

**POSITION DESCRIPTION** (Please Read Instructions on the Back)

1. Agency Position No.  
**11F011**

2. Reason for Submission  
 Redescription  New  
 Reestablishment  Other

3. Service  
 Hdqtrs  Field

4. Employing Office Location  
**Multiple**

5. Duty Station  
**Multiple**

6. OPM Certification No.

Explanation (Show any positions replaced)  
In lieu of PD# 98F069

7. Fair Labor Standards Act  
 Exempt  Nonexempt

8. Financial Statements Required  
 Executive Personnel Financial Disclosure  Employment and Financial Interest

9. Subject to IA Action  
 Yes  No

10. Position Status  
 Competitive  
 Excepted (Specify in Remarks)  
 SES (Gen.) SES (CR)

11. Position Is  
 Supervisory  Managerial  Neither  
 12. Sensitivity  
 1-Non-Sensitive  2-Noncritical Sensitive  3-Critical  4-Special Sensitive

13. Competitive Level Code  
**00NX**

14. Agency Use

15. Classified/Graded by	Official Title of Position	Pay Plan	Occupational Code	Grade	Initials	Date
a. Office of Personnel Management						
b. Department, Agency or Establishment	<b>CHEMIST</b>	<b>GS</b>	<b>1320 (14)</b>	<b>11</b>	<i>[Signature]</i>	<b>6/13/2011</b>
c. Second Level Review						
d. First Level Review						
e. Recommended by Supervisor or Initiating Office						

16. Organizational Title of Position (if different from official title) \_\_\_\_\_  
 17. Name of Employee (if vacant, specify) \_\_\_\_\_

18. Department, Agency, or Establishment  
**Department of Health and Human Services**

a. First Subdivision  
**Food and Drug Administration**

b. Second Subdivision  
**Office of Regulatory Affairs**

c. Third Subdivision  
**Office of the Regional Food and Drug Director**

d. Fourth Subdivision  
**Field Laboratory**

e. Fifth Subdivision

19. Employee Review: This is an accurate description of the major duties and responsibilities of my position.  
 Signature of Employee (optional)

20. **Supervisory Certification.** I certify that this is an accurate statement of the major duties and responsibilities of this position and its organizational relationships, and that the position is necessary to carry out Government functions for which I am responsible. This certification is made with the knowledge that this information is to be used for statutory purposes relating to appointment and payment of public funds, and that false or misleading statements may constitute violations of such statutes or their implementing regulations.

a. Typed Name and Title of Immediate Supervisor  
Signature \_\_\_\_\_ Date \_\_\_\_\_

b. Typed Name and Title of Higher-Level Supervisor or Manager (optional)  
**David K. Elder, Acting Associate Commissioner for Regulatory Affairs for Field Operations**  
Signature *[Signature]* Date **5/31/11**

21. **Classification/Job Grading Certification.** I certify that this position has been classified/graded as required by Title 5, U.S. Code, in conformance with standards published by the U.S. Office of Personnel Management or, if no published standards apply directly, consistently with the most applicable published standards.  
 Typed Name and Title of Official Taking Action  
**Frances Reynolds**  
 Human Resources Specialist, BCSD  
 Signature *[Signature]* Date **6/13/11**

22. Position Classification Standards Used in Classifying/Grading Position  
**USOPM Job Family Position Classification Standard for Professional Work in the Physical Science Group, GS-1300 (12/1997)**

Information for Employees. The standards, and information on their application, are available in the personnel office. The classification of the position may be reviewed and corrected by the agency or the U.S. Office of Personnel Management. Information on classification/job grading appeals, and complaints on exemption from FLSA, is available from the personnel office or the U.S. Office of Personnel Management.

23. Position Review	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date
a. Employee (optional)										
b. Supervisor										
c. Classifier										

24. Remarks  
**BUS: 0076 Promotion Potential to GS-12 PD# 11F012.**

25. Description of Major Duties and Responsibilities (See Attached)

**CHEMIST**  
**GS-1320-11**

**INTRODUCTION**

The senior trainee position of a Chemist in an FDA/ORA Field laboratory and is expected to bring full professional competence in his/her discipline to bear in carrying out analyses and interpreting the significance of test results. The incumbent is assigned scientific analyses on a wide range of samples including those that are difficult, complex, or unusual. This position is a senior trainee level position in a GS-5/7/9/11/12 career ladder. Promotion to the GS-12 is dependent upon meeting all promotion requirements.

**MAJOR DUTIES**

- Performs the full range of analytical chemistry on a variety of samples, including the difficult, complex or unusual samples submitted by agency personnel in connection with regulatory monitoring and enforcement activities.
- Before analyzing a sample, reviews the background material submitted with the sample, agency reports on similar samples or situations, and pertinent regulations.
- Determines the approach, methods, and procedures to use to obtain the information requested, taking into consideration the requirements established by Agency regulations and Federal law.
- Modifies the methods and procedures as needed to satisfy special requirements and to solve problems. Includes performing the analyses on known samples to validate the modification.
- Writes a report that identifies the sample, shows the methods and procedures used, any modifications with validation data, the results and their interpretation, and whether the sample appears to be in violation of any agency regulation.
- Provides training for less experienced scientists on the precedents, analytical methods and instrumentation related to the particular scientific discipline of the position.
- As assigned, accompanies Agency personnel on field inspections/investigations and acts as a technical advisor.
- Performs other duties as assigned.

**Factor 1 - Knowledge Required by the Position**

Professional knowledge of chemical principles, theories, practices, and established methodology sufficient to perform the full range of duties involved in analyzing a wide variety of drug, food, and cosmetic samples.

Knowledge of established FDA laboratory procedures, the FD&C Act and related regulations, other laws, and court precedents which apply to laboratory operations, inspections, investigations, and various regulatory actions.

Knowledge of practices and related problems associated with the raw materials, products or manufacturing for the industries or commodities in the area of assigned responsibility.

### **Factor 2 - Supervisory Controls**

The supervisor assigns the work by setting the overall objectives and the resources available. The incumbent is then responsible for planning, organizing and performing the work, determining the best approach and methods to use making modifications as needed, and interpreting the results. The completed work is reviewed from an overall standpoint for feasibility and effectiveness in meeting the assignment's requirements.

### **Factor 3 - Guidelines**

The guidelines include precedents, scientific literature, laboratory procedures and methodology manuals, instrument handbooks, and agency policies. These guides are not always specifically applicable to the assignment at hand. Judgment must be used to interpret and adapt the guidelines to specific cases. The incumbent will analyze results and recommend changes.

### **Factor 4 - Complexity**

The chemistry analytical assignments include the difficult, complex, or unusual samples and analytical requests received in the laboratory. Typically, the specific data needed and the approach to be taken to obtain these data are uncertain. To make these decisions and to interpret the final results, the work requires evaluation and interpretation of data from a wide range of sources such as the background material submitted with the analytical request, reports on similar samples or problems, technical references, and trade literature, in addition to consideration of pertinent regulations. Adaptation or modification of the established methods and procedures is often required to plan and carry out the work.

### **Factor 5 - Scope and Effect**

The work primarily involves fulfilling a range of conventional chemical analytical requests by applying established precedents and methods to the scientific analyses of a variety of foods, drugs, or cosmetics and making method modifications if necessary. The work efforts affect the scientific adequacy and accuracy of regulatory field investigations and studies.

### **Factor 6 - Personal Contacts**

The personal contacts are with scientific personnel in the Agency, other governmental and state organizations, and private industry.

### **Factor 7 - Purpose of Contacts**

The personal contacts are to discuss with other scientists methodological problems, possible solutions, and method modification projects in addition to reporting the status of the work and the results.

### **Factor 8 - Physical Demands**

The work requires prolonged standing, lifting of large or heavy samples or equipment. Work may involve exposure to chemical and biological hazards that may require special safety precautions. The regulatory scientist may need to use protective clothing and equipment. Persons with physical limitations may, as appropriate, be accommodated by other employees.

To perform the work of the position, the employee must possess a valid driver's license to drive a Government or privately owned motor vehicle to inspections and investigations.

Candidates for this position must complete a statement regarding their physical ability and may be required to undergo physical examination because the position requires:

- the need to work long and unscheduled hours;
- exposures to all kinds of extremes of weather and noise;
- the need to lift heavy objects up to 50 pounds, walk, bend, stand, stoop, kneel, and climb;
- the need to meet the vision, hearing and olfactory requirements necessary to perform the work of the position; and
- the need to travel, as required by management needs, may require the incumbent to be away from the regular duty station for up to two to three weeks at a time.

### **Factor 9 - Work Environment**

The work involves regular and recurring exposure to irritant chemical and biological hazards. Special safety precautions are required, and the regulatory scientist may be required to use protective clothing and gear such as a laboratory coat, safety glasses, latex gloves, mask, *etc.*

When serving as an Investigator, inspection and sample collection duties are performed either inside buildings and other structures, outdoors or both depending on the type and location of the facility. As a consequence, employees are exposed to a variety of environmental conditions including extremes of heat, cold or humidity; excessive noise; excessive dust; uneven surfaces and slippery floors; and extremely adverse conditions during natural and other disasters such as floods, fires, hurricanes, *etc.* During these periods, employees must eat and sleep in primitive conditions with little or no privacy. As Investigators, incumbents must travel into and work in areas that have been the subject of violence and that are otherwise considered unsafe.

PD# 11F011

## EVALUATION STATEMENT

**REQUESTED POSITION TITLE/SERIES/GRADE:** Chemist GS-1320-11

**ORGANIZATIONAL LOCATION:** DHHS, FDA, Office of Regulatory Affairs (ORA), Office of Regulatory Operations (ORO), Field Laboratories

**BACKGROUND:** As a result of recruitment needs and requirements, this position is being established as a rewrite of Interdisciplinary Scientist PD# 98F069 into individual series. This trainee position is part of a GS-5/7/9/11/12 career ladder. Promotion to the GS-12 is dependent upon meeting all promotion requirements.

### ANALYSIS AND EVALUATION OF THE POSITION

#### References:

- GS-1320 Chemistry Series Definition
- USOPM Job Family Position Classification Standard for Professional Work in the Physical Science Group, GS-1300 (12/1997)

**Determination of Series and Title:** In accordance with OPM instructions on titling and series determination in the *Job Family Position Classification Standard for Professional Work in the Physical Science Group, GS-1300*, the final title and series is determined to be Chemist GS-1320 since this position involves work that requires full professional education and training in the field of chemistry. This work includes the investigation, analysis, and interpretation of the composition, physical and chemical properties, molecular structure and chemical reactions of substances; the prediction of transformation they undergo; and the amount of matter and energy included in these transformations.

**Determination of Grade:** The grade analysis for these duties and responsibilities was based on "Grading Criteria" in the *Job Family Position Classification Standard for Professional Work in the Physical Science Group, GS-1300*. To assign a GS-11 grade level the duties and responsibilities have to meet the grading criteria for a GS-11 as described in the law and the standard. In addition illustrations provided are intended to show the nature of assignment and level of responsibility *typical* of professional physical science positions in a variety of work situation.

The law states that "Grade GS-11 includes those classes of positions the duties of which are -- (B) with wide latitude for the exercise of independent judgment, to perform responsible work of considerable difficulty requiring somewhat extended professional, scientific, or technical training and experience which has demonstrated important attainments and marked capacity for independent work ..."

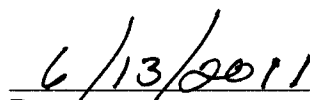
According to the standard GS-11 professional physical scientists plan and execute complex studies. These studies usually involve intensive investigations into one or more recognized

phenomena. The work typically involves conventional methods and techniques, though going beyond clear precedents, and requires adapting methods to the problems at hand and interpreting findings in terms of their scientific significance. Finished products are reviewed for adequacy of conclusions and soundness of the procedures and methods used. Assignments generally do not involve radical departures from past practices or require the development of new, novel or innovative approaches, methods or techniques. By comparison, GS-9 scientists perform assignments that have fewer variables and produce relatively obvious results and conclusions. Some GS-11 scientists provide technical guidance and instructions to lower graded professional or technical employees generally for the duration of a given assignment.

## CONCLUSION

According to the preceding analysis, this position is classified as Chemist GS-1320-11.

  
\_\_\_\_\_  
Frances Reynolds  
Human Resource Specialist

  
\_\_\_\_\_  
Date

**Bethesda Client Services Division  
Fair Labor Standards Act (FLSA)  
CHECKLIST**

Date: 6/13/2011

**B. REQUIRED POSITION INFORMATION:**

Position Title: Chemist  
Pay Plan/Series/Grade: GS-1320-9/11/12 (e.g. GS-0301-12)  
Organization: HHS, FDA, ORA, ORFDD, Field Laboratory  
Administrative Code: Any Field Laboratory (e.g. GAGA)  
PD Number: 11F010/011/011 (e.g. HQ1234)

**B. NON-EXEMPT CRITERIA (5 CFR 551.203)**

Position classified at GS-04 or below  
 Meets one of the requirements for nonexempt.  
Explain: \_\_\_\_\_

**C. EXEMPTION CRITERIA**

**1. Executive Exemption Criteria (5 CFR 551.205)**

A. Primary duty of position is management or supervision.  
 Meets requirements of management or supervision position.  
OR  
 B. Meets 80% Test (Alternate to A. - applies to certain positions only).  
 Meets requirement of 80% Test

Explain: \_\_\_\_\_

**2. Administrative Exemption Criteria (CFR 551.206)**

A. Primary Duty is Management, General Business Functions, or Supporting Services.  
 Meets requirements of Administrative Exemption Criteria  
OR  
 B. Meets 80% Test (Alternate to A. - applies to GS-05 and GS-6 - see below).  
 Meets 80% Test

Explain: \_\_\_\_\_

**3. Professional Exemption Criteria (5 CFR 551.207, 208, 209, 210)**

A. Primary Duty is Work Requiring Advanced\* Knowledge in a Field of Science or Learning. Note: "Advanced" means education above high school level.  
OR

B. Meets 80% Test (Alternate to A. - applies to GS-05 and GS-6 - see below).

Explain: \_\_\_\_\_

**D. FINAL DETERMINATION (Circle One):**

Non-Exempt

Exempt

*David K. Elder*  
Name and Title of Immediate Supervisor  
David K. Elder, Acting Associate Commissioner  
for Regulatory Affairs for Field Operations

5/31/11  
Date

*Frances Reynolds*  
Frances Reynolds  
Human Resource Specialist  
Name and Title of BCSD Classifier

6/13/11  
Date