



**Patient Group Direction for the Administration of Japanese
 Encephalitis Vaccine (IXIARO®) for Travel by Approved Healthcare
 Professionals Working Within NHS Grampian, Highland, Orkney,
 Shetland, Tayside and Western Isles**

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	Consultation Group: See relevant page in the PGD	Approver: NoS PGD Group Authorisation: NHS Grampian
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Signature: 		Signature: 
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NoS Identifier: NoS/PGD/Travel_JapE/MG PG1261	Review Date: June 2024 Expiry Date: June 2025	Date Approved: June 2022
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NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have
 authorised this Patient Group Direction to help individuals by providing them with
 more convenient access to an efficient and clearly defined service within the NHS
 Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are
 completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from PHS national PGD for travel.	
Date of change	Summary of Changes	Section heading
March 2022	New PGD.	
June 2022	Pregnancy and breastfeeding added as exclusions as an in-depth risk assessment is required before prescribing in pregnancy and breastfeeding and the use of JapE vaccine in this cohort is off-label. A PSD must be sought for individuals who are pregnant or breastfeeding.	Exclusion criteria

NoS Identifier:

NoS/PGD/Travel_JapE /MGPG1261

Keyword(s):

PGD Patient Group Direction Japanese encephalitis Vaccine IXIARO

Policy Statement:

It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:

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
Amended &

reauthorized:


Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

<p>Medical practitioner</p>	<p>Name: Dr Jenny Wares Health Board: NHSH Title: Consultant in Public Health Medicine (Health Protection) Contact email: jenny.wares@nhs.scot Signature  Date: 23/07/2022</p>
<p>Senior representative of the professional group who will provide care under the direction</p>	<p>Name: Sarah Buchan Health Board: NHSG Title: Pharmaceutical Care Services Manager Contact email: sarah.buchan3@nhs.scot Signature  Date: 22/07/2022</p>
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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		20/06/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		29/07/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	Lead Author: Medicines Management Specialist Nurse NHSG
Jackie Agnew	Pharmacist: Head of Community Pharmacy Services NHSH
Dr Jenny Wares	Medical Practitioner: Consultant in Public Health Medicine (Health Protection) NHSH
Sarah Buchan	Senior Representative: Pharmaceutical Care Services Manager NHSG
Mary McFarlane	Principal Pharmacist NHSS
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Clinical indication to which this PGD applies

<p>Definition of situation/Condition</p>	<p>This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer Japanese encephalitis vaccine (IXIARO®) for active immunisation of individuals who are deemed to be at risk from exposure to Japanese encephalitis virus related to travel.</p> <p>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 20, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).</p>
<p>Inclusion criteria</p>	<p>Individuals aged 2 months and older who:</p> <ul style="list-style-type: none"> • Intend to travel to or reside in countries where Japanese encephalitis vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX www.travax.nhs.uk/destinations/ <p>The risk of exposure should be determined after careful risk assessment of an individual’s itinerary, season of travel, duration of stay, planned activities and medical history.</p> <p>Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.</p>
<p>Exclusion criteria</p>	<p>Individuals who:</p> <ul style="list-style-type: none"> • Are under 2 months of age • Require vaccination unrelated to travel purposes • Who are pregnant • Who are breastfeeding • Who have had an anaphylactic reaction to previous dose of any Japanese Encephalitis containing vaccine or to any of its excipients including the residues protamine sulphate, formaldehyde, bovine serum albumin, host cell DNA, sodium metabisulphite (refer to relevant SmPC)

	<ul style="list-style-type: none"> • Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free • Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Where there is no valid consent.
<p>Precautions and special warnings</p>	<p>Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.</p> <p>The Green Book advises there are very few individuals who cannot receive Japanese encephalitis containing vaccines. When there is doubt, appropriate advice should be sought from the lead clinician rather than withholding the vaccine.</p> <p>The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.</p> <p>Individuals with immunosuppression can be given Japanese encephalitis containing vaccines although these individuals may not make a full antibody response. Immunological response may be diminished in those receiving immunosuppressive treatment.</p>
<p>Action if excluded from treatment</p>	<p>Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.</p> <p>Inform or refer to the lead clinician in charge. Individuals who have had a confirmed anaphylactic reaction to a previous dose of cholera vaccine, or any components of the vaccine, should be referred to a clinician for specialist advice and appropriate management.</p> <p>Advise the individual on other preventative measures that may be implemented such as mosquito bite avoidance.</p>

	<p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged.</p> <p>Individuals who have had a confirmed anaphylactic reaction to a previous dose of a Japanese encephalitis containing vaccine or any components of the vaccines should be referred to a clinician for specialist advice and appropriate management.</p> <p>Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.</p>
<p>Action if treatment is declined</p>	<p>Advise about the protective effects of the vaccine and the risk of infection and disease complications. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached.</p> <p>Advise the individual on other preventative measures that may be implemented such as mosquito bite avoidance.</p> <p>Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.</p>

Description of vaccine available under the PGD

<p>Name form and strength of vaccine</p>	<p>Japanese encephalitis vaccine (inactivated, adsorbed) available as IXIARO® suspension for injection/dose 0.5mL.</p>
<p>Legal status</p>	<p>Japanese encephalitis vaccine (IXIARO®) is a Prescription-only Medicine (POM).</p> <p>Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed. The rapid schedule administered at days 0 and 7 for age 2 months to 17 years and adults 65 years of age and older constitutes an off-label use of the vaccine. However, the use of the vaccine in this way is in-line with recommendations in the Green Book Chapter 20.</p>

	<p>The individual or the person with parental responsibility should be informed prior to the administration that the use is off-label however the vaccine is being offered in accordance with national guidance.</p>
<p>Dosage/Maximum total dose</p>	<p>Children aged two months to under 3 years – 0.25mL Children three years and over, and adults – 0.5mL</p>
<p>Frequency of dose/Duration of treatment</p>	<p>Primary pre-exposure immunisation:</p> <p>Children from two months and adults:</p> <p>Standard schedule:</p> <ul style="list-style-type: none"> • First dose on day 0 • Second dose on day 28 <p>Rapid schedule*</p> <ul style="list-style-type: none"> • First dose on day 0 • Second dose on day 7 <p>*licensed for adults aged 18-64 years of age. For age 2 months to 17 years and adults 65 years of age and older, the rapid schedule can be used (off label) in circumstances where there is genuinely insufficient time to complete the standard schedule prior to travel.</p> <p>With both schedules, primary immunisation should ideally be completed at least one week prior to potential exposure but can be given up to the day of departure. Travellers should be reminded that optimum protection will not be immediate and should practice mosquito bite avoidance measures.</p> <p>Reinforcing Immunisation:</p> <p>First booster Children (from two months) and adults: Individuals who remain at risk of exposure should be given a booster dose 12 months after primary immunisation.</p> <p>Second booster</p> <p>Adults 18-64 years of age: A second booster dose (4th dose) should be offered at 10 years from the first booster to those who remain at risk or prior to potential re-exposure to Japanese Encephalitis.</p>

	<p>Children <18 years and adults 65 years of age and older: The length of protection following the first booster dose is not known. Refer to lead clinician.</p> <p>IXIARO® may be used as a booster for those who received Green Cross vaccine or Biken vaccine previously</p>
<p>Maximum or minimum treatment period</p>	<p>See Frequency of dose/Duration of treatment section above.</p>
<p>Route/Method of administration</p>	<p>Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm or the anterolateral area of the thigh muscle in small children.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4.</p> <p>The pre-filled syringe is for single use only and should not be used for more than one person. The pre-filled syringe is ready to use.</p> <p>Do not use if the blister foil is not intact or packaging is damaged.</p> <p>Preparation of a 0.25mL dose of IXIARO for use in children below 3 years of age;</p> <ul style="list-style-type: none"> • Shake the syringe to obtain a homogeneous suspension. • Remove the syringe tip cap by gently twisting it. Do not attempt to snap or pull the tip off as this may damage the syringe. • Attach a needle to the pre-filled syringe. • Hold the syringe in an upright position. • Push the plunger stopper up to the edge of the red line on the syringe barrel, indicated by a red arrow*, to discard excess volume. • Attach a new sterile needle prior to injection of the remaining volume. <p>*If you pushed the plunger stopper beyond the red line, a 0.25mL dose is not guaranteed and a new syringe should be used.</p> <p>Preparation of a 0.5mL dose of IXIARO for use in children above 3 years of age and adults;</p> <ul style="list-style-type: none"> • Shake the syringe to obtain a homogeneous suspension.

	<ul style="list-style-type: none"> • Remove the syringe tip cap by gently twisting it. Do not attempt to snap or pull the tip off as this may damage the syringe. • Attach a needle to the pre-filled syringe. <p>When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to IXIARO[®]. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.</p> <p>The vaccine should be visually inspected for particulate matter and discoloration prior to administration. Upon storage, a fine white deposit with a clear colourless supernatant can be observed. Before administration, shake the syringe well to obtain a white, opaque, homogeneous suspension. Do not administer if particulate matter remains following shaking or if discoloration is observed or if the syringe appears to be physically damaged.</p>
<p>Quantity to be administered</p>	<p>One dose per occasion of either 0.25mL or 0.5mL dependant on age.</p>
<p>Storage requirements</p>	<p>Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Do not freeze.</p> <p>Store in original packaging in order to protect from light.</p> <p>Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.</p>
<p>Follow-up (if applicable)</p>	<p>Following immunisation patients should remain under observation in line with individual NHS Board policy.</p> <p>Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the</p>

	<p>vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.</p> <p>Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.</p>
<p>Advice (Verbal)</p>	<p>Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions.</p> <p>If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24.</p> <p>Advise the individual on other preventative measures that may be implemented such as mosquito bite avoidance.</p> <p>The individual/person with parental responsibility should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.</p> <p>When administration is postponed advise the individual/person with parental responsibility when to return for vaccination.</p> <p>If appropriate, advise the individual/person with parental responsibility when subsequent doses are due and if any follow up is required.</p>
<p>Advice (Written)</p>	<p>The PIL contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</p> <p>Further information on travel health is available at https://www.fitfortravel.nhs.uk/home</p>
<p>Identifying and managing possible adverse reactions</p>	<p>Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p> <p>The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site.</p>

	<p>Other reactions commonly reported are headache, myalgia, erythema, hardening, swelling and itching at the injection site, influenza-like illness, pyrexia and fatigue. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.</p> <p>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</p> <p>BNF/BNFC: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE</p> <p>SmPC/PIL/Risk Minimisation Material: Home - electronic medicines compendium (emc) MHRA Products Home RMM Directory - (emc)</p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA</p>
<p>Facilities and supplies required</p>	<p>The following are to be available at sites where the vaccine is to be administered:</p> <ul style="list-style-type: none"> • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual’s right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

<p>Professional qualifications</p>	<p>Those registered healthcare professionals that are listed and approved in legislation as able to operate under Patient Group Directions, as identified and included in individual Board immunisation delivery plans.</p>
<p>Specialist competencies</p>	<p>Approved by the organisation as:</p> <ul style="list-style-type: none"> • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD.
<p>Ongoing training and competency</p>	<p>All professionals working under this PGD must:</p> <ul style="list-style-type: none"> • Have undertaken NoS PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with individual Board requirements • Have undertaken immunisation training where available • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct • Have knowledge and familiarity of the following; <ul style="list-style-type: none"> ○ Current edition of the Green Book ○ SmPC for the vaccine to be administered in accordance with this PGD ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
<p>Responsibilities of professional manager(s)</p>	<p>Professional manager(s) will be responsible for;</p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p>

	Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.
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Documentation

Authorisation of administration	<p>Qualified health professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following:</p> <p>Nurses, midwives and health visitors can be authorised by their line manager.</p> <p>Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration.</p> <p>The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).</p> <p>A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.</p>
Record of administration	<p>An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:</p> <ul style="list-style-type: none"> • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered

	<ul style="list-style-type: none"> • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). <p>Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate.</p> <ul style="list-style-type: none"> • Individual service specific systems.
<p>Audit</p>	<p>All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</p>
<p>References</p>	<p>Electronic Medicines Compendium http://www.medicines.org.uk IXIARO® – Date of revision of text 12/04/19, accessed 15/03/22.</p> <p>British National Formulary for Children and the British National Formulary https://about.medicinescomplete.com/ accessed 15/03/22.</p> <p>Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</p> <p>GreenBook chapter 20 - Japanese encephalitis (publishing.service.gov.uk)</p> <p>American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.</p>



Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction for the Administration of Japanese Encephalitis Vaccine (IXIARO®) for Travel by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

Appendix 2

**Healthcare Professionals Authorisation to Administer Vaccine
 Under Patient Group Direction**

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.

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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date