DEPARTMENT OF HEALTH AND HOSPITALS

OFFICE OF PUBLIC HEALTH

POLICY MEMORANDUM NO. 205 (REVISED) May 20, 2016

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Subject: Protocol for Managing Needle Stick Injuries and HIV/Other Unintentional Exposures to Blood or Potentially Infectious Body Fluids

This policy updates and amends Policy Memorandum No. 205 (REVISED) issued June 7, 2007. This updated and amended policy is in accordance with the recently updated U.S. Public Health Service Guidelines for Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Post-Exposure Prophylaxis (PEP). The recommendations are published in *Infection Control and Hospital Epidemiology* 2013;34(9):875-892. https://stacks.cdc.gov/view/cdc/20711.

As in the previous policy, reference may also be made to Policy Memorandum No. 170 (December 1, 1990) "Hepatitis B Vaccine Recommendations for Office of Public Health Employees" and Policy Memorandum No. 128 Addendum 2 Revised (October 13, 1997) "Policy on Blood Specimen Collection and Infectious Waste Management in Office of Public Health Facilities."

Form Epi-31 is included in this policy and, if needed, should be photocopied as necessary. Other forms are available from the Regional or Central Office Safety Administrator or the forms warehouse.

This Policy Memorandum must also be included in the Employee Health and Safety Index in your facility. Questions regarding this memorandum may be addressed to the STD/HIV Program Medical Director at (504)568-7474.

OFFICE OF PUBLIC HEALTH PROTOCOL FOR MANAGING NEEDLE STICK INJURIES AND HIV/OTHER UNINTENTIONAL EXPOSURES TO BLOOD OR POTENTIALLY INFECTIOUS BODY FLUIDS

I. Evaluation of Exposure and Exposure Source

Health care workers (HCW) are at risk for occupational exposures to Human Immuno-deficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through injuries involving needle sticks and other unintentional exposure to blood and body fluids. The most important response to this risk is prevention by strict adherence to guidelines, the "universal precautions," which minimize the likelihood of such exposures. The guidelines that follow are meant to be used when an exposure of this type occurs in an Office of Public Health (OPH) facility.

Following national guidelines issued by the United States Public Health Service Centers for Disease Control and Prevention (CDC), exposure is contact with blood or body fluids, for which universal precautions apply, from a known or unknown patient source, through percutaneous inoculation (such as injury with a hypodermic needle or other "sharps") or through contact with an open wound, non-intact skin or mucous membranes (splatter into eyes, nose or mouth). The body fluids for which universal precautions apply are: blood, amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, and vaginal secretions. Feces, nasal secretions, saliva, sputum, sweat, tears, urine and vomitus are not considered potentially infectious for HIV, HBV, or HCV unless they contain blood. The purpose of this protocol is to guide employees, who have had such exposure through the appropriate procedures, prophylaxis, follow-up and reporting the incident.

II. Immediate Wound Care

Immediately following percutaneous exposure the site should be washed with soap and water, following a mucous membrane exposure flush with copious amounts of water, and following exposure to the eye irrigate with copious amounts of saline solution or other sterile irrigants. There is no data to suggest that use of other antiseptic agents is of additional benefit.

III. Occupational HIV Post-Exposure Prophylaxis (PEP)

- The recommendations for PEP apply to situations in which a healthcare provider has been exposed to a source person who either has, or there is a reasonable suspicion of, HIV infection.

- Rapid determination of source patient HIV status provides essential information about the need to initiate and/or continue PEP.

- If rapid HIV testing is not available, administration of PEP should not be delayed while waiting for test results.

- If the source patient is determined to be HIV-negative, PEP should be discontinued and no follow-up HIV testing for the exposed provider is indicated.

New National Guidelines:

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Post-exposure Prophylaxis. **Infection Control and Hospital Epidemiology 2013;34(9):875-892.**

- The first line medications for HIV post-exposure prophylaxis have changed. Instead of Combivir [Ziduvodine (AZT) + Lamivudine (3TC)] and Kaletra (Lopinavir/Ritonavir) The new recommended first line agents are:

Truvada (tenofovir 300 mg + emtricitabine 200 mg) 1 PO once daily
Plus
Raltegravir (Isentress) 400 mg PO twice daily

- Another change in the recommendation is that all occupational exposures to HIV should receive 3 (or more) PEP medications. This is in contrast to the last recommendation that stratified exposures by severity and the clinician chose "basic" (2 drug PEP which was Combivir) or "expanded" (3 or more drug PEP which was Combivir + Kaletra).

- HIV PEP medication duration is still a **4 week course**.

- The Office of Public Health will provide a **1 week supply** of the PEP medications recommended above to employees after an occupational exposure.

- PEP should be started as soon as possible after exposure, preferably within 1 to 2 hours.

- The intent of this provision is to **begin the course of PEP only ("Starter Course").**

- Employees must follow-up with their personal physicians as soon as possible to obtain PEP medications to **complete the 4 week course** and to receive the necessary medical follow-up. It is recommended that the initial appointment should be scheduled within 72 hours following the exposure.

- Pregnant health-care providers will require a different regimen and should seek follow-up with her personal physician as soon as possible. (Combivir 1 tab PO twice a day PLUS Kaletra (lopinavir/ritonavir) 200/50 – take 2 tablets PO twice a day.) This PEP regimen is not stocked on the emergency cart.

- Office of Public Health clinical facilities must always be stocked with **one-week** course of PEP medications.

- In the extremely rare event that two healthcare providers have an HIV exposure simultaneously, or from the same incident, both providers should be given a **3 day** supply from the one-week course and instructed to see their physician within 72 hours per the needle stick/HIV exposure protocol.

- PEP medications will be kept in the emergency cart and should be re-stocked immediately after a course is used.

- PEP Resource - National Clinician's Postexposure Hotline (PEPline) 1-888-448-4911 (available from 9 AM to 2 AM Eastern).

- HIV testing should be used to monitor HCP for seroconversion after occupational HIV exposure. After baseline testing at the time of exposure, follow-up testing should be performed at 6 weeks, 12 weeks, and 6 months after exposure.

- Use of fourth generation HIV Ag/Ab combination immunoassays allow for earlier detection of HIV infection. If a provider is certain that a fourth generation combination HIV Ag/Ab test is used, HIV follow-up testing could be concluded earlier than 6 months after exposure. In this instance, an alternative follow-up testing schedule could be used (e.g., baseline testing, 6 weeks, and then concluded at 4 months after the exposure).

IV. HIV Post-Exposure Prophylaxis and Pregnancy

The decision to offer HIV PEP to a pregnant or breastfeeding healthcare provider should be based upon the same considerations that apply to any provider who sustains an occupational exposure to HIV. The risk of HIV transmission poses not only a threat to the mother, but also to the fetus and infant, as the risk of mother-to-child HIV transmission is markedly increased during acute HIV infection during pregnancy and breastfeeding. However, unique considerations are associated with the administration of antiretroviral agents to pregnant HCP, and the decision to use antiretroviral drugs during pregnancy should involve both counseling and discussion between the pregnant woman and her healthcare provider(s) regarding the potential risks and benefits of PEP for both the healthcare provider and for her fetus.

The potential risks associated with antiretroviral drug exposure for pregnant women, fetuses and infants depend on the duration of exposure as well as the number and type of drugs. Information about the use of newer antiretroviral agents, administered as PEP to HIV-uninfected pregnant women, is limited.

For reasons including the complexities associated with appropriate counseling about the risks and benefits of PEP, as well as the selection of antiretroviral drugs in pregnant women, expert consultation should be sought in all cases in which antiretroviral medications are prescribed to pregnant HCP for PEP.

V. HIV Post-Exposure Follow-up

- Employees with an exposure that is high risk for HIV should be tested for HIV antibodies at baseline, six weeks, twelve weeks and six months after HIV exposure. In rare cases, seroconversion has occurred more than six months after HIV exposure; therefore for severe injuries with a high risk of infection, testing should also be conducted twelve months after exposure.

- Extended HIV follow-up, e.g. for twelve months, is recommended for any HCW who becomes infected with HCV following exposure to a source patient co-infected with HIV and HCV.
- Whether or not extended follow-up is indicated in other circumstances, e.g. exposure to a source patient co-infected with HIV and HCV in the absence of HCV seroconversion or for exposed persons with a medical history suggesting an impaired ability to develop an antibody response to acute infection, is unclear. Although rare instances of delayed HIV seroconversion have been reported in the medical literature, the infrequency of this occurrence does not warrant adding to the anxiety level of the exposed persons by routinely extending the duration of post-exposure follow-up.

- Employees who take prophylactic drugs should discuss with the prescribing physician the possibility of tests for medication toxicity at baseline and at the time of the two week follow-up. These tests would be complete blood count, renal and hepatic function tests.

- HIV testing should be performed on any exposed person who has an illness that is compatible with an acute retro-viral syndrome, regardless of the interval since exposure. When HIV infection is identified, the person should be referred to a specialist, knowledgeable in the area of HIV treatment and counseling, for medical management.

VI. Hepatitis B

All OPH employees with potential occupational exposure to blood or body fluid should be vaccinated against Hepatitis B. Such pre-exposure vaccination is the best protection against Hepatitis B infection in the event of an exposure occurring. Employees with potential occupational exposures who have not already been immunized should consult their supervisors to obtain the Hepatitis B immunization series.

The actions to be taken after an exposure are to:

- Determine the HBsAg status of the source patient. This may be done by searching the medical records or requesting a blood specimen from the source patient and sending it to the OPH Laboratory for testing for HBsAg. In most circumstances source patients are willing to consent to have their blood tested. If the source patient refuses and his or her blood has already been drawn for other purposes, under certain circumstances the blood may be used to test for HBsAg after it is used for the reason for which it was originally drawn. Please **consult the Epidemiology section if this situation arises**.

- Determine the Hepatitis B vaccination status and if possible the Hepatitis B antibody status of the exposed person. Vaccination records of exposed persons should be examined to verify whether or not vaccination was initiated and completed, and if post-exposure antibody testing was ever done. If this information is not available, consideration should be given to test the exposed person for Hepatitis B surface antibody (anti-HBs), depending on whether or not this information would influence the vaccination decision following the guidelines given below.

- Decide whether or not vaccination of the exposed person is recommended. In general, previously unvaccinated persons should receive Hepatitis B vaccine for all exposures,

because it is advisable for all HCW's to be protected against Hepatitis B. If in addition the source patient is known to HBsAg+, the exposed person should be given HBIG in combination with Hepatitis B vaccine.

- Previously vaccinated persons should be managed according to the status of the source patient and their own antibody response to the previous Hepatitis B vaccination.

Recommended Post-Exposure Prophylaxis for Exposure to Hepatitis B Virus

Treatment

Vaccination and Antibody Response Status of Exposed HCW*	**Source HBsAg† positive**	**Source HBsAg† negative**	**Source Unknown or not available for testing**
Unvaccinated	HBIG § x 1and initiate Hepatitis B vaccine series¶	Initiate Hepatitis B vaccine series	Initiate Hepatitis B vaccine series
Previously vaccinated Known responder**	No treatment	No treatment	No treatment
Known non-responder††	HBIG x 1 and initiate revaccination or HBIG x 2§§	No treatment	If known high risk source patient , treat as if source patient were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs 1. If adequate,** no treatment is necessary 2. If inadequate††, administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate, no treatment is necessary 2. If inadequate, administer vaccine booster and re-check titer in 1-2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require post-exposure prophylaxis.
† Hepatitis B surface antigen
§ Hepatitis B immune globulin; dose is 0.06 ml/kg intramuscularly
** A responder is a person with adequate levels of serum antibody to HBSAG (i.e. anti-HBs - 10 mIU/ml)
†† A non-responder is a person with inadequate response to vaccination (i.e. serum anti-HBs less than 10 mIU/ml)
§§ The option of giving one dose of HBIG and re-initiating the vaccine series is preferred for non-responders who have not completed a second three dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

VII. Hepatitis B Follow-up

- Employees of unknown anti-HBs status who begin Hepatitis B vaccination, pending the results of testing and who later are found to have anti-HBs in the baseline blood sample, do not need to complete the Hepatitis B vaccination series, and do not need additional Hepatitis B testing.

- Employees who begin Hepatitis B vaccination and do not have measurable anti-HBs in the baseline blood sample should finish off the three dose Hepatitis B vaccine series with the standard one month and six month doses.

- One to two months after the Hepatitis B series is complete, these employees should be tested for HBsAg and Anti-HBs to assess whether or not an infection occurred and whether or not the employee responded to the vaccination.

VIII. Hepatitis C

- The risk of transmission of Hepatitis C following a needle stick from an infected source patient is probably greater than the risk for HIV but less than the risk for Hepatitis B.

- Following a needle stick, it is recommended that, if possible, the source patient be tested for anti-HCV antibodies. For employees exposed to an anti-HCV positive source patient, baseline and follow-up anti-HCV testing are recommended. Employees with positive anti-HCV tests should be referred to their physician for evaluation and supplemental Hepatitis C testing, e.g. RT-PCR.

IX. Hepatitis C Follow-Up

- Employees who have had a needle stick injury from anti-HCV positive source patient and who are tested at baseline, should have follow-up testing for anti-HCV antibodies and liver enzymes (Alanine aminotransferase [ALT]) six months later.

- The purpose of this testing is to document whether or not Hepatitis C infection occurred, and to initiate treatment, if infection did occur.

X. Reporting and Documentation

A. Forms Needed

- Incident Reporting Form (DA 200 Rev 08-12-99), from the Office of Risk Management
- Employer's Report of Occupational Injury or Diseases (DA 1973 Rev 09-99), from Human Resources office, if Workmen's Compensation claim is considered
- Epi-31 (Employee's Report of Exposure to Known or Possible Contaminated Blood or Body Fluids) (attached)

B. Procedure

- Report the incident of injury or exposure to the supervisor using the incident reporting form.

- Complete the first two pages of the Epi-31 (with the exception of the source patient's test results) within 24 hours of the incident.

- Get a baseline test for HBV, HCV, and HIV antibodies on the exposed person and the source patient within 48 hours of the incident and enter on the Epi-31 (in Follow-Up section).

- Make sure that consent forms are signed by the source patient and the exposed individual. Also validate that the exposed individual signed the Epi-31 form.

C. Supervisor Follow-Up:

- Contact the employee to assure the follow-up vaccinations and follow-up tests for HIV and Hepatitis B are conducted on schedule as described above. Enter the results on the Epi-31 form.

- When the Epi-31 form is complete it should be sent to the regional nurse manager and kept on file at the regional office.

Resource Tables

Table 1

Primary Side Effects Associated with the Recommended Three Drug PEP Regimen

Anti-retroviral Agent	Advantages	Primary Side Effects and Toxicities
Truvada (Tenofovir 300 mg + Emtricitabine 200 mg)	**Tenofovir** 1. Well tolerated 2. Take without regard for food **Emtricitabine** 1. Well tolerated 2. Minimal toxicity 3. Minimal drug interactions 4. Take without regard for food	**Tenofovir** 1. Asthenia, headache, diarrhea, nausea, vomiting 2. Nephrotoxicity 3. If the PEP recipient has chronic hepatitis B, withdrawal of this drug may cause an acute hepatitis exacerbation 4. Drug interactions **Emtricitabine** 1. Rash 2. Skin hyperpigmentation or discoloration 3. If the PEP recipient has chronic hepatitis B, withdrawal of this drug may cause an acute hepatitis exacerbation
Raltegravir (Isentress) 400 mg twice daily	1. Well tolerated 2. Minimal drug interactions 3. Take without regard for food	1. Insomnia, nausea, fatigue, headache 2. Severe skin and hypersensitivity reactions have been reported

Table 2

OCCUPATIONAL EXPOSURE MANAGEMENT RESOURCES AND REFERENCES

National Clinicians' Postexposure Prophylaxis Hotline (PEPline) Run by University of California-San Francisco/San Francisco General Hospital staff;l supported by the Health resources and Services Administration Ryan White Care Act, HIV/AIDS Bureau, AIDS Education and Training Centers, and CDC	Phone: 1(888) HIV-4911 1(888) 448-4911 Internet: http://www.ucsf.edu/hivcntr
Needlestick! CDC Website devoted to needlestick and blood borne pathogens in the occupational setting to help healthcare personnel manage and document occupational blood and body fluid exposures.	http://www.cdc.gov/niosh/topics/bbp/#prevent
Hepatitis Hotline	Phone: 1(800) CDC-INFO (800-232-4636) Internet: http://www.cdc.gov/hepatitis
HIV/AIDS Treatment Information Service	http://aidsinfo.nih.gov.
LSU-Delta Region AIDS Education and Training Center - Clinical Consultation Educational and medical consultative service for HIV infection, AIDS and AIDS-related disorders.	http://www.deltaaetc.org

Instructions - EPI - 31 Form

Page 1
Employee Last Name: Please print name clearly.
Employee First Name: Please print name clearly.
Home Phone Number: Include Area Code and home telephone number
Work Phone Number: Include Area Code and work telephone number
Date of Incident: Write in month, day and year in the spaces provided.
Place Incident Occurred: Please be as specific as possible; e.g. Immunization Room of X Parish Health Unit
Description of Incident: Please be as specific as possible as to circumstances of incident, including time of day it occurred, and others involved in the incident, e.g. other employees by name and/ or patients, by name.
Hepatitis B Vaccination Status: Please be specific as to dates and please do not check unknown unless verification of vaccination history has been impossible to obtain.

Source Person: Please complete this section as completely as possible, including laboratory data requested, in a timely manner. Antigen and antibody test results and dates, and medical history of risk should be sought in the source person's medical records as thoroughly as possible.

Baseline Counseling/Testing of Source Patient: Please complete this section as completely as possible and fill in test results as soon as they are obtained back from the testing laboratory.
Note: NA = not applicable, is to be checked only if deemed that testing is not needed at time of exposure incident.

Page 2
Recommendations Regarding Prophylaxis: This must be completed by the parish health unit nursing supervisor, the regional medical director, or a laboratory unit supervisor. The name and title of the person providing the recommendations must be included, and may be, for example, the exposed person's own physician, the regional medical director, and/or an AIDS medical consultant from a medical center or Office of Public Health central office. Include all names and titles of persons consulted regarding recommendations.

Employee Selection of Options: This is an informed consent. Employee's full name must be printed in the blank space in this section. Circle all applicable answers (yes or no) for the Baseline testing and for Prophylactic Vaccination and Medications section. Employee signature must match the employee name as printed on the form in the blank space, as noted above. The Supervisor's signature should be the person completing the form, as mentioned above, e.g. the parish health unit nursing supervisor, the regional medical director, or a laboratory unit supervisor.

Page 3
Follow Up: The supervisor completing this section should be the same person completing the previous sections, unless there has been a change in supervisors. If so, then that should be explained on the form after the name of the new supervisor has been printed in the space on this page. The appropriate drug names should be checked if applicable, the time interval between exposure and first dose should be expressed in hours, e.g. 1 ½ hours = one hour and thirty minutes, and the name of the physician prescribing the drugs should be printed in the space provided.

The serological testing information requested must be filled out completely; as is also true for the vaccine, immune globulin, and ALT (alanine aminotransferase liver function test) information requested. Dates should be specified by month, day and year in the spaces provided. The follow-up completed date should also be specified by month, day and year in the space provided and the supervisor's signature should be that of the supervisor named at the top of page 3.

EMPLOYEE REPORT OF EXPOSURE TO KNOWN OR POSSIBLE CONTAMINATED BLOOD OR BODY FLUIDS

Exposed Employee Data:

Employee Last Name:_____ Employee First Name:_____

Home Telephone number:_____ Work Telephone Number:_____

Date of Incident:___/____/____ Place Incident Occurred:_____

Description of
Incident:_____
_____
_____
_____
_____
_____

Hepatitis B Vaccination Status: (check one) _____completed three dose vaccination; month/year_____

_____incomplete HBV vaccination: # doses_____

Month/year last dose_____

_____not vaccinated against Hepatitis B

_____vaccination status unknown

Source person: (check one) _____Known ____Unknown

If known, source person's Last Name:_____ First Name:_____
Clinic Number:_____

Previous test results (if known): anti-HCV_____
HBsAg _____ HBsAg test date_____
HIV antibody_____ HIV antibody test date

Known Risk Status of Source (if known): (check all that are known)
_____Intravenous drug user _____Man who has sex with men
_____Sex partner HIV+ _____Chronic liver disease

Baseline Counseling/Testing of Source Patient:

Patient consented to HIV testing _____Yes _____No _____NA

If yes, result of HIV test: _____Negative _____Positive _____Indeterminate

Date of HIV test:_____

Patient consented to HBsAg testing _____Yes _____No _____NA

If yes, result of HBsAg test: _____Negative _____Positive _____Indeterminate

Date of HBsAg test:_____

Patient consented to anti-HCV testing _____Yes _____No _____NA

If yes, result of anti-HCV test: _____Negative _____Positive _____Indeterminate

Date of anti-HCV test:_____

Hepatitis B:	Hepatitis B Vaccine recommended:	_____Yes	_____No	_____N/A
	HBIG recommended:	_____Yes	_____No	_____ N/A
HIV:	Truvada and Raltegravir recommended	_____Yes	_____No	

Person providing above recommendations: Name_____

Title_____

Employee Selection of Options Regarding HIV and HBV testing and therapy:

I, _____, have reported an incident of exposure to blood or body fluids. I have been offered confidential testing to establish baseline HIV antibody status, with the option of counseling and testing by qualified persons outside of the program in which I work. I have been counseled regarding the post-exposure use of Truvada and Raltegravir if the source patient was HIV positive or suspected to be so and had these medications offered to me. I have also been offered the opportunity to receive Hepatitis B vaccine and referred for Hepatitis B immune globulin (If unvaccinated).

Circle yes or no for each:

<u>Baseline testing:</u>

I consent to have a baseline test for anti-HBS and HBsAg _____Yes _____No

I consent to have a baseline test for anti-HCV _____Yes _____No

I consent to have a baseline test for HIV antibodies _____Yes _____No

<u>Prophylactic vaccination and medications:</u>

I agree to receive hepatitis B vaccine _____Yes _____No

I agree to receive hepatitis B immune globulin _____Yes _____No

I agree to receive Truvada and Raltegravir to prevent HIV infection _____Yes _____No

I choose to follow up with my own physician and supply him or her with this protocol _____Yes _____No

I realize that if I am not tested for HIV at this time, it will be impossible to document HIV serconversion as a result of this injury.

_____ _____

Employee signature Supervisor signature

Follow Up on Exposed Employee, to be completed by Unit Supervisor

Name of Supervisor Completing Follow Up_____

Medications Taken (check all that apply): _____ Truvada (tenofovir and emtricidabine) (1 week supply from OPH)

_____ Reltagravir (Isentress) (1 week supply from OPH)

_____ _____ (Other from personal MD)

_____ _____ (Other from personal MD

Time interval between exposure and first dose (hours): _____

Medications prescribed by (physician): _____

HIV Serology:	Date due	Date drawn	Result
Baseline	__/__/__	__/__/__	_____
6 week follow up	__/__/__	__/__/__	_____
12 week follow up	__/__/__	__/__/__	_____
6 month follow up	__/__/__	__/__/__	_____

Hepatitis B Vaccine: Dose 1 Date__/__/__ administered by_____

Dose 2 Date__/__/__ administered by_____

Dose 3 Date__/__/__ administered by_____

HBIG given: YES [ ] NO [ ] Date__/__/__ administered by_____

Hepatitis B serology results:	Date due	Date drawn	HbsAg	Anti-HBS
Baseline	__/__/__	__/__/__	_____	_____
Follow up*	__/__/__	__/__/__	_____	_____

*one to two months after vaccination series completed, if vaccinated post-exposure or six months after incident occurred, if employee does not have antibodies at baseline and is not vaccinated post-exposure

Hepatitis C Serology Results:	Date due	Date drawn	Anti-HCV	ALT
Baseline	__/__/__	__/__/__	_____	_____
6 month follow up	__/__/__	__/__/__	_____	_____

Comments:_____

_____

Follow up completed Date __/__/__ Signature of supervisor_____

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