

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 100 — Safe Place for Newborns

PROPOSED RULE

19 CSR 30-100.010 Newborn Safety Incubators.

PURPOSE: This rule establishes the specifications governing the installation, maintenance, and oversight of newborn safety incubators.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) As used in this rule, the following terms and phrases shall mean:

(A) Department shall mean the Department of Health and Senior Services;

(B) Facility shall mean the entity registered with the Department of Health and Senior Services and approved to utilize an installed newborn safety incubator;

(C) Newborn safety incubator shall mean a medical device used to maintain an optimal environment for the care of a newborn infant; and

(D) Relinquishing parent shall mean the biological parent or person acting on such parent's behalf who leaves a newborn infant in a newborn safety incubator.

(2) Specifications for a newborn safety incubator.

(A) Each newborn safety incubator shall:

1. Be a medical bassinet in compliance with 21 CFR 880.5145 with the exception of bassinet wheels. The bassinet wheels shall be removed for installation in compliance with (2)(A)2;

2. Have the supporting frame of the medical bassinet physically anchored to a position that aligns the plastic basket or bed portion of the bassinet with the wall directly beneath the access portal door and prevents movement of the unit as a whole; and

3. Provide a safe sleep environment which includes:

A. A firm flat bassinet mattress;

B. A bassinet mattress sheet that fits snugly on a mattress and overlaps the mattress so it cannot be dislodged by pulling on the corner of the sheet; and

C. Is free from any bedding, including pillows, bumpers, and blankets.

(3) Installation of a Newborn Safety Incubator.

(A) Access Portal Door.

1. The newborn safety incubator shall have an access portal door. This access portal door shall only be installed on an exterior wall that ensures anonymity of the relinquishing parent and provides access to an area within the interior of the building. The newborn safety incubator access portal door shall only be installed in a manner within the interior of the building that provides unencumbered access from the exterior of the building through the access portal door for the surrender of the child into the medical bassinet. The access portal door shall have a lock that can lock automatically upon closure by the relinquishing parent after the newborn has been placed in the newborn safety incubator. The placement of the newborn safety incubator

access portal door and the medical bassinet within the interior of the building shall provide unencumbered access to the medical bassinet so a facility trained individual can respond to an alarm notification that a child has been surrendered into the newborn safety incubator.

2. The access portal door shall:

- A. Lock automatically upon closure;
- B. May only be unlocked from the interior of the building;
- C. Trigger a series of alarms that, at a minimum, shall include:

(I) An audible alarm triggered to a central location within the facility one (1) minute after the opening of the access portal door; and

(II) An automatic call to 911 triggered from the alarm system if the alarm is not turned off from within the facility within one (1) minute of the commencement of the initial alarm; and

3. The installation of the access portal door shall be completed by a general contractor who shall affirm in the “General Contractor Attestation” form, included herein, that the access portal door and the area where the newborn safety incubator is located meets the requirements of (3)(A) and (3)(B). The general contractor signing the form maintains ultimate responsibility for all work performed in the process of the construction of the access portal door and the area where the newborn safety incubator is located.

(B) Interior of the Building.

1. The interior of the building shall provide a monitored climate controlled environment, including temperature control within the range of sixty-eight to seventy-five degrees.

2. The interior of the building shall provide air circulation that is free from pollutants, exhaust, chemical fumes, and smoke.

3. The interior of the building shall have an Automated External Defibrillator (AED) within close vicinity to the newborn safety incubator.

4. The interior of the building shall have appropriate lighting for relinquishing parents and staff to be able to see the newborn safety incubator and signage. This lighting shall have battery backup in the event that the electricity is out.

(C) Alarm System.

1. There shall be an alarm system installed in relation to the access portal door and the location where the newborn safety incubator is located that will alert a facility trained individual overseeing the newborn safety incubator that the access portal door has been opened, so that the facility trained individual can then check to see if a newborn has been placed in the newborn safety incubator.

2. The access portal door alarm shall only be capable of being turned off from within the facility once a response is made to the newborn safety incubator.

3. The access portal door alarm shall be:

- A. Wired into the existing structure’s electrical or telecommunications system;
- B. If wired into the structure’s existing electrical system:

(I) Be in compliance with the NFPA 70, National Electrical Code (NEC) and NFPA 1, Fire Code if applicable. The NFPA 70, NEC, Revised 2020 and NFPA 1, Fire Code, Revised 2021 are incorporated by reference in this rule as published by the National Fire Protection Agency, 1 Batterymarch Park, Quincy, Massachusetts, 02169-7471, or can be found at www.nfpa.org. This rule does not incorporate any subsequent amendments or additions;

(II) Be installed by a licensed electrical contractor; and

(III) If the facility has a secondary or back-up power supply, then the alarm system shall be wired into the secondary or back-up power supply to ensure continued operation of the alarm system during outages of the structure’s primary power supply. If the facility does not have a secondary or back-up power supply, then the alarm system shall have battery back-up; and

C. Tested following installation to ensure the activation of the audible, 911, and disarming components of the system.

4. The installation of the alarm system shall be completed by either a licensed electrical contractor/electrician if wired into the structure's existing electrical system and the facility's secondary or back-up power supply if applicable or a telecommunications installation professional if wired into the structure's existing telecommunications network.

The licensed electrical contractor/electrician or telecommunications installation professional who completes the installation of the alarm system shall affirm in the "Licensed Electrical Contractor/Electrician or Telecommunications Installation Professional Attestation" form, included herein, that the alarm system meets the requirements of (3)(A)2 and (3)(C) in this rule. The licensed electrical contractor/electrician or the telecommunications installation professional who signs the form maintains ultimate responsibility for all work performed in the process of the installation of the alarm system.

(D) Signage.

1. Each location where a newborn safety incubator is installed shall post signage that clearly identifies the newborn safety incubator access portal door and provides both written and pictorial instruction to the relinquishing parents. This written signage shall be in both English, Spanish and any other language that is commonly used in the community. The written and pictorial instruction shall depict how to do the following:

- A. Open the access portal door;
- B. Place the infant inside the medical bassinet; and
- C. Close the access portal door to engage the lock.

2. The written signage shall also provide contact information for the Children's Division at the Missouri Department of Social Services, including the hotline number, in order to direct any questions the relinquishing parents(s) may have regarding the newborn after the newborn is placed in the newborn safety incubator to the Children's Division.

(4) Maintenance/Staff.

(A) Each registered facility shall have a medical contact in order to obtain the required newborn safety incubator. The newborn safety incubator is a prescription device per 21 CFR 880.5145.

(B) Each registered facility shall have at least one individual trained, present and on duty in the facility at all times, twenty four hours (24) a day, seven days a week to take possession of a newborn placed in the newborn safety incubator. Training shall occur before the individual is initially placed on duty with the facility and as needed as issues/problems arise. Training shall consist of compliance with this rule including at least what to do when taking possession of a newborn from a newborn safety incubator; how to care for the newborn before the newborn is transferred to the hospital; who to call for immediate transportation of the newborn to the nearest hospital; how to test the alarm system, how to recognize the alarm, how to silence the alarm, how to check the newborn safety incubator twice a day for debris; how to clean and sanitize the newborn safety incubator; how to access the newborn safety incubator from the interior of the building; how to complete required paperwork; and who to contact if there are any problems related to the relinquishment of a newborn. These staff shall also be current in cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) certification which includes CPR and AED use specifically for infants. The facility shall complete documentation of the required training and maintain a list of individuals trained to be on duty. The facility shall also complete documentation regarding the individuals on duty each day. This documentation shall be maintained onsite and current as long as the newborn safety incubator is registered at that facility's location. Documentation of the required training, the list of trained individuals and which individuals were on duty shall be made available to the department upon the department's request. This documentation shall be maintained for a period of five (5) years.

(C) Upon taking possession of a newborn from a newborn safety incubator facility staff shall arrange for the immediate transportation of the child to the nearest hospital licensed pursuant to chapter 197, RSMo.

(D) The facility shall test the alarm system a minimum of once a week to ensure the activation of the audible, 911, and disarming components of the system are properly working. The facility shall complete documentation of this required testing of the alarm system. This documentation shall be maintained onsite and current as long as the newborn safety incubator is registered at that facility's location. Documentation of the required testing shall be made available to the department upon the department's request. This documentation shall be maintained for a period of five (5) years.

(E) The facility shall test the access portal door locking system at least once a week to ensure the activation of the automatic locking system. The facility shall complete documentation of this required testing of the access portal door automatic locking system. This documentation shall be maintained onsite and current as long as the newborn safety incubator is registered at that facility's location. Documentation of the required testing shall be made available to the department upon the department's request. This documentation shall be maintained for a period of five (5) years.

(F) The newborn safety incubator shall be checked a minimum of twice daily for debris. The facility shall complete documentation of this twice daily check for debris. This documentation shall be maintained onsite and current as long as the newborn safety incubator is registered at that facility's location. Documentation of the required twice daily check for debris shall be made available to the department upon the department's request. This documentation shall be maintained for a period of five (5) years.

(G) The newborn safety incubator shall be cleaned at least weekly and after any child surrender. The cleaning of the bassinet shall include:

1. An inspection for breaks in integrity that would impair either cleaning or disinfection/sterilization;

2. Sanitization of the basket or bed portion of the bassinet with an EPA-registered hospital disinfectant (e.g. phenolics) using the label's safety precautions and directions. The surfaces of the bassinet shall be rinsed with water after sanitizing and then dried before being returned to use; and

3. The facility shall complete documentation of this required cleaning and sanitization. This documentation shall be maintained onsite and current as long as the newborn safety incubator is registered at that facility's location. Documentation of the required cleaning and sanitization shall be made available to the department upon the department's request. This documentation shall be maintained for a period of five (5) years.

(H) The facility shall keep track of the number of newborns placed into the newborn safety incubator at its facility. This documentation shall be maintained onsite and current as long as the newborn safety incubator is registered at that facility's location. This documentation shall be made available to the department upon the department's request. This documentation shall be maintained for a period of five (5) years.

(5) Oversight.

(A) Prior to utilizing an installed newborn safety incubator, each facility that has a newborn safety incubator installed at a location shall register with the department. This registration shall include:

1. A completed "Newborn Safety Incubator – Location, Contact Information and Attestation of Compliance" registration form, included herein;

2. A completed "General Contractor Attestation" form completed by the general contractor, included herein; and

3. A completed “Licensed Electrical Contractor/Electrician or Telecommunications Installation Professional Attestation” form completed by the licensed electrical contractor/electrician or telecommunications installation professional, included herein;

(B) After receiving a completed registration packet, the department shall complete an inspection of the facility to confirm compliance with this rule. If the department finds any deficiencies during the inspection that do not conform with this rule, the department will provide the facility written notice of all deficiencies. The facility shall send the department a plan of corrections within ten (10) calendar days to demonstrate how the facility has corrected or is planning to correct the deficiencies set forth by the department.

(C) Once all deficiencies have been corrected by the facility and approved by the department, then the facility may begin utilizing the installed newborn safety incubator at the location and area of the facility that was reviewed and approved by the department. If the facility changes the location of the newborn safety incubator, then the facility shall immediately contact the Department within twenty-four (24) hours and shall not use the newborn safety incubator until the department has inspected and approved the new location. Depending on where the newborn safety incubator has been relocated, the facility may need to complete new registration forms set forth in (5)(A).

(D) The department will post the location of approved facilities on its website at www.health.mo.gov.

(E) The facility shall make the department aware of any change(s) in the contact or contact information listed on the “Newborn Safety Incubator- Location, Contact Information and Attestation of Compliance” registration form within ten (10) days of any change(s) occurring by completing a new “Newborn Safety Incubator- Location, Contact Information and Attestation of Compliance” registration form and submitting it to the department.

(F) The facility shall annually complete a “Newborn Safety Incubator- Location, Contact Information and Attestation of Compliance” registration form, included herein, and submit this completed form to the department within thirty (30) days of the anniversary of the initial or previous renewal registration date.

(G) The department may, at any time, request additional information that the department determines to be necessary to assess compliance with the applicable criteria, standards, and requirements established by this rule. The facility shall submit any additional information requested by the department within thirty (30) days of the department’s request. The department may require any additional information requested to be submitted in less than thirty (30) days if health or safety is of concern.

(H) Any facility that has a newborn safety incubator registered with the department may choose to voluntarily terminate their registration by doing the following:

1. Removing the newborn safety incubator from use by locking the access portal door and removing all signage for the newborn safety incubator; and
2. Notifying the department within seven (7) days of removing the newborn safety incubator from use so the department can close out the registration and remove the facility’s name and location from the department’s website.

(I) The department may inspect the facility at any time to determine compliance with the requirements of this rule. If the department finds any deficiencies during the inspection that do not conform with this rule, the department will provide the facility written notice of all deficiencies. The facility shall send the department a written plan of corrections within ten (10) calendar days to demonstrate how the facility has corrected or is planning to correct the deficiencies set forth by the department. The plan of corrections shall include the date and time the facility plans to resume normal operation of the newborn safety incubator and what measures will be taken to mitigate any risk identified by cited deficiencies until the deficiency or deficiencies are corrected. Failure of the facility to be in compliance with the requirements of this rule may result in legal action against the facility by the department.

AUTHORITY: section 210.950, RSMo Supp. 2021. Original rule filed July 29, 2022.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions nine hundred five thousand nine hundred thirty dollars (\$905,930) in the aggregate.

PRIVATE COST: This proposed rule will cost private entities four hundred forty-seven thousand nine hundred sixty-five dollars (\$447,965) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Taz Meyer at Taz.Meyer@health.mo.gov or Missouri Department of Health and Senior Services, P.O. Box 570, Jefferson City, Missouri 65101-0570. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
 DIVISION OF REGULATION AND LICENSURE
**NEWBORN SAFETY INCUBATOR- LOCATION, CONTACT INFORMATION AND
 ATTESTATION OF COMPLIANCE**

REGISTRATION OF NEWBORN SAFETY INCUBATORS

There is/are _____(number) newborn safety incubator/s located at the following location in Missouri:

_____ Name of Facility
 _____ Street Address of Facility
 _____ City and Zip Code

Please also list the mailing address if it is different from the address above, which may include PO Boxes

_____ Name of Facility
 _____ Address of Facility, which may include PO Boxes
 _____ City, State, and Zip Code

Please also provide additional contact information:

_____ Name of CEO/COO/Administrator
 _____ Email address of CEO/COO/Administrator
 _____ Fax number (if applicable)
 _____ Phone number of CEO/COO/Administrator
 _____ Phone number of facility which can be reached 24 hours a day

ATTESTATION OF COMPLIANCE

I have read and reviewed 19 CSR 30-100.010 and 210.950, RSMo, and agree to ensure compliance with 19 CSR 30-100.010 and 210.950, RSMo. I will make the Department aware of any change(s) in the contact or contact's information listed on this form within ten (10) days of the change(s) occurring. If I change the location of the newborn safety incubator, then I agree to immediately contact the Department within twenty-four (24) hours and to not use the newborn safety incubator until the Department has inspected and approved the new location. I agree to annually complete this form and send it to the Department within thirty (30) days of the anniversary of the initial or previous renewal registration date. In the event that I decide to voluntarily terminate my registration of a newborn safety incubator and stop using the newborn safety incubator, I agree to remove the newborn safety incubator from use by locking the access portal door and removing all signage for the newborn safety incubator. I will also notify the department within seven (7) days of removing the newborn safety incubator from use so the Department can close out the registration and remove the facility's name and location from its website.

SIGNATURE OF COO/CEO/ADMINISTRATOR	DATE
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Please return this form to the following email or mailing address:

Missouri Department of Health and Senior Services
 Bureau of Emergency Medical Services
 P.O. Box 570
 920 Wildwood Drive
 Jefferson City, MO 65102-0570
 emslicensing@health.mo.gov



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
 DIVISION OF REGULATION AND LICENSURE
**LICENSED ELECTRICAL CONTRACTOR/ELECTRICIAN OR TELECOMMUNICATIONS
 INSTALLATION PROFESSIONAL ATTESTATION**

ATTESTATION

This form shall be completed and signed by the licensed electrical contractor/electrician or telecommunications installation professional who completed the installation of the alarm system.

The installation of the alarm system was completed on _____
 DATE

I affirm that the alarm system complies with the following requirements in 19 CSR 30-100.010(3)(A)2 and (3)(C):

1. The alarm system installed in relation to the access portal door and the location where the newborn safety incubator is located will alert a facility trained individual overseeing the newborn safety incubator that the access portal door has been opened.
2. The access portal door alarm is only capable of being turned off from within the facility once a response is made to the newborn safety incubator.
3. The access portal door alarm is wired into the existing structure's: (please check one)
 - electrical
 - telecommunications system
 If wired into the structure's existing electrical system, then I attest that a licensed electrical contractor installed this wiring and the wiring is in compliance with the NFPA 70, National Electrical Code and NFPA 1, Fire Code (if applicable).
4. The facility (please check one)
 - does have a secondary power supply
 - does have a back-up power supply
 - does not have a secondary or back-up power supply
 If the facility has a secondary or back-up power supply, the alarm system was wired into the secondary or back-up power supply by a licensed electrical contractor/electrician to ensure continued operation of the alarm system during outages of the structure's primary power supply.
5. A series of alarms trigger within one (1) minute after opening the access portal door (both an audible alarm triggered to a central location within the facility and an automatic call to 911 triggered from the alarm system if the alarm is not turned off from within the facility within one (1) minute of the commencement of the initial alarm).
6. The audible alarm, automatic call to 911 and the disarming component for the alarm system have been tested and are working appropriately.

By signing this form, I attest that the installation of the access portal door complies with the requirements set forth in 19 CSR 30-100.010(3)(A)2 & (3)(C).

SIGNATURE OF ELECTRICAL CONTRACTOR/ELECTRICIAN OR TELECOMMUNICATIONS INSTALLATION PROFESSIONAL WHO COMPLETED THE INSTALLATION OF THE ACCESS PORTAL DOOR	DATE
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BUSINESS NAME (IF APPLICABLE)

STREET ADDRESS

CITY, STATE AND ZIP CODE

LICENSE NUMBER/JURISDICTION FOR THIS PROJECT (IF APPLICABLE)

PHONE NUMBER AND EMAIL ADDRESS (IF APPLICABLE)

Please return this form to the following email or mailing address:

Missouri Department of Health and Senior Services
 Bureau of Emergency Medical Services
 P.O. Box 570
 920 Wildwood Drive
 Jefferson City, MO 65102-0570
 emslicensing@health.mo.gov



MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
 DIVISION OF REGULATION AND LICENSURE
GENERAL CONTRACTOR ATTESTATION

This form shall be filled out and signed by the general contractor who completed the installation of the access portal door.

The installation of the access portal door was completed on _____
DATE

I affirm that the access portal door complies with the following requirements in 19 CSR 30-100.010(3)(A) & (B):

1. The newborn safety incubator has an access portal door.
2. The access portal door was installed on an exterior wall and provides access to an area within the interior of the building.
3. There is unencumbered access from the exterior of the building through the access portal door.
4. The access portal door has a lock that can be engaged by the relinquishing parent after the newborn has been placed in the newborn safety incubator. The access portal door locks automatically upon closure. This lock may only be unlocked from the interior of the building.
5. A series of alarms trigger within one (1) minute after opening the access portal door (both an audible alarm triggered to a central location within the facility and an automatic call to 911 triggered from the alarm system if the alarm is not turned off from within the facility within one (1) minute of the commencement of the initial alarm).

By signing this form, I attest that the installation of the access portal door complies with the requirements set forth in 19 CSR 30-100.010(3)(A) & (B).

GENERAL CONTRACTOR'S SIGNATURE

DATE

GENERAL CONTRACTOR'S BUSINESS (IF APPLICABLE)

GENERAL CONTRACTOR'S STREET ADDRESS

GENERAL CONTRACTOR'S CITY, STATE AND ZIP CODE

GENERAL CONTRACTOR'S LICENSE NUMBER/JURISDICTION FOR THIS PROJECT (IF APPLICABLE)

GENERAL CONTRACTOR'S PHONE NUMBER AND EMAIL ADDRESS (IF APPLICABLE)

Please return this form to the following email or mailing address:

Missouri Department of Health and Senior Services
 Bureau of Emergency Medical Services
 P.O. Box 570
 920 Wildwood Drive
 Jefferson City, MO 65102-0570
 emslicensing@health.mo.gov