

population. Thus, we believe it is appropriate to specifically address these immunizations in these requirements. We also believe that the details, including dates and documentation, are also necessary to ensure appropriate immunizations for the residents. Although EHRs are not specifically addressed in this requirement, we do discuss health IT in other sections of this final rule. We expect that LTC facilities that use EHRs will include documentation concerning immunizations in those EHRs, as LTC facilities that use paper charts are expected to include the immunization documentation in the paper record. We have decided to retain the wording about "education" in the requirement. We believe further details concerning this requirement are best addressed in sub-regulatory guidance, which we will be producing for this final rule after it is published.

#### Implementation

*Comment:* One commenter recommended that LTC facilities be allowed a minimum of two and up to three years to meet the requirements for a healthcare professional with additional training to serve as an IP and that there be a waiver process when the facility can not comply when due diligence has been followed but such a person is not available. They also recommend a minimum of two years and up to three years for a LTC facility to fully develop and implement the ICP.

*Response:* We understand that for some facilities, especially the smaller and rural LTC facilities, coming into compliance with the infection control requirements in this final rule may require an extended period of time. We are finalizing a phased in delay of the implementation date for these requirements. We refer readers to Section II, B for a detailed discussion regarding the implementation deadline for these specific requirements.

#### Costs

*Comment:* Commenters pointed out that the proposed infection control requirements, especially those concerning the IP, are unnecessary and will increase costs.

*Response:* We agree that coming into compliance with the infection control requirements in this final rule will require additional resources for many facilities. However, we have modified the requirements for the IP, now the infection control professional or ICP, which we believe will decrease the burden associated with this provision

and address many of the commenters' concerns related to increased costs.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified § 483.80(a)(1) by changing the reference from § 483.75(e) to § 483.70(e).
- We have modified § 483.80(a)(2)(iv) by inserting after, "[w]hen and how isolation should be used for a resident," the following language, "including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and a requirement that the isolation should be the least restrictive possible for the resident under the circumstances."
- We have modified § 483.80(b) to change the infection prevention and control officer (IPCO) to an infection preventionist (IP).
- We have modified § 483.80(b) to allow LTC facilities to designate more than one IP.
- We have modified § 483.80(b)(1) and (2) to establish that IPs must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field and can be qualified by education, training, experience or certification.
- We have modified § 483.80(b) by removing the requirement that the ICP be a major responsibility for the IP.

#### X. Compliance and Ethics Program (§ 483.85)

As noted previously, section 6102 of the Affordable Care Act amended the Act by adding new section 1128I. Subsection 1128I(b) of the Act requires the operating organizations for SNFs and NFs to have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care consistent with regulations developed by the Secretary. In the proposed rule we included a robust discussion regarding several industry-specific guidance documents on compliance issued by the DHHS OIG. In addition, we also included a detailed discussion regarding a September 23, 2010 proposed rule entitled, "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers," in the **Federal Register** (75 FR 58204), to which we received feedback through

public comment regarding compliance program requirements that are required by both sections 6102 and 6401(a) of the Affordable Care Act. We encourage readers to review the proposed rule for this background information.

#### Proposed § 483.85(a) and § 483.85(b)

At § 483.85(a), we proposed to define the terms "compliance and ethics program," "high-level personnel", and "operating organization." We proposed to define "compliance and ethics program" to mean with respect to a facility, a program of the operating organization that has been reasonably designed, implemented, and enforced so that it is effective in preventing and detecting criminal, civil, and administrative violations under the Act, and in promoting quality of care; and includes, at a minimum, the required components specified in § 483.85(c). We did not propose using the term "managing employee" that is contained in the current LTC facility requirements, but rather proposed to retain the use of the term "high-level personnel", which is used in the Affordable Care Act. We proposed to define "high-level personnel" as individuals who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization. We indicated that the individuals considered "high-level personnel" will differ according to each operating organization's structure. However, some examples include, but are not limited to, the following: (1) A director; (2) an executive officer; (3) an individual in charge of a major business or functional unit; and (4) an individual with a substantial ownership interest as defined in section 1124(a)(3) of the Act in the operating organization.

We also proposed to define "operating organization" to mean the individual(s) or entity that operates a facility. Section 1128I(b)(1) of the Act defines an "operating organization" as "the entity that operates the facility." Although many LTC facilities are part of corporate chains, there are still some LTC facilities that are owned by an individual or a small group of individuals. Therefore, we proposed to add "individual(s)" to the definition to make it clear that all LTC facilities, regardless of their legal structure, are required to comply with these requirements.

In § 483.85(b), we proposed that the operating organization for each facility must have in operation a compliance and ethics program (as defined in § 483.85(a)) that meets the requirements of this section beginning on the date

that is one year after the rule's effective date.

#### Proposed § 483.85(c)

In § 483.85(c), we proposed that the operating organization for each facility be required to develop, implement, and maintain an effective compliance and ethics program that contains at a minimum several components. First, at § 483.85(c)(1) we proposed that the operating organization must establish written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Second at § 483.85(c)(2), we proposed that the operating organization must assign specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization (proposed § 483.85(c)(2)). At § 483.85(c)(2), we proposed that the program must include provisions ensuring that the specific individuals designated with oversight responsibility in proposed § 483.85(c)(2) have sufficient resources and authority to assure compliance with these standards, policies, and procedures.

Next at § 483.85(c)(4), we proposed that the operating organization is required to use due care not to delegate discretionary authority to individuals whom the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, or administrative violations under the Act.

We also proposed at § 483.85(c)(5) that the operating organization be required to effectively communicate the standards, policies, and procedures in the operating organization's compliance

and ethics program to the operating organization's entire staff including individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training or orientation programs, and/or dissemination of information that explained in a practical manner what was required under the program.

Next at § 483.85(c)(6), we proposed that the compliance program must ensure that reasonable steps were being taken to achieve compliance with the program's standards, policies, and procedures, such as utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retaliation, and having a process for ensuring the integrity of any reported data. We also proposed at § 483.85(c)(6) that the operating organization be required to enforce consistently the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the appropriate party identified in the operating organization's compliance and ethics program. We proposed that an operating organization is required to consistently enforce its standards and procedures through appropriate disciplinary mechanisms.

Lastly, at § 483.85(c)(8) we proposed that after an operating organization detected a violation, it must ensure that all reasonable steps identified in its program were taken to respond appropriately to the violation and, to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act. We noted in the proposed rule that in sections 1128I(b)(3)(F) and (G) of the Act, which correspond to § 483.85(c)(7) and (8), the term "offense," is used instead of "violation" and that the previously described components are mandatory for all of the SNF and NF operating organizations' compliance and ethics programs.

#### Proposed § 483.85(d)

At § 483.85(d), we proposed to require operating organizations that operate five or more facilities to designate a compliance officer, and require that such individuals be designated as high-level personnel of the operating organizations with the overall responsibility to oversee the compliance and ethics program. In addition, the designated compliance officer must report directly to the governing body for the operating organization. We also proposed that all operating organizations designate a compliance and ethics program contact.

In addition at § 483.85(d), we proposed that operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:

- A mandatory annual training program on the operating organization's compliance and ethics program (§ 483.85(d)(1)).
- A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility (§ 483.85(d)(2)).
- Designated compliance liaisons located at each of the operating organization's facilities (§ 483.85(d)(3)).

#### Proposed § 483.85(e)

Lastly, at § 483.85(e), we proposed that the operating organization for each facility must review its compliance and ethics program annually, and revise its program, as needed to reflect changes in all applicable laws or regulations and within its organization and facilities to improve its performance in deterring, reducing, and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care.

#### General Comments

*Comment:* Some commenters were very supportive of the proposed requirements for compliance and ethics programs, especially the components that are required for all facilities. Some commenters also appreciated the recognition of the different levels of resources that were available to smaller and larger operating organizations to develop, implement, and maintain compliance and ethics programs.

*Response:* We thank the commenters for their support. We do recognize that there would be varying levels of resources available to smaller and larger organizations. Although the requirements for compliance and ethics programs finalized in this rule go to all operating organizations, with additional requirements for those with five or more

facilities, we would expect that all operating organizations would also use the facility assessment they developed according to § 483.70(e) in developing and maintaining their programs. For example, the operating organization must provide, among other things, sufficient resources to reasonably assure compliance with the program's standards, policies, and procedures (§ 483.85(c)(3)). In addition, operating organizations must also take steps to effectively communicate the standards, policies, and procedures of its program to its entire staff, individuals providing services under contractual arrangements; and volunteers, consistent with their expected roles (§ 483.85(c)(5)). This can be accomplished by mandatory training, orientation programs, or disseminating information that explains in a practical manner what is required under the operating organization's program (§ 483.95(f)). Operating organizations should use the facility assessment to determine the resources they need to devote to their compliance and ethics programs to reasonably assure compliance with the requirements finalized in this rule.

*Comment:* Some commenters supported the proposed requirements, but also recommended certain individuals who they believed should be involved in developing and maintaining the facility's compliance and ethics program. Some commenters said that professional social workers, who are guided by the National Association of Social Work (NASW) *Code of Ethics* (2008), would be well equipped to contribute to and help to lead such programs.

*Response:* We appreciate the commenters support for the proposed requirements. We also agree that social workers could play an important role in compliance and ethics programs. However, not all LTC facilities are required to have a full-time social worker on staff so we cannot require that a social worker be involved in developing, implementing, and maintaining these programs. We also believe that each facility needs the flexibility to determine how it will comply with the requirements finalized in this final rule, including choosing the individuals who will be involved in compliance and ethics programs.

*Comment:* Some commenters noted there were definitions for some terms used in proposed § 483.85, including "compliance and ethics program", "high-level personnel", and "operating organization"; however, there was no definition for "reasonable" or "reasonably". They also noted that CMS

did ask for comments on how to evaluate "reasonableness" in the proposed rule (80 FR 42221). The commenters supported our statement that "reasonableness" may depend on the applicable facts and circumstances. Some commenters also recommended that the term "reasonable" be defined and that we use the Black's Law Dictionary definition of "reasonable person" as it is often used in other areas of the law, such as, an ordinary person who exercises care while avoiding extremes of boldness and carefulness.

*Response:* We do believe that reasonableness depends upon the applicable facts and circumstances surrounding any particular situation. As stated in the July 16, 2015 proposed rule (80 FR 42168), the terms "reasonable" and "reasonably" were used in the section 6102 of the ACA and consequently used in proposed § 483.85(c)(1), (6), and (8). We did not propose a definition of these terms in the proposed rule, but did state that "[w]e would appreciate comments on how to evaluate the reasonableness of the design, implementation, and enforcement of an operating organization's compliance and ethics program and how to determine the reasonableness of the steps an operating organization has taken to achieve compliance with its standards and the steps an operating organization should take in response to offenses and prevent similar occurrences (80 FR 42221). We will not be finalizing a definition of "reasonable" or "reasonably" in this rule. However, we will be publishing further sub-regulatory guidance on how to determine reasonableness for these requirements".

*Comment:* Some commenters were concerned about including contractual staff and volunteers in some of the requirements. Specifically, proposed § 483.85(c)(1), (5), and (6) that state that LTC facilities must establish "disciplinary standards," communicate "the standards, policies, procedures . . . includ[ing] . . . mandatory participation in training or orientation programs and/or dissemination of information," and "ensure that reasonable steps were being taken to achieve compliance" by the facility's staff, and "individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles." They argued that it would not be a good use of the facility's time and resources and that some LTC facilities could find it burdensome to train and orient contractor staff and volunteers to their compliance and ethics program. It should be the contractor that it

responsible for training the contract staff and the LTC facility should only be responsible for orienting the contract staff to the nuances in their program. In addition, they argued that training for these individuals could be inconsistent with the best practices that are currently in place for LTC facilities, which is to educate contractors or volunteers about the facility's compliance program, seven core elements of an effective compliance program, code of conduct, reporting processes (hot line numbers and other alternative reporting mechanisms) and correction processes by furnishing written materials to contractors or volunteers to review and having them attest to reviewing the materials. The contracting agency should be discussing compliance and ethics matters with their employees and this is often covered in their contracts with the LTC facilities. It should be understood that the LTC facility would be responsible for orienting contractual staff to the individual nuances of the compliance and ethics program for the facility. The commenters recommended that LTC facilities not be required to provide full training and education to volunteers and contractor agency personnel but that the facilities be required to provide these individuals with an overview of their programs.

*Response:* For any operating organization's compliance and ethics program to be effective, it is crucial that all of the organization's staff, including those who are providing services under contract, and volunteers, consistent with their roles, need to understand the standards, policies and procedures for that program. If these individuals do not understand the program's requirements and their responsibilities under that program, they will not be able to comply appropriately and that will severely reduce, or perhaps eliminate, the effectiveness of the program. Operating organizations with four or less facilities "must effectively communicate" to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. It could be formal training, but they could also comply with this requirement through dissemination of materials, as the commenters noted above. For operating organizations with five or more facilities, annual training is required. However, these requirements do not specify how the training or dissemination of information is to be performed. Further, as set forth in § 483.95, it states that "[a] facility must determine the amount and types of

training necessary based on a facility assessment as specified at § 483.70(e).” We believe that each operating organization needs to have the flexibility to determine the best way for each of them to comply with this requirement and this final rule provides them that flexibility to determine what kind of dissemination of information or training they need to provide. In addition, it is the training or dissemination of the information that is crucial. For example, the operating organization could choose to arrange with the contractor to have the contractor provide the required training or dissemination of information for the compliance and ethics program as some commenters indicated happens today.

*Comment:* Some commenters recommended that LTC facilities be required to integrate the information from the compliance program into the facility’s QAPI program. The commenters believed that compliance must be coordinated into the current ongoing activities so that the primary focus remains on doing the right thing in the right way routinely, and on proper clinical reasoning and problem solving, with regulatory and legal compliance always kept in mind but not as a separate or predominant activity. They were concerned that an excessive or separate focus on compliance could potentially result in clinically questionable activities in the name of “compliance” that could be inconsistent with desirable care approaches.

*Response:* We agree that the information and data obtained through the facility’s compliance and ethics program should be integrated into the facility’s QAPI program. However, the QAPI requirements finalized in this rule already provide for this integration. The facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility and must address, among other things, all of the systems of care and management practices (§ 483.75(b)(1)). In addition, each facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring (§ 483.75(c)). Also, the QAA committee must regularly review and analyze data and act on available data to make improvements (§ 483.75(g)(2)(iii)). Thus, LTC facilities should be integrating the information and data they collect or arises out of their compliance and ethics programs into their QAPI program.

The requirements for compliance and ethics and the QAPI programs should work together or be coordinated to not

only ensure compliance with the requirements in this final rule but also improvements in the quality of care provided to the residents. Also, we do not believe this will result in an excessive or separate focus on compliance or result in negative consequences to the residents, staff, or facility.

#### Additional Requirements for Operating Organizations With Five or More Facilities

*Comment:* Some commenters were concerned that our proposal for additional requirements for operating organizations with five or more facilities was imposing additional requirements on certain operating organizations based upon an arbitrary number of facilities. Some commenters recommended that only operating organizations with 15 or more facilities be required to comply with the additional requirements.

*Response:* We proposed additional requirements for operating organizations with five or more facilities, because section 1128I(b)(2)(B) of the Act, as added by section 6102 of the ACA (Pub. L. 111–148 (2010), states that “with respect to specific elements or formality of a program, in the case of an organization that operates 5 or more facilities, vary with the size of the organization.” Since the statutory language specifically indicates that the compliance and ethics programs for operating organizations with five or more facilities should be a more formal program or have more elements, we will be not finalize § 483.85(d) to apply to operating organizations with 15 or more facilities. Hence, we have finalized that section so that the additional requirements apply to operating organizations that have five or more facilities.

*Comment:* Other commenters were very supportive of the proposed additional requirements for operating organizations with five or more facilities as set forth in § 483.85(d): Mandatory annual training programs on the operating organizations’ compliance and ethics programs that meet the requirements set forth in § 483.95(f); designated compliance officers for whom their operating organization’s compliance and ethics program is a major responsibility; and designated compliance liaisons located at each of the operating organization’s facilities.” These commenters recommended that all operating organizations, regardless of size, be required to comply with these additional requirements.

*Response:* We appreciate the commenters support for these additional requirements. However, in developing

requirements, we must balance the necessity of the requirement for the health and safety of the residents with the burden of that requirement to the operating organization. We believe that the additional requirements are necessary for larger operating organizations to develop and maintain effective compliance and ethics programs. Larger organizations will generally be caring for more residents and have more locations for which they are responsible. We believe this requires that the larger operating organizations have a compliance officer. Since that compliance officer will be responsible for the organization’s program at five or more facilities, we believe he or she will need someone at each facility, the compliance liaison, to assist them with the program at each facility. In addition, considering the number of facilities, we believe this requires annual training to ensure that all staff, including those who are providing services under a contract and volunteers, consistent with their roles, are knowledgeable about the operating organization’s program and how they are expected to comply with its standards, policies, and procedures. For operating organizations with four or fewer facilities, we believe they can develop and maintain a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act as required by section 1128I(b)(1) of the Act without the additional requirements for larger operating organizations. However, we would encourage operating organizations with four or fewer facilities to incorporate these additional elements if their facility assessments indicate that they are necessary to ensure that their compliance and ethics programs are effective. Thus, we will not be extending the additional requirements set forth in § 483.85(d) to all operating organizations.

*Comment:* Some commenters were concerned about the requirement for designated compliance liaisons at each facility for operating organizations with five or more facilities (§ 483.85(d)(3)). They did not believe it was good policy to appoint someone at each facility who does not have the critical experience, education, or knowledge of a compliance officer. It is also not feasible to expect that each facility could hire someone with the background or expertise to be a compliance officer in the operating organization’s compliance and ethics program.

*Response:* Compliance liaisons are not compliance officers. In the proposed rule, we did not define “designated compliance liaison” but stated that

“[w]e would expect that operating organizations would develop a description for these positions and the duties and responsibilities these individuals would have in the operating organization’s compliance and ethics program . . . [a]t a minimum, these liaisons should be responsible for assisting the compliance officer with his or her duties under the operating organization’s program at their individual facilities” (80 FR 42220). We believe that each operating organization needs the flexibility to determine what the qualifications, duties, and responsibilities that these compliance and ethics program liaisons should have in their organization. Thus, it is the operating organization with five or more facilities that will develop its own definition for the position of “designated compliance liaison” and determine the qualifications, duties, and responsibilities for the individuals in this position.

*Comment:* Some commenters noted that compliance officers could not be subordinate to the general counsel (GC), chief financial officer (CFO) or chief operating officer (COO) in proposed § 483.85(d)(2). They were very supportive and noted that in many large organizations the GC is the compliance officer and is often the best qualified to address potential legal violations and other areas of concern. In addition, the commenters noted that in many mid-sized organizations the GC, CFO, or COO is the compliance officer because the organization cannot financially support a full-time compliance officer. Some commenters recommended that we insert a sentence that specifically indicates that the GC, CFO, or COO may serve as the compliance officer. Other commenters recommended that the compliance officer also not be subordinate to the facility’s chief executive officer (CEO) or the administrator.

*Response:* We agree with the commenters that it is very important that the compliance officer not be subordinate to certain individuals in the operating organization. We agree that the compliance officer should also not be subordinate to an administrator; however, we believe that the compliance officer would be within the operating organization’s staff and not located at an individual facility to avoid any interference or influence of the compliance officer by an administrator. We do not agree that the compliance officer could not be subordinate to the CEO, who is generally the highest ranking officer in an operating organization. For these reasons, we did not propose that the compliance officer could not be

subordinate to the CEO or an administrator. The compliance officer must be able to communicate with the governing body without being subject to any coercion or intimidation. This is why we proposed § 483.85(d)(2) that states that the compliance officer must be able to report directly to the governing body. Thus, we have finalized § 483.85(d)(2) as proposed. We believe any further detail on who can and cannot serve as the compliance officer should be provided in the sub-regulatory guidance for this requirement. We refer facilities to additional guidance the OIG has published for nursing home compliance programs, “OIG Supplemental Compliance Program Guidance for Nursing Facilities” (73 Fr 56832) ([https://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg\\_fr.pdf](https://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf)).

#### Implementation and Costs

*Comment:* Some commenters were concerned about the 1-year timeframe for implementation of the compliance and ethics programs. Commenters wanted at least 2 years for LTC facilities to develop their compliance and ethics programs. They based the 2 years on both the statutory language in ACA that stated that the Secretary had 2 years to promulgate regulations for compliance and ethics programs and to allow adequate time to change and adjust current compliance and ethics programs allow adequate time to change and adjust current processes and procedures and to reconfigure facility budgets.

*Response:* We appreciate the commenters’ concerns about the implementation of the requirements for compliance and ethics programs. We are finalizing a phased in delay of the implementation dates for this final rule. We refer readers to Section II.B. for a detailed discussion regarding the implementation deadlines for these requirements. The estimated costs for complying with these requirements are discussed in sections V. Collection of Information Requirements and VI. Regulatory Impact Analysis (RIA).

*Comment:* Some commenters believed that the requirements for the compliance and ethics program were unduly prescriptive and costly and could impose an unnecessarily onerous burden on some LTC facilities. However, some of these commenters also indicated that a major organization for long-term care facilities had already been educating its membership on the requirements in ACA for compliance and ethics program in LTC facilities and had educational tools on its Web site.

*Response:* Section 6102 of the ACA mandated compliance and ethics programs in LTC facilities. Hence, these are not discretionary requirements. In developing these regulations, we have established the requirements contained in the ACA and have been mindful of the burden which will be required to comply with these requirements. In finalizing these requirements, we strived to avoid not only any unnecessary burden but also to provide maximum flexibility for operating organizations to comply with the requirements established in ACA.

#### Surveys

*Comment:* Some commenters were concerned about how the LTC facilities would be surveyed for the compliance and ethics program requirements. Some commenters wanted a tangible observational process established for the surveyors, which would validate that facilities are providing compliance and ethics policies and procedures to the staff and that governing bodies are implementing those policies and procedures.

*Response:* We understand that commenters have concerns about how surveyors would determine compliance with these requirements. As discussed above, we will be developing and publishing or disseminating sub-regulatory guidance, including interpretative guidelines (IGs), before surveyors begin to survey LTC facilities for these requirements. That guidance will provide the detailed information surveyors need to determine compliance with these requirements.

After consideration of the comments we received on the proposed rule, we are finalizing the requirements as proposed.

#### Y. Physical Environment (§ 483.90)

In the proposed rule we indicated that the facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public. Many of these provisions relate to Life Safety Code (LSC) requirements. We recently published a final rule which adopts many provisions of the 2012 LSC “Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities,” (81 FR 26871, May 4, 2016). As part of our comprehensive review and restructuring, we re-designate the existing provisions of § 483.70 as new § 483.90; however, the language in existing § 483.70(a) “Life safety from fire” and § 483.70(b) “Emergency power” are unchanged, including new provisions related to the requirement that long term care