DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

March 31, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jeff Immelt
Chairman and Chief Executive Officer
General Electric, Inc.
3135 Easton Turnpike
Fairfield, Connecticut 06828

Ref. # - DEN-05-09

Dear Mr. Immelt:

An inspection of your firm located at 384 Wright Brothers Drive, Salt Lake City, Utah was conducted between November 15 – December 1, 2004, by Consumer Safety Officers from the Food and Drug Administration, Denver District Office. This inspection determined that your firm manufactures x-ray and fluoroscopic systems and accessories. These x-ray and fluoroscopic systems and accessories are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacture, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

Failure of management with executive responsibility to ensure the quality system requirements are effectively established and effectively maintained in accordance with 21 CFR 820, as required by 21 CFR 820.20 (b)(3)(i).

For example, our inspection disclosed that your firm discovered that test technicians were not completing original test procedure documentation (Process History Records), but instead were copying test results from one device to another

for a period of at least one year. There is no indication that your firm conducted periodic checks or audits of the records during this time to assure the validity of the data. Also, your firm failed to take corrective action to ensure that devices produced during this time period met your firm's specifications, but chose instead to handle this situation XXXXXX There is no assurance that the testing was actually performed by the employees who falsified the records.

Failure to establish and maintain procedures for implementing corrective and preventive actions (CAPA) to include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1).

For example, members of the executive management team did not investigate the breadth of the copying of the test results or perform risk analysis to determine how the copying of test records may have affected the finished devices. Your firm initiated corrective and preventive actions only after this issue was noted by our investigators. There is no evidence that your firm verified that this practice was limited to only X test technicians or was more widespread throughout your facility, or that the actions taken as a result of this incident will prevent a future incident. Additionally, our investigation found that the results of quality audit reports are not included as sources of product non-conformance/quality data to be reviewed by your XXXXXX

Failure to establish and maintain corrective and preventive action procedures to investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2).

For example, your firm performed risk assessments for product failures without documenting how the severity or likelihood of occurrence used in the assessment was determined, in violation of your own procedures. There is no evidence that this practice was identified by your corrective and preventive action program prior to our inspection.

Failure to establish and maintain procedures for corrective and preventive actions to include requirements to assure corrective actions are implemented and changes in methods and procedures to correct and prevent identified quality problems are recorded, as required by 21 CFR 820.100(a)(5).

For example, your firm uses electronic database systems to document, track, and control corrective and preventive actions. The Corrective Action/Preventive Action System procedure, XX, does not reference the use of these database systems, nor does it describe the steps necessary to close corrective and preventive actions. Also, our inspection found that additions and changes had been made to CAPAs after they had been verified or closed. There are no provisions for this in your procedure.

Failure to adequately validate a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a).

For example, the validation of the workstation test equipment used as part of the final device testing system did not include a process capability challenge, did not ensure that the test equipment used was capable of functioning as necessary to capture results at both the high and low ends of the test specifications, and did not include challenges with known failures to ensure the equipment detected fault conditions. Also, the validation was reviewed and accepted by X individuals, although computational errors were noted in the test procedure report. There is no evidence your personnel detected the error in the calculations prior to approval.

Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b).

For example, not only were test technicians found to be using photocopied device test results as noted above, but supervisory staff and management who reviewed and signed off on these records never caught this practice which occurred for at least one year. Various errors noted in Device History Records (DHR) were apparently undetected upon review by quality assurance personnel, who subsequently accepted the DHRs as complete and released the devices for distribution. Medical Device Reports (MDR) filed by your complaint coordinator were incomplete and not submitted on time. Your training procedure does not include a provision to notify employees of defects resulting from the performance of their job functions as required by the Quality System Regulation.

Failure to evaluate complaints to determine whether the complaint represents an event which is required to be reported to FDA under part 803, the Medical Device Reporting (MDR) requirements, as required by 21 CFR 820.198(a)(3).

For example, there was no evidence that eight of thirty-five complaint records reviewed by our investigators were evaluated for patient involvement or MDR reporting.

Failure to establish and maintain procedures for complaints to ensure that records of any investigation made are maintained by the formally designated unit and include any device identification(s) and control numbers used, as required by 21 CFR 820.198(e)(3), and the dates and results of the investigation, as required by 21 CFR 820.198(e)(6).

For example, complaint investigations are not completely documented in that a review of the device history records (DHRs) and complaint tracking and trending is not recorded. Links between product processes and related defects cannot be established and the need for corrective and preventive action may not be identified if these sources of information are not evaluated. Also, review of thirty-five complaint records found at least three records which failed to contain complete

records, such as e-mail correspondence regarding the complaint, field service reports, complaint investigator's notes, correspondence with the medical facilities, or make reference to the dates of complaint investigations.

Failure to establish and maintain device history records to include acceptance records which demonstrate the device is manufactured in accordance with the device master record (DMR), as required by 21 CFR 820.184(d), and failure to include the primary identification label and labeling used for each production unit, as required by 21 CFR 820.184(e).

For example, DHRs failed to include the signatures of the employees who completed the work or had test records signed off by a different employee than the one who initiated the testing. In addition, twelve of fifteen DHRs reviewed by our investigators failed to contain the required labeling.

Failure to assure that rework and reevaluation activities, including a determination of any adverse effect from the rework upon the products, are documented in the DHR, as required by 21 CFR 820.90(b)(2).

For example, a review of DHRs indicated that your Quality Assurance unit does not consistently review and verify that rework has been performed. Discrepancy reports were generated as the result of in-processing device testing failures. There was no evidence that Quality Assurance personnel verified that rework was performed on the devices as required by your procedures. The DHRs were reviewed and approved, and the devices were subsequently released, by Quality Assurance.

Failure to establish and maintain written procedures for changes to a specification, method, process, or procedure and to verify or validate that change before implementation, as required by 21 CFR 820.70(b).

For example, your System Release Activities procedure allows for the re-release of systems for distribution. The procedure does not define the circumstances under which a released DHR may be re-opened and re-released. There is no requirement to document the re-release in the DHR.

The inspection also revealed that your devices are misbranded within the meaning of section 502(t)(2) of the Act, in that your firm failed to furnish information to the Food and Drug Administration (FDA) as required under section 519 of the Act and regulations implementing that section at 21 CFR Part 803, Medical Device Reporting, and 21 CFR Part 806, Reports of Corrections and Removals.

Failure to report information to FDA within 30 days after receiving or otherwise becoming aware of information, from any source, that reasonably suggests that a device marketed by your firm has malfunctioned, and such device or similar device marketed by you would be likely to cause or contribute to a death or serious injury, if the malfunction

were to recur, as required by 21 CFR 803.50(a)(2). For example, our inspection found that your firm submitted MDR 1720753-2004-00003 on August 19, 2004, although you initially received the information on June 25, 2004. This MDR involved the uncommanded table motion of one of your firm's UroView 2600 models.

Failure to obtain and provide all information to FDA regarding an MDR report without providing a statement explaining why such information was incomplete and the steps taken to obtain the information, as required by 21 CFR 803.50(b)(2). For example, two MDR reports, 1720753-2004-00002 and 1720753-2004-00003, were submitted to FDA lacking patient information. MDR 1720753-2004-00002 did not indicate patient outcome (permanent injury/illness, disability) as a result of the initial injury sustained from the use of the InstaTrack 3500 Surgical Navigation System. MDR 1720753-2004-00003 lacked information indicating whether a patient was involved in the equipment malfunction and, if so, whether the patient sustained injury.

Failure to submit a written report to FDA of any correction or removal of a device initiated by the manufacturer in order to reduce a health risk, as required by 21 CFR 806.10(a)(1). For example, corrective actions taken for tracking inaccuracies in the Axcess and Insta Trak 3500 Plus systems distributed to the field or intended to be released to the field were not reported to FDA although the field corrections were taken to reduce the risk to health posed by the devices.

We are in receipt of correspondence dated December 15, 2004, and signed by Messrs. Lewis E. Dudley and Gary Harding, in response to the FDA 483 issued at the end of the November 15 – December 1 inspection, and a progress update dated March 1, 2005 signed by Gary Harding. Regarding the December 15th response, we have the following comments:

Observation 1 – This response is inadequate. Your firm states that you handled this deviation as a [redacted] to determine whether product integrity was compromised. From these [redacted] your firm decided that products had not been compromised and no CAPA was initiated. Your firm failed to take any corrective actions regarding the products involved until it was brought to your attention by our investigators in November. Your response also states that you hold Quality Management Reviews [redacted] times more frequently than required by your procedure in order to keep executive management informed. However, we would like to point out that increasing the frequency of your reviews did not preclude this falsification from occurring. A question that should have been raised is why these falsifications weren't caught sooner since it appears employees were copying records for at least one year. It would appear that the management systems you have in place are not adequate to catch this type of deficiency.

Observation 2 – This response is inadequate. You state that your firm became aware of the compromised data during an employee performance review in [redacted] documentation regarding the risk assessment made in November as a result of our investigators' inspection does not appear to support your conclusion that the hazard resulting from the unverifiable testing is minimal. The risk assessment indicates two potential hazards: [redacted]

[redacted] In both risk assessments, your firm concluded that the initial risk and the residual risk after implementation of the change remain the same. It appears that your firm used a "Not Credible" Hazard Likelihood Estimation to assess risk without any apparent justification for this probability.

In addition, your firm is relying on signed statements from the employees involved to justify the fact that the testing was, in fact, performed. It does not appear that your firm has made an effort to verify these statements by retrieving the affected units from your customers or notifying them to be aware of any potential risks that may be associated with this lack of testing. The extent of the problem is undetermined as your firm did not review all records during the affected time period, but instead performed a ' [redacted] of the records. Therefore, the degree of your record fabrication problem cannot be known with certainty. While updating procedures and retraining employees may be effective actions to prevent the occurrence of a similar situation, they do not remedy the prior deviations.

Observation 3 – The corrective actions proposed appear adequate and will be verified at the next inspection of your facility. However, as noted in your response, it appears that your firm did not have adequate controls of your CAPA system in place prior to our inspection. This is evidenced by an e-mail issued just prior to our inspection which states, [redacted] responsibility to assure the Quality System Regulations are met **at all times** and not rely on the threat of an FDA inspection to implement the actions that are necessary.

Observation 4 – This response appears adequate and will be verified at the next inspection of your facility. It is imperative that your personnel follow the current procedures and that written instructions accurately reflect your operations. If the procedures you have in place are ambiguous or outdated, the potential for errors, and production of defective devices, is likely.

Observation 5 – This response is inadequate. Your Quality Assurance procedure, [redacted] states, [redacted] Your response indicates that you will only amend your Quality Management Review procedure, [redacted] to include the audit results with the audit trending data. Your Quality Assurance procedure should also reflect the inclusion of these results to ensure that all sources of quality data are addressed as required by the Quality System Regulation.

Observation 6 – This response appears adequate and will be verified at the next inspection of your facility. It is important that you emphasize to employees with the responsibility for reviewing/approving procedures or documentation that they verify the accuracy of the work before signing off.

Observations 7 – This response is not adequate. The requirement under 21 CFR 820.25 (b) regarding training is specific to defects that may result from the improper performance of an individual employee's job functions. You indicate that your corrective action will entail a more

global or nonspecific training of all employees with respect to defect awareness. It is not sufficient to give only overview training; a training program must also include how particular job functions relate to the overall quality system. Also, please note that whenever design changes are made to devices or revisions are made to procedures, re-training should take place regarding defects employees should look for as a result of improper performance. This re-training should be documented in the employee's records. Your response does not indicate that this will occur whenever production changes are made.

Observation 8 – This response is inadequate. We agree with your decision to review the Product Safety Reports listed by our investigators on the FDA 483. However, your firm should review all Product Safety Reports (and not limit your corrective actions to just the examples shown) to assure information regarding patient involvement has been captured and, if applicable, MDRs are filed.

Observation 9 – This response appears adequate and will be verified at the next inspection of your facility. During our inspection, our investigator directed numerous questions regarding complaint investigations to [redacted] In most cases, [redacted] could not provide an answer, and had to perform a subsequent investigation/inquiry to provide an answer. None of the information he subsequently provided was referenced or included in the original complaint report from the [redacted] system.

Observation 10 – This response appears adequate and will be verified at the next inspection of your facility.

Observation 11 – This response appears adequate and will be verified at the next inspection of your facility.

Observation 12 – This response appears adequate and will be verified at the next inspection of your facility. This observation, as well as several previously discussed above, indicate that your firm has serious problems, not only with production personnel, but also within your quality assurance staff. Your Reprocessing procedure states, [redacted] If both units fail to operate in accordance with your procedures, there is a serious risk that you will produce devices that are not within your firm's specifications and can potentially be ineffective or unsafe.

Observation 13 – Your response is inadequate. You attached a draft CAPA [redacted] in reply to the deficiencies noted in this observation. This CAPA refers to updating your Systems Release Activities, SOP [redacted], along with several other procedures. The CAPA appears to be a generic response and does not contain specific information regarding how you intend to address this observation. In addition, you referenced this CAPA in response to observation 11, stating applicable SOPs have been modified and employees retrained. The copy of the SOP, [redacted] attached to your response is marked, "Draft". You cannot train employees using a draft procedure. Additionally, there does not appear to be any change from section [redacted] our investigators reviewed during the inspection (version [redacted] effective [redacted], versus the draft version attached to your response (version [redacted] effective [redacted]

Observation 14 – Your response appears adequate and will be verified at the next inspection of your facility. As per your response, the fact that changes made to your procedures were not caught by your Manufacturing, Engineering or Regulatory approvers again points to systemic problems within your organization.

Observation 15 – Your response appears adequate and will be verified at the next inspection of your facility.

Observations 16, 17, 19, 20, 21, & 22 - Your response appears adequate and will be verified at the next inspection of your facility.

Observation 18 – Your response appears adequate and will be verified at the next inspection of your facility.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that each of your facilities is in compliance with all requirements of the Federal regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection (a copy of which is included for your information) may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action to your Quality System at this and at all your other locations. Continued distribution of violative devices may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so that they may take this information into account when considering the award of contracts.

You should notify this office in writing within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed.

Your reply should be sent to the Food and Drug Administration, Denver District Office, P. O. Box 25087, Denver, CO 80225-008, Attention: Regina A. Barrell, Compliance Officer. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,

B. Belinda Collins
District Director

Enclosure