



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

DATE: September 28, 2020
TO: State Survey Agency Directors
FROM: Director
Quality, Safety & Oversight Group

Ref: QSO-20-41-ALL
REVISED 06.21.2021
REVISED 05.26.2022

SUBJECT: Guidance related to Emergency Preparedness- Exercise Exemption based on A Facility's Activation of their Emergency Plan

**** Revised to provide additional guidance and clarifications due to the ongoing COVID-19 public health emergency (PHE) ****

Memorandum Summary

- ***Emergency Preparedness Training and Testing Program Exemption*** - CMS regulations for Emergency Preparedness (EP) require facilities to conduct exercises to test the facility's EP plan to ensure that it works and that staff are trained appropriately about their roles and the facility's processes. During or after an actual emergency, the regulations allow for a one-year exemption from the requirement that the facility perform testing exercises.
- This worksheet presents guidance for surveyors, as well as providers and suppliers, with assessing a facility's compliance with the EP requirements, in light of many of the response activities associated with the COVID-19 Public Health Emergency (PHE).
- As the PHE continues, many facilities continue to operate under their respective activated emergency plans. Therefore, CMS is providing additional guidance related to the exercise requirements (full-scale/functional drills and exercises) for **inpatient and outpatient providers/suppliers**.
- This exemption only applies to the next required full-scale exercise (not the exercise of choice), based on the facility's 12-month exercise cycle. The cycle is determined by the facility (e.g. calendar, fiscal or another 12-month timeframe).

Background

On September 30, 2019, the Centers for Medicare & Medicaid Services (CMS) published the *Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care* [Final Rule](#) (84 FR 51732) which revised the requirements for emergency preparedness. Revisions in the Final Rule include:

- CMS removed the requirements for facilities to document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and for facilities to document their participation in collaborative and cooperative planning efforts;
- CMS revised cycles for review and updates requirements to the emergency preparedness program. Specifically, all applicable providers and suppliers review their emergency program biennially, except for Long Term Care (LTC) facilities, which will still be required to review their emergency program annually.
- CMS revised training program requirements, specifically, that facilities develop and maintain a training program based on the facility's emergency plan annually by requiring facilities to provide training biennially (every two years) after facilities conduct initial training for their emergency program, except for LTC facilities, which will still be required to provide training annually. However, additional training is required when the emergency plan is significantly updated.

Additionally, the Final Rule revised the emergency preparedness testing exercise requirements. As discussed below, the regulations allow for an exemption to the testing requirements during or after an actual emergency. If a provider experiences an actual natural or man-made emergency that requires activation of their emergency plan, inpatient and outpatient providers will be exempt from their next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the actual event. In light of the PHE, CMS is clarifying the testing exercise requirements to ensure that surveyors and providers, and suppliers are aware of the exemption available based on the activation of their emergency plans.

Testing Exercise Definitions:

CMS defines the testing exercises required under the emergency preparedness regulations in two categories. Specifically, 1) full-scale, functional, and individual-facility-based exercises as the "required" exercises; and 2) mock disaster drills, table-top exercises, or workshops as the "exercises of choice," which could also include the full-scale functional and individual-facility based exercises. CMS further defines the exercises as follows:

Full-Scale Exercise (FSE): A full scale exercise is an operations-based exercise that typically involves multiple agencies, jurisdictions, and disciplines performing functional (for example, joint field office, emergency operation centers, etc.) and integration of operational elements involved in the response to a disaster event, i.e. "boots on the ground" response activities (for example, hospital staff treating mock patients).

Functional Exercise (FE): "FEs are designed to validate and evaluate capabilities, multiple functions and/or sub-functions, or interdependent groups of functions. FE's are typically focused on exercising plans, policies, procedures, and staff members involved in management, direction, command, and control functions" as defined by DHS's Homeland Security Exercise and Evaluation Program (HSEEP).

Mock Disaster Drill (Exercise of Choice Only): A drill is a coordinated, supervised activity usually employed to validate a specific function or capability in a single agency or organization. Drills are commonly used to provide training on new equipment, validate

procedures, or practice and maintain current skills. For example, drills may be appropriate for establishing a community- designated disaster-receiving center or shelter. Drills can also be used to determine if plans can be executed as designed, to assess whether more training is required, or to reinforce best practices. A drill is useful as a stand-alone tool, but a series of drills can be used to prepare several organizations to collaborate in an FSE.

Table-top Exercise (TTX) (Exercise of Choice Only): A table-top exercise involves key personnel discussing simulated scenarios in an informal setting. TTXs can be used to assess plans, policies, and procedures. A table-top exercise is a discussion-based exercise that involves senior staff, elected or appointed officials, and other key decision making personnel in a group discussion centered on a hypothetical scenario. TTXs can be used to assess plans, policies, and procedures without deploying resources.

Workshop (Exercise of Choice Only): A workshop, for the purposes of this guidance, is a planning meeting/workshop, which establishes the strategy and structure for an exercise program as defined in HSEEP guidelines.

Changes Specific to Testing Exercise Requirements

For providers of inpatient services: The testing exercises were expanded to include workshops as an exercise of choice. However these providers are still required to conduct two emergency preparedness testing exercises annually.

Inpatient providers and suppliers include: Inpatient hospice facilities, Psychiatric Residential Treatment Facilities (PRTFs), hospitals, long-term care (LTCs) facilities, Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IIDs), and Critical Access Hospitals (CAHs).

For providers of outpatient services: These providers must continue to test their program annually, by participating in a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise every other year. In the opposite years off the full- scale exercise, the providers are required to conduct a testing exercise of their choice, which may include either a community-based full-scale exercise (if available), an individual, facility-based functional exercise, a drill, or a table-top exercise or workshop that includes a group discussion led by a facilitator.

Outpatient providers and suppliers include: Ambulatory Surgical Centers (ASCs), freestanding/home-based hospice, Program for the All-Inclusive Care for the Elderly (PACE), Home Health Agencies (HHAs), Comprehensive Outpatient Rehabilitation Facilities (CORFs), Organizations (which include Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services), Community Mental Health Clinics (CMHCs), Organ Procurement Organizations (OPOs), Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), and End-Stage Renal Disease (ESRD) facilities.

Exemption Based on Actual Natural or Man-made Emergency

The emergency preparedness regulations allow an exemption for providers or suppliers that experience a natural or man-made event requiring activation of their emergency plan. On Friday, March 13, 2020, the President declared a national emergency due to COVID-19 and subsequently many providers and suppliers have activated their emergency plans in order to address surge and coordinate response activities. **Facilities that activate their emergency plans are exempt from the next required full-scale community-based or individual, facility-based functional exercise.** Facilities must be able to demonstrate, through written documentation, that they activated their program due to the emergency.

CMS requires facilities to conduct an exercise of choice annually for inpatient providers and every two years for outpatient providers (opposite the year of the full-scale or facility-based functional exercise). For the "exercise of choice," facilities must conduct one of the testing exercises below:

- Another full-scale exercise;
- Individual-facility-based functional exercise;
- Mock disaster drill; or
- A table-top exercise or workshop.

Facilities may choose to conduct a table-top exercise (TTX) which could assess the facility's response to COVID-19. This may include but is not limited to, discussions surrounding availability of personal protective equipment (PPE); isolation and quarantine areas for screening patients; or any other activities implemented during the activation of the emergency plan. The emergency preparedness provisions require that facilities assess and update their emergency program as needed.

Therefore, lessons learned and challenges identified in the TTX may allow a facility to adjust its plans accordingly.

CMS recognizes many facilities are still operating under disaster/emergency conditions during the PHE, i.e., under an activated emergency plan. We are therefore providing additional guidance for inpatient *and outpatient* providers/suppliers, consistent with the exemption authorized by the EP regulations. This exemption applies to the next required full-scale exercise only, not the exercise of choice, based on the facility's 12-month exercise cycle. The exercise cycle is determined by the facility (e.g. calendar year, fiscal year or another 12-month timeframe).

The updated guidance only applies if a facility is still currently operating under its activated emergency plan *or reactivated its emergency plan for COVID-19 in 2021 or 2022*. Facilities which have resumed normal operating status (not under their activated emergency plans) *are required to conduct their testing exercises based on the regulatory requirements for their specific provider or supplier type. This guidance provides clarifications on testing exemptions for those providers/suppliers who continue to operate under their activated emergency plan and those which may have reactivated their emergency plans for COVID-19. This guidance will also apply for any subsequent 12-month cycles in the future, in the event facilities continue to operate under their activated emergency plans for COVID-19 response activities.*

For Inpatient Providers and Suppliers: If the facility is still operating under its currently activated emergency plan *during its specified 12-month cycle of testing exercises*, any currently-activated emergency plan will be recognized by surveyors as having met the full-scale exercise requirement for *that 12-month cycle*.

If the facility claimed the full-scale exercise exemption in 2020 *and 2021* based on its activated emergency plan *for COVID-19 response* and has since resumed normal operating status, the inpatient provider/supplier is expected to complete its required full-scale exercise, unless it has reactivated its emergency plan for an actual emergency during its 12-month cycle for 2022.

For Outpatient Providers: *If the facility claimed the full-scale exercise exemption in 2020 based on its activated emergency plan for COVID-19 response and has since resumed normal operating status, the outpatient provider/supplier is expected to complete its required full-scale exercise in 2022, unless it has reactivated its emergency plan for an actual emergency during its 12-month cycle for 2022. If the facility claimed the full-scale exercise exemption in 2021 based on its activated emergency plan for COVID-19 response and has since resumed normal operating status, the outpatient provider/supplier is expected to complete its required full-scale exercise in 2024.*

Individual Facility-Based Exercises & Important Reminders

Testing exemptions apply only for the next-full scale exercises, not any exercises of choice. Facilities are expected to continue to conduct all exercises of choice. Additionally, while facilities may be continuing to operate under an activated emergency plan for COVID-19 response, we encourage facilities to consider conducting their individual facility-based exercises, if possible. As noted in Appendix Z of the SOM, individual facility-based exercises are specific to a facility and its geographic location; dependent patient/resident/client and community population; facility type and potential surrounding community assets -- i.e., rural area versus a large metropolitan area; and do not require state emergency officials to participate. We encourage facilities to conduct these exercises to ensure maintaining a high level of preparedness based on the risks identified and to ensure patient safety in emergency events.

While facilities may claim the exemption if operating under an activated emergency plan, CMS encourages facilities to conduct full-scale or individual facility-based exercises in order to ensure facilities are fully prepared to respond to all emergencies, should they arise.

We also note that some facilities may be operating under an activated emergency plan for the COVID-19 PHE and are required to activate additional plans or procedures based on another disaster or emergency such as inclement weather. Full-scale exemptions due to an actual disaster are based on any activation of the emergency plan during the facility's 12-month cycle. Exemptions do not accumulate or carry over to following full-scale exercises. For example, if a facility was required by their testing cycle to conduct a full-scale exercise in 2022, but is operating under their activated emergency plan in January 2022 for COVID-19 response and faces a winter storm/wildfire, etc. and activates additional protocols under its plan, the exemption for a full-scale exercise will apply to their full-scale exemption in 2022. It would not carry over because the facility was faced with two separate emergency activations.

Conducting Assessments & Documentation

As a reminder, all providers and suppliers must continue to analyze their facility's response to and maintain documentation of all drills, table-top exercises, and activation of their emergency plan. This would include documentation showing any revisions to the facility's emergency plan as a result of the after-action review process.

Further, we note, CMS released the revised State Operations Manual, Appendix Z on March 26, 2021, which is located at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_z_emergprep.pdf

Contact: Questions about this memorandum should be addressed to QSOG_EmergencyPrep@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated to all survey and certification staff, their managers and the State/Regional Office training coordinators immediately.

/s/
David R. Wright

Attachment (s)- Revised Emergency Preparedness Surveyor Worksheet

cc: Survey and Operations Group Management

Emergency Preparedness Surveyor Worksheet Requirements for Surveying for Testing Exercises Standard (d)(2) Exemptions

Purpose: This worksheet presents guidance relevant to determining compliance with the testing exemption following activation of emergency plans during actual emergency events. We note that the testing requirements changed for inpatient and outpatient providers with the *Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care* Final Rule published on September 30, 2019 (<https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf>).

Requirement for Outpatient Providers

Requirement & Guidance: Outpatient providers must conduct a full-scale exercise (or individual facility-based exercise when a full-scale is not available) every 2 years pursuant to standard (d)(2) of their respective "Emergency Preparedness" regulation and in opposite years conduct any one of the "exercises of choice," which include another full-scale or individual facility-based functional exercise, table top exercise, workshop, or mock drill.

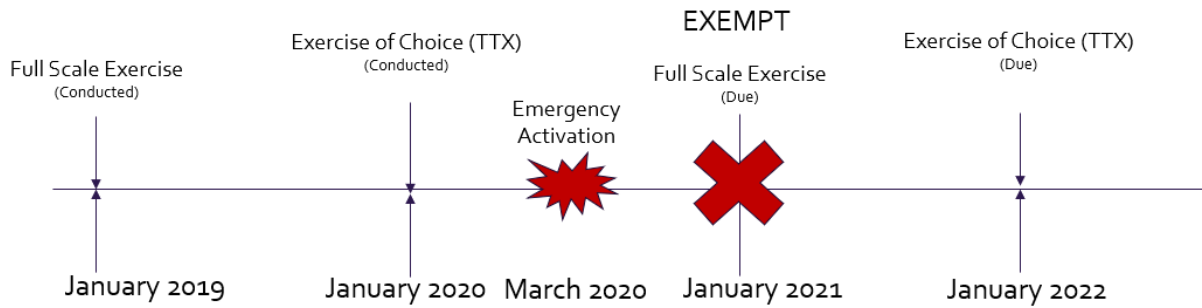
The Exemption Clause: In the event a facility activates its emergency plan due to an actual emergency, the outpatient provider would be exempt from engaging in its **next required community-based full-scale exercise or individual facility-based functional exercise following the onset of the emergency event.** Facilities must be able to demonstrate, through written documentation, that they activated their emergency plan.

Outpatient Provider Scenarios

Scenario #1. Facility X conducted a full-scale exercise in January 2019 and a table-top exercise for January 2020 (opposite year). In March 2020, Facility X activates its emergency preparedness plan due to the COVID-19 Public Health Emergency (PHE).

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

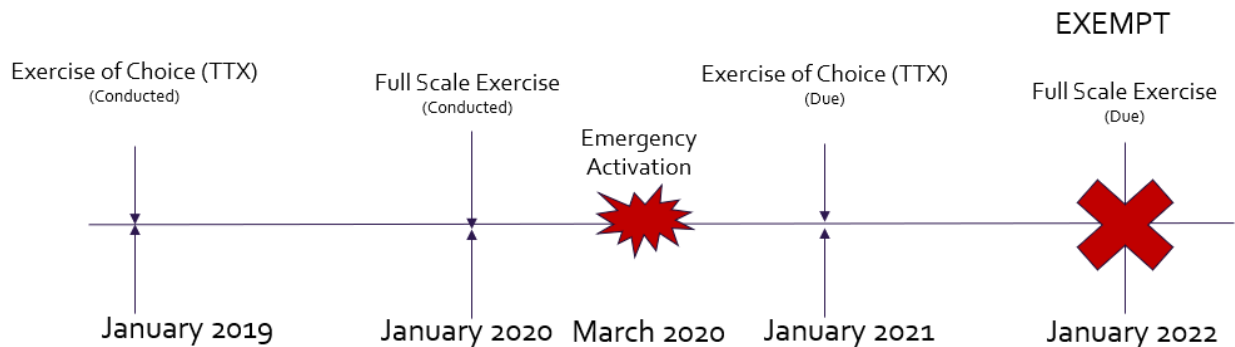
Answer: The facility is exempt from the next scheduled exercise (January 2021 full-scale exercise). It would then be required to complete their opposite year exercise of choice by January 2022.



Scenario #2. Facility Y conducted a table top exercise in January 2019 as the exercise of choice and conducted a full-scale exercise in January 2020. In March 2020, Facility Y activates its emergency preparedness program due to the COVID-19 PHE.

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

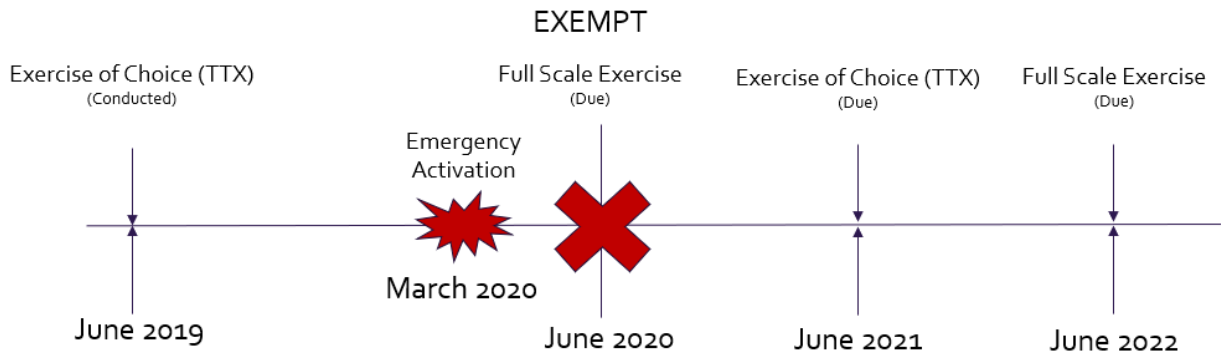
Answer: The facility is exempt from the January 2022 full-scale exercise for that "annual year". However, the facility must conduct its exercise of choice by January 2021, and again in January 2023.



Scenario #3. Facility Z conducted a table-top exercise in June 2019 (based on its annual cycle). It is scheduled to conduct a full-scale exercise in June 2020. In March 2020, Facility Z activates its emergency preparedness program due to the COVID-19 PHE.

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

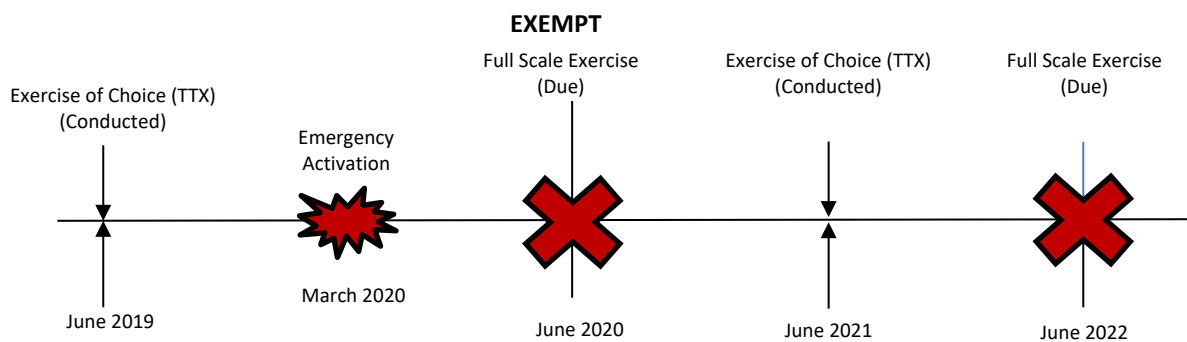
Answer: The facility is exempt from the June 2020 scheduled full-scale exercise for that "annual year" and is required to complete an exercise of choice in June 2021, and a following full-scale exercise in June 2022. It is exempt from its **next required** full-scale or individual facility-based exercise which would have been in June 2020.



Scenario #4. Facility Z conducted a table-top exercise in June 2019 (based on its annual cycle). It is scheduled to conduct a full-scale exercise in June 2020. In March 2020, Facility Z activates its emergency preparedness program due to the COVID-19 PHE. The facility conducts its required exercise of choice in June 2021. As of March 2022, the facility continued to operate under an activated emergency plan.

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

Answer: The facility is exempt from the June 2020 scheduled full-scale exercise for that "annual year" and is required to complete an exercise of choice in June 2021, and a following full-scale exercise in June 2022. It is exempt from its **next required** full-scale or individual facility-based exercise which would have been in June 2020. However, since the facility is continuing to operate under its activated emergency plan in early 2022, the facility is exempt from the full-scale exercise in June 2022.



Survey Steps for Determining Use of the Exemption Clause:

- Determine the facility's annual cycle.
- For outpatient providers, ensure the facility has conducted one full-scale/functional exercise within the 12-month period followed by an exercise of choice on opposite years, dependent on the scenarios above.
- Ask the facility to describe the exemption to ensure understanding that exemption is based on the scheduled next-required full-scale exercise, not the exercise of choice.

- Verify documentation evidence that the facility activated its emergency plan (in order to determine whether the testing exemption is acceptable for use). Documentation may include, but is not limited to, the following:
 - Notice of activation to staff via electronic systems (alerts);
 - Proof of patient transfers and changes in daily operations based on the emergency;
 - Initiation of additional safety protocols, for example, mandate for use of personal protective equipment (PPE) for staff, visitors and patients as applicable;
 - Coordination with state and local emergency officials;
 - Minutes of board/facility meetings;
 - 1135 Waiver (individual or use of blanket flexibilities); or,
 - Incident command system related reports, such as situation reports or incident action plans.
- Determine, based on the above examples, whether the facility is compliant with the exemption clause and has conducted the appropriate required exercises.

Requirement for Inpatient Providers

Requirement & Guidance: Inpatient providers must conduct a full-scale exercise (or individual facility-based exercise when a full-scale is not available) annually pursuant to standard (d)(2) of their respective "Emergency Preparedness" regulation, and also conduct any one exercise of the "exercises of choice" which include another full-scale or individual facility-based exercise, table top exercise, workshop or mock drill annually.

The Exemption Clause: In the event a facility activates its emergency program due to an actual emergency, the inpatient provider would be exempt from engaging in its **next required** community-based full-scale exercise or individual facility-based exercise following the onset of the emergency event. Facilities must be able to demonstrate through written documentation, that they activated their program due to the emergency.

Inpatient Provider Scenarios

Scenario #1. Facility X conducted a full-scale exercise in January 2019 and a table-top exercise as their exercise of choice in November 2019. It also conducted another full-scale exercise in January 2020, and is scheduled to conduct its workshop in November 2020. In March 2020, Facility X activates its emergency preparedness program due to the COVID-19 Public Health Emergency (PHE). *The facility has resumed normal operating status and is no longer under an activated emergency plan as of December 2021.*

When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

Answer: Since the facility already conducted its full-scale requirement for 2020, it is only required to conduct the scheduled workshop for November 2020. The facility is exempt from its next required full-scale, in January 2021. However, the facility *was expected to* complete an exercise of choice by November 2021. *Since the facility is no longer operating under its activated emergency plan, the facility would resume its normal cycle. The facility would conduct its next full-scale exercise in January 2022 and an exercise of choice in November 2022.*

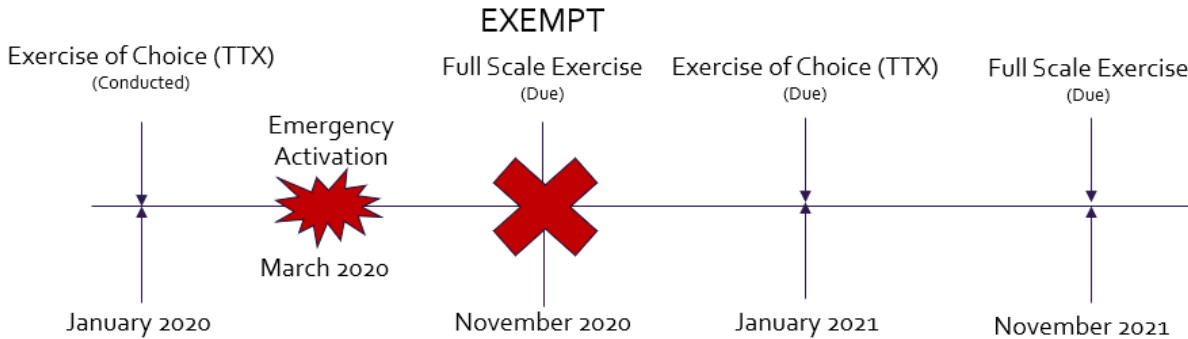


Scenario #2. Facility Y conducted a table-top exercise in January 2020 as the exercise of choice and is scheduled to conduct its full-scale exercise in November 2020. In March 2020, Facility Y activates its emergency preparedness program due to the COVID-19 PHE. *As of 2021, the facility has returned to normal operating status (e.g. no longer operating under an activated emergency*

program).

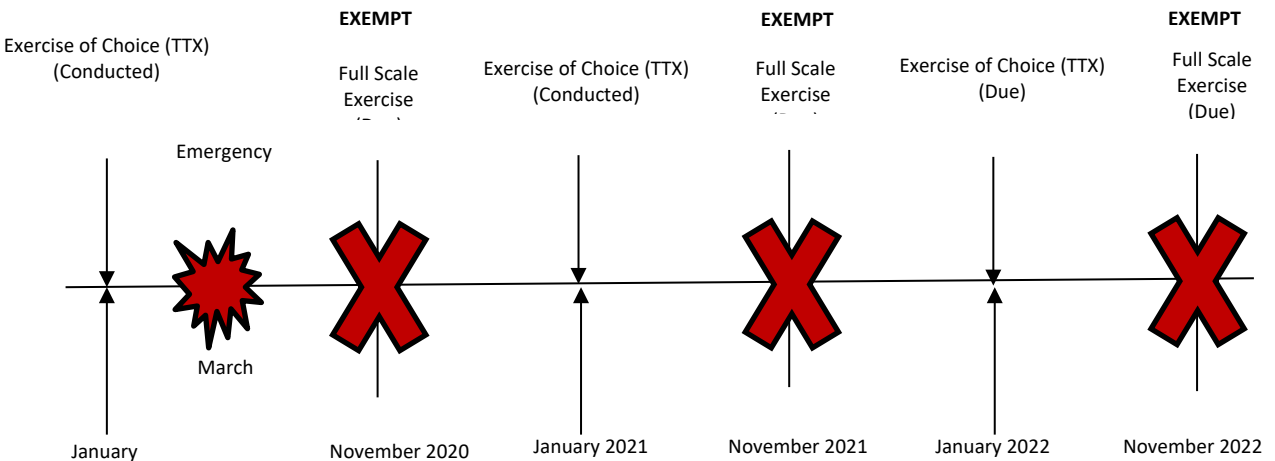
When must the facility conduct its next required full-scale exercise? What is the exemption based on the requirements?

Answer: The facility is exempt from the November 2020 scheduled full-scale exercise for that "annual year". However, the facility must conduct both the full-scale and exercise of choice in 2021 based on its defined cycle (January 2021 and November 2021). *Since the facility resumed normal operations, the facility is required to conduct the full-scale exercise in November 2021, and the exercise of choice in January 2022.*



Scenario #3. *Facility Y conducted a table-top exercise in January 2020 as their exercise of choice and was exempt from its scheduled full-scale exercise in November 2020 due to the activation of its emergency plan as a result of the COVID-19 PHE (that began in March 2020). The facility continues to operate under its activated emergency plan during its 2021 exercise cycle (due to continued surge of COVID-19 in their local area).*

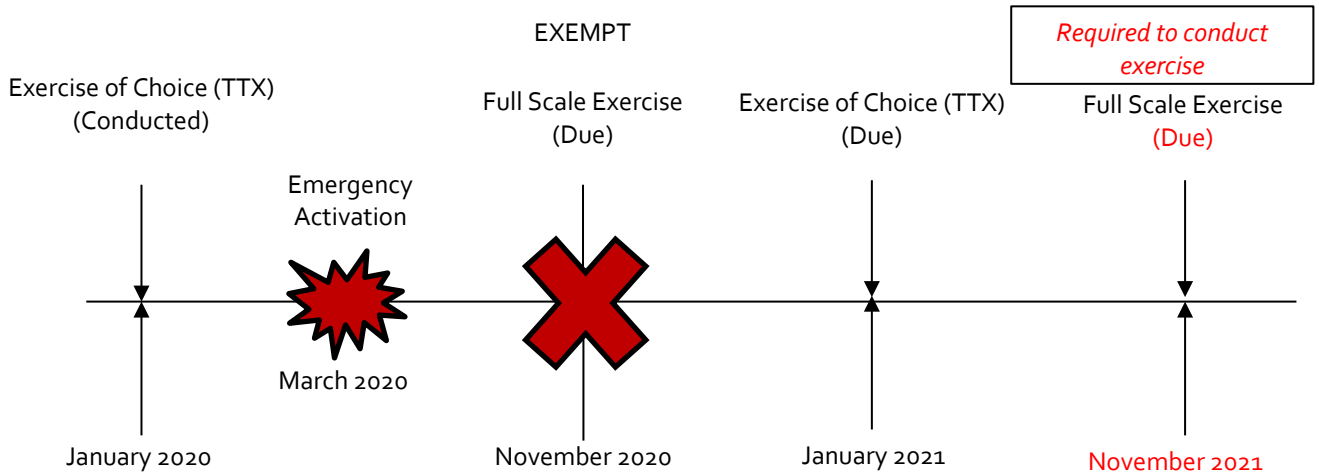
When must the facility conduct its next required full-scale exercise?



Answer: *If the facility is still operating under its activated emergency plan, any currently-activated emergency plan will be recognized by surveyors as having met the full-scale exercise requirement for 2021 and 2022. The facility would continue to conduct its exercises of choice in January 2021 and January 2022.*

Scenario #4. Facility Y conducted a table-top exercise in January 2020 as the exercise of choice and was exempt from its scheduled full-scale exercise in November 2020 due to the activation of its emergency plan as a result of the COVID-19 PHE (that began in March 2020). The facility resumed normal operations in March 2021 and is no longer operating under activation of its emergency plan.

When must the facility conduct its next required full-scale exercise?



Answer: Since the facility is no longer under its activated emergency plan and did not reactivate its emergency plan during that same 12-month cycle, the facility is required to conduct its next full-scale exercise or individual facility-based exercise when it is due. The facility would be required to resume the 12-month exercise cycle and the next required full-scale exercise would be due in November 2021 in this example. In the event the facility reactivated its emergency plan in 2022 for the COVID-19 PHE or any other emergency or disaster, the facility would be exempt from the November 2022 full-scale exercise, but would need to conduct the exercise of choice in January 2022.

Survey Steps for Determining Use of the Exemption Clause:

- Determine the facility's annual cycle.
- For inpatient providers, ensure the facility has conducted two required exercises within the 12-month period, dependent on the scenarios above. *Since the COVID-19 PHE is ongoing (over a 12-month period), CMS is clarifying that the inpatient provider/supplier is exempt from the 2021 and 2022 full-scale exercises so long as it is still currently operating under an activated emergency plan or has reactivated its plan at the onset of its 12-month cycle period (exercise cycle).*
- Ask the facility to describe the exemption to ensure understanding that exemption is based on the scheduled next-required full-scale exercise, not the exercise of choice.
- Verify documentation evidence that the facility activated its emergency plan in order to determine whether the testing exemption is acceptable for use. Documentation may include, but is not limited to, the following:
 - Notice of activation to staff via electronic systems (alerts);

- Proof of patient transfers and changes in daily operations based on the emergency;
 - Initiation of additional safety protocols, for example, mandate for use of personal protective equipment (PPE) for staff, visitors and patients as applicable;
 - Coordination with state and local emergency officials;
 - Minutes of board/facility meetings;
 - 1135 Waiver (individual or use of blanket flexibilities); or,
 - Incident command system related reports, such as situation reports or incident action plans.
- Determine based on the above examples, whether the facility is compliant with the exemption clause and has conducted the appropriate required exercises.