I. Bethesda System for Reporting Cervical/Vaginal Cytological Diagnoses:

- A. Specimen Adequacy
 - 1. Satisfactory for evaluation.
 - 2. Unsatisfactory for evaluation.
- B. General Categorization (optional)
 - 1. Negative for intraepithelial lesion or malignancy.
 - 2. Epithelial cell abnormality: see interpretation/result
 - 3. Other: see interpretation/result
- C. Descriptive Diagnosis
 - 1. Negative for intraepithelial lesion or malignancy
 - a. Organisms
 - (1) Trichomonas vaginalis
 - (2) Fungal organisms morphologically consistent with Candida
 - (3) Shift in flora suggestive of bacterial vaginosis
 - (4) Bacteria morphologically consistent with Actinomyces
 - (5) Cellular changes consistent with herpes simplex virus
 - b. Other non-neoplastic findings (optional to report; list not inclusive):
 - (1) Reactive cellular changes associated with
 - (a) Inflammation (includes typical repair)
 - (b) Radiation
 - (c) Intrauterine contraceptive device (IUD)
 - (2) Glandular cells status post hysterectomy
 - (3) Atrophy
 - c. Other:
 - Endometrial cells (in a woman > 40 years of age)
 - (Specify if "negative for squamous intraepithelial lesion")
 - 2. Epithelial cell abnormality
 - a. Squamous cell
 - (1) Atypical squamous cells (ASC)
 - (a) Of undetermined significance (ASC-US)
 - (b) Cannot exclude HSIL (ASC-H)
 - (2) Low grade squamous intraepithelial lesion (LSIL) encompassing: Human Papillomavirus (HPV) / mild dysplasia / Cervical intraepithelial neoplasia CIN I
 - (3) High grade squamous intraepithelial lesion (HSIL)

encompassing: moderate and severe dysplasia, CIN 2 and CIN 3 / carcinoma in situ (CIS) with features suspicious for invasion (if invasion is suspected)

- (4) Squamous cell carcinoma
- b. Glandular cell
 - (1) Atypical glandular cells (AGC)

Specify endocervical, endometrial or not otherwise specified (NOS)

(2) Atypical glandular cells, favor neoplastic

Specify endocervical or not otherwise specified (NOS)

- (3) Endocervical adenocarcinoma in situ (AIS)
- (4) Adenocarcinoma
- 3. Other malignant neoplasms (specimens)

II. Pap Test Screening Guideline

In 2009, the OPA instructed that the delivery of clinical services be consistent with nationally recognized standards of care and the protocols should be reviewed on a regular basis, and modified as needed. The American College of Obstetricians and Gynecologists (ACOG) issued new cervical cytology screening guidance in a December 2009 clinical management guideline, which the CDPHE Family Planning Program has used in to 2012. In early 2012 the U.S. Preventative Task Force (USPSTF) <u>http://www.uspreventiveservicestaskforce.org/uspstf/uspscerv.htm</u> and a multidisciplinary partnership including the American Cancer Society (ACS), the American Society for Colposcopy and Cervical Pathology (ASCCP) and the American Society for Clinical Pathology (ASCP) <u>http://journals.lww.com/jlgtd/PublishingImages/ASCCP%20Guidelines.pdf</u> released two separate but very similar cervical cancer screening recommendations. The

two separate but very similar cervical cancer screening recommendations. The guidelines do not address high risk populations which include women: with a history of cervical cancer, who have been exposed in utero to diethylstilbestrol (DES), or who are immune compromised (e.g. HIV infection).

	USPSTF and ACS/ASCCP/ASCP
Age to begin screening	Age 21, regardless of the age of initiation of sexual intercourse.
When to discontinue screening	At greater than 65 years old if the woman has had adequate negative prior screening. Women with a history of CIN2 or more severe diagnosis should continue routine screening for at last 20 years.
Screening Intervals, Ages 21-29	Pap testing alone every 3 years.
Screening Intervals for women 30-65 years old	Pap testing alone every 3 years or Pap testing with high risk HPV testing every 5 years.
Screening Intervals for women with total hysterectomy	No Pap test screening if the woman has had adequate negative prior screening and the woman does not have a cervix and does not have a history of CIN2 or a more severe diagnosis in the past 20 years or cervical cancer ever.
Use of high risk HPV Testing in conjunction with Pap test screening and follow-up in specific circumstances. For further recommendations for the use of high risk HPV testing in the management of abnormal Pap or biopsy results, please refer to the American Society for Colposcopy and Cervical Pathology algorithms referenced in Sections III and VIII below.	 Should not be used for screening in women under 30 years HPV co-testing can be used in women 30 years old or older, every 5 years. If co-testing HPV positive and Pap test negative then repeat co-testing in 12 months or do immediate HPV genotype-specific testing for HPV16 alone or for HPV16/18. If co-testing is repeated at 12 months: a) Women testing positive on either test (HPV positive or LSIL or more severe cytology) should be referred to colposcopy. b) Women testing negative on Pap and HPV should return to routine screening. If co-testing HPV is negative and the Pap test is ASC-US, continue with routine screening according to age specific guidelines.

III. Follow-Up of Abnormal Pap Reports

NOTE: Please refer to the American Society of Colposcopy and Cervical Pathology algorithms found at the following website:

http://www.asccp.org/ConsensusGuidelines/AbnormalCervicalScreeningTests/tabid/5958/D efault.aspx

Please note that the follow-up for women over 20 is different than for women 20 and younger. Individual providers are permitted by copyright law to print these algorithms for use in the clinic. The CDPHE Family Planning Program has also provided your clinic with a set of all algorithms, in booklet format.

Many labs will recommend follow-up. Where the lab recommendations and CDPHE Family Planning Program protocols differ, the agency must decide, through consultation with its Medical Director, what follow-up to pursue.

Document all client contacts and attempted contacts regarding the abnormal Pap test in the client's chart. Consider the use of a certified return receipt letter if the client is unresponsive to follow up contacts (if the client has previously indicated receiving mail is acceptable).

IV. Patients Refusing The Recommendation For Colposcopy Follow-Up

- A. Document the refusal in the patient's chart.
- B. When a patient refuses colposcopy, cryotherapy or LEEP, the case should be reviewed by a consulting physician.

V. Management Of Patients Reporting Previously Abnormal Pap Tests:

- A. If a patient provides a verbal report of an abnormal Pap test (or colposcopy, cryotherapy, conization, or laser ablation) within the last year, efforts should be made to obtain medical records. Do an initial exam or a delayed exam as appropriate.
- B. If records cannot be obtained and the initial Pap test is negative, patients shall have a repeat Pap test six **to 12** months later.
- C. If the initial Pap test (through Family Planning clinic) is other than negative, the patient shall be followed for the abnormality described, as outlined in the algorithms referenced in Section III above.

VI. Abnormal Pap Tests and Hormonal Contraceptives

An abnormal Pap test does not constitute a contraindication to hormonal contraceptives.

VII. Management of Diethylstilbestrol (DES) - Exposed Women

- A. Women who were born between 1940 and 1970 who were exposed to DES should be counseled about the potential risks, provided with DES information, and offered a baseline colposcopic evaluation, with iodine staining.
 - 1. Physiological changes that occur include circular ridges in the wall of the vagina, cervical hood, and cervical cockscomb, adenosis, or persistence of immature glandular epithelium in the vaginal walls and/or endocervix.

- B. Pap test sampling should include a vaginal 4-quadrant technique in addition to cervical sampling. Using the spatula, scrapings are taken from the upper to the lower third of the vagina. These samples should be submitted on two slides. One slide should have the endocervical/ectocervical sample, and the rest of the four quadrant samples should be placed on the second slide. If using liquid based media, the four quadrant vaginal specimen is put in one specimen container and the endocervical/ectocervical sample in another specimen container. Label the slides or specimen containers appropriately, indicating cervical specimen and vaginal specimen. Send each specimen with a corresponding requisition noting a history of DES exposure. Examination of a DES exposed woman must include palpation of the vagina. Any unexplained vaginal or cervical mass or nodule detected on visual inspection or digital examination should be biopsied. Clear cell carcinoma of the cervix which occurs after DES exposure often originates along the anterior vaginal wall as opposed to vaginal cancer of older women which often occurs along the posterior wall.
- C. A history of DES exposure or adenosis on a Pap test is not a contraindication to the use of hormonal contraceptives.
- D. See the following links for more information. <u>http://www.cancer.gov/cancertopics/causes/des/daughters-exposed-to-des</u> <u>http://www.cancer.org/Cancer/CancerCauses/OtherCarcinogens/MedicalTreatments/de</u> <u>s-exposure</u>
- E. Follow up
 - 1. If the baseline colposcopy is negative, the client may be followed with annual cervical and vaginal Pap tests, examination, and vaginal palpation.
 - 2. If the baseline colposcopic evaluation with iodine staining reveals minimal DES changes and the DES-based cytology is normal, the client should have a fourquadrant Pap test, examination, and vaginal palpation yearly.
 - 3. If any of the colposcopies reveal malignant changes at any time, the client must be referred immediately for further evaluation and treatment.
 - 4. Any client with an abnormal Pap test must be examined and worked up in the same manner as a non-DES-exposed patient.

VIII. Post-Colposcopy Management

NOTE: Please refer to the algorithms from the American Society for Colposcopy and Cervical Pathology found at the following website:

http://www.asccp.org/ConsensusGuidelines/ManagementofCINAIS/tabid/5959/Default.aspx

Please note that the follow-up for women over 20 is different than for women 20 and younger. Individual providers are permitted by copyright law to print these algorithms for use in the clinic. The CDPHE Family Planning Program has also provided your clinic with a set of all algorithms, in booklet format.

Many labs will recommend follow-up. Where the lab recommendations and the CDPHE Family Planning Program protocols differ, the agency must decide, through consultation with its consulting physician, what follow-up to pursue.

Document all client contacts and attempted contacts regarding the colposcopy results in the client's chart.