel and participants prior to entering the MR environment,
e) screening of devices and objects to be brought into the MR environment,
f) standard operating procedures for systems and devices.

In the North American context, the most recognized resource for safe practice in MR is the ACR Manual on MR Safety (2020). The MGH MRI Platform staff follow these guidelines. Canadian guidelines in MR safety were proposed in 2011 by the Canadian Association of Radiologists, but new internationally accepted guidelines, such as those from the ACR, are more recent.

6. MR Environment Zoning and Access

The suite and surrounding area of the MGH MRI Platform are divided and designated into MR safety zones in accordance with the guidelines of the ACR (2020).

Definitions

Zone I: This includes all areas that are freely accessible to the general public, outside of the MR environment.

Zone II: This area is the interface between the publicly accessible uncontrolled Zone I and the strictly controlled Zone III. It is in Zone II that participant screening is reviewed using the previously completed MR screening questionnaire, and that participant history and participant consent, can be collected.

Zone III: Access to Zone III is strictly physically restricted, and access to Zones III and IV is controlled by, and entirely under the supervision of, Level 2 MR personnel. Individuals can only be granted access to zones III and IV by level II MR personnel after written screening.

Zone IV: Zone IV presents the greatest risk. ACR guidelines define Zone IV as the zone containing the magnet and any areas where a fringe field of 0.5 mT (5 G) extends significantly beyond the walls of the suite.

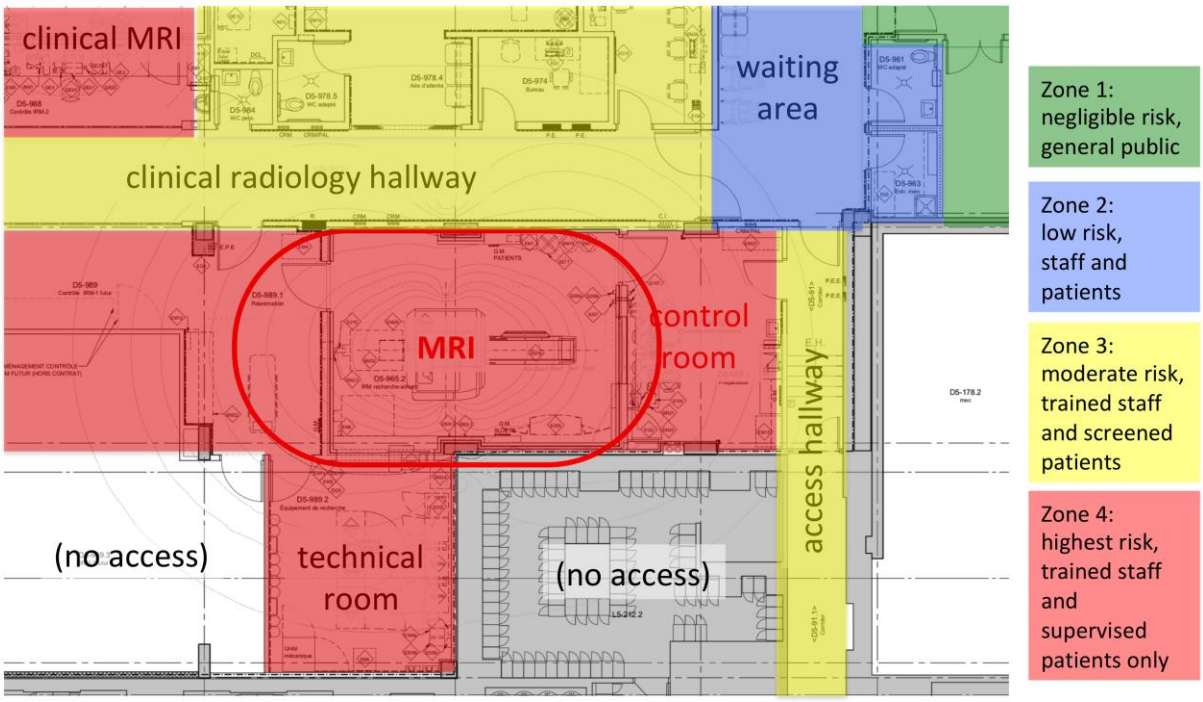
MR Safety Zones of the MGH MRI suite

In our facility, Zone IV includes the magnet room, the control room, the preparation area located at the back of the magnet room, and the technical room (Figure 1). The preparation area the back end of the magnet room has measurable fringe field penetrating through the common wall with the magnet suite, and has direct access to the magnet (via locked door). This area is therefore designated as MR safety Zone IV (highest risk) and signage is present.

Zone III consists of the access hallways and is also a controlled area. Zone III acts as a buffer, providing a safe area for staff to carry out their duties while ensuring that final screening procedures can be appropriately carried out before entering Zone IV. Changing rooms and lockers provided by MUHC Radiology are considered zone III.

Zone II is a monitored area where participants are brought for preparation to enter the MRI suite (Zones III and IV). In our suite, this consists of the waiting area near the MRI suite. Zone I is any area outside of those listed above, open to the public.

Figure 1: *Designated safety zones.*



7. MR personnel and safety training

MR safety is the responsibility of all who work in the MRI suite. ACR guidelines define MR personnel as those who have completed Level 1 (basic) or Level 2 (advanced) safety training. Only staff members who have completed safety training are permitted to work in the facility and to enter zones III and IV unaccompanied. MR personnel for the MGH MRI Platform complete their safety training through the Platform's program. A list of all trained personnel will be documented electronically and stored by the MR Safety Officer. All training and access will be reviewed annually with the MR Safety Officer.

Level 1 training is the minimum required for all staff who participate in technical, research, or clinical duties in the MR suite. Level 1 training is encouraged for researchers and staff who do not have regular duties in MRI. Level 1 MR personnel can move freely in Zones III and IV and are responsible for their own safety. Level 1 staff cannot authorize access to, or supervise non-MR personnel in, Zones III and IV.

Level 2 MR personnel are trained, experienced staff and researchers that are most regularly involved in the MR practice. Level 2 personnel accept an increased level of responsibility: only Level 2 MR personnel are allowed to authorize access to, and to supervise others (especially non-MR personnel) in, the MR suite. The names and contact of all Level 2 personnel shall be posted at the entrance to Zone III.

In addition to training, MR personnel requesting ID-card access to the MGH MRI suite must attend an orientation to the suite and its emergency procedures. Level 1 and 2 staff may be granted ID-card access.

The Scientific Director and Associate Director shall designate an **MR Safety Officer**, who will be a specially-trained Level 2 MR personnel, approved by the safety committee, tasked with overseeing all MR-safety related issues in day-to-day activities in the facility. In the absence of the MR Safety Officer, the MR Safety Officer will designate an acting MR Safety Officer among Level 2 personnel for the designated period and obtain approval in writing from the Scientific Director or Associate Director.

The Scientific Director and Associate Director shall designate an **MR Medical Director**, who shall be a physician approved by the safety committee, and who will review all safety procedures related to medical interventions and emergencies, review research protocols for medical issues, and provide guidance for safe scanning of research participants who present with items listed on the safety screening form. The MR Medical Director will review all protocols that make use of drugs or healthcare interventions within the MGH MRI facility, including injected contrast agents. The MR Medical Director may delegate specific tasks or responsibilities to other platform personnel.

Training must be renewed annually for all MR personnel. Training is conducted by the MR Safety Officer, and a record of trained staff is kept by the MR Safety Officer. Staff must contact the MR Safety Officer to initiate arrangements for MR safety training.

Training is *required* for access but *does not guarantee* access. ID-card access to the suite is detailed in Section 9.

All non-MR personnel who expect to enter Zone III on a regular basis (*e.g.*, staff and researchers from outside the MGH MRI platform) must receive Level 1 training and become MR personnel.

8. Responsibilities and Authority

All MR-personnel who work in the MRI suite have a responsibility of safe practice in the MR environment.

a) Level 1 staff may enter Zones III and IV unsupervised. Level 1 staff may not authorize access to, or supervise non-MR personnel, in Zones III and IV.

b) Level 2 staff can work unsupervised and may grant access to and supervise non-MR personnel in Zones III and IV. Level 2 staff are also responsible for MR screening of non-MR personnel, participants, and visitors.

c) The MR Safety Officer oversees all MR and non-MR personnel working in the MRI suite, and can authorize or deny access to the MRI suite. The MR Safety Officer provides MR safety training and evaluates all requests for ID card access to the MRI suite. Questions or concerns raised by Level 1 or 2 MR personnel regarding an MR screening, must be addressed by the MR Safety Officer.

When the MRI scanner is not in use, Level 2 staff need not be present when Level 1 trained staff undertake quality control, maintenance, or research activities without human participants, on their own or with other Level 1 staff. The training of Level 1 staff allows them to work unsupervised in Zones III and IV.

A safe work environment has been created in the MRI facility because:

- all staff working in the facility must have completed at least Level 1 MR safety training,
- all non-MR personnel are screened before entering and supervised during their time in the MR Platform,
- the physical design of the facility takes MR safety principles into account, and
- the room status checklist that is completed at the beginning of each day includes important safety checks.

9. Security and access

1) Access to the suite will be secured by key card lock (door to Zone III) and key (door to Zone IV). Level 2 personnel are responsible for overseeing access and individuals throughout the suite.

2) At the start and end of all daily activities, MR Level 2 personnel must perform a room status check to look for MR-unsafe objects.

3) At the end of all activities for the day, the facility must be secured by:
   a) locking both doors to the magnet room,
   b) locking the door to the control room,
   c) locking the magnet and control room keys in the lock-box located in Zone III,
   d) ensuring access doors to Zone III are closed.

4) Temporary supervised access to the suite for non MR personnel may only be granted by Level 2 MR personnel, after screening in writing. Visitors, non-MR personnel, and third-party workers must be accompanied at all times by Level 2 MR personnel.

5) MR personnel with at least Level 1 training and who regularly work in the MRI suite may be given ID-card access to the facility by the MR Safety Officer. Requests for unsupervised ID-card access must be made in writing, with a justification related to the staff member's activities in the suite. Requests must be endorsed by the Scientific Director or Associate Director. ID-card access is reviewed annually for all platform staff and researchers. ID card access can be removed from researchers whose training has lapsed or who have had no active studies for more than 6 months.

Access and responsibilities are summarized in

Non-MR **personnel**

All untrained staff, participants, visitors (including family members), and third-party individuals, are considered non-MR personnel. Access to Zone III is restricted to all non-MR personnel and requires prior screening, in writing, by Level 2 MR personnel. They must be accompanied by Level 2 MR personnel throughout their presence in Zones III and IV. Level 1 personnel are not allowed to supervise non-MR personnel in the suite (Zones III and IV). Non-MR personnel requesting to enter Zone IV for reasons other than to participate in studies—such as visitors or service personnel—can only do so under express approval of the MR Safety Officer and must be screened using the participant screening form.

Table 1.

Non-MR personnel

All untrained staff, participants, visitors (including family members), and third-party individuals, are considered non-MR personnel. Access to Zone III is restricted to all non-MR personnel and requires prior screening, in writing, by Level 2 MR personnel. They must be accompanied by Level 2 MR personnel throughout their presence in Zones III and IV. Level 1 personnel are not allowed to supervise non-MR personnel in the suite (Zones III and IV). Non-MR personnel requesting to enter Zone IV for reasons other than to participate in studies—such as visitors or service personnel—can only do so under express approval of the MR Safety Officer and must be screened using the participant screening form.

***Table 1**: MR access and supervisory privileges*

	Level 2 MR personnel	**Level 1 MR personnel**	**Non-MR personnel**
Definition	Those who have extensive training and education in MR safety issues, including, *e.g.*, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients	Those who have passed minimal safety educational training to ensure their own safety as they work within Zones III and IV.	Anyone who has not passed the designated formal training in MR safety within the previous 12 months. Includes participants, service personnel not employed by the Platform, and visitors.
Access	Unsupervised access throughout Zones III and IV. ID-card access is standard.	Unsupervised access throughout Zones III and IV. ID-card access can be requested.	Supervised access only, to Zone III, following MR safety screening by Level 2 MR personnel. Zone IV access only by approval of the Level 2 MR personnel. Non-MR personnel not participating in a specific study must be screened and authorized by the MR Safety Officer.

Supervision privileges	Level 2 MR personnel are permitted to be responsible for accompanying non-MR personnel into and throughout Zones III and IV.	Level 1 MR personnel not are permitted to be responsible for accompanying non-MR personnel into Zones III and IV.	Must be under the immediate supervision of (i.e. in visual or verbal contact with) one specifically identified Level 2 MR person at all times while present in Zones III and IV.
Activity	May operate MRI scanner with appropriate training	May not operate MRI scanner; may assist MR operator	May not operate MRI scanner; may assist MR operator

10. Participant privacy

MRI exams reveal personal information that our participants should not have to share with anyone other than the required personnel. To respect the privacy of our research study participants, the number of individuals in the MRI suite (Zones III and IV) during an exam shall be kept to a reasonable minimum.

MR personnel should not be present in the MRI suite (Zones III and IV) during an active MRI procedure in which they are not involved.

Non-MR personnel shall not be admitted to the MR suite during an active MRI exam in which they are not involved. Exceptions will be made for teaching purposes with the express permission of the MR Safety Officer and of the study principal investigator.

Investigators shall only interact with data from their studies and refrain from inspecting data from studies that are not theirs. This also includes retrieval and export of data by investigators from studies other than their own.

11. Activity in the MGH MRI suite

a) Use of the MGH MRI facility for research purposes is subject to the *Terms of Use Policy of the MGH MRI Facility*.
b) Activities in the MGH MRI suite include training, research activities, and technical service (on the MRI system itself, peripheral systems, or physical plant). For all activities, the safety policies and procedures outlined herein must be followed.
c) Level 2 MR personnel will oversee MR safety in the MRI suite at all times.

d) To ensure safety, all clinical/research/third-parties should work in pairs.
e) All staff who work in the MRI suite must be trained in MRI safety and emergency procedures and will be considered trained if they have completed at least MRI Level 1 safety training.
f) Non-MR personnel (untrained individuals) may not enter the facility unsupervised or be left in the facility unsupervised at any time.
g) Recognizing that, like many technically demanding tasks, operation of the MRI scanner can be involved and complicated work, and distractions can lead to mistakes and wasted time. Care must be taken by all individuals in the MRI suite (Zones III and IV) during research procedures not to disrupt or impede the work of those performing the procedure and operating the MRI system.
h) For third-parties, Level 1 MR safety training must be completed in order to conduct unsupervised activities within the MRI suite. Their work must be approved in advance by the MR Safety Officer.
i) Use of the facility for research purposes is under the direct supervision of the Scientific Director. All research projects must be approved by the Scientific Director.

12. MR Safety Screening

MR personnel (Level 1 and Level 2)

a) All MR personnel must undergo an MR safety screening process in writing to ensure their safety in the MRI suite. The written screening form will be kept on file at the MGH MRI platform. MR personnel who experience physical trauma, a medical procedure, or surgery where an object or device may have been introduced within or on them must be reported to the MR Safety Officer, to enable re-assessment of personal safety.
b) Screening of MR personnel will be performed, at a minimum, at the first MR safety training and reviewed annually.
c) All non-MR personnel wishing to enter Zones III and IV must first complete an MR safety screening in writing. Only MR personnel are authorized to perform an MR safety screen before permitting non-MR personnel into Zones III and IV.
d) The MGH MRI Platform will maintain a detailed policy for screening of MR personnel and non-MR personnel.

Participants

e) Participants in research studies should be screened for MR safety, in writing, by an investigator of the research study before the MRI procedure is booked. The completed screening form must accompany the booking request.
f) For studies with repeat scans, a new written screening is required at every visit of the participant to the MGH MRI facility. The screening form must be signed by the researcher and the participant.
g) The MR Safety Officer will approve the screening form before the participant comes to the facility for the procedure.

h) The participant's screening form must be reviewed verbally on site by Level 2 MR personnel before allowing entry into the MRI facility.
i) A third and final interactive verbal screening must be repeated by Level 2 MR personnel before entering the magnet room.
j) The screening form of each participant scanned at the MGH MRI platform will be retained by the facility. These contain identifying information and therefore will be kept in a secure location.

Visitors
k) All non-MR personnel who are not screened participants are considered visitors.
l) All visitors to the MGH MRI facility must be screened by Level 2 MR personnel. Permission to bring visitors into the suite must be obtained in writing from the MR Safety Officer. The MR Safety Officer must be notified in writing of all visitors to the suite.

13. Devices

a) All devices entering the MRI magnet room (Zone IV) must be screened and approved as “MRI-SAFE” or “MRI-CONDITIONAL” by the MR Safety Officer, according to the recommendations of the ACR and ASTM guidelines.
b) Devices labeled as “MR-UNSAFE” may enter Zones III and IV only under very specific conditions and only with the express approval in writing of the MR Safety Officer. Such operations will be supervised by the MR Safety Officer.
c) All MR personnel working in the facility are collectively responsible for controlling the movement of MR conditional and MR unsafe objects in Zones III and IV. The entry and exit of these objects must be accounted for by the MR personnel who bring the object or device into Zones III and IV.
d) All objects entering Zone III will be assessed by the MR Safety Officer. Devices to be used in the MRI magnet room (within zone IV) must be labeled with the following:
    - MR Safe, MR Conditional, or MR Unsafe
    - Date of assessment
    - If the device is damaged or modified, the MR Safety Officer or delegate must be informed immediately.
    - The MR Safety Officer will keep a list of approved devices with date of approval.
e) Standard operating procedures will be maintained for all devices introduced to the MR environment by the platform for the benefit of its users, as determined by the Platform Manager.
f) Standard operating procedures will be maintained for all non-standard devices introduced to the MR environment for specific studies, as assessed by the Platform Manager.

14. Incident Reporting

a) An **Incident** is an unexpected, unusual, or unplanned occurrence or near-miss involving the MRI (including the control room, technical room, waiting and preparation areas), including ferromagnetic objects inadvertently brought in the suite.
b) All MRI safety incidents must be reported in writing by email to the MR Safety Officer as soon as the situation is stable enough to do so. The MR Safety Officer will keep records on all reported incidents.
c) The MR Safety Office will report incidents to RI-MUHC Environmental Health and Safety according to the procedure outlined on the RI Portal.
d) Preventative measures will be prescribed by the MR Safety Officer.
e) Incidents that result in harm to participants and/or visitors must be reported to the Director, the Associate Director, and to the MRI Platform Manager in writing by email.

15. Workflow

a) The MRI facility was designed with the intention of performing MRI exams and experiments for research purposes. Workflows in the facility are developed by research teams in conjunction with the MR Platform Manager.
b) Specifically, any object or device that is needed inside the MR room must be assessed prior to use by the MR Safety Officer. Once approved, the device must reside inside the MR room for the duration of the study—it is NOT to be taken in and out of the MR room. Exemptions may be granted on a case-by-case basis by the MR Safety Officer only.
c) New MRI protocols or changes to existing MRI protocol that involve a device must first be approved by the MR Safety Committee prior to use of the device. Such devices may not have the appropriate safety certification and the MR Safety Committee is uniquely qualified to evaluate the safety and certification of such devices. All changes to research protocols should also consider any expectations and rules of the Research Ethics Board.

16. Specific policies and procedures

a) Procedures for emergency situations, such as system failures, medical emergencies, and general emergencies will be developed and maintained the MR Safety Officer, and approved by the MRMD, Scientific Director, and Associate Director. These will be reviewed annually in conjunction with this policy. See the *Policy on Emergencies and Technical Support*.
b) Individual procedures or policies to be maintained include:

1) Magnet quench
2) Medical emergency including cardio-respiratory emergency (Code blue)
3) Safety of high-risk participants
4) Safety of participants who are pregnant, potentially pregnant, or breastfeeding.
5) Daily system checks

References

American College of Radiology (ACR) *Manual on MR Safety* (2020). https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf (retrieved 2023-05-11)