

**NEW YORK STATE DEPARTMENT OF HEALTH
COUNCIL ON HUMAN BLOOD AND TRANSFUSION SERVICES**

GUIDELINES

RESPONSIBILITIES OF DIRECTOR OF BLOOD BANK, MEDICAL DIRECTOR OF
BLOOD BANK AND DIRECTOR OF TRANSFUSION SERVICES

GENERAL DESCRIPTION:

Any facility where blood or blood products are collected must designate an individual as its director of blood bank.

Any facility where blood is collected shall have a medical director of blood bank who must be a qualified physician licensed to practice medicine, and currently registered under the laws of the State of New York or of the state of practice. The medical director may also be the director of the blood bank. Such facilities may or may not also transfuse blood and blood products.

Any facility which issues blood or blood products for transfusion must designate an individual as the director of transfusion services, who must be a licensed physician and currently registered in New York State. If the facility also collects blood, the director of transfusion services may also be the director of blood bank and/or medical director of blood bank.

Appointment and Qualifications:

The appointment of the director of blood bank, medical director of blood bank and director of transfusion services must be made in accordance with the hospital or institutional bylaws and, in the case of hospitals, must include attending staff privileges. Directors must, at minimum, hold an appropriate certificate of qualification from the New York State Department of Health or the New York City Department of Health. At each blood bank which collects blood, either the director or medical director must hold a certificate of qualification in the blood banking collection category. The director of transfusion services must hold a certificate of qualification in transfusion services.

Two types of certificates of qualification for blood banking collection are available:

1. blood banking collection - limited: includes the collection of autogeneic blood for transfusion and excludes testing for transmissible disease markers; and
2. blood banking collection - comprehensive:
 - a. referred testing: includes the collection of allogeneic and autogeneic blood for transfusion and excludes testing for transmissible disease markers;
 - b. on-site testing: includes the collection of allogeneic and autogeneic blood for transfusion and includes all testing required in Subpart 58-2 of 10 NYCRR.

Responsibility and Authority:

Directors' responsibilities should be clearly defined in the hospital or institutional regulations, rules or bylaws, and these should be made known to the entire staff. Directors may delegate certain responsibilities to designees approved by the hospital or institution.

RESPONSIBILITIES:

The director of blood bank is responsible for:

- direction of the blood bank and for ensuring that all applicable regulations, as specified in 10 NYCRR, Subpart 58-2, and requirements are met;
- procurement of the safest possible blood and the operation of the donation facility;
- operation of laboratory facilities, including quality control, necessary to ensure that blood released has been tested as required. The director must approve the written laboratory procedures necessary to carry out these functions;

- investigation of cases of possible release of contaminated or improperly derived products;
- selecting the source of blood to be imported into the facility in compliance with all applicable rules and regulations. The director may refuse to accept blood from any given source at his/her sole discretion.
- decision making for retaining or relieving of responsibility all physicians, nurses, technologists and technicians associated with the blood bank.

The medical director of blood bank is responsible for:

- all aspects of donor selection and donor safety.

The director of transfusion services is responsible for:

- supervision of the transfusion service and ensuring that all applicable regulations, as specified in 10 NYCRR, Subpart 58-2, and requirements are met;
- operation of the laboratory facilities necessary to ensure adequate compatibility testing and appropriate quality control necessary to ensure safe and compatible transfusion. The director must approve the written laboratory procedures necessary to carry out these functions;
- selecting the source of blood to be transfused in the facility in compliance with all applicable rules and regulations. The director may refuse to use blood from any given source at his/her sole discretion;
- being appraised of and investigating all alleged or potential transfusion complications. To perform this function, the director may recommend to the patient's physician discontinuance of any transfusion in progress if in the best interests of the patient. Furthermore, to perform this function, he/she must have full access to all transfused patients and their medical records.

- promulgating criteria for the appropriate use of blood and blood components and educating attending physicians, housestaff and other hospital staff in the proper use of blood and blood components. It is the director's ultimate responsibility and authority to establish priorities, indications and written procedures for transfusion of blood, blood components and derivatives. He/she directly, or through designees, has the authority to approve all blood or blood components released for transfusion. The director has the authority to decide whether blood may be released for transfusion;
- decision making for retaining or relieving of responsibility all physicians, nurses, technologists and technicians associated with the transfusion service;
- providing all reports required by the transfusion committee and authorized accrediting and regulatory agencies.

ACCESS AND PEER REVIEW:

- The director of transfusion services should be a member of the medical staff and must have access to the governing boards and the administration of the hospital, either directly or through well-defined channels in accordance with established institutional practice.
- The performance of directors is subject to peer review by accrediting agencies, the medical board and, finally, the governing board of the appointing institution.

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