UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

**New England Office – Region I** One Congress Street, Suite 1100

Boston, Massachusetts 02114-2023

December 09, 2005

Mr. Andrew T. Silfer, P.E.

General Electric Company

159 Plastics Avenue

Pittsfield, Massachusetts 01201

**RE: Interim Media Protection Goals Proposal** 

Dear Mr. Silfer:

EPA has completed its review of GE's report entitled "Interim Media Protection Goals

Proposal for Housatonic River, Rest of River" (hereinafter "IMPGs" or "IMPG Proposal")

dated September 6, 2005, which was submitted pursuant to the requirement in Appendix G to

the Consent Decree (the "Reissued RCRA Permit" and the "Decree", respectively).

Section II.C. of the Reissued RCRA Permit references the IMPG Proposal. Within that

Section, Section II.C.1 states as follows: "The proposed IMPGs shall consist of preliminary

goals that are shown to be protective of human health and the environment and that will serve

as points of departure in evaluating potential corrective measures in the subsequent Corrective

Measures Study." Pursuant to Section II.D, EPA, after review and comment by MDEP and

CT DEP, disapproves the IMPG Proposal due to the Deficiencies outlined below.

The EPA comments have been grouped into two categories, Deficiencies and Specific

Comments. First, EPA identified four Deficiencies which render the document unacceptable.

EPA requires that GE, in its revision of the IMPG Proposal, address these deficiencies each

time they are referenced or implicated. Second, the Specific Comments provide background

and/or require specific revisions by GE to the IMPG Proposal.

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GE shall submit a revised IMPG Proposal within 30 days of receipt of these comments, unless GE invokes the dispute resolution procedures for Interim Submittals in Section II.N of the Reissued RCRA Permit. The revised IMPG Proposal shall address the Deficiencies listed below and Specific Comments (attached), and incorporate any modifications made by EPA herein.

## **DEFICIENCIES**

Inclusion of Alternative IMPGs – In Section 3 of its IMPG Proposal, GE developed an
"alternative" set of IMPG calculations based upon GE's risk assumptions, and
included these alternative calculations in the IMPG Proposal, in addition to the IMPG
calculations developed based on the outcome of the Human Health Risk Assessment
(HHRA) and Ecological Risk Assessment (ERA) Peer Reviews and resulting
revisions incorporated in the final Risk Assessments.

The Decree required completion of the HHRA and ERA, and the subsequent completion of the agreed-upon independent Peer Review processes for the HHRA and ERA. The Decree also afforded GE extensive participation in the HHRA, the ERA and in the Peer Review processes for the HHRA and ERA. Those processes resulted in the HHRA and ERA findings. GE's alternative assumptions for the IMPGs are not consistent with such findings. Accordingly, it is not acceptable to use GE's alternative calculations and the resultant IMPGs as points of departure in evaluating potential corrective measures in the Corrective Measures Study. In addition, GE's presentation of alternative IMPG calculations does not take into account the conclusions of the risk assessments conducted by EPA. Furthermore, EPA does not believe that these alternative calculations are protective of human health and/or the environment, and thus are not IMPGs pursuant to the Reissued RCRA Permit.

GE shall remove the alternative risk calculations (Section 3) from the revised IMPG Proposal and all supporting references and appendices.

2. Absence of the Point of Departure – There is no reference included in the IMPG Proposal to the "point of departure" for the IMPGs in the discussion of the Risk-Based Media Concentrations (RMCs) associated with EPA's acceptable risk range for human health or for the ecological receptors. The use of a "point of departure" is a necessary prerequisite and critical starting point from which the analyses of corrective measures can proceed in a logical manner. Pursuant to Section II.C.1 of the Reissued RCRA Permit, the proposed IMPGs are to be protective of human health and the environment and to serve as points of departure in evaluating potential corrective measures in the Corrective Measures Study.

As GE has expressed the IMPGs, every RMC is given equal weight in the process. In addition to being inconsistent with the IMPG requirements, this approach vastly

complicates linear analysis of the extent to which protection of human health and the environment may be achieved in the Corrective Measures Study.

EPA defines the point of departure for human health preliminary cleanup goals to be 1 x  $10^{-6}$  for cancer risks or a Hazard Index = 1 for noncancer risks for the Reasonable Maximum Exposure (RME) scenario, as defined in EPA regulations and guidance. For example, the National Contingency Plan ("NCP"), in its requirements regarding known or suspected carcinogens, further explains the point of departure, as follows: "the  $10^{-6}$  risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure". 40 C.F.R. Section 300.430(e)(2)(i)(A)(2) (see also the Preamble to the NCP, at 55 Fed. Reg. 8718).

The point of departure for ecological IMPGs has been defined in practice in making remedial decisions at other contaminated sites and as a level of concern in other EPA programs as a contaminant concentration that falls within the range of the No Observed Adverse Effect Level (NOAEL) to the Lowest Observed Adverse Effect Level (LOAEL). In the case of the Housatonic River, the procedures recommended by the Peer Review Panel for the Ecological Risk Assessment were used to develop Maximum Acceptable Threshold Concentrations (MATCs) specific to the site and ecological Assessment Endpoints where there was sufficient information; these MATCs are generally equivalent to LOAELs. EPA considers these MATCs to be the point of departure for the IMPGs for ecological receptors; EPA also notes that the MATCs are already at the high end of the range in concentration considered to be protective of the environment.

During discussions of the concepts behind the IMPG Proposal and prior to its submittal, EPA clearly communicated to GE the expectation that the points of departure described above would be highlighted (either directly in the text and/or in the tables). At the same time, EPA afforded GE the opportunity to present in the IMPG Proposal a range in concentrations associated with EPA's acceptable risk range for RME, Central Tendency Exposure (CTE) and for risk levels protective of ecological receptors, as long as the point of departure was clearly delineated. While these ranges in risk levels for the human health scenarios were generally presented in Section 2 of the IMPG Proposal, GE inappropriately included concentrations associated with virtually all endpoints for ecological receptors (including those that are not ecologically significant and/or sensitive), not just the concentrations that represent a range in risk levels that are protective of the environment. Also the point of departure for each receptor was not indicated in any way in the IMPG Proposal for either human health pathways or ecological endpoints, which is not consistent with Appendix G, and Agency regulation, policy and practice. In addition, the specification of such wide ranges of concentrations, many of which are not protective, becomes, from a practical perspective, meaningless, uninformative, and needlessly complicates the application of the IMPGs to the screening of remedial alternatives in the CMS.

Accordingly, GE shall identify the points of departure in the revised IMPG Proposal for both the human health and ecological risk endpoints. For human health exposure pathways, the point of departure for each pathway is both the concentration associated with the  $10^{-6}$  cancer risk for the RME, and the concentration associated with a noncancer Hazard Index =1 for the RME.

For the ecological Assessment Endpoints, GE shall revise the discussion of ranges of concentrations to constrain it to inclusion of the MATC (when available) or, for those Assessment Endpoints where a MATC was not calculated, the concentration that equates to an effect level of 20%, or to the 20% probability of exceeding the threshold effect level for the most sensitive species identified in the ERA. These concentrations are ecologically relevant and provide adequate, however nonconservative, levels of protection for the Assessment Endpoint and the local subpopulations of species represented by the Assessment Endpoint.

These points of departure shall be clearly indicated in the text of the IMPG Proposal and also clearly highlighted in the tables of proposed IMPG (RMC) concentrations.

3. <u>Narrative Goals</u> – GE has provided descriptive narrative goals in the IMPG Proposal for both human health and ecological scenarios that include the use of numerous ambiguous and undefined terms which cloud the interpretation of the meaning of these narrative goals, and in some cases render the narrative goals potentially at odds with the numeric goals.

GE shall incorporate in the revised IMPG Proposal the modified narrative criteria as described in the Specific Comments provided below.

4. <u>Identification of ARARs</u> – Among the requirements of the Reissued RCRA Permit is that, at Section II.C.9, "The IMPG Proposal shall take into account applicable or relevant and appropriate federal and state requirements." Section 4.0 of GE's IMPG Proposal presents site-specific RMCs which GE states address the same receptors and pathways as criteria and standards (chemical-specific applicable or relevant and appropriate requirements, or ARARs) and argues that therefore there is no need to further consider these chemical-specific ARARs in the IMPG proposal.

EPA does not agree that the development of a site-specific concentration is a substitute for a promulgated federal or state standard for the media of concern.

As identified in Section II.G.1.c of the Reissued RCRA Permit, compliance with ARARs is one of three General Standards (the other two being protection of human health and the environment and control of sources of releases) against which remedial alternatives shall be evaluated. Therefore, chemical-specific ARARs must be identified in the IMPG Proposal to then be used as an evaluative criterion in the CMS.

If it is determined during the CMS that an ARAR cannot be achieved, then it will be subject to waiver.

The IMPG Proposal must contain all chemical-specific concentrations of interest for surface water, sediment, and soil that will be considered in the evaluation of remedial alternatives, including the chemical-specific ARARs. The additional location-specific or action-specific ARARs shall be identified later in the CMS Proposal, as review against these other types of ARARs will be based on factors other than contaminant concentration.

As with the point of departure, EPA clearly indicated to GE in discussions preceding the submittal of the IMPG Proposal the expectation that chemical-specific ARARs must be identified in the IMPG Proposal. GE shall identify the chemical-specific ARARs in the revised IMPG proposal.

The Specific Comments are included as Attachment A.

Please contact me if you have any questions.

Susan C. Svirsky, Project Manager Rest of River

cc:

M. Carroll, GE
R. McLaren, GE
K. Mooney, GE
J. Bieke, Goodwin Proctor
R. Cavagnero, EPA
R. Cianciarulo, EPA
D. Tagliaferro, USEPA
T. Conway, USEPA
J. Kilborn, USEPA
H. Inglis, USEPA
R. Howell, USEPA

S. Steenstrup, MDEP
A. Symington, MDEP
S. Peterson, CTDEP
T. Iott, CTDEP
D. Young, MA EOEA
K. Finkelstein, NOAA
K. Munney, FWS
J. Roberto, Mayor, City of Pittsfield
S. Campbell, Weston Solutions
R. McGrath, SHD, Inc.
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