Chemotherapy and Other Hazardous Drugs Safe Use Guidelines

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EH&S Chemotherapy and Other Hazardous Drugs

I. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) has defined hazardous drugs as those that exhibit one or more of the following six characteristics in humans or animals:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

NIOSH recommends that all hazardous drugs be handled safely and has published guidelines in their 2004 <u>NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other hazardous Drugs in Health Care Settings</u>. This applies primarily to workers in health care settings, but also applies to those who work with hazardous drugs in research laboratories, which is the focus in this document.

Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs and other miscellaneous drugs. See <u>NIOSH sample listing of major</u> hazardous drugs (2014, or most recent edition), the majority of which are chemotherapy drugs.

Note: The Medical Centers have developed their own guidelines and procedures for handling chemotherapy/hazardous drugs. The guidelines in this document focus on use in research settings.

The nature of chemotherapy drugs* (cancer chemotherapeutic drugs, antineoplastic agents or cytotoxic drugs) makes them harmful to healthy cells and tissues as well as cancerous cells. For cancer patients with a life-threatening disease, treatment with these agents can be beneficial. However, for researchers and workers who are exposed to chemotherapy drugs as part of their work, precautions must be taken to eliminate or reduce the potential for exposure as much as possible. Chronic effects that have been identified in patients given these drugs include cancer, infertility, miscarriage, birth defects, damage to the liver and kidney, bone marrow, the lungs and heart, and hearing impairment. Acute effects may include headache, nausea, irritation of eyes, skin and mucous membranes, allergic reactions and skin rash. Employees inadvertently exposed may have similar effects. The risk varies with the specific drug and its concentration and with the frequency and duration of exposure. Other hazardous drugs may produce comparable effects.

In a research laboratory setting, researchers may be exposed to chemotherapy or other hazardous drugs by inhalation of agent powder or aerosol produced during preparation, administration or cleanup activities. Skin exposure with agents may occur during preparation or administration of the agent, contact with contaminated work surfaces, clothing and equipment, or by needlestick incidents. Exposure risks can be greatly reduced by (1) making sure that engineering controls such as fume hoods, exhausted biological safety cabinets (BSC) and other exhausted enclosures are used and (2) using proper procedures and protective equipment for handling chemotherapy and other hazardous drugs.

Principal Investigators (PIs) are required to assess the exposure hazards of their work with chemotherapy and other hazardous drugs to determine the appropriate precautions and controls to be taken. The assessment includes, at a minimum, the types, forms and volumes of hazardous drugs used, the procedures performed, engineering controls, personal protective equipment (PPE), decontamination and cleaning, spill response, waste handling and emergency procedures in case of possible exposure or other emergency. EH&S will assist PIs as needed in their exposure hazard assessment.

PIs must provide personnel laboratory-specific chemical training for the specific agents they are working with. The hazardous chemical training must include but is not limited to the health and physical hazards of the agents, signs and symptoms associated with exposure, appropriate work practices, PPE, work practices and emergency procedures in case of spill or possible exposure. Review of the safety data sheet/material safety data sheet (SDS/MSDS) is required and practice with less hazardous materials is recommended prior to work with the agents. Section 7 of the EH&S Laboratory Safety Manual has additional information about safety training.

* "chemotherapy drugs" are also referred to in this document as "antineoplastic agents", "chemotherapeutic drugs", "chemo" and "agents"

II. LABORATORY PLANNING AND PREPARATION FOR USE

- Develop a written laboratory-specific SOP specific to the chemotherapy or hazardous drug being used. A <u>template SOP</u> is linked to this document to help in preparation of a customized SOP.
- 2. Provide and document hazardous chemical training and specific agent SOP training to personnel working with chemotherapy/hazardous drugs and any others authorized or required to be in the laboratory or shared space during work with the agent(s). A sample training documentation form is attached to the template SOP.
- 3. Ensure the agent SDS/MSDS is available to staff at all times.
- 4. Enter agent into MyChem inventory, the online UW chemical inventory system. Attach SDS/MSDS in the process
- Determine any special procedures and precautions needed for the agents used. This
 may include precautions for work with volatile chemotherapy drugs (details given in III.
 ENGINEERING CONTROLS section).
- 6. Select appropriate chemotherapy gloves that will be used with the specific agents. Determine any special procedures and precautions needed if working with agents that may readily permeate chemotherapy gloves (details given in IV. PERSONAL PROTECTIVE EQUIPMENT section).
- 7. Designate a laboratory, work space and certified exhausted BSC, fume hood, glove box or other approved containment for agent work. The laboratory facilities required may vary based on the level of hazard posed by the specific agent and the procedures being performed.
- 8. Store chemotherapy and other hazardous drugs in an area labeled chemotherapeutic/hazardous drugs.
- 9. Post the EH&S Exposure Response Poster in the laboratory.
- 10. Purchase the smallest amount of agent feasible for work, or purchase the agent in the concentration for use. If possible, do not work with chemotherapy/hazardous drugs in solid or powder form. If it is necessary to purchase it in powder or solid form, purchase pre-diluted or pre-weighed agent in the least quantity needed to perform work.
- 11. Ensure supplies are available for agent waste handling and disposal, and for routine cleaning of surfaces.
- 12. Ensure supplies for spill cleanup are appropriate for the specific agent, maintained in a clearly marked spill cleanup kit and readily available in the laboratory.

III. ENGINEERING CONTROLS

- Prepare agents in an exhausted BSC, fume hood, glove box or other approved
 containment that does not exhaust into the room. Do not use laminar flow cabinets or
 hoods for agent work. Consider the properties of the specific agent and procedures
 when selecting a containment device. Working with intact tablets or capsules is not
 required to be done in exhausted containment. However, if crushing tablets, perform
 work in exhausted containment.
- 2. Do not use a ventilated cabinet that recirculates air inside the cabinet when working with volatile agents. Most agents are not volatile, but some are. The following agents have been reported in publications to be volatile under certain conditions:

Carmustine Ifosfamide

Cyclophosphamide Mechlorethamine (Mustargen)

Doxorubicin ThioTEPA

Note: Use special procedures and precautions when working with volatile chemotherapy drugs. For more information and guidance, contact an EH&S occupational health and safety specialist at uwcho@uw.edu or 206-543-7388, or contact the agent manufacturer.

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IV. PERSONAL PROTECTIVE EQUIPMENT (PPE)

- Wear disposable, powder-free chemotherapy gloves that are approved by the Food and Drug Administration (FDA) and have been tested for use with chemotherapy drugs.
 These gloves are also recommended for handling other hazardous drugs.
 - Gloves that are labeled as "chemotherapy gloves" must be approved by the FDA and be tested by the manufacturer for permeation resistance to specific chemotherapy drugs using ASTM standard method D6978-05 "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."
 - The results of permeation testing are available from the glove manufacturer and
 may be included on the box label and will be reported as "breakthrough time", or
 the time it takes for the chemical to permeate from the outer surface of the glove to
 the inside surface (tests are conducted for at least 240 min.). The breakthrough time
 should be longer than the glove wear time to ensure adequate protection.
- 2. The following criteria can be used to help select chemotherapy gloves for work with a specific chemotherapy drug and have the greatest protection:
 - Review glove permeation test data for the specific agent(s) that will be used. Refer
 to the <u>Chemotherapy Glove Permeation Test Data</u> table at the back of this
 document for test data collected on chemotherapy powder-free nitrile exam gloves

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from various manufacturers. Select gloves that have been tested with the specific agent(s) to be used and had breakthrough times >240 min.

- If no breakthrough test data is available for the specific agent(s) being used, agent
 properties should be considered in glove selection. Based on studies with agents
 that readily permeate chemotherapy gloves, including carmustine and thioTEPA, the
 following agent properties were shown to potentially indicate low and unacceptable
 breakthrough times:
 - Molecular weights lower than 250 g/mole
 - Highly lipophilic
 - Low water solubility
- Take extra precautions when there is a significant risk of permeation, including double gloving and changing gloves every 30 minutes or less.
- Provide latex-free chemotherapy gloves to employees with latex sensitivities.

For more information and guidance, contact an EH&S occupational health and safety specialist at www.edu.or.206-543-7388, or contact the glove manufacturer.

- 3. Wear two pairs of gloves for most activities working with hazardous drugs. A single pair of gloves should provide adequate protection when working with intact tablets or capsules.
- 4. When double gloving, place one glove under the gown cuff and one over. Change the outer glove immediately if contaminated. Change both gloves if an outer glove is torn, punctured, or overtly contaminated with the agent (as in a spill) and every hour during preparation. If there is a risk of permeation, change gloves every 30 minutes or less.
- 5. Other glove notes:
 - Gloves must be protective from any solvents used, in addition to the chemo/hazardous drug.
 - The lab should have several sizes of gloves available for best fit not too tight to impede movement and not too loose to decrease dexterity.
- 6. Wear a protective gown or equivalent that is lint-free, non-permeable with a solid front, long sleeves, and tight-fitting elastic or knit cuffs. Wear long pants or long skirt, and fully closed shoes.
- 7. Wear safety glasses with side shields or goggles.
- 8. Wear face protection, such as a face shield, when splash/splatter is possible.
- Disposal of disposable PPE, is described in Section IX. AGENT WASTE COLLECTION AND DISPOSAL.
- 10. Respiratory protection (requires enrollment in UW's respirator program) may be required if an airborne hazard is present when work is done outside of approved containment or when cleaning up a spill. Surgical masks or dust masks do not provide adequate protection. For information see EH&S Respiratory Protection Program or contact the EH&S respiratory program specialist at 206-616-3777.

V. SAFE USE PRACTICES (reconstitution, dilution)

- 1. All agent preparation must be performed in a chemical fume hood, glove box, exhausted BSC or other approved containment.
- 2. Perform preparations over plastic backed absorbent pads. Dispose of pads after completion of tasks or immediately upon contamination as chemotherapy waste.
- 3. Transport agents only in labeled, leak/spill-proof, non-breakable secondary containers. An example is a Ziploc bag with chemo labels.
- 4. Decontaminate surfaces by cleaning with detergent and water followed by thorough rinsing. The use of detergent is recommended because there is no single accepted method of chemical deactivation for all agents involved. 70% isopropyl alcohol may be used with the cleaner if the contamination is soluble only in alcohol.
- Clean work surfaces before and after each activity and at the end of the work shift. Establish periodic cleaning routines for all work surfaces and equipment that may become contaminated.
- 6. Decontaminate the chemical fume hood, BSC or glove box, and other work surfaces before and after each task and at the end of the work shift.
- 7. Decontaminate containers before they are removed from the fume hood, BSC, or glove box. Also decontaminate the exterior of the closed primary container and place it in a clean secondary container.
- 8. Dispose of unused excess chemotherapy and hazardous drug in the proper waste container (details given in IX. AGENT WASTE COLLECTION AND DISPOSAL section). Submit request to EH&S for waste pickup.
- 9. Place all visibly contaminated disposable items, such as gloves, paper towels and absorbent pads, in a plastic bag while in the fume hood, BSC or other containment and then in the proper waste container (details given in IX. AGENT WASTE COLLECTION AND DISPOSAL section).
- 10. When work completed, remove gloves and wash hands with soap and water.

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VI. PRECAUTIONS FOR AGENT ADMINISTRATION

- 1. Wear double gloves for all procedures involving administration of chemotherapy/hazardous drugs.
- 2. Change gloves every 30 to 60 minutes or after each use, or immediately when torn, punctured, or contaminated.
- 3. Wear protective gown with solid front. Change gowns every two to three hours or when contaminated.
- 4. Utilize safe sharps procedures. Dispose of sharps in a yellow sharps container specific for chemotherapy or other hazardous drugs. The sharps container must be in the immediate vicinity of work and labeled as holding chemotherapy/hazardous drug items.

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Do not overfill syringes with agent so that excess agent remains in the syringe when disposed. Needle locking syringes or disposable syringe needle units are recommended and should be disposed of promptly after use.

5. In animal studies, restrain or anesthetize animals when possible before injecting chemotherapy/hazardous drugs.

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VII. AGENT SPILL CLEANUP

Chemotherapy and other hazardous drug spills must be cleaned up as soon as possible by properly protected and trained personnel. All other persons should leave the area. Spill response procedures must be developed based on the hazardous agent present and potential spill or release conditions. Clean up spills using contents of the chemotherapy/hazardous drug spill kit. Do not attempt to clean up any spill if not trained or comfortable. Evacuate the area and call 911 for help. If the spill is out of control, call 911. If a person is injured, exposed or suspected of being exposed, call 911. Follow Section VIII. ACUTE EXPOSURE procedures below.

Spills inside a BSC, fume hood, glove box or approved containment

- 1. Personnel must wear a lab coat or smock, safety goggles, two pairs of disposable chemotherapy gloves (or one pair of non-disposable nitrile or butyl gloves (minimum 10 mil thickness) or Silver Shield gloves), when cleaning up spills.
- 2. **Liquids:** Wipe up spilled liquids with absorbent pads.
- 3. **Powders:** Gently cover powder spill with wetted paper towels or absorbent pads to avoid raising dust and then wipe up.
- 4. Clean the spill area thoroughly with detergent solution followed by clean water.
- 5. If spill is extensive within the containment, clean all interior surfaces after completion of the spill cleanup.
- 6. Double bag all waste in plastic bags labeled with the contents. Submit request to EH&S for waste pickup.

Small Spills (less than 5 ml) outside of containment

- 1. Personnel must wear a gown or coveralls with solid front, safety goggles, shoe covers as needed and two pairs of disposable chemotherapy gloves (or one pair of non-disposable nitrile or butyl gloves (minimum 10 mil thickness) or Silver Shield gloves), when cleaning up spills.
- 2. Wear an N95 or equivalent respirator for either powder or liquid spills where airborne powder or aerosol is or has been generated. Spills of volatile agents require the use of an appropriate combination particulate/chemical cartridge-type respirator. Most chemotherapy drugs are not volatile, but some are. Assess the volatility of the agent. Please contact the EH&S Respiratory Protection Program administrator to discuss

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respiratory protection or to enroll in the program. Program enrollment includes medical evaluation, training and fit testing for an appropriate respirator. For information see EH&S Respiratory Protection Program or call EH&S at 206-616-3777.

- 3. **Liquids:** Wipe up spilled liquids with absorbent pads.
- 4. **Powders:** Gently cover powder spill with wetted paper towels or absorbent pads to avoid raising dust and then wipe up.
- 5. Clean the spill area thoroughly with detergent solution followed by clean water.
- 6. Double bag all waste in plastic bags labeled with the contents. Submit request to EH&S for waste pickup.

Large spills (greater than 5 ml) outside of containment

- 1. Evacuate all personnel from the laboratory and restrict access.
- 2. As soon as possible report the spill by notifying EH&S (during business hours (M-F/8-5) 206-543-0467, outside business hours 911); tell them that a spill has occurred, and that you need help managing the spill. EH&S will contact a spill cleanup contractor. Notify supervisor.
- 3. Be prepared to provide the following information:
 - Name and phone number of knowledgeable person that can be contacted
 - Name of agent spilled, concentration and amount spilled, liquid or solid type spill
 - Number of injured, if any (refer below to Section VIII, Acute Exposure)
 - Location of spill

This information should also be reported to the Emergency Department (ED) after a potential exposure.

- 4. Only if staff are trained, have the proper PPE and are comfortable with cleaning up the spill, they may proceed to clean it up. Personnel must wear a gown or coveralls with solid front, safety goggles, shoe covers as needed, and two pairs of disposable chemotherapy gloves (or one pair of non-disposable nitrile or butyl gloves (minimum 10 mil thickness) or Silver Shield gloves), when cleaning up spills.
- 5. Wear an N95 or equivalent respirator when cleaning large spills. Spills of volatile agents require the use of an appropriate combination particulate/chemical cartridge-type respirator. Most chemotherapy agents are not volatile, but some are. Assess the volatility of the agent. Please contact the EH&S Respiratory Protection Program administrator to discuss respiratory protection or to enroll in the program. Program enrollment includes medical evaluation, training and fit testing for an appropriate respirator. For information see EH&S Respiratory Protection Program or call EH&S at 206-616-3777.
- 6. Liquids: Wipe up spilled liquids with absorbent pads.
- 7. **Powders:** Gently cover powder spill with wetted paper towels or absorbent pads to avoid raising dust and then wipe up.
- 8. Clean the spill area thoroughly with detergent solution followed by clean water.
- 9. Double bag all waste in plastic bags labeled with the contents. Submit request to EH&S for waste pickup.

Any spill incident requires the involved person or supervisor to complete and submit the Online Accident Reporting System (OARS) form to EH&S within 24 hours (8 hours if serious injury or hospitalization).

For questions on spill cleanup, contact EH&S spill consultants at 206-543-0467.

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VIII. ACUTE EXPOSURE

Follow the steps below for any exposures to chemotherapy or other hazardous drugs or refer to the EH&S Exposure Response Poster that is posted in the laboratory.

1. Provide First Aid Immediately

Inhalation

Move out of contaminated area. Get medical help.

Sharps injury (needlestick and subcutaneous exposure)

Scrub exposed area thoroughly for 15 minutes using warm water and sudsing soap.

Skin exposure

Use the nearest safety shower for 15 minutes. Stay under the shower and remove clothing. Use a clean lab coat or spare clothing for cover-up.

Eye exposure

Use the eye wash for 15 minutes while holding eyelids open.

2. Get Help

- Call 911 or go to nearest Emergency Department (ED). Give details of exposure:
 - Agent
 - o Dose
 - Route of exposure
 - Time since exposure
- Bring to the ED the SDS/MSDS and SOP for specific agent.
- **Notify your supervisor** as soon as possible for assistance.
- Secure area before leaving. Lock doors and indicate spill if needed.

3. Report Incident to Environmental Health & Safety

- Notify EH&S immediately after providing first aid and/or getting help.
 - During business hours (M-F/8-5) call 206-543-7262.
 - o After hours call 206-685-UWPD (8973) to be routed to the EH&S staff on call.
- For all incidents and near misses, the involved person or supervisor completes and submits the UW <u>Online Accident Reporting System (OARS)</u> form to EH&S within 24 hours (8 hours if serious injury or hospitalization).

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IX. AGENT WASTE COLLECTION AND DISPOSAL

Manage chemotherapy and hazardous drug waste separately from other waste streams such as biohazardous waste. Never autoclave chemotherapy/hazardous drug waste since it can produce hazardous chemical vapors or aerosols, and autoclaving conditions may not be sufficient to deactivate chemotherapy/hazardous drug waste. Collect chemotherapy/hazardous drug waste as either trace or non-trace waste as defined below.

1. Trace Chemotherapy/Hazardous Drug Waste

"Trace" chemotherapy/hazardous drug waste refers to empty containers or containers that have less than 3% of the original quantity of drug remaining, such as sharps, empty syringes, and vials. An "empty" container is one in which all contents have been removed by normal means such as aspiration, pouring, or flushing.

Trace Chemotherapy/Hazardous Drug Waste Collection

Collect in a yellow sharps waste container:

- Sharps with trace chemotherapy/hazardous drugs
- Sharps with mixed waste (trace chemotherapy/hazardous drugs and biohazards)
- Empty chemotherapy/hazardous drug vials and containers (<3% of original quantity)

Label as "trace chemo waste" with PI name and room number. Containers are available for purchase from <u>Biochemistry Stores</u> or lab/medical supply vendors. See <u>Sharps and Laboratory Glass</u> for sharps definitions.

Trace Chemotherapy/Hazardous Drug Waste Disposal

All trace chemotherapy/hazardous drug waste generated at the University of Washington is collected and shipped off site for disposal by incineration at a regulated facility. Before preparing waste for shipment, the person preparing the waste must complete the EH&S Shipping Regulated Medical Waste class. Waste generators can set up an account for shipping trace chemotherapy/hazardous drug waste at Biohazardous/Regulated Medical Waste VendorCollection Set Up.

2. Non-Trace Chemotherapy/Hazardous Drug and EPA P-Listed Waste

Non-trace chemotherapy/hazardous drug waste refers to unused or expired drugs, containers with more than trace chemotherapy/hazardous drugs, and visibly contaminated items including PPE and visibly contaminated items used preparation, use, and cleanup. Dispose of non-contaminated PPE and other items in the trash.

Environmental Protection Agency (EPA) P-listed drugs are acutely hazardous drugs regulated by federal law. Handle **all** P-listed drug waste (including empty containers and trace amounts) as non-trace chemotherapy/hazardous drug waste. P-listed chemotherapy/hazardous drugs include:

Waste Code	Constituent of Concern	Product Name Examples:
P001	Warfarin & salts (concentration > 0.3%)	Coumadin; Warfarin
P012	Arsenic trioxide	Trisenox
P042	Epinephrine	Adrenalin; EpiPen; Eppy/N; Epifrin; Epinal; Anaphalaxis kit; Epinephrine (inhalants, injectibles, kits); Racepinephrine; Racord; Primatene aerosol inhaler
P046	Phentermine	Phentermine (CIV)
P075	Nicotine & salts	Nicotine patches; Habitrol; Nicoderm; Nicorette; Nicotrol; Tetrahydronicotyrine
P188	Physostigmine salicylate	aka Eserine salicylate
P204	Physostigmine	aka Eserine

Source: WA Dept. of Ecology RCRA List

Non-Trace and P-Listed Waste Collection

Collect for pick up by EH&S:

- Unused or expired chemotherapy/hazardous drugs
- Containers with more than trace amounts of chemotherapy/hazardous drugs
- All P-listed drug waste (including empty containers)
- Sharps with P-listed drugs
- Sharps with P-listed drugs **and** biohazards
- Visibly contaminated items from preparation, use, and cleanup (PPE, pads, etc.)

Label with EH&S Hazardous Waste label available at <u>Hazardous Chemical Waste Disposal</u>.

Non-Trace and P-Listed Waste Disposal

All non-trace chemotherapy/hazardous drug and P-listed drug waste generated at the University of Washington is collected by EH&S Environmental Programs and shipped off site for disposal by incineration at a regulated RCRA facility. To request pick up of non-trace chemotherapy/hazardous drug waste or any P-listed drug waste, visit the EH&S <u>Hazardous</u> Chemical Waste website.

3. Contacts

For questions regarding chemotherapy/hazardous drug waste collection and disposal, contact an EH&S occupational health and safety specialist at uwcho@uw.edu or 206-543-7388.

X. RESOURCES

- NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other hazardous Drugs in Health Care Settings. DHHS (NIOSH) Publication Number 2004–165, September 2004.
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (2014)
- Washington State Department of Labor & Industries: Hazardous Drugs
- Washington State Department of Labor & Industries: Veterinary Hazardous Drug <u>Program Guide</u> (for veterinary clinical care)
- Washington State Department of Ecology, Pharmaceutical Waste
- EH&S Chemical Hygiene Officer at uwcho@uw.edu
- EH&S Chemotherapy and Other Hazardous Drugs

Chemotherapy Glove Permeation Test Data* ASTM D6978-05**

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^{*}all nitrile, non-latex, powder free exam or surgical gloves unless noted; data provided from glove manufacturers

^{**}includes 9 chemicals to test: carmustine, cyclophosphamide, doxorubicin hydrochloride, etoposide, 5-fluorouracil, methotrezate, paclitaxel, thioTEPA, vincristine sulfate NR = not recommended