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Documentation Requirements/ Plans

Q: Can continuity of operations, delegations of authority, succession planning be included in the Emergency Operations Plan, or do you expect to see separate plans?

A: We are not requiring a specific format for how a facility should have their Emergency Plans documented and in which order. Upon survey, a facility must be able to provide documentation of these requirements in the plan and show where the plans are located.

Q: For formatting of the documentation, the standard state policies & procedures are required. Our documents are structured as an Emergency Operations Plan with addendums. Is this allowable?

A: We are not requiring a specific format for the manner in which a facility should have their Emergency Plans documented. Upon survey, a facility must be able to provide documentation of the policies and procedures and show surveyors where the policies and procedures are located.

Q: There are repeated references in the rule to business continuity, business resilience and continuity of operations, but not much clarity is provided as to how the rule differentiates these things or specific requirements. Can you provide more detail as to what will be surveyed?

A: We did not find any references to the term "business resilience" in the final rule. B*usiness continuity* and *continuity of operations* have the same meaning in the context of this rule.

The Assistant Secretary for Preparedness and Response has developed a document that includes information to assist facilities in planning for continuity of operations. The document may be found at: http://www.phe.gov/Preparedness/planning/hpp/reports/Documents/hc-coop2-recovery.pdf

Q: How does this regulation affect facilities participating in the Hospital Preparedness Program (HPP)?

A: The regulation does not affect providers and suppliers participating in the HPP. There is no relationship between the HPP and the regulation, as HPP works with the Health Care Coalitions (HCC) and State Departments. The Assistant Secretary for Preparedness and Response (ASPR) administers the HPP which provides leadership and funding through grants and cooperative agreements to states, territories, and eligible municipalities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. For additional information, please contact ASPR's Technical Resources, Assistance Center, and Information Exchange (TRACIE) at askasprtracie@hhs.gov.

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Q: CMS does not require an approved emergency preparedness plan from the local emergency official but must show coordination with local emergency management officials. What level of coordination will be considered acceptable for the facility emergency plan approval? Will a facility only need an approval for their emergency plan from the CMS servicing agency?

A: Providers and suppliers must document efforts made by the facility to cooperate and collaborate with emergency preparedness officials. While we are aware that the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the rule states that providers and suppliers must document efforts made by the facility to cooperate and collaborate with emergency preparedness officials. Since some aspects of collaborating with various levels of government entities may be beyond the control of the provider/supplier, we have stated that these facilities must include in their emergency plan a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials. We also encourage providers and suppliers to engage and collaborate with their local HCC, which commonly includes the health department, emergency management, first responders, and other emergency preparedness professionals. Facilities are required to coordinate with local management officials, such as with their communication plans. For instance, facilities are required to have documentation of their efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts. Facilities are required to have contact information for emergency officials and who they should contact in emergency events; maintain an emergency preparedness communication plan that complies with both federal and state law; and be able to demonstrate collaboration through the full-scale exercises. We are not requiring official "sign-off" from local emergency management officials; however, if the state requires this action, we would expect that facilities comply with their state laws.

Q: In the past, new facilities seeking licensure needed an approved Comprehensive Emergency Management Plan from local officials. Who will review and approve plans for new facilities in order for them to obtain their licensure?

A: We cannot address how the new regulation will affect state licensure laws. Facilities should contact their state licensing agencies for clarification.

Q: What is the regulation's definition or intent behind the word "community"?

A: We did not define ''community'', to afford providers the flexibility to develop disaster drills and exercises that are realistic and reflect their risk assessments. However, the term could mean entities within a state or multi-state region. The goal of the provision is to ensure that healthcare providers collaborate with other entities within a given community to promote an integrated response. In the proposed rule, we indicated that we expected hospitals and other providers to participate in healthcare coalitions in their area for additional assistance in effectively meeting this requirement. Conducting exercises at the healthcare coalition level could help to reduce the administrative burden on individual healthcare facilities and demonstrate the value of connecting

into the broader medical response community, as well as the local health and emergency management agencies, during emergency preparedness planning and response activities.

Survey Process Requirements

Q. Which agencies will be involved in monitoring compliance? Will monitoring for compliance include State and/or local health officials and emergency management? Are there ways to coordinate monitoring and compliance with local Health/Emergency Management Officials? Will CMS ask local Health/Emergency officials to sign-off (or at least be involved in the process) verifying that these organizations have met the requirements or at least involved in the process of signing-off on?

A: The State Survey Agencies (SA), Accreditation Organizations (AOs), and CMS Regional Offices (ROs) will be involved in monitoring for compliance as is the case with all other requirements for participation in Medicare. Facilities may choose to work with local health and emergency management officials to review the facility's plan to meet local requirements. The facility has the option of choosing to seek approval of its plan from state/local emergency preparedness officials. We do not regulate state and local emergency management officials.

Q: What are the consequences for not meeting these new requirements? Will any leniency be given for organizations that have started this type of planning but didn't complete by November 15, 2017? Will any warnings be issued before any actions taken against a particular organization?

A: Providers/suppliers have one year to implement the emergency preparedness requirements. Surveying for compliance to these requirements will begin in November 15, 2017. There will be no exceptions for the requirements and non-compliance will follow the same process non-compliance with any other Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) for the facility at hand.

Q: Will this be an incentive - penalty such as those associated with Meaningful Use? Will it just be a penalty? How will surveys be conducted? When will we have access to the survey tool?

A: The implementation of this new regulation is not linked to an incentive program. Facilities found to be out of compliance with the requirements will follow the same enforcement process as with any other CoP/CfC that is found to be out of compliance. These new regulations are a condition or requirement to participate in Medicare. We anticipate releasing the Interpretive Guidelines and Survey Procedures in spring of 2017. In the interim, we are posting helpful tools and relevant information on the Survey and Certification Group (SCG) Emergency Preparedness Website to assist facilities in meeting the requirements.

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Q: What process/documentation/resources will SA surveyors use to assure compliance with the various facility types?

A: As always, surveyors will use the Interpretive Guidelines and Survey Procedures in the State Operations Manual (SOM). Surveyors will also be trained on the requirements before implementation.

Accrediting Organizations (AOs)

Q: Could CMS provide a listing to the different Accrediting Organizations?

A: Please see: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf

Q: How are AOs expected to implement the new rule into their programs?

A: AOs will follow the same process for developing standards that will meet or exceed CMS requirements of the new rule.

Q: If an AO already has emergency preparedness standards or emergency preparedness program requirements, how does the new rule affect their current standards?

A: AOs will need to submit their emergency preparedness standards/programs to CMS for review. AOs are required to meet or exceed the CMS CoPs/CfCs requirements; therefore the AOs must demonstrate to CMS that their standards meet or exceed all CMS' new emergency preparedness requirements.

Testing and Training

Q: What does the term "training" encompass? Is the content and the extent of the training at the discretion of the facility?

A: A well organized, effective training program must include initial training for new and existing staff in emergency preparedness policies and procedures as well as annual refresher trainings. The facility must offer annual emergency preparedness training in which staff can demonstrate knowledge of emergency procedures. The facility must also conduct drills and exercises to test the emergency plan to identify gaps and areas for improvement. We expect facilities to delineate responsibilities for all of their facility's workers in their emergency preparedness plans and to determine the appropriate level of training for each professional role. Therefore facilities will have discretion in determining what encompasses appropriate training for the different staff positions/roles.

Q: Please define "all-employees" in the term of being able to demonstrate knowledge of emergency plans and procedures.

A: Employee's or the term ''staff'' refers to all individuals that are employed directly by a facility. The phrase ''individuals providing services under arrangement'' means services furnished under arrangement that are subject to a written contract conforming with the requirements specified in section 1861(w) of the Act. We refer providers back to the regulation text for further information (81 FR. 63891).

Q: What kind of training will be developed specifically for providers and suppliers to prepare for implementation of the rule?

A: CMS does not expect to develop training specifically for providers and suppliers. Healthcare associations and state, local and other Federal healthcare agencies may provide training for providers and suppliers. However, training provided by these organizations is only a tool to assist facilities in preparing for implementation of the rule and does not mean that a provider or supplier is in compliance by having received the training.

Miscellaneous

Q: Does the Final Rule apply to pharmacies (both community as well as hospital)?

A: No, the regulation does not apply to stand alone, community pharmacies. The rule does apply to pharmacies that are considered a department of a Medicare participating facility (hospital, ASC, CAH, etc.).

Q: Does this regulation apply to physician offices?

A: The new Emergency Preparedness requirements do not apply to physician offices that are not part of a certified Medicare participating facility. Physicians' offices or practices that are considered part of a certified Medicare participating facility would be required to meet the regulations.

Q: Does the rule apply to providers/suppliers participating in Medicaid?

A: If a Medicaid provider is required to meet the requirements for participation in Medicare in order to receive Medicaid payment, that provider is required to comply with the Emergency Preparedness requirements, along with all of the other Medicare CoPs or CfCs for that provider. For example, Medicaid only hospitals must meet the Medicare requirements so they must comply with all of the hospital CoPs, including the Emergency Preparedness requirements. Note that not all provider types have a provision requiring them to meet the Medicare requirements in order to be Medicaid participating.

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Risk Assessments and Documentation

Q: Which Hazard Vulnerability Assessment (HVA) or Risk Assessment is recommended for use by providers? How will surveyors review the Risk Assessments for compliance?

A: Providers and suppliers must have a written Risk Assessment based on an "all-hazards" approach, or HVA. We are not requiring a specific format to be used, however, we recommend facilities who have not prepared a Risk Assessment to reach out to ASPR TRACIE who can provide additional resources. Additional guidance will be forthcoming in the Interpretive Guidelines that will include survey procedures for surveyors.

Training and Testing

Q: What are the requirements for Ambulatory Surgical Centers (ASCs) regarding the participation in a community full- scale exercise?

A: Per 416.54(d)(2)(i) of the final rule an ASC is required to participate in a full-scale exercise that is community-based. If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event. (**64024 Federal Register** / Vol. 81, No. 180 / Friday, September 16, 2016 / Rules and Regulations)

Please refer to page 63900 of the final rule that stated if a community disaster drill is not available, we would require an ASC to conduct an individual facility-based disaster drill.

Transfer Agreements and Coordination Required

Q: Are there specific Memorandum of Understanding (MOU) requirements in the new guidelines such as a required MOUs list to be sure all the bases are covered?

A: The regulation does not specify provider and supplier MOUs; however, the regulation does speak to the need for transfer agreements depending on the facility type. For example, during an emergency, if a patient requires care that is beyond the capabilities of the ASC, we would expect that ASCs would transfer patients to a hospital with which the ASC has a written transfer agreement, as required by existing § 416.41(b), or to the local hospital, that meets the requirements of §416.41(b)(2), where the ASC physicians have admitting privileges. (**Federal Register** /Vol. 81, No. 180 / Friday, September 16, 2016 /Rules and Regulations **63899)** Therefore, we recommend facilities review current CoPs/CfCs for specific details on transfer agreements. A sample Transfer Agreement is also located under the download section at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html. ASPR TRACIE may also provide sample transfer agreements currently available.

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Life Safety Code (LSC)

Q: General inquiry on generator: Does the generator have to be able to power up AC/Heat. Can you please clarify for me, is that a requirement with the final rule?

A: The Emergency Preparedness regulation requires Hospitals, Critical Access Hospitals and Long-term Care Facilities to have generators. The regulation also requires health care facilities to have alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. If a facility needs a generator to meet the temperature requirement then it must provide the necessary level of generator with a capacity to run a HVAC system.

Q: Do PACE programs need to meet generator requirements?

A: The LSC may require a generator at certain PACE locations if the services provide electrical life support or other critical care.. The Emergency Preparedness regulation also requires PACE facilities to have alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. If a facility needs a generator to meet the temperature requirement then it must provide the necessary level of generator with a capacity to run a HVAC system.

Q: What is the frequency of generator testing according to the NFPA 110?

A: NFPA 110, *Standard for Emergency and Standby Power Systems* has many requirements for the installation, maintenance and testing of generators, depending on the type of generator. Basic requirements are that a generator be inspected weekly and test run for 30 minutes monthly.

Q: Are all Nursing Homes required to have a generator? What if the Nursing Home doesn't currently have a generator? Must they install one? Is compliance with NFPA 70 & NFPA 110 sufficient, or are there additional requirements regarding the generator and/or fuel capacity?

A: The emergency preparedness rule requires long term care (LTC) facilities to have a generator. The regulation also requires LTC facilities to have alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. If a facility needs a generator to meet the temperature requirement then it must provide the necessary level of generator with a capacity to run a HVAC. There may be state and local regulations that have additional requirements regarding the generator and any required fuel capacity.

Q: Are there recommended types of generators?

A: CMS does not recommend a specific type of generator. Generator selection is dependent on the needs of the facility to meet the requirements of the regulation.

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Q: Can you tell me what the requirements are for generators in a nursing home under the new emergency preparedness rule? Are "whole building" generators required or would portable generators that only power certain things be sufficient?

A: The requirements for LTC facilities are located at 483.73(e) of the final rule (**Federal Register** /Vol. 81, No. 180 / Friday, September 16, 2016 /Rules and Regulations page 64031.) Regarding "whole building" generators, the new rule does not specify that a facility must have a generator that would support the operations of a "whole building."

Q: Does the requirement to maintain temperatures via alternate power (Generators) apply to areas where pharmaceuticals and other temperature limited storage criteria is specified by the manufacturer?

A: Under 482.15 (b)(1)(ii)(A) temperatures to protect patient health and safety and for the safety and sanitary storage of provisions. Refer also to (i) provisions which refers to pharmaceutical supplies as provisions. So yes they need to maintain temperatures of storage areas**.**

Q: Can you explain the difference between the Emergency and Standby Power Systems requirement and the requirement to have policies and procedures for alternate sources of energy to maintain temperatures to protect resident health and safety and for the safe and sanitary storage of provisions, emergency lighting, fire detection, extinguishing, alarm systems and sewage and waste disposal?

A: The "emergency and standby power systems" requirement only applies to hospitals, CAHs and LTC facilities and requires these facilities to have a generator. The "alternate sources of energy" requirement applies to hospitals, CAHs, LTC facilities, RNCHIs, hospices, PRTFs, PACE organizations, and ICF/IIDs. This standard/requirement does not specify that the facility (other than hospitals, CAHs and LTC facilities) must have a generator. However, in order maintain safe temperatures, emergency lighting, etc., facilities may have to install generators if they do not have other adequate alternate sources of energy to be in compliance with the rule.

Misc.

Q: Does the rule apply to Adult Day Healthcare Programs (ADHCPs)? What if the ADHCP or other entity is co-located or housed in a nursing home's building?

A: The regulation is applicable to 17 Medicare and/or Medicaid providers and suppliers. The complete listing can be found under our download section on this website. This regulation does not apply to ADHCPs. If a non-participating entity (such as a ADHCP) is located within a Medicare and/or Medicaid participating facility, we would expect the participating facility to consider the non-participating entity when developing its emergency plans.

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Policies and Procedures and Documentation

Q: If a large health system has operating guidelines which include language described in the policies and procedures section, but does not have formal policies as approved by the hospital board etc., are healthcare facilities required to have formal policies or are official operating guidelines sufficient?

A: The regulation is clear that facilities must have "policies and procedures" in place as opposed to "operating guidelines." Policies are considered a more formal, definite method or course of action to be adhered to. Therefore facilities must develop and maintain "policies" and procedures to meet the requirements of the regulation. Facilities may choose to include relevant language from their "operating guidelines" in their policies and procedures as appropriate. Facilities should be aware that surveyors may ask to see a copy of the facilities "policies" and not "operating guidelines."

Q: If we choose to conduct a functional versus a community based test of the plan, what kind of justification do we have to provide on why we chose one over the other? Do we have to demonstrate that we tested our coordination with referrers and hospitals and community providers under a functional assessment?

A: We are not specifying the format of documentation to allow for flexibility. However, we would encourage facilities who chose a functional versus community based test to show why this approach was more favorable- i.e. community based testing is not available due to the rural area/geographic location of the facilities.

Q: The rule implies that facilities need to ensure their vendors have a business continuity plan to continue to provide a supply source during times of emergency. Do you have any guidance as to what vendors need to have or what they should provide to these facilities that will make the facilities compliant?

A: Facilities are required to provide subsistence needs for staff and patients, whether they evacuate or shelter in place. Those provisions include but are not limited to: food, water, medical supplies and pharmaceutical supplies.

Training and Testing

Q: Regarding fulfilling the testing needs: Do we indeed to conduct two tests a year? And minimally one of them needs to be a community based test? If an emergency presents itself between November 15, 2017 and December 31, 2017, would that satisfy one testing need? Would that be the community based need? And would that cover us for the period until November 15, 2018 or until the end of the calendar year 2017?

A: Facilities are required to participate in a full-scale exercise that is community-based or when a an individual facility-based exercise when a community-based exercise is not accessible AND

conduct an additional exercise that may include a second full-scale community or facility-based exercise or a tabletop exercise (as described in the regulations.) So yes, a facility is required to conduct two tests annually. If the facility experienced an emergency and had to activate its emergency plan between November 15, 2017 and December 31, 2017 that would satisfy one of the annual testing requirements and would exempt the facility from engaging in a community or facility based exercise for one year following the date of the actual emergency event. The "annual" testing requirement will not be measured on a calendar year basis which is January 1 through December 31. The annual requirement will be measured from the date of the last actual emergency event or the date the exercise/testing took place.

Alternative Sources of Energy

Q: What are the requirements for facilities regarding HVAC systems and alternate source energy?

A: The following providers have a mandatory requirement based on the new EP regulation to have an emergency and standby power system, i.e. a generator: Hospitals, LTC, and CAHs.

The following providers have a mandatory requirement based on the new EP regulation to have an alternate source of energy to maintain temperatures to protect [patient, resident, participant, client] health and safety and for the safe and sanitary storage of provisions: RNHCI, Hospice (inpatient), PRTF, PACE, Hospitals, LTC, ICF/IIDs, and CAH.

During an emergency situation, the providers listed above with a mandatory requirement for alternate sources of energy, must be able to maintain temperatures. Maintaining temperatures could involve heating or cooling the facility to maintain temperature levels within the facility to protect the individual's health and safety, as well as the safe and sanitary storage of provisions.

During the risk assessment a provider will need to determine how they will be able to maintain temperatures that will protect the health and safety of (patient, resident, participant, client) and the safe and sanitary storage of provisions if their facility loses power. The provider needs to determine how they will provide heating or cooling to their facility, if required, to maintain temperatures during an emergency situation, if they lose power.

We recommend facilities also review the preamble at Page 63882 Federal Register / Vol. 81, No. 180/ Friday, September 16, 2016. Additional guidance will be forthcoming in the Interpretive Guidelines.

Q: Do generator requirements apply to the following provider types: Small ICF/IID's; Home and Community Based Waiver (1915(c))?

A: The regulation does not make a distinction between ICF/IIDs and "small" ICF/IIDs. According to §483.475(b)(ii) ICF/IIDs have a mandatory requirement to provide alternate sources of energy to maintain the following items:

§483.475(b)(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect client health and safety and for the safe and sanitary storage of provisions.
(B) Emergency lighting.
(C) Fire detection, extinguishing, and alarm systems.
(D) Sewage and waste disposal.

As per the previous FAQs posted (11-18-16), the above provision does not specify or require that a facility must have a generator. The Emergency Preparedness regulation requires Hospitals, Critical Access Hospitals and Long-term Care Facilities to have generators.

Additionally, the Home and Community Based Waiver (1915(c)) participate in Medicaid only and are not surveyed for the emergency preparedness requirements.

Q: The regulation states: (ii) Alternate sources of energy to maintain the following: (A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions. (B) Emergency lighting. (C) Fire detection, extinguishing, and alarm systems. (D) Sewage and waste disposal. What is meant by "provisions" in (ii)(a)?

A: Provisions include: food, water, pharmaceuticals or medications and medical supplies. At §482.15(b)(1)(ii)(D), we proposed that the hospital develop policies and procedures to address the provisions of sewage and waste disposal including solid waste, recyclables, chemical, biomedical waste, and waste water. This provision also includes policies and procedures which address 'pharmaceuticals or medications/medical *supplies (Reference Page 63880 Federal Register / Vol. 81, No. 180).*

Misc.

Q: Some vendors are telling healthcare facilities that they need to purchase certain quantities of medically related supplies in order to be in compliance with the new Emergency Preparedness rule. What supplies and quantities (if any) do healthcare facilities need to purchase to be in compliance?

A: The regulation does not require any specific items and quantities that facilities must have to be in compliance with the rule. It is up to each individual facility to conduct an assessment of its facility's supply needs during an emergency and make purchases based on its assessment.

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Clarifications on Definitions

Definitions

All-Hazards Approach: An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters, including internal emergencies and a man-made emergency (or both) or natural disaster. This approach is specific to the location of the provider or supplier and considers the particular type of hazards most likely to occur in their areas. These may include, but are not limited to, care-related emergencies, equipment and power failures, interruptions in communications, including cyber-attacks, loss of a portion or all of a facility, and interruptions in the normal supply of essentials such as water and food. Rather than managing planning initiatives for a multitude of threat scenarios all-hazards planning focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. Thus, all-hazards planning does not specifically address every possible threat but ensures those hospitals and all other providers and suppliers will have the capacity to address a broad range of related emergencies

Business Impact Analysis (BIAs)[1] are a method of identifying and evaluating the effects various threats/ hazards may have on the ability of an organization to perform its essential functions and the resulting impact of those effects. It is through the BIA that organizations can identify problem areas (gaps, weaknesses, vulnerabilities) and in turn, organization leadership may use the BIA results to support risk management decision making.

Emergency/Disaster: An event that can affect the facility internally was well as the overall target population or the community at large.

Emergency Preparedness Program: The Emergency Preparedness Program is a facility's comprehensive approach to meeting the health and safety needs of their patient population and provides facilities with guidance on how to respond to emergency situations that could impact the operation of the facility, such as natural or man-made disasters. It includes (1) all-hazards risk assessment and emergency planning, development and implementation of policies and procedures, a communication plan, and training and testing. The program as a whole consists of the Emergency Plan, which is based on the four core elements.

Emergency Plan: An emergency plan is one part of a facility's emergency preparedness program and provides the framework which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing patient needs along with the continuity of business operations. Additionally, a plan will support, guide and ensure a facility's ability to collaborate with local emergency preparedness officials.

[1] The Department of Homeland Security, Federal Emergency Management Agency (FEMA) Continuity Guidance Circular 2 (CGC 2) July 22, 2010
https://www.fema.gov/pdf/about/org/ncp/coop/cont_guidance2.pdf

Facility-Based: When discussing the terms "all-hazards approach" and facility-based risk assessments, we consider the term "facility-based" to mean that the emergency preparedness program is specific to the facility. Facility-based includes, but is not limited to, hazards specific to a facility based on the geographic location; Patient/Resident/Client population; facility type and potential surrounding community assets (i.e. rural area versus a large metropolitan area).

Full-Scale Exercise: A full scale exercise is a multi-agency, multijurisdictional, multi-discipline exercise involving functional (for example, joint field office, emergency operation centers, etc.) and ''boots on the ground'' response (for example, firefighters decontaminating mock victims).

Hazard Vulnerability Assessments (HVAs)[2] are systematic approaches to identifying hazards or risks that are most likely to have an impact on a healthcare facility and the surrounding community. The HVA describes the process by which a provider or supplier will assess and identify potential gaps in its emergency plan(s).

Potential loss scenarios should be identified first during the risk assessment. Once a risk assessment has been conducted and an facility has identified the potential hazards/risks they may face, the organization can use those hazards/risks to conduct a Business Impact Analysis.

Risk Assessment: This is general terminology that is within the emergency preparedness regulations and preamble to the Final Rule (81 Fed. Reg. 63860, Sept. 16, 2016) which describes a process facilities are to use to assess and document potential hazards within their areas and the vulnerabilities and challenges which may impact the facility. Additional terms currently used by the industry are all-hazards risk assessments are also referred to as Hazard Vulnerability Assessments (HVAs) , or all-hazards self-assessments. For the purposes of these guidelines, we are using the term "risk assessment," which may include a variety of current industry practices used to assess and document potential hazards and their impacts.

This guidance is not specifying which type of generally accepted emergency preparedness risk assessment facilities should have, as the language used in defining risk assessment activities is meant to be easily understood by all providers and suppliers that are affected by this final rule and is aligned with the national preparedness system and terminology (81 Fed. Reg. 63860, at 63875). However, facilities are expected to conduct a full assessment of hazards based on geographical location and the individual facility dynamics, such as patient population.

Staff: The term "staff" refers to all individuals that are employed directly by a facility. The phrase "individuals providing services under arrangement" means services furnished under arrangement that are subject to a written contract conforming with the requirements specified in section 1861(w) of the Social Security Act.

Table-top Exercise (TTX): A table-top exercise is a group discussion led by a facilitator, using narrated, clinically-relevant emergency scenario, and a set of problem statements, directed

[2] The Assistant Secretary for Response and Preparedness (ASPR) Technical Resources Assistance Center and Information Exchange (TRACIE) Hazard Vulnerability/Risk Assessment. https://asprtracie.hhs.gov/technical-resources/3/Hazard-Vulnerability-Risk-Assessment/0

messages, or prepared questions designed to challenge an emergency plan. It involves key personnel discussing simulated scenarios, including computer-simulated exercises, in an informal setting. TTXs can be used to assess plans, policies, and procedures.