

# ALASKA VACCINE DISTRIBUTION HANDBOOK

Revised: January 2015



Alaska Department of  
Health and Social Services  
Division of Public Health



ALASKA  
IMMUNIZATION  
PROGRAM

# Alaska Vaccine Distribution Handbook

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**Revised: January 2015**

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# Alaska Immunization Program Contact Information

## Epidemiology Vaccine Depot (Distribution center for state-supplied vaccine)

Phone:	(907) 341-2202
Email:	<a href="mailto:vaccinedepot@alaska.gov">vaccinedepot@alaska.gov</a>
Fax:	(907) 341-2228
Website:	<a href="http://www.epi.alaska.gov/id/immune.stm">www.epi.alaska.gov/id/immune.stm</a>

## VacTrAK (State immunization information system)

Phone:	1-866-702-8725 or, in Anchorage, (907) 269-0312
Email:	<a href="mailto:vactrak@alaska.gov">vactrak@alaska.gov</a>
Fax:	(907) 562-7802
Website:	<a href="http://www.vactrak.alaska.gov">www.vactrak.alaska.gov</a>

## Other Information

Immunization Helpline:	1-888-430-4321 or, in Anchorage, (907) 269-8088
Office Phone:	(907) 269-8000
Email:	<a href="mailto:immune@alaska.gov">immune@alaska.gov</a>
Fax:	(907) 562-7802

**Patient education & provider resources** (i.e., free printable materials, blank immunization records, posters, etc.) available at [www.epi.alaska.gov/id/iz/imrs/default.htm](http://www.epi.alaska.gov/id/iz/imrs/default.htm).

# Introduction

The Alaska Immunization Program's vision is that all Alaskans are protected against vaccine-preventable diseases. Our mission is to prevent and control vaccine-preventable diseases statewide by:

- Providing vaccines to health care providers at no charge;
- Providing an immunization information system for use by health care providers and schools to maintain consolidated immunization records for Alaskans of all ages;
- Ensuring school and childcare compliance with immunization regulations;
- Providing immunization education and training for health care providers and the general public;
- Coordinating surveillance and control efforts for vaccine preventable diseases; and
- Supporting efforts to increase vaccinations for all Alaskans

One way of accomplishing our vision is by using federal and state funds to obtain vaccines for distribution to eligible health care providers. These funding sources require both the Alaska Immunization Program and enrolled providers to be accountable for the use and management of these publicly-funded vaccines. Accountability requirement changes for 2015 include, but are not limited to, the following:

- On January 1, 2015, the State implemented the new Alaska Vaccine Assessment Program (AVAP). To facilitate the adoption of this new program, there are changes in the screening and documentation criteria for child and adult eligibility to receive state-supplied vaccines.
- "Borrowing" practices within a single facility involving temporary sharing between a provider's privately purchased vaccine and state-supplied vaccine stock is no longer permitted.
- Certificates of calibration for each temperature monitor used in storage units for state-supplied vaccine must continue to meet Vaccines for Children (VFC) Program criteria. In addition, back up temperature monitors utilized for temporary storage units must be calibrated. Documentation of calibration certification must be kept on file and be readily available to the Alaska Immunization Program upon request.
- A new vaccine management education webinar will be available in the spring and must be completed by June 30, 2015 for all enrolled vaccine and back-up coordinators.
- As of January 2016, providers using a combination storage unit (with dual controls) will only be allowed to use the refrigerator section for vaccine storage.

By signing the Provider Agreement to receive state-supplied vaccines, providers agree that facility staff involved with vaccine management will comply with federal and state requirements. This handbook and associated documents found on the Alaska Immunization Program's website and linked throughout this handbook contain information that is part of each enrolled provider's vaccine management plan. All records related to state-supplied vaccine administration and management must be maintained for a minimum of three years.

If you have any questions or need assistance, please contact the Epidemiology Vaccine Depot.

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# Acronyms

ACIP	Advisory Committee on Immunization Practices
AFIX	Assessment, Feedback, Incentives, eXchange
AVAP	Alaska Assessment Program
CDC	Centers for Disease Control and Prevention
FQHC	Federally Qualified Health Center
PIN	Provider Identification Number
RHC	Rural Health Center
VacTrAK	(State Immunization Information System)
VFC	Vaccines for Children Program
VIS	Vaccine Information Statement
VOMS	Vaccine Ordering and Management System

# 1. Enrollment

## 1.1 Who May Enroll

Providers enrolling to receive vaccine from the Alaska Immunization Program must hold a license in Alaska, have prescribing authority for vaccines, and be a person (or persons) who will be responsible (and liable) for the conditions outlined in the provider enrollment agreement for the facility or organization. Qualifying providers include: Medical Doctor (MD), Doctor of Osteopathy (DO), Advanced Nurse Practitioner (ANP), or Physician Assistant (PA) with their signing collaborating physician. Providers in remote areas of the state may need to meet additional criteria, including having the ability to receive a vaccine shipment from the Epidemiology Vaccine Depot within 48 hours. Organizations self-identifying as a Federally Qualified Health Center (FQHC) must include a copy of their federal documentation each year with enrollment that validates their FQHC designation. Please contact the Epidemiology Vaccine Depot for additional information.

Providers enrolling in the Alaska Immunization Program to receive state-supplied vaccines agree to ALL conditions contained in this handbook and the Provider Agreement.

## 1.2 Enrollment & Re-enrollment Process

Providers are required annually to complete both the VacTrAK Application and the Provider Agreement in order to receive state-supplied vaccine. Filling out the VacTrAK Application gives the provider access to the VacTrAK immunization information system and designates user authorizations and permissions. The Provider Agreement located within VacTrAK allows a provider to enroll to receive state-supplied vaccine.

For detailed instructions on how to fill out the VacTrAK Application and Provider Agreement, please refer to the [2015 Vaccine Provider Agreement Instructions](#).

### 1.2.1 Enrollment Process

<b>1. Complete the VacTrAK Application</b>	Click <a href="#">here</a> to fill out and print the VacTrAK Application. Submit the VacTrAK Application to VacTrAK Support by email at <a href="mailto:vacktrak@alaska.gov">vacktrak@alaska.gov</a> or (907) 562-7802.
<b>2. Complete the Provider Agreement</b>	After completing the VacTrAK application, login to VacTrAK and submit the Provider Agreement within VacTrAK. Print the "PDF Full" and submit the signature page (and if applicable, the frozen vaccine certification page) to the Epidemiology Vaccine Depot by email at <a href="mailto:vaccinedepot@alaska.gov">vaccinedepot@alaska.gov</a> or fax (907) 341-2228.

	If your facility is a FQHC or Rural Health Center (RHC), fax the additional federal documentation that validates your designation.
<b>3. Provider Enrollment Visit</b>	Once enrollment has been approved, new providers will be contacted by the Epidemiology Vaccine Depot to arrange a Provider Enrollment site visit.
<b>4. Order Vaccines</b>	New providers will receive the ability to order vaccines after submitting two weeks of approved storage unit temperatures, reviewing the VOMS training resources and completing the Provider Enrollment visit.
<b>5. Education Webinar</b>	<p>The certifying provider, vaccine coordinator and the back-up vaccine coordinator of all facilities receiving state-supplied vaccine are required to complete an education webinar. Certificates of completion must be submitted to the Epidemiology Vaccine Depot within 30 days of enrollment.</p> <p>New enrolling providers must complete the following CDC webinar: <a href="#">Immunization: You Call the Shots-Module Sixteen-Vaccines for Children Program—2015 (WB2486)</a>.</p>

## 1.2.2 Re-enrollment Process

<b>1. Complete the VacTrAK Application</b>	Previously enrolled providers will be contacted by VacTrAK support to update their application information.
<b>2. Complete the Provider Agreement</b>	After completing the VacTrAK application process, login to VacTrAK and submit the Provider Agreement within VacTrAK. Print the “PDF Full” and submit the signature page (and if applicable, the frozen vaccine certification page) to the Epidemiology Vaccine Depot by email at <a href="mailto:vaccinedepot@alaska.gov">vaccinedepot@alaska.gov</a> or fax (907) 341-2228. If your facility is a FQHC or RHC, fax the additional federal documentation that validates your designation.
<b>3. Provider Enrollment Visit</b>	If re-enrolling providers have experienced a lapse of time in between enrollments, an enrollment visit may be required.
<b>4. Order Vaccines</b>	Re-enrolling providers will be able to resume ordering vaccines after the enrollment is approved.
<b>5. Education Webinar</b>	The vaccine coordinator and the back-up vaccine coordinator of all facilities receiving state-supplied vaccine are required to complete an education webinar annually. Providers will be notified when the new education webinar is available.

## 1.3 Fee Policies for Vaccines

Providers receiving state-supplied vaccine must comply with the following fee policies:

- Providers **cannot** charge a patient or health plan (i.e., payer) for the cost of a vaccine received from the Alaska Immunization Program.
- For non-Medicaid VFC, the administration fee cap is \$27.44.
- For Medicaid patients, the cap is the State Medicaid fee cap (see the following for more information: [manuals.medicaidalaska.com/medicaidalaska/providers/FeeSchedule.asp](http://manuals.medicaidalaska.com/medicaidalaska/providers/FeeSchedule.asp)).
- For privately insured patients, the administration fee is your contracted vaccine administration fee.
- State-supplied vaccine may not be denied to a patient due to the inability of recipient to pay an administration fee.

## 1.4 Provider Identification Number (PIN)

The Epidemiology Vaccine Depot will issue each facility a unique six-digit Provider Identification Number (PIN). Use this number in all email, fax, mail and phone interactions with the Epidemiology Vaccine Depot. Referencing the PIN number in the subject line of any correspondence with the Alaska Immunization Program will expedite the processing of your information.

## 1.5 Provider Practice Profile

The Provider Practice Profile is a section within the Provider Agreement in VacTrAK. This section of the agreement defines the number of children and adults who received vaccinations for the full prior year at each facility. The Provider Practice Profile identifies eligibility status by age group. If you are a re-enrolling provider, the Provider Practice Profile will auto-populate with prior year administration data that was entered into VacTrAK by your facility. Review carefully and update the numbers accordingly. When developing the profile, it is essential to be accurate when describing your patient population. Billing staff may be able to help you respond to this section of the Provider Agreement if you are using patient records to help determine your Provider Practice Profile. The Alaska Immunization Program uses the information in the profiles to determine the amount of vaccine each provider will need.

## 1.6 Changes in Staff/Facility Status

Providers are required to contact the Epidemiology Vaccine Depot within ten days of any change including, but not limited to: the certifying provider, vaccine coordinator, back-up vaccine coordinator, mailing/shipping address, vaccine delivery hours and facility status. New certifying providers, vaccine coordinators, and back-up vaccine coordinators must complete the following CDC webinar within 30 days, [Immunization: You Call the Shots-Module Sixteen-Vaccines for Children Program – 2015 \(WB2486\)](#). Submit a copy of the certificate of completion to the Epidemiology Vaccine Depot.

## 1.7 Inactivation

Enrolled facilities may be inactivated due to:

<b>Facility request:</b>	In the event of a facility closure or decision to discontinue receipt of state-supplied vaccine, immediately notify the Epidemiology Vaccine Depot.
<b>Alaska Immunization Program designation:</b>	During enrollment to receive state-supplied vaccines, providers agree to adhere to federal and state requirements. If at any time it is determined that these requirements are not being followed, the Alaska Immunization Program may investigate for fraud and abuse and, if necessary, will inactivate the provider.
<b>Failure to complete the enrollment forms:</b>	If currently enrolled providers do not submit the enrollment forms during the re-enrollment period each year, the Alaska Immunization Program may inactivate the provider.

Inactivated providers will be contacted by the Epidemiology Vaccine Depot for instruction on the proper transfer or return process for all vaccines on hand.

## 1.8 Fraud and Abuse

If it is determined that providers are not adhering to federal and state requirements, the Alaska Immunization Program may investigate for fraud and abuse and, if necessary, will implement corrective actions or inactivate the provider from the program. Fraud or abuse can occur in many ways. Some examples of potential fraud and abuse are:

- Providing state-supplied vaccine to non-eligible patients
- Selling or otherwise misdirecting state-supplied vaccine
- Billing a patient or third party for state-supplied vaccine
- Charging more than the established maximum regional fee cap for administration of a state-supplied vaccine to a VFC non-Medicaid eligible child
- Denying VFC-eligible children state-supplied vaccine because of a parents' inability to pay for the administration fee
- Failing to implement requirements of the Alaska Immunization Program
- Failing to screen and document eligibility status for every vaccine dose administered
- Failing to maintain all records for three years
- Failing to fully account for state-supplied vaccine
- Failing to properly store and handle state-supplied vaccine

- Ordering state-supplied vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering vaccine
- Excessive waste of state-supplied vaccine

## 2. Vaccine Funding, Eligibility, and Administration Documentation

### 2.1 State-supplied Vaccine Funding

The Alaska Immunization Program currently receives both federal and state funds to procure child and adult vaccines. These funding sources, which are noted below, allow enrolled providers to receive state-supplied vaccine. Accurate eligibility screening and documentation is required to ensure accountability and ongoing availability of each funding source.

**(A). Vaccines for Children (VFC) Program:** This federal entitlement program provides funds to purchase all Advisory Committee on Immunization Practices (ACIP) recommended vaccines for administration only to children ages 0 through 18 years who meet at least one of the following eligibility criteria:

- Medicaid eligible/enrolled
- Uninsured
- American Indian or Alaska Native
- VFC-Underinsured

Providers receiving state-supplied vaccines who serve VFC-eligible children must offer ALL age appropriate ACIP recommended vaccines for their patients 0 through 18 years of age. It is the intent of the federal program that all VFC vaccines be available for any entitled child at all VFC provider locations. The only exceptions to this requirement are: (1) a provider who may not be able to receive varicella vaccine by direct ship from the manufacturer and (2) specialty providers (e.g., OB/GYNs or providers serving only adults) may limit state-supplied vaccines to those that are relevant for their practice.

For additional information and answers to frequently asked questions about the VFC Program, visit the Centers for Disease Control and Prevention's (CDC) VFC website at: [www.cdc.gov/vaccines/programs/vfc/index.html](http://www.cdc.gov/vaccines/programs/vfc/index.html).

Because all pediatric vaccines (those supplied for persons ages 0 through 18 years) provided by the Alaska Immunization Program are partially supported with VFC funds, vaccine providers enrolled to receive childhood and adolescent state-supplied vaccine are considered VFC providers.

**(B). Section 317 of the U.S. Public Health Service Act:** "317" federal funds are available for the purchase of vaccines, but are not intended to routinely vaccinate fully insured individuals. Section 317 vaccines are a critical resource for filling gaps in the nation's immunization services.

- (C). **Alaska Vaccine Assessment Program (AVAP) and State general funds:** To ensure universal statewide access to vaccines, the State created a vaccine assessment account. AVAP is a State program that funds vaccine purchases for Alaskans. AVAP’s goal is to make vaccines available for residents of all ages, free of charge. The program is authorized in Alaska statute [18.09.200](#) and establishes a Vaccine Assessment Account that will enable DHSS to purchase all pediatric and select adult vaccines at costs below those of private purchase alternatives.

A combination of AVAP and state funds are used to procure vaccines for:

- Children ages 0 through 18 years (Governor’s budget/AVAP for all ACIP recommended vaccines)
- Adults age 19 and above are covered for the following select vaccines:
  - HPV (females ages 19 through 26 years and males ages 19 through 21 years)
  - Meningococcal (for ages 19 through 20 years)
  - Pneumovax
  - Td/Tdap
  - Zoster (ages 60 through 64 years)

Regardless of the funding source, all vaccines distributed through the Alaska Immunization Program are considered “state-supplied” vaccines.

## 2.2 Patient Eligibility: Children (ages 0 through 18 years)

*All children 0 through 18 years of age are eligible to receive state-supplied vaccines.* While patients are not required to provide verification of eligibility status, parents/guardians of children with health insurance should review their policy prior to receiving vaccines since some eligibility criteria is determined by insurance coverage.

### 2.2.1 Criteria

The state-supplied vaccine eligibility criteria for children are through one of the following programs:

#### **Vaccines for Children (VFC) Program**

- Medicaid eligible/enrolled
- Uninsured
- Alaska Native/American Indian
- Underinsured children (available only at Federally Qualified Health Center (FQHC) or deputized provider)
  - A child who has health insurance, but coverage does not include vaccines; or
  - A child whose insurance covers only selected vaccines is eligible to receive only those vaccines that are not covered by the child's insurance through the VFC program; or

- A child whose insurance caps the cost for vaccine coverage is eligible to receive VFC vaccines only after the insurance cap has been reached

### Alaska Vaccine Assessment Program (AVAP)

- All other children

For additional information on state-supplied vaccine eligibility for children, click [HERE](#).

## 2.2.2 Documentation

Eligibility status documentation (electronic or paper) must include the following:

- Child's first and last name and middle initial
- Child's date of birth
- Parent/Guardian/Individual of Record's first and last name and middle initial
- Primary provider's name
- Date of each immunization visit
- One of the following eligibility status:
  - Medicaid eligible/enrolled
  - Uninsured
  - American Indian/Alaska Native
  - Underinsured (served at FQHC, RHC, or a deputized facility)
  - State vaccine (AVAP)
  - Private vaccine

Providers not performing direct data entry into VacTrAK must use a format that meets federal and state requirements for eligibility documentation as described above.

Eligibility documentation must be maintained in the patient's written or electronic medical record for at least three (3) years.

## 2.3 Patient Eligibility: Adults (age 19 years and older)

### 2.3.1 Criteria

Adults are eligible to receive select state-supplied vaccines if they meet one of the following criteria:

- An individual's health plan participates in AVAP (a list of participating payers will be posted on [www.akvaccine.org](http://www.akvaccine.org)).

- Medicare health plan is not a participating payer. For Medicare recipients, see uninsured bullet below.
- An uninsured individual's medical provider pays (opt-in) into AVAP for uninsured adults.
  - Opt-in providers are able to provide for all adults.
- An individual is covered by Medicaid only.

For additional information on state-supplied vaccine eligibility for adults, click [HERE](#).

### 2.3.2 Documentation

Eligibility status documentation (electronic or paper) must include the following:

- Patient's first and last name and middle initial
- Patient's date of birth
- Primary provider's name
- Date of each immunization visit
- One of the following eligibility status:
  - Uninsured
  - Private insured
  - Private vaccine

Providers not performing direct data entry into VacTrAK must use a format that meets federal and state requirements for eligibility documentation as described above.

Eligibility documentation must be maintained in the patient's written or electronic medical record for at least three (3) years.

Patients are not required to provide verification of eligibility status.

## 2.4 Vaccine Administration Documentation

Per Federal Law 42 US Code 300aa-25 the following must be documented in the patient's medical record for each vaccine administered:

- Vaccine name
- Date administered
- Publication date of VIS
- Date VIS provided to patient
- Name of vaccine manufacturer
- Vaccine Lot number

- Name and title of vaccinator
- Clinic address

Per Alaska Administrative Code 7 AAC 27.650 (a): Within 14 days of administering a vaccine, a health care provider must document dose-level eligibility status in VacTrAK. This reporting requirement is applicable for any vaccine administered, including state-supplied and privately purchased vaccines.

### **7 AAC 27.650. Health care provider disclosure to the immunization information system**

- (a) Not later than 14 days after administering an immunization, a health care provider shall report information concerning the patient and the immunization in accordance with this section to the immunization information system maintained by the department. A health care provider shall disclose participation in the immunization information system to patients.
- (b) A health care provider, public health agent, or designee may report demographic and immunization data, and other pertinent information, permitted under [AS 18.15.360](#) (c), to the immunization information system.
- (c) A health care provider shall submit vaccine information to the immunization information system either through electronic or manual entry in a format approved by the department, and shall include the following data elements:
  - (1) if not already submitted by the state registrar under 7 AAC [05.931](#), the name, address, sex, race, and date of birth of a patient;
  - (2) the date of administration of the vaccine;
  - (3) the lot number of the vaccine;
  - (4) the dose amount and manufacturer of the vaccine;
  - (5) the dose-level vaccine eligibility code;
  - (6) other data elements as specified by the department, if essential for adequate public health response.
- (d) A health care provider who administers state-supplied vaccine shall utilize
  - (1) the ordering module of the immunization information system for ordering state-supplied vaccines; and
  - (2) the inventory module of the immunization information system for tracking public or public and private vaccine supply.
- (e) Data in the immunization information system may be used for the following purposes:
  - (1) any use permitted under 7 AAC [27.892](#) and 7 AAC [27.893](#);
  - (2) to ensure necessary immunizations are provided and over-immunization is avoided;

**7 AAC 27.650 (continued). Health care provider disclosure to the immunization information system**

- (3) to assess immunization coverage rates and determine areas of under-immunization;
- (4) to assist individuals or entities in the evaluation of immunization data for the purpose of disease management, care management, case management, or quality management programs.
- (f) An immunization record provided by the immunization information system is an official certificate of immunization, as required under [AS 14.30.125](#) and 4 AAC [06.055](#) for attendance at a school, under 7 AAC [50.455](#) for a child in care in a foster home or residential child care facility, and under 7 AAC [57.550](#) for admission to a child care facility.

Providers must distribute a current Vaccine Information Statement (VIS) to a patient each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at [www.vaers.hhs.gov/](http://www.vaers.hhs.gov/).

## 3. Vaccine Distribution

### 3.1 Vaccine Availability

The Alaska Immunization Program makes every effort to maintain consistency in stocking vaccine brands. Typically, when the program does not have a particular brand of vaccine available, it is due to constraints and limitations at a national level. CDC annually negotiates vaccine contracts with manufacturers. As a result, occasional changes are necessary in the brand of vaccine supplied. If this occurs, the Alaska Immunization Program may send your facility an alternate vaccine from a different manufacturer.

### 3.2 Accountability Requirements

Providers receiving state-supplied vaccine are required to complete the following accountability measures. Any gaps in data will cause a delay in processing vaccine orders.

<b>Daily:</b>	<p>Document temperatures on the state-specific <b>temperature log</b>.</p> <p>Providers must review and document the temperature status twice a day on all storage units containing state-supplied vaccine. For storage units containing a LogTag, you must review and document the alarm status and temperature from the state-supplied calibrated temperature monitoring device only. The temperature log(s) must be completed in full for all storage units. Providers are no longer required to submit the log(s) to the Epidemiology Vaccine Depot each month; however, temperature log(s) must be made readily available to the Alaska Immunization Program upon request. See the Inventory Management chapter for more information on monitoring temperatures.</p>
<b>Weekly:</b>	<p>Download and submit the state-supplied LogTag temperature monitoring <b>graphs</b>.</p> <p>Providers must download graph data from state-supplied LogTag temperature monitoring device(s) and submit to the Epidemiology Vaccine Depot weekly. See the Inventory Management chapter for more information on monitoring temperatures.</p>
<b>Monthly:</b>	<p>Perform inventory <b>reconciliation</b> in VacTrAK of state-supplied vaccine stock(s).</p> <p>Providers must perform a monthly reconciliation of their state-supplied vaccine stock(s) regardless of their ordering cycle. This includes processing any returns or adjustments to account for any discrepancies in their state-supplied stock(s). Reconciliation must be performed prior to submitting a vaccine order. VacTrAK will not permit a vaccine order if reconciliation has not been performed within a 14 day period prior to order submission.</p>

<b>Ongoing:</b>	Providers <b>must enter patient vaccine administration data</b> into VacTrAK within 14 days of service either manually or electronically per 7 AAC 27.650. This reporting requirement is applicable for any vaccine administered, including state-supplied and privately purchased vaccines. This provides dose-level accountability for all vaccines used in Alaska within VacTrAK. Tracking dose-level accountability in VacTrAK is used to meet federal and state mandates.
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### 3.3 How to Order Vaccines

All state-supplied vaccine requests must be placed through VacTrAK's Vaccine Ordering and Management System (VOMS). Training materials consisting of short videos and/or PDF instructions are available on the VacTrAK homepage under [Vaccines Ordering Management System \(VOMS\) Training Materials](#).

To ensure an accurate order, a provider must take into consideration their ordering cycle schedule, the amount of space available in the storage unit, what stock is on hand and seasonal needs. Choose an individual order set that corresponds to the type of vaccine order being placed (i.e., standard pediatric order set, seasonal flu order set, adult order set, etc.). The Alaska Immunization Program will monitor requests and may adjust order quantities according to administration data, the provider practice profile and current inventory in VacTrAK. If reported administration data and inventory do not support the quantities requested or if specific vaccine(s) are in short supply, the vaccine quantity ordered may be reduced by program staff.

### 3.4 When to Order Vaccines

The Alaska Immunization Program will assign facilities a standard ordering cycle based on routine rate of vaccine use and/or patient population as identified in the Provider Practice Profile. An order which is placed outside an assigned scheduled ordering cycle will be reviewed to determine the reason for the off-schedule order and the possible need to change your ordering cycle. This additional review may cause a delay in receipt of your order.

It normally takes one week to fill an order after verifying that accountability requirements have been met, but may be delayed up to three weeks during periods of high order demand. Please keep in mind that you should NOT place a vaccine order if your facility will be closed for a holiday or an extended vacation. It is your responsibility to notify the Epidemiology Vaccine Depot if your facility is going to be closed or if there has been a change in your business hours or delivery information.

### 3.5 Direct Ship Vaccines (varicella and zoster)

Varicella and zoster vaccine types require special shipping and storage conditions. They are only available by direct shipment from the manufacturer (Merck) to the provider. This special shipping process usually requires one to three weeks once an order is approved. Once shipped from Merck, the

vaccine will typically be in transit for two to three days. Contact the Epidemiology Vaccine Depot and Merck if your shipment was in transit greater than 72 hours so that viability of the vaccine may be determined. Varicella vaccine is funded through two funding sources; therefore, Merck may send your order in two separate shipments. The minimum order of varicella that can be placed is 20 doses to accommodate the two funding sources.

### 3.6 Shipment and Receipt of Vaccine Orders

Providers can check the status of a submitted order in VacTrAK. Once an order is in the status of “Shipped or Ready for Pick Up” the order is considered “completed” in VacTrAK. This indicates that: (1) Local orders are filled and are awaiting pick up at the Epidemiology Vaccine Depot by the provider or (2) Out of town orders have been shipped to local airports or sent via long distance courier service.

Both local pick up and out of town shipments must be carefully planned by both parties so that the cold chain is maintained. Once the vaccine is picked up from the Epidemiology Vaccine Depot or airport, you must transport vaccine to your facility within two hours. The Epidemiology Vaccine Depot is open for local vaccine pick up only during the days/times shown below:

**Epidemiology Vaccine Depot**  
**Hours Open for Vaccine Local Pick Up**

Day	Time
Monday	8:00am – 1:00pm
Wednesday	8:00am – 4:30pm
Friday	8:00am – 1:00pm

Note: The Epidemiology Vaccine Depot continues to be available for telephone consultation during business hours Monday – Friday, 8:00am – 5:00pm (excluding State holidays).

### 3.7 Procedures upon Vaccine Receipt

All facilities must have procedures in place for immediate receipt and storage of vaccine due to its temperature sensitivity. All facility staff must be trained to recognize a vaccine shipment when it is delivered and what should be done upon its arrival in your facility. Follow these steps for receiving vaccine:

1. Pick up shipment from the Epidemiology Vaccine Depot or airport and transport it back to your facility within two hours.
2. Review any temperature indicators included with shipping container(s). Complete this process one box at a time. If multiple boxes are received, each box may experience different temperatures.

3. Unpack each box and verify the contents against the invoice for vaccine quantity, lot number, and expiration date.
4. Immediately store all vaccines in your storage unit following all storage requirements. (Isolate vaccines with possible temperature issues and label them as “do not use” until the Epidemiology Vaccine Depot is able to determine the viability of the vaccine.)
5. Contact the Epidemiology Vaccine Depot with any discrepancies, possible temperature issues or concerns about an order.
6. Immediately login to VacTrAK and receive the order in the Orders/Transfer menu.

# 4. State-supplied Vaccine Formularies

Revised January 2015

State-supplied Pediatric Vaccines	Brand Name®
DT (Diphtheria/ Tetanus)	No trade name
DTaP (Diphtheria/ Tetanus/ acellular Pertussis)	INFANRIX
DTaP/ Hepatitis B/ IPV	PEDIARIX
DTaP/ IPV	KINRIX
Hepatitis A	HAVRIX
Hepatitis B	Recombivax HB
Hib (Haemophilus influenza type b)	PedvaxHIB
HPV4 (Human papillomavirus)	Gardasil
Influenza	Varies each season
IPV (Inactivated poliovirus)	IPOL
MCV4 (Meningococcal conjugate)	Menactra
MMR (Measles/ Mumps/ Rubella)	M-M-R II
PCV13 (Pneumococcal conjugate)	Prennar 13
PPSV23 (Pneumococcal polysaccharide)	Pneumovax 23
RV5 (Rotavirus)	RotaTeq
Td (Tetanus/ Diphtheria)	Tenivac
Tdap (Tetanus/ Diphtheria/ acellular Pertussis)	BOOSTRIX
Varicella (chickenpox)	Varivax

State-supplied Adult Vaccines	Brand Name®
HPV4 (Human papillomavirus)	Gardasil
Influenza	Varies each season
MCV4 (Meningococcal conjugate)	Menactra
PPSV23 (Pneumococcal polysaccharide)	Pneumovax 23
Td (Tetanus/ Diphtheria)	Tenivacc
Tdap (Tetanus/ Diphtheria/ acellular Pertussis)	BOOSTRIX
Zoster (shingles)	Zostavax

# 5. Inventory Management

## 5.1 Storage and Handling

Even a small practice is likely to have thousands of dollars' worth of vaccine in the refrigerator at a time. Vaccines must be stored appropriately in order to maintain potency. A temperature controlled environment used to maintain and transport vaccines in optimal condition is called the vaccine cold chain. The vaccine cold chain relies on three main elements:

- Effectively trained personnel
- Appropriate transportation and storage equipment
- Efficient management procedures

A staff member at each facility must be designated as the vaccine coordinator who will be responsible for ensuring that all vaccines are stored and handled correctly. One back-up vaccine coordinator must be designated who can assume the same responsibilities in the absence of the primary vaccine coordinator.

## 5.2 Vaccine Storage Units

Providers must have appropriate equipment that is used only for vaccine storage and pharmaceuticals (i.e., no food or drink is in the unit) and maintains proper temperature required conditions for vaccine storage.

## 5.3 Refrigerators and Freezers

It is highly recommended that providers use pharmaceutical (i.e., "purpose-built" vaccine or laboratory-grade) refrigerators for vaccine storage. Stand-alone separate refrigerator and freezer units provide the next best option. However, a combination refrigerator and freezer unit sold for home or commercial use is acceptable for vaccine storage if the refrigerator and freezer compartments each have separate external doors **AND** the unit has dual controls (i.e., the refrigerator and freezer are controlled separately) **OR** only one compartment of the unit is used to store vaccines. **NOTE:** Starting in 2016, providers using a combination storage unit (with dual controls) will only be allowed to use the refrigerator section for vaccine storage.

Dormitory or bar-style refrigerators are not permitted for **ANY** vaccine storage. A dormitory or bar-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one external door and has an evaporator plate (cooling coil) which is usually located inside the "freezer" within the refrigerator. Dormitory or bar-style refrigerators place vaccine at a high risk of freezing.

Storage units should be placed in a well-ventilated room and have space around the sides and tops to allow for appropriate heat exchange and cooling functions.

## 5.4 Vaccine Storage

Placement and organization within the storage unit is vital to maintaining vaccine stability.

- Place the vaccines in the center of the refrigerator, leaving adequate space for air circulation. (Some areas of the refrigerator – e.g., in the door or near the sides – may hold different temperatures than the center of the unit.) Vaccines must be stored on the shelves of the refrigerator or freezer, not in the door or in crisper drawers. (Crisper drawers should be removed from the refrigerator.)
- Small trays may be used to help quickly move stock within a refrigerator, reducing the amount of time the door must remain open, potentially exposing vaccines to warmer air temperatures.
- Store all vaccines in their original box. Protect the following vaccines from light: Varivax, Zostavax, MMR, Gardasil and RotaTeq.
- State-supplied vaccines must be segregated and/or marked in such a way that they are easily distinguished from privately purchased vaccines. This does NOT mean that state-supplied and privately purchased vaccines must be stored in separate refrigerator(s) or freezer(s).
- Do not store food or drink in vaccine refrigerators or freezers.
- If using a combination refrigerator/freezer unit, do not place the vaccine directly under the outlet that blows air from the freezer into the refrigeration area.

## 5.5 Storage Unit Temperatures

Refrigerator storage units must maintain temperature between 35°F and 46°F at all times. Setting the temperature to achieve an average of 40 degrees will provide the best safety margin.

Freezer storage units must maintain temperatures between -58°F and +5°F at all times.

Water bottles and gel packs may be placed in the refrigerator. Gel packs may also be placed in the freezer to help stabilize internal temperatures, including those times in which power outages occur. (Additionally, this practice will provide readily available cold packs for storing or moving vaccine in the event you need to activate your emergency plan.) Label water bottles with “Do NOT drink.”

## 5.6 Temperature Monitoring

Temperatures in all vaccine storage units must be monitored. Permanent storage units must be monitored using the calibrated LogTag – the temperature monitoring device – provided by the Alaska Immunization Program.

Instructions on how to install the software and produce required graphs on the LogTag are found at [LogTag Software and Device Initial Setup](#) and [LogTag Instructions for Daily Use](#).

Providers are required to have a back-up calibrated continuous monitoring device on hand in case of emergency or vaccine transport. Providers may calibrate and use the previous state-supplied LogTag as their back-up device.

Certificates of calibration that meet ISO 17025 standards (see appendix B) must be maintained for all devices which are used for monitoring state-supplied vaccine at your facility. Documentation must be readily available to the Alaska Immunization Program upon request.

Temperature monitoring devices must be placed in each vaccine storage unit. Place the device inside the storage unit, in the **middle section** as close to the vaccine stock as possible. This will allow the device reading to more closely reflect the actual temperature of the vaccine. (Some areas of the refrigerator – e.g., in the door or near the sides – may hold different temperatures than the center where the vaccine is properly stored.) Improper placement of the monitor may result in vaccine wastage.

If using a combination refrigerator/freezer unit, do **not** place temperature monitoring device directly under the outlet that blows air from the freezer into the refrigeration area.

All other vaccine refrigerators/freezers (temporary or day use storage units) must be monitored by using a calibrated temperature monitoring device supplied by your facility. For information on how to recalibrate temperature monitoring devices, contact the monitor manufacturers.

Each day the facility is staffed, temperatures for all state-supplied vaccine storage units must be recorded at least twice daily on the current version of the [Vaccine Temperature Log and Action Taken Form](#). It is no longer necessary to submit your completed temperature logs to the Epidemiology Vaccine Depot for review each month. Maintain all completed logs at your facility for a minimum of three years. This documentation must be readily available to the Alaska Immunization Program upon request. It is still a requirement to submit your downloaded temperature LogTag graphs to the Epidemiology Vaccine Depot once a week.

LogTag graphs must be downloaded and reviewed at least once a **week**. When reviewing the LogTag display screen for the twice a day log, view and record the current temperature, ensure the battery life indicator says “ok” and that the word “Alarm” is not displayed. Write down the current temperature on the log, write Y or N for the alarm status and sign your initials. If temperatures are found outside acceptable parameters, immediately contact the Epidemiology Vaccine Depot. If the word “Alarm” is displayed on the screen, this means that the device has recorded an out of range temperature since your last review and the graph must be downloaded immediately and emailed to the Epidemiology Vaccine Depot. If the battery life indicator is low, change the battery.

The [Vaccine Temperature Log and Action Taken Form](#) is a tool available for your use by your staff to track temperature adjustments made to the storage unit and other actions taken.

## 5.7 Temperature Deviations

Notify the Epidemiology Vaccine Depot each time vaccine storage temperatures fall outside the acceptable range for **any length** of time.

- Complete the [Facility Incident Report](#) form and submit to the Epidemiology Vaccine Depot along with your temperature logs and graphs whenever storage unit temperatures are out of acceptable range.
- Label potentially compromised vaccine(s) as “Do NOT use” and store within a storage unit with appropriate temperatures until the Epidemiology Vaccine Depot has contacted you with further instructions.
- Do not waste or return vaccines unless instructed; in some instances the vaccine may be approved for continued use based on stability data from the manufacturer.

For temperature deviations outside the recommended storage range, the following documentation will be required prior to reinstatement of vaccine deliveries:

- Explained Deviation (e.g., refrigerator door left open, power loss, etc.): 24 hours of stable temperatures shown on data logger graph(s)
- Unexplained Deviation: Two weeks of temperature logs and data logger graphs indicating stable temperatures are maintained within acceptable ranges

## 5.8 Rotating Stock

Rotate stock so that vaccine with the earliest date to expiration is used first. Store so that vaccine with the earliest expiration date is in front of vaccine with a later expiration date.

## 5.9 Vaccine Returns

All state-supplied vaccines that have expired or are spoiled/wasted must be documented in VacTrAK in the Orders/Transfer menu. For training resources on documenting Vaccine Returns in VacTrAK, please refer to Vaccine Ordering Management System Training Materials. Print the VacTrAK Vaccine Returns page and include this page along with vaccine being returned to the Epidemiology Vaccine Depot within 30 days. The non-viable vaccines can be hand-delivered or mailed in a box with enough packing material to prevent breakage during transport. Cold packs are not required. The Alaska Immunization Program obtains a partial credit on all vaccines returned. **Do not return any privately purchased vaccines or needles to the Epidemiology Vaccine Depot** and dispose according to your facility policies and procedures.

After returned vaccines are received at the Epidemiology Vaccine Depot and verified, your facility will receive a notification with the actual number of doses received.

Vaccine inventory must be monitored carefully to keep vaccine wastage to less than five percent of your annual vaccine shipments or you may be subject to corrective actions.

## 5.10 Emergency Planning

Each facility is required to have a written emergency response plan outlining your methodology to ensure that vaccines are appropriately handled in the event of a power outage or storage unit failure. All staff must be familiar with your facility's emergency response plan.

The written plan must:

- Be posted on or near your vaccine storage unit
- Be updated annually with staff signature and date of review
- Be updated whenever there is a change to the procedures or emergency contact staff
- Include a primary vaccine coordinator and at least one back-up vaccine coordinator responsible for vaccine management

An [Emergency/ Power Outage Plan for Vaccines](#) template to assist in the development of this plan are available.

## 5.11 Vaccine Transfers (State approved between different enrolled facilities)

All state-supplied vaccine transfers must be pre-authorized by the Epidemiology Vaccine Depot prior to transfer and should be a rare occurrence. This authorization allows the Epidemiology Vaccine Depot to ensure that the receiving provider is enrolled to receive state-supplied vaccine and appropriate vaccine accountability has been maintained. In addition, the Epidemiology Vaccine Depot will provide guidance to ensure cold chain management during the transfer.

Transfer Procedure:

1. If the cold chain has been maintained, a transferring provider should contact a potential enrolled local provider to obtain their approval to receive the vaccine.
2. The provider requesting the transfer must complete the [Vaccine Transfer Request Form](#) and submit the form to the Epidemiology Vaccine Depot for approval before vaccine is moved.
3. All requests will be reviewed and facilities will be contacted within 48 hours.
4. If the transfer is approved, the vaccine may be transported to the other provider maintaining storage and handling requirements.
5. The Epidemiology Vaccine Depot will adjust both providers' inventory in VacTrAK.

## 5.12 “Borrowing” between State-supplied and Privately Purchased Vaccine within your Facility

“Borrowing” occurs within a single facility and involves temporary sharing between a provider’s privately purchased and state-supplied vaccine stock. This type of practice is no longer permitted.

## 5.13 Vaccine Ordering Suspension

Vaccine orders may be suspended by the Alaska Immunization Program for providers identified as having an excessive amount of vaccine wastage (i.e., five percent or more of vaccine doses lost/year), insufficient storage capacity, an inadequate storage unit or noncompliance with any program requirements. Providers may be asked to develop and submit a corrective action plan addressing the problems which led to the suspension. If needed, the Epidemiology Vaccine Depot can provide technical consultation in the development of the plan. The Epidemiology Vaccine Depot will review and approve the plan, as appropriate. After a provider has instituted corrective action(s), the suspension will be lifted and vaccine shipments may be resumed.

## 6. Quality Assurance (QA) Visits, Assessments and Education

### 6.1 What are QA Visits, Assessments and Education?

Federal and state requirements mandate that the Alaska Immunization Program conduct Quality Assurance (QA) visits, assessments and education with each enrolled provider receiving state-supplied vaccine.

To request additional education and training, please contact the Epidemiology Vaccine Depot.

### 6.2 Types of QA Visits, Assessments and Education

<b>Provider Enrollment:</b>	This visit is required for new enrolling providers or providers that have had a break between enrollments with the Alaska Immunization Program. The purpose of this appointment is to ensure providers and their staff is provided with education about requirements, and has appropriate resources to implement program requirements.
<b>Annual Education Requirement:</b>	Vaccine coordinators and back-up vaccine coordinators must complete an annual education webinar. Certificates of completion must be submitted to the Epidemiology Vaccine Depot by June 30, 2015.
<b>Compliance:</b>	<p>A compliance site visit consists of an examination of vaccine management and delivery practices to ensure compliance with federal and state guidelines. It involves administration of a questionnaire, evaluating compliance with requirements and providing education. During the visit, there will be a formal review of vaccine management practices as well as a review of patient records and other documentation to assure appropriate vaccine eligibility screening and administration documentation is occurring.</p> <p>The Alaska Immunization Program will contact providers by phone to schedule compliance visits. A visit confirmation letter and a pre-visit questionnaire will be sent prior to the visit. Completion and return of the pre-visit questionnaire prior to the visit provides us with an opportunity to better prepare for your visit.</p>
<b>Unannounced Storage and Handling:</b>	The Alaska Immunization Program is required to perform unannounced storage and handling site visits to serve as “spot checks” on facility vaccine management practices.

When **Compliance and Unannounced Storage and Handling Visits** are completed, providers will receive a report outlining visit findings, and if applicable, identifying areas of noncompliance in need of

correction. Corrective actions for noncompliant practices will be required for continued participation in the Vaccine Distribution Program.

### 6.3 Assessment, Feedback, Incentives, eXchange (AFIX)

The Alaska Immunization Program is required to perform an AFIX assessment with providers receiving state-supplied vaccines. AFIX is a four part dynamic quality improvement strategy to raise immunization coverage levels and improve standards of practice at the provider level. Additional information regarding the process can be found at: [www.epi.hss.state.ak.us/id/iz/afix.htm](http://www.epi.hss.state.ak.us/id/iz/afix.htm).

# Appendix A: Resources

**Table A1.** List of National Resources

Resource	Further Information about Resource
CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook	Includes principles of vaccination, immunization general recommendations and strategies, and information regarding vaccine safety, storage and handling, and details regarding administration of individual vaccines.  <b>Website:</b> <a href="http://www.cdc.gov/vaccines/pubs/pinkbook/index.html">www.cdc.gov/vaccines/pubs/pinkbook/index.html</a>
CDC: Immunization: You Call the Shots – Module 10 – Storage and Handling – 2015	Updated information for 2015 vaccine storage and handling practices.  <b>Website:</b> <a href="http://www.cdc.gov/vaccines/ed/youcalltheshots.htm">www.cdc.gov/vaccines/ed/youcalltheshots.htm</a>
CDC: Immunization: You Call the Shots – Module 16 – Vaccines for Children Program – 2015	Completion of this course meets annual vaccine management education requirement for enrolled providers. Resource includes information regarding various elements of the VFC Program.  <b>Website:</b> <a href="http://www.cdc.gov/vaccines/ed/youcalltheshots.htm">www.cdc.gov/vaccines/ed/youcalltheshots.htm</a>
CDC: Vaccines and Immunizations	Provides information on immunization schedules, publications about vaccine-preventable diseases, and much more.  <b>Website:</b> <a href="http://www.cdc.gov/vaccines">www.cdc.gov/vaccines</a> <b>Phone:</b> 1-800-CDC-SHOT (1-800-232-4636)
CDC: Vaccine Information Statements (VIS) and Email VIS Update Service	Current VIS and sign up to receive update notices via email.  <b>Website:</b> <a href="http://www.cdc.gov/vaccines/hcp/vis/index.html">www.cdc.gov/vaccines/hcp/vis/index.html</a>
CDC: Vaccine Storage & Handling Toolkit	Information regarding vaccines and vaccine cold chain.  <b>Website:</b> <a href="http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf">www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf</a>
Immunization Action Coalition (IAC)	Evidence-based vaccine information, VISs in multiple languages, “Ask the Experts”, free print materials, information on vaccine-preventable diseases, and much more  <b>Website:</b> <a href="http://www.immunize.org">www.immunize.org</a>
Medication Errors Reporting Program (MERP)	National voluntary reporting system operated by the Institute for Safe Medication Practices  <b>Website:</b> <a href="http://www.ismp.org/orderforms/reporterrortoism.asp">www.ismp.org/orderforms/reporterrortoism.asp</a>

**Table A1 (continued).** List of National Resources

Resource	Further Information about Resource
U.S. Licensed Vaccine Information	Includes package inserts.  Website: <a href="http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm">www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm</a>
Vaccine Adverse Event Reporting System (VAERS)	National vaccine safety surveillance program for collection of information about adverse events (possible side effects) occurring after administration of U.S. licensed vaccines  Website: <a href="http://www.vaers.hhs.gov/">www.vaers.hhs.gov/</a> Phone: 1-800-822-7967

**Table A2.** List of U.S. Vaccine Manufactures

Vaccine Manufacture	Website (i.e., link to products)
GlaxoSmithKline (GSK)	<a href="http://www.gsksource.com/gskprm/en/US/partnerMkt/gskprm?cmd=ProductsByPrescriptionVaccine&amp;ProductType=Vaccine">www.gsksource.com/gskprm/en/US/partnerMkt/gskprm?cmd=ProductsByPrescriptionVaccine&amp;ProductType=Vaccine</a>
MedImmune	<a href="https://www.medimmune.com/medicines">https://www.medimmune.com/medicines</a>
Merck	<a href="https://www.merckvaccines.com/Products/Pages/ProductHome">https://www.merckvaccines.com/Products/Pages/ProductHome</a>
Novartis	<a href="http://www.novartisvaccines.com/products-diseases/index.shtml">http://www.novartisvaccines.com/products-diseases/index.shtml</a>
Pfizer (Wyeth)	<a href="https://www.pfizerpro.com/pfizer-products">https://www.pfizerpro.com/pfizer-products</a>
Sanofi Pasteur	<a href="http://www.sanofipasteur.us/vaccines">http://www.sanofipasteur.us/vaccines</a>

# Appendix B: Links to Vaccine Management Forms and Resources

1. ["Do Not Unplug" Signs](#)
2. [Emergency/ Power Outage Plan for Vaccines](#)
3. [Facility Incident Report](#)
4. [LogTag Temperature Monitoring Device Instructions for Daily Use](#)
5. [LogTag Temperature Monitoring Device Software and Device Initial Setup](#)
6. [2015 Vaccine Provider Agreement Instructions](#)
7. [Vaccine Information Statements \(VIS\)](#)
8. [Vaccine Temperature Monitoring Log and Action Taken Form](#)
9. [Vaccine Transfer Request Form](#)
10. [VacTrAK Participant Notice](#)
11. [VacTrAK Participant Notice \(half-page\)](#)

# Appendix C: Calibration Certificate Checklist

## CHECKLIST FOR CERTIFICATE OF CALIBRATION/VALIDATION/TESTING REPORTS

**A**

If Certificate Identifies an Accredited Laboratory:



ILAC/MRA Signatory body accredited Laboratory

The Following Table lists the accredited laboratories

A2LA	L-A-B	ACLASS	IAS	PJLA	NVLAP
					

AND

- Name of Device (Optional)
- Model Number
- Serial Number
- Date of Calibration (Report or Issue Date)
- Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F (0.5C))

**B**

If Certificate Does Not Identify an Accredited Laboratory:

- Name of Device (Optional)
- Model Number
- Serial Number
- Date of calibration testing (Report or Issue Date)
- Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F (0.5C))
- Statement that calibration testing conforms to ISO 17025